BEFORE THE INDUSTRIAL ACCIDENT BOARD OF THE STATE OF DELAWARE

KEVIN KURYCH,	)	
	)	
Claimant,	)	IAB Hearing No. 1504289
	)	
v.	)	
	)	
IDEXX-US VIRTUAL,	)	
	)	
Employer.	)	

DECISION ON PETITION TO DETERMINE ADDITIONAL COMPENSATION DUE

Pursuant to due notice of time and place of hearing served on all parties in interest, the above-stated cause came before the Industrial Accident Board in a hearing room of the Board in Dover, Delaware, on September 14, 2022.

PRESENT:

VALENCIA HAYES

WILLIAM HARE

Angela M. Fowler, Workers' Compensation Hearing Officer, for the Board

APPEARANCES:
Joseph Stanley, Esquire, Attorney for the Employee
Wade Adams, III, Esquire, Attorney for the Employer

NATURE AND STAGE OF THE PROCEEDINGS

Kevin Kurych ("Claimant") was involved in a compensable industrial motor vehicle accident on October 7, 2020, while working as a traveling salesman for Idexx-US Virtual ("Employer"). While Employer acknowledges that Claimant suffered some minor injury in the form of a strain to his low back in the accident and has thus provided Claimant with certain workers' compensation benefits including payment of initial medical expenses, Employer denies the compensability of specific medical care that Claimant received to include spinal injections, ablations, stem cell treatment, hardware block, and hardware removal.

On April 15, 2022, Claimant filed a Petition to Determine Additional Compensation Due seeking a finding of compensability for his lumbar spine condition as well as payment of medical expenses related to the treatment that Employer has thus far denied as unrelated and/or unreasonable and unnecessary.[1]

A hearing was held on Claimant's Petition on September 14, 2022. This is the Board's decision on the merits.

SUMMARY OF THE EVIDENCE

Claimant testified that he is a 55 year old, University of Delaware college graduate with a bachelor's degree in science. He has spent more than 30 years in sales working mainly in biotech, pharmaceuticals, and veterinary medical supply sales. It was this kind of work that Claimant was performing for Employer, going from client to client with products, when he experienced his October 7, 2020 work-related motor vehicle accident. He explained that he works out of his office and home, traveling to see clients in Delaware and throughout the Eastern Shore of Maryland. This work provides a base salary but is also heavily commission based creating an environment, according to Claimant, wherein his failure to work and make sales reduces his income dramatically.

[1] *See* Joint Exhibit 1 (Stipulation of Facts).

As it relates to the accident and injuries at issue, Claimant explained that on October 7, 2020, while traveling between clients, he stopped to make a left hand turn when he was rear ended. Claimant acknowledges that he did not go to the hospital or seek medical care right away and instead just went home and took the rest of the day off. He indicated that he felt shaken up by the accident and was experiencing tightness in his back and neck with his back being the main culprit. When his symptoms did not resolve, Claimant was sent by Employer for medical treatment at Concerta. There he received pain medications, had x-rays performed, and was seen by Dr. Kennedy several times for neck and low back concerns. Eventually when these treatments did not help and Claimant's low back pain persisted, Claimant was referred by Concerta to First State Orthopedics and Dr. Zaslavsky.

Claimant confirmed that in 2006 he had similar back pain following an unrelated motor vehicle accident that subsequently resulted in him undergoing a spinal fusion. Claimant testified that the 2006 surgery was a success such that he had few low back complaints thereafter, at least until the October 7, 2020 work accident occurred. In fact, he had worked full duty without restriction or difficulty for the intervening years between the 2006 surgery and October 2020 industrial event.

According to Claimant, when he initially presented to First State Orthopedics, he received conservative care. He could not however get relief and continued to suffer constant pain that caused him to struggle with activities of daily living including walking, standing, and driving. As such, he accepted the recommendations for injections, ablations and ultimately a stem cell procedure, all in the hopes of returning to his baseline pre-accident. Claimant elaborated noting that the injections he received provided some significant but short-lived relief while the ablations, also effective, worked slightly longer before again wearing off. It was after these treatments that Claimant was willing to undertake the proposed regenerative medicine option as a possible means of avoiding additional back surgery. Claimant indicated that he was advised that he was a healthy, relatively fit individual who would make an ideal candidate for

orthobiologics and a stem cell treatment that could potentially heal his low back condition. While it was not a procedure covered by insurance or approved by the Food and Drug Administration (FDA), and despite his appreciation of the pros and cons, Claimant felt strongly enough that the potential dangers of a stem cell intervention were outweighed by the promise of relief, and so he undertook the procedure and paid the $12,000 cost out of pocket.

Following his stem cell procedure, Claimant advised that he received some but not substantial relief of his low back symptoms. As such, the next medical recommendation was to perform a hardware block to determine if the instrumentation that had been installed in his 2006 unrelated spinal fusion required removal. After this procedure, Claimant received significant improvement and so the next step was taken and a hardware removal surgery was performed to remove the prior instrumentation and afford Claimant the more long-term version of the relief he received from the diagnostic hardware block. Claimant again followed the medical recommendations and undertook the hardware removal surgery after which he has experienced marked improvement that is not waning with time. While Claimant still has low back pain that he rates at two to three out of ten on the pain scale, he maintains that the hardware removal surgery was a success.

Claimant testified that he is not making a claim for disability compensation because he worked almost the entire time since his industrial accident with Employer. He only took a short time off for the hardware removal surgery but otherwise because he does not get paid if he does not make sales, continued to work as much as he could throughout and despite his physical difficulties.

On cross examination Claimant maintained that his 2006 spinal fusion was a success. Nevertheless, Claimant confirmed that on April 1, 2015, he saw Dr. Rudin with seven out of ten pain that was described as achy and shooting. He also confirmed that on January 17, 2020 he was directed by his primary care physician to have a bone scan performed which showed Claimant to be osteopenic and that

a month later, on February 18, 2020, he reported to Dr. Adam Ginsberg as part of a medical consultation that he was taking Aleve for neck and back pain as well as Vitamin D for osteoporosis. Claimant explained that after his 2006 spinal fusion, his back would only hurt occasionally if he overused it or participated in particularly demanding activities such that over the counter medications may be necessary or he may experience a temporary flare up of symptomatology.

Claimant confirmed that he has taken Prilosec for approximately the last five years at the urging of his gastroenterologist who maintains that the benefits of that medication outweigh its risks. Claimant also confirmed that he takes Stellera for treatment of a skin condition, psoriasis.

As it relates to the actual accident at issue, Claimant confirmed that he did not go to the hospital emergency department following the crash and that it was two days before he was seen at Concerta for nagging low back pain. Claimant maintained that he declined the offer of no work notes as he had to work from a financial perspective.

Claimant confirmed that he went to physical therapy after the accident and confirmed that at several of his therapy sessions he reported feeling better and enjoying improved function.

Claimant confirmed that he had a nerve block performed on April 9, 2021 that provided temporary relief. Subsequently, after seeing Dr. Zaslavsky on April 21, 2021 and reporting 80% relief from his nerve block, given the bulging discs above his fusion, an ablation was performed, the relief from which was also relatively short-term. It was then that Dr. Zaslavsky told him about the $12,000 stem cell option. Claimant acknowledged that it was clear to him that he was not part of a clinical trial as it related to the stem cell treatment but denied that Dr. Zaslavsky advised him of all of the specific FDA warnings referable to the procedure.

Claimant confirmed that as of December 2021, he was reporting that he had not seen improvement from the stem cell procedure such that a hardware block was offered to him as potential diagnostic tool to determine if hardware from his earlier surgery needed to be removed.

Dr. James Zaslavsky, a board certified orthopedic surgeon and Claimant's treating physician, testified by deposition on Claimant's behalf.[2] Having reviewed Claimant's relevant medical history in addition to providing direct care to Claimant following his October 2020 work accident, Dr. Zaslavsky opined that the unpaid medical care now at issue was all reasonable, necessary, and causally related to the industrial accident Claimant sustained with Employer.

Dr. Zaslavsky testified that his initial visit with Claimant occurred on December 9, 2020, at which time Claimant reported to him that he had been a seat-belted driver who was rear-ended while waiting at a stop sign. Dr. Zaslavsky confirmed that prior to coming to him, Claimant had treated with an outpatient clinic, Concerta, however, Claimant reported that since the time of the accident he had experienced increasing pain across his low back as well as some cervical spine discomfort. Claimant advised at that time of his 2006 lumbar fusion as performed by a different physician but indicated that he had been doing well up until the October 2020 motor vehicle accident. Claimant reported occasional soreness and stiffness before the accident but advised that he was not living with any limitations or constant discomfort until the new event occurred with Employer.

Physical examination of Claimant showed him to have complaints of right lower extremity radicular symptoms, shooting pain into his calf, leg pain with standing and walking, trouble putting socks and shoes on and a list of other difficulties. There were palpable spasms across his lumbar region, diminished reflexes on the right side, he had difficulty bending past 25 degrees, and he had a positive straight-leg raise – a provocative finding of radiculopathy. As such, according to Dr. Zaslavsky, Claimant

[2] *See* Claimant's Exhibit 1 (August 3, 2022 deposition of Dr. James Zaslavsky).

was diagnosed with lumbar radiculopathy and more specifically a chemical radiculopathy from the L4-5 annular tear. Dr. Zaslavsky testified that he reviewed a lumbar MRI film performed relative to Claimant on November 10, 2020, prior to the inception of his care. According to Dr. Zaslavsky, the imaging showed an obvious annular tear and an inflammatory zone lesion at L4-5, as well as a disc protrusion on the right side as well. The protrusion was mildly compressive of the spinal canal and the foramen. Dr. Zaslavsky confirmed that ongoing conservative care was the plan after that first meeting.

Dr. Zaslavsky testified that Claimant's diagnosis of lumbar radiculopathy is entirely consistent with his mechanism of injury. He explained that at the time of the accident, Claimant's L4-5 disc was under a certain load and stress, which, when combined with the force of the accident, resulted in a tear of the disc and a protrusion extruding from the disc. Dr. Zaslavsky further explained that while Claimant's MRI falls short of allowing him to date Claimant's lumbar spine condition, when there's a high intensity zone lesion visualized in the annular tear with inflammation, such as that seen in Claimant's imaging, the lesion typically occurred within six months to a year of the imaging. In Claimant's case, having actually reviewed the MRI film in addition to conducting his own assessment of Claimant and his history, Dr. Zaslavsky maintained the opinion that Claimant sustained an acute injury to his lumbar spine that is consistent with Claimant's subjective complaints, physical examination findings including positive straight leg raise testing, diminished patellar reflex, and palpable spasms, the mechanism of injury, and the actual imaging. Moreover, Dr. Zaslavsky testified that had Claimant had this symptomatology prior to the October 2020 motor vehicle accident, he would likely have been actively seeking treatment.

In terms of the treatment Claimant had received, Dr. Zaslavsky confirmed that Claimant had physical therapy, medical massage, and was recommended to start supplements known to help with inflammation. When these measures did not produce relief for Claimant, Dr. Newell performed a January 4, 2021 right-sided transforaminal injection localized to the L4-5 level, allowing it to be both diagnostic

and therapeutic. Claimant reported 50% relief two weeks after the injection and on physical examination his findings had improved slightly. A second injection was administered on April 9, 2021, where in addition to injecting the actual tear itself, they proceeded with an injection for the joints. According to Dr. Zaslavsky, when the injection for the joints helped temporarily, the decision was made to burn the nerves to the joints hoping for more permanent relief, also known as ablation. Three injections were undertaken at L4-5, all of which helped temporarily, however after the last injection on May 6, 2021, Claimant's symptoms were returning. According to Dr. Zaslavsky, by July 2021, Claimant was clearly getting worse inasmuch as Claimant was reporting difficulties with both his work and home life. As such a discogram was recommended; an invasive and somewhat provocative procedure that Dr. Zaslavsky described as the gold standard for corroborating and confirming the annular tear with which Claimant's mechanism of injury, MRI findings, subjective complaints, and physical findings all appeared concordant. Claimant's discogram, says Dr. Zaslavsky, was performed on October 4, 2021 showing concordant symptoms at L4-5 as well as leakage of dye from L4-5 and L3-4, evidencing two annular tears. More notable, however, according to Dr. Zaslavsky, is the comparison of Claimant's November 2020 low back MRI and his post discogram CT scan performed 11 months later which evidences severe spinal stenosis and a large amount of extruded disc compressing the spinal canal at the L4-5 spinal level as well as considerable disc protrusion at L3-4, also affecting the spinal canal itself. Dr. Zaslavsky explained that the moderate stenosis at L3-4 and severe stenosis at L4-5, which was not present in November 2021, is the kind of progression that would typically take 20 years with a natural degenerative process but because of the development of the annular tear and obvious slow leak in the tear, produced rapid disc extrusion and rapid compromise of the nerves in Claimant's low back in a very short time period.

Dr. Zaslavsky testified that appreciating the gravity of Claimant's spinal deterioration but still hoping to avoid surgery, Dr. Bruce Rudin recommended Claimant for orthobiologic treatment. The goal

was to treat the annular tears non-surgically with a stem cell orthobiologic procedure, to stabilize the discs, and avoid further degeneration and further collapse. In this regard, Dr. Zaslavsky testified that this is what our vast body of literature on stem cells says is possible with stem cell therapy as long as the cells are extracted in proper fashion such that proper cell counts are taken from the stem cells; they can be a valuable tool in avoiding additional fusion procedures. Dr. Zaslavsky maintained that Claimant had exhausted conservative measures and was a good candidate for this type of treatment because he is a young, healthy, 55 year old, who doesn't smoke or drink appreciable amounts, was amenable to the requisite pre-stem cell preparation and had concordant annular tears in the lumbar spine for which he was desperately trying to avoid a fusion surgery.

As such, Claimant underwent the stem cell procedure at his own cost on December 2, 2021. He was seen in follow-up at two weeks, six weeks and three months post procedure but unfortunately did not show any significant improvement as a result of the treatment. A physicians' assistant in Dr. Zaslavsky's practice, labeling the stem cell procedure a failure, felt strongly that the hardware installed at L5-S1 as part of Claimant's earlier, unrelated fusion may be affecting Claimant's symptoms. Dr. Zaslavsky explained that the hardware was abutting the joint at L4-5 and definitely causing some irritation. Claimant had previously received good, albeit temporary relief from injections and ablations of the joints at L4-5. The thought, says Dr. Zaslavsky, being the hardware that was abutting the joint and causing inflammation in the joint after the motor vehicle accident was related to Claimant's ongoing low back symptoms. As such, a diagnostic hardware block was performed on March 10, 2022 which gave Claimant 100% relief initially and ongoing relief of sixty to sixty-five percent for two weeks. These results thus prompted a recommendation for the removal of the prior hardware; a suggestion that Claimant was eager to pursue.

Dr. Zaslavsky testified that he performed the hardware removal surgery for Claimant on March 31, 2022. Operatively, when the hardware was removed and extracted across the joint at L5-S1, there was

still motion across the joint itself and so he proceeded with augmentation of the fusion, placing bone graft over the joint. According to Dr. Zaslavsky, the surgery went very well. Postoperatively Claimant has reported doing well. While he had some days of significant postoperative pain, sometimes worse than his preoperative pain, that was related to the surgery itself and has resolved. He is back to working full-time, full duty and doing much better. Claimant has reported that he is not having any leg pain or tightness at this point and only requires over the counter medication and topical ointment for pain control.

Dr. Zaslavsky opined that all of the medical care that Claimant has received has been reasonable, necessary, and causally related to the industrial accident he experienced with employer in the October 7, 2020 motor vehicle accident. He further added that it has all been compliant with the Delaware Worker's Compensation Guidelines and that said treatment is the gold standard of care that would be provided under the American Academy of Orthopedic Surgeons. Having reviewed the defense medical opinions authored by Dr. Rushton in this matter, Dr. Zaslavsky testified that he takes issue with Dr. Rushton's criticism of discography insisting instead that it is the gold standard for the diagnosis and treatment of annular tears if looking to the Delaware Worker's Compensation Guidelines or the American Academy of Orthopedic Surgeons. Similarly, Dr. Zaslavsky confirmed that he takes issue with Dr. Rushton's criticism of orthobiologics and specifically the criticism that their use is controversial and poorly supported. To the contrary, Dr. Zaslavsky testified that there are a host of Level 1 studies supporting stem cells as a valid treatment option for various conditions of the lumbar spine, including annular tears of the lumbar spine. Furthermore, Dr. Zaslavsky testified that he entirely disagrees with Dr. Rushton's criticism of what Dr. Rushton alleges to be the overutilization of treatment including minimally invasive modalities. In this regard, Dr. Zaslavsky testified that Claimant's MRI shows obvious changes at L4-5 concordant with his complaints immediately following the work-related motor vehicle accident, and concordant to his physical exam findings. As such, explained Dr. Zaslavsky, utilizing three injections, one of which was a

transforaminal injection, another being a facet injection, and then subsequent ablations or neurolysis at L4-5, where the obvious concordant changes have occurred, was absolutely appropriate and within the Delaware Worker's Compensation Guidelines. Finally, Dr. Zaslavsky called Dr. Rushton's opinions challenging the competence of the mechanism of Claimant's injury to cause the conditions alleged to be completely unsupported by the vast body of literature in orthopedics supporting the truth that there is no minimum velocity required to cause disc damage in the lower back as the position the patient is much more important than the velocity. Unlike Dr. Rushton who opines that Claimant has reached maximum medical improvement, Dr. Zaslavsky opined that Claimant will continue to need follow-up and may well require occasional interventions with exacerbations while being monitored for adjacent segment issues.

Dr. Zaslavsky reiterated the causal nexus between Claimant's motor vehicle accident and the medical care he has received in the months and now years since. He testified that Claimant became very symptomatic after the accident. He subsequently failed to get any long-term relief through conservative care including physical therapy, massage, medication management, use of natural supplements, multiple injections, and orthobiologic treatment. His pain was progressive and considerable but now, since the hardware removal, is significantly improved. Dr. Zaslavsky opined that Claimant aggravated two discs in his lumbar spine in the work accident. He indicated that Claimant has an annular tear at L4-5 and a progressive disc protrusion at L3-4. Dr. Zaslavsky also offered the opinion that the accident led to an aggravation of the L4-5 joints as the hardware impinged on the joints at the time of the accident and led to increasing inflammation in the joints which also led to worsening pain from areas of micromotion at L5-S1 that had previously not been problematic to Claimant for some time. To a high degree of medical probability Dr. Zaslavsky testified that it is his opinion that Claimant's injuries are acute in nature. More specifically, Dr. Zaslavsky's diagnosis for Claimant is aggravation of previously paced hardware in the lumbar spine at L5-S1, annular tear L4-5, annular tear L3-4. He further opined, to a high degree of medical

probability, that these diagnoses are directly related to the October 7, 2020 work-related motor vehicle accident. In fact, Dr. Zaslavsky testified that if not for the accident at issue, Claimant would likely have continued his course of minimal discomfort after a 2006 lumbar fusion and continued to live without the need for the ongoing treatment that he has required and continues to require.

On cross examination Dr. Zaslavsky again confirmed his knowledge of Claimant's 2006 spinal fusion as well as a January 17, 2020 bone density test Claimant had submitted to which ultimately identified Claimant as Osteopenic. He also confirmed that Claimant had seen Dr. Adam Ginsberg of his practice, First State Orthopedics, on February 18, 2020, for both low back and neck pain which Claimant then reported treating with Advil.

As it relates to the use of stem cells and orthobiologics, Dr. Zaslavsky confirmed that Spine Care Delaware, a separate entity, administers and performs the actual stem cell procedures. While he refers his patients for whom he has developed a recommendation for potential orthobiologics to Dr. Bruce Rudin, his long-time surgical partner, to determine if a patient is a good candidate for such a procedure, if Dr. Rudin agrees, the actual procedure is performed by Spine Care Delaware. Medicare, Medicaid, and private health insurance will not cover these procedures, says Dr. Zaslavsky, and it is not specifically part of the Delaware Worker's Compensation Guidelines nor has it been specifically approved by the FDA. Nevertheless, Dr. Zaslavsky maintained that many things, such as use of pedicle screws in fusion procedures, are not approved by the FDA but are still embraced as part of routine medicine and spinal care. In fact, Dr. Zaslavsky testified that most things that surgeons do in and to the spine are not FDA approved. Dr. Zaslavsky confirmed that he is aware of many of the FDA warnings and advisements relative to stem cell use but maintained that his own review of the literature and the steps taken to ensure the efficacy of the process through use of orthobiologic experts in his own practice and within the facility where these procedures are performed provides the guarantee that cells are being collected and counted

properly to ensure a safe stem cell procedure. He confirmed that he is unaware of any investigational new drug application being applied for relative to Claimant and further denied that Claimant was part of any clinical trial as would seemingly be the requirement of the FDA to know that he was not being improperly treated. More specifically, in Claimant's case, while Dr. Zaslavsky confirmed that he discussed with Claimant some of the risks, which he maintains are relatively low compared to alternative treatment means to address Claimant's injuries, the rest of the warnings and advisements would have been something that Claimant would have discussed with Dr. Rudin as part of that assessment and recommendation process. Dr. Zaslavsky maintained that in Claimant's case, his option was a stem cell procedure or multilevel fusion, given that his changes were so acute, evolving, and progressing so quickly. Because Claimant was such an excellent candidate, with concordant findings, a history of generally good health, and the recommendation of Dr. Rudin, use of stem cells was a good choice, says Dr. Zaslavsky.

Dr. Zaslavsky confirmed his knowledge of the treatment history Claimant had engaged from the time of the accident forward including his initial medical treatment two days after the accident. As part of this review, Dr. Zaslavsky confirmed that Claimant's condition got progressively worse, despite the use of a host of conservative measures and injections, beginning as an issue on the right side of his lower back until eventually including his entire low back and radiation down his leg. After the discogram was positive for Claimant showing findings at the two levels above Claimant's 2006 fusion, L3-4 and L4-5, the two levels that had received most of the care since the work accident, fusion surgery at those levels was considered to address Claimant's rapid and unnatural spinal deterioration however again, trying to avoid another fusion procedure, alternative means were attempted including use of stem cells. It was only after the failure of the stem cell procedure that Dr. Zaslavsky's physician's assistant questioned the possibility that Claimant's prior instrumentation at the L5-S1 level could be contributing to his low back symptomatology. This is where the hardware block was employed as part of the process of properly

identifying the actual pain generator for Claimant; a test which also proved concordant. Dr. Zaslavsky confirmed that following the actual hardware removal, his postoperative diagnosis for Claimant was painful hardware removal nonunion, L5-S1 bilaterally. Dr. Zaslavsky further confirmed, later in his testimony, that while Claimant has gotten temporary relief with other treatments, only the hardware removal has provided lasting relief.

Dr. Zaslavsky confirmed that Claimant self-limits at work and has thus not been placed on a total disability status during their time together.

Dr. Scott Rushton, a board certified orthopedic spine surgeon, testified by deposition on Employer's behalf.[3] Having reviewed Claimant's relevant medical records in addition to conducting his own assessment of Claimant, Dr. Rushton opined that much of the treatment Claimant has received, and specifically the injections, ablations, stem cell procedure, hardware block and hardware removal surgery, were all unreasonable, unnecessary, and unrelated to the underlying industrial accident with Employer.

Dr. Rushton testified that he met with Claimant on December 10, 2021. Both as part of this initial assessment and in an effort to keep track of Claimant's treatment and condition, Dr. Rushton reviewed Claimant's relevant medical records as well as subsequent updated records reflecting Claimant's care since their meeting, thus resulting in the production of both an initial report, reflecting his opinions, as well as an addendum report dated June 7, 2022, reflecting any updates to those opinions based on Claimant's ongoing care.

Dr. Rushton confirmed that when he met with Claimant on December 10, 2021, Claimant was 54 years old and reported having been involved in a work-related motor vehicle accident on October 7, 2020, wherein he was the driver of a vehicle that sustained rear end impact. Claimant advised Dr. Rushton that he experienced soreness in his neck and low back following the incident but did not require an emergency

[3] *See* Employer's Exhibit 1 (August 23, 2022 deposition of Dr. Scott Rushton).

room or acute hospital evaluation; a happening that Dr. Rushton indicates is indicative of a low impact, low-energy event. Instead, several days later Claimant began treating with Concerta and undertook some physical therapy. Claimant, says Dr. Rushton, was eventually referred to First State Orthopedics but even after consultation there, surgery was not the first recommendation. Claimant reported that his neck got better and resolved within a week while his low back condition persisted. Claimant also advised Dr. Rushton of the injections, ablation, and stem cell procedure he had undertaken to address his low back pain.

At the time of their December 2021 meeting, Claimant reported to Dr. Rushton that he had ongoing low back pain but denied any leg pain or radicular complaints; an anomaly as much of Claimant's treatment history is riddled with leg complaints and treatments designed to address leg complaints according to Dr. Rushton. Claimant openly reported no overall improvement in the wake of the stem cell procedure, advising instead that he continued to have difficulty with activities of daily living such as sitting and standing tolerances. Claimant reported undertaking multiple MRIs as well as a discogram but had been discontinued from all prescription medications excepting Gabapentin twice a day.

In terms of his physical assessment of Claimant, Dr. Rushton testified that Claimant's gait was non-antalgic, showing no pathologic issues and not requiring Claimant to use any assistive devices in his ambulation. Claimant's lumbar range of motion was limited to 20 degrees and he reported pain from his recent stem cell procedure. Neurologically, says Dr. Rushton, Claimant was completely intact. There were no provocative radicular test findings and his reflexes were normal as well. As such, Dr. Rushton concluded that from a problem-focused examination standpoint, Claimant's lumbar spine was completely normal.

Having had the benefit of physically assessing Claimant in addition to reviewing Claimant's medical and other records related to the work accident, Dr. Rushton testified that a number of the findings

in the records are significant in context. Specifically, Dr. Rushton noted that in the accident itself, there was contact with the bumper of Claimant's vehicle and no injuries reported at the scene. While Claimant subsequently presented to Concerta two days later with tenderness at the lumbosacral junction and the left sacroiliac joint, the Concerta diagnosis only included cervical strain, history of lumbar fusion and a lumbosacral strain. In relation to this specific finding and in light of Claimant's earlier fusion procedure, Dr. Rushton explained that over time and following a fusion in particular, the spine continues to degenerate over a natural continuum. Once a fusion is completed, the risk of degenerative changes at other segments in the spine, especially the segments adjacent to the original fusion, increases. In looking at Claimant's specific MRIs of the low back, Dr. Rushton confirmed that the MRI report from April 26, 2005, prior to Claimant's first fusion, showed a L4-5 mild diffuse disc bulge, a paracentral right-sided annular fissure, mild central canal stenosis, mild bilateral foraminal narrowing, and really mild disc desiccation and loss of disc height at L3-4. According to Dr. Rushton, his reading of the November 10, 2020 low back MRI for Claimant demonstrated virtually similar findings to include disc desiccation at L3-4, mild loss of disc contour, fairly minimal facet arthritis at L4-5, no disc herniation, and no significant nerve root compromise other than mild stenosis at L4-5. Dr. Rushton acknowledged that the 2020 MRI also showed an annular fissure at L4-5 absent any corresponding herniation associated with that fissure which he characterized as being consistent with a degenerative fissure. He also maintained that there was no evidence of critical canal stenosis. As such, Dr. Rushton confirmed his belief that there was no evidence of an acute injury on the November 10, 2020 MRI and instead only findings consistent with Claimant's age and prior history of lumbar fusion. Dr. Rushton testified that Dr. Zaslavsky's use of the term "high intensity zone lesion" as it relates to the appearance of Claimant's annular tear on this MRI is antiquated in the field of spine surgery insisting instead that the findings are all consistent with an annular fissure occurring within the

setting of degenerative disc disease. He pointed out that this fissure occurred at the level directly adjunct to Claimant's 2006 fusion which would also be consistent with age related changes.

Dr. Rushton addressed Claimant's January 4, 2021 injection as performed by Dr. Ginsberg. He indicated that it had not been overly helpful. While the injection was reported to have provided some improvement in Claimant's symptomatology, the degree of improvement was short term. Similarly, the April 9, 2021 nerve block, while reported to have given Claimant 80 percent relief, was characterized by Dr. Rushton as insignificant because it was a report based on subjective parameters. Dr. Rushton, in fact, testified that there are no studies confirming the diagnostic value of minimally invasive interventions in general.

As it relates to stem cell treatment, Dr. Rushton testified that stem cell procedures are very complicated and currently very controversial in the field of orthopedic surgery. The basic principle is to use stem cells to recreate architecture in soft tissue elements. He maintained, however, that stem cell use in orthopedics, and particularly orthopedic spine surgery, has not been appropriately or clearly defined. He indicated that stem cell treatment in the musculoskeletal systems in certain applications is not FDA approved and there have been no high-level studies that have confirmed their utility. As such, he does not recommend or advise patients in his practice to consider stem cell treatment. Dr. Rushton explained that Level 1 studies are strong studies generally conducted via double blind study method. As such, these studies can show a strong indication that a treatment works. Dr. Rushton maintained that there have been no such studies related to the efficacy of stem cell use in spinal disorders; a fact with which he, as a university instructor, is obligated to stay abreast of given his current teaching status. As such, not only does he not teach the use of stem cells in such a context to his current medical students and will not recommend it to patients under his care, but Dr. Rushton also opined that there are no valid studies that support Dr. Zaslavsky's opinion regarding use of stem cells in clinical spine practice. He testified that

this is not an FDA approved product or application. Moreover, the procedure itself brings to bear a number of risks or potential complications when used in a lumbar spine procedure. Dr. Rushton detailed complications including infection, abscesses, and adverse reactions to the preparation of the materials. In support of this contention, Dr. Rushton confirmed the FDA consumer warnings and advisements on stem cell use dated June 3, 2021 which provides in part that consumers offered such stem cell treatments outside of clinical trials are likely being deceived and/or offered a product illegally and that stem cell treatments have not been approved for use in orthopedic conditions including disc disease. As such, Dr. Rushton confirmed his opinion that someone receiving a stem cell treatment in the lumbar spine should only be doing so as part of a clinical trial because, as he explained, there is no data to support that what we are doing is efficacious, safe, or effective. Dr. Rushton further confirmed that the FDA Bulletin specifically provides that manufacturers, clinics, and healthcare practitioners have been repeatedly notified of the need for Investigational New Drug applications to legally administer these products and to ensure safety measures are in place prior to administration. The fact that this did not occur in Claimant's case, or that Dr. Zaslavsky is not aware of whether it occurred or not, is concerning, says Dr. Rushton. Based on all of this, Dr. Rushton testified that he is sadly not surprised that Claimant did not enjoy any significant improvement from the treatment that he paid for out of pocket, particularly given the statistical chances of getting better from an experimental device for which the efficacy and application are unknown. Accordingly, Dr. Rushton opined that there was no role for stem cell utilization following Claimant's work accident.

In regard to the appropriateness or necessity of the discogram and post discogram CT that Claimant undertook, Dr. Rushton opined that they too were unreasonable and unnecessary, particularly in the context of Claimant's work accident. While acknowledging that he did not have the opportunity to review the actual discogram, Dr. Rushton confirmed his review of the corresponding report issued by Dr.

Ginsberg dated October 4, 2020. According to Dr. Rushton, Dr. Ginsberg's opinion was that the study showed concordant pain of six out of ten at the L4-5 level. This test, however, says Dr. Rushton, was conducted to determine Claimant's location of pain and candidacy for stem cell intervention, which is controversial and unsupported.

Similarly, Dr. Rushton opined that the injections and ablations Claimant received were also unreasonable. He testified that the timeline of treatment suggests that these minimally invasive treatments did not target or correlate with Claimant's diagnosis of radiculopathy and annular tear. According to Dr. Rushton, moving next to epidural injection and then stem cell treatment, it appears that Dr. Zaslavsky was using a "poke-and-hope" approach to managing Claimant's complaints. He opined, however, that there was no role for facet injections or ablations based on Claimant's mechanism of injury, complaints, and MRIs.

Dr. Rushton testified that as far as diagnosis, after he met with Claimant, as of December 2020, he felt that Claimant had suffered both a cervical and lumbar spine sprain and strain.

Subsequent to their initial meeting, Dr. Rushton reviewed additional of Claimant's records and received updated records of care as well. In doing so, Dr. Rushton developed concern related to some of the medications Claimant is taking and has taken long-term that may be impacting his spinal condition. More specifically, Dr. Rushton testified Prilosec and Stelara, both listed in Claimant's records, can lead to bone mineralization and spinal degeneration. Claimant has also been diagnosed as osteopenic, a significant concern for a male of Claimant's age with a history of spinal fusion. In this regard, Dr. Rushton opined that, unlike Dr. Zaslavsky who believes that the rapid deterioration in Claimant's spine is due to injuries sustained in the motor vehicle accident at issue, he believes that Claimant has a degree of degeneration consistent with his age, prior fusion surgery, and bone mineralization from his long-term medications. Nevertheless, Dr. Rushton admitted that the earlier fusion occurred prior to the

demineralization and so none of these issues should impact the 2006 fusion or hardware. As such, he confirmed that by MRI and x-ray, the 2006 fusion showed no signs of implant malposition, no instability, and no loosening of hardware.

Dr. Rushton confirmed his opinion that, like the earlier treatments at issue, he again finds the hardware block that Claimant undertook to be unreasonable and unnecessary in the context of his work accident. Dr. Rushton took issue with the fact that this test came about based on a hunch from the physician assistant.

Dr. Rushton confirmed that after the hardware block, on March 31, 2022, Claimant had hardware removal surgery which again he finds unreasonable and unnecessary in the context of the pending matters. Dr. Rushton indicated that operatively, Dr. Zaslavsky noted micromotion at L5-S1, where the earlier fusion had occurred. This is something that could show up on x-ray or as evidence of a nonunion in the post-discogram CT scan which also preceded this surgery. There was no such evidence in Claimant's case, however. Dr. Rushton testified that there was no mention of concern for a nonunion in any of Claimant's treatment records and yet it appeared both as a preoperative and postoperative diagnosis. Dr. Rushton further questioned Dr. Zaslavsky's approach at mending the nonunion as he used a technique that is typically not used for an established nonunion. In any event, Dr. Rushton concluded that the shift in treatment approach from L3-4 and L4-5 to L5-S1 underscores the inconsistencies in the treatment Claimant received including variation and targeting of multiple anatomical sites, completing a poorly indicated discogram in advance of a controversial stem cell procedure, and an out of the blue painful hardware removal and nonunion augmentation at L5-S1. According to Dr. Rushton, any suggestion on Dr. Zaslavsky's part that the decision making was made by trial and error undervalues the magnitude of literature and Level 1 scientific studies available referable to surgical management in the field of orthopedic spine surgery and provides cause for concern regarding the medical decision making.

Dr. Rushton clearly opined that Claimant does not have adjacent segment syndrome but does have adjacent segment disease, an independent and unrelated diagnosis. In either event, Dr. Rushton maintained that the L4-5 level was not implicated in any way or made a problem in any sense secondary to the work-related motor vehicle accident with Employer.

On Cross examination, Dr. Rushton confirmed that he does not have an office or practice in Delaware such that his greatest involvement in this state is for purposes of conducting defense medical examinations. In the context of patient care, Dr. Rushton explained that he typically diagnoses a patient through history, physical examination, use of medical records, diagnostic studies, experience, and familiarity with various diagnoses. He further explained that the treatment algorithm that he references is the treatment that is being utilized to manage a specific diagnosis or clinical syndrome and follows once an individual is diagnosed. Applying that model in Claimant's case, Dr. Rushton confirmed that Claimant, for instance, reported to him a history of low back pain but no leg pain. That report was different from the history documented in his medical records says Dr. Rushton. Dr. Rushton also acknowledged, however, that at least as of November 13, 2020, in a Concerta medical record referable to Claimant it is documented that Claimant complained of lower extremity radiation of his symptoms.

Dr. Rushton, despite some great debate as to what the parameters of his definition of a low impact accident are, admitted that a rear end collision is capable of aggravating a prior surgery where one has preexisting hardware in the back.

Dr. Rushton confirmed that he did not review any of Claimant's medical records from prior to the work accident now at issue. As such, he is unsure of whether Claimant had any active symptoms proceeding the October 2020 industrial accident.

Dr. Rushton confirmed his belief that injections, when they provide subjective relief, are therapeutic in nature only and have not been proven to be diagnostic. He further indicated that while he

believes in the use of stem cells when proven clinically, he does not believe in their use under circumstances such as Claimant's. Similarly, he confirmed his belief that a successful response to a hardware block does not render a patient an automatic candidate for hardware removal absent something corroborating the subjective relief achieved and warranting the removal such as evidence of fractured, loose, or displaced hardware. While he claims to have never seen it himself, Dr. Rushton acknowledged the possibility that hardware can be a pain generator.

Dr. Rushton maintained his opinion that Claimant has a degenerative annular fissure in his lumbar spine and not an acute tear brought about by the work event.

During a brief exchange of re-direct and re-cross examination, Dr. Rushton confirmed that as close in time as February 2020, Claimant was seen by Dr. Ginsberg for neck and low back pain. He further testified that he would not expect and induvial with a history of a well healed fusion to have ongoing symptoms related to that condition.

FINDINGS OF FACT AND CONCLUSONS OF LAW

Evidentiary Issues

Prior to taking testimony in this matter, the Board heard the competing Motions filed by Claimant and Employer referable to the testimony of Dr. James Zaslavsky and inclusion of the deposition testimony of Dr. Bruce Rudin from an unrelated worker's compensation matter (in the context of a deposition of Dr. Zaslavsky in this matter).

Motion in Limine: Claimant filed a Motion *in Limine* seeking to exclude attachment of the deposition of Dr. Bruce Rudin, offered as evidence in an unrelated Board matter, to the deposition testimony of Dr. James Zaslavsky offered in this matter. To this end Claimant, who was not provided a copy of the Rudin deposition ultimately offered as an exhibit to the deposition of Dr. Zaslavsky, argues that the testimony that Dr. Rudin provided in the other case is wholly unrelated to the matter currently

before the Board inasmuch as the parties are all different, the attorneys are different, and Dr. Rudin was not asked by anyone to testify in this matter. Accordingly, counsel asserts that Claimant is denied the benefit of cross examining Dr. Rudin as it may relate to the statements contained therein. Employer, in opposition to this motion, asserts that Board decisions are available to the public and that Claimant should have been aware of Dr. Rudin's opinions as he was consulted in Claimant's case.

Having heard the argument of the parties, the Board determined that Claimant's Motion *in Limine* shall be GRANTED. While Employer is correct that Board Determinations are available to the public, the specific depositions offered as sworn testimony therein are not readily available. While Dr. Rudin may have issued a statement in an unrelated matter that one may construe as inconsistent with an opinion offered by Dr. Zaslavsky, absent the opportunity to cross examine him regarding the alleged difference leaves Claimant at a marked disadvantage and, in the view of the Board, proves to be more prejudicial than probative. As such and recognizing that either side had the ability to directly solicit the testimony of Dr. Rudin in this matter had they so desired, the Board is satisfied that the Motion should be granted and the Exhibit otherwise attached be stricken from consideration.

Daubert Motion to Strike Dr. Zaslavsky's testimony: Employer, in filing this motion, argues that pursuant to the principles espoused in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 589 (1993), Dr. Zaslavsky's deposition testimony, specifically as it relates to the issue of stem cell use for treatment of orthopedic spine issues, should be stricken and the underlying claim for relief as it relates to payment of care rendered for stem cell procedures be dismissed with prejudice. Claimant, by contrast, asserts that any issue Employer has raised with regard to the testimony of Dr. Zaslavsky goes to the credibility of that testimony rather than the admissibility of the testimony. To this end, the Board again agrees with Claimant.

Daubert objections to the testimony of a medical expert must be considered in the context of whether or not a legitimate issue has been raised regarding the methodology employed by the expert in question. The purpose of *Daubert* scrutiny is to ensure that the reasoning or methodology of an expert's proposed testimony is scientifically valid and can properly be applied to the facts in issue.[4] *Daubert* focuses on the scientific foundation for a witness' opinion and should not be confused with consideration of the appropriate weight to be given that testimony. As such, a *Daubert* challenge, strictly speaking, goes to the scientific methodology employed by an expert witness[5] with the relevant inquiry considering: (1) Whether or not the reasoning or methodology underlying the opinion is scientifically valid? (2) Can that reasoning or methodology be properly applied to the facts at issue? (3) Has the theory or technique been tested, subject to peer review and publication? (4) Is it generally accepted?[6]

In the instant case, Dr. Zaslavsky testified that he met with Claimant, obtained his history, both subjective and the history of treatment Claimant had received to that point, reviewed imaging studies, attempted conservative and minimally invasive care for both therapeutic and diagnostic purposes and then in an effort to avoid an unwanted spinal fusion, referred Claimant to orthobiologic experts, Dr. Rudin and eventually Spine Center Delaware, for additional consideration of the efficacy of Claimant's candidacy for this procedure. That approach is entirely consistent with the diagnostic model and treatment algorithm that Dr. Rushton described as the model that he follows. As such, the Board is satisfied that element one of the *Daubert* factors is met. The Board sees no reason why that reasoning and the basis for the recommendations that were made for Claimant by Dr. Zaslavsky cannot be applied and examined in the instant matter while being juxtaposed against the explanations and testimony offered on the same issues

[4] *See Daubert,* 509 U.S. at 592-93.
[5] *Daubert,* 509 U.S. at 592-593 ("This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.").
[6] *Bolden v. Kraft Foods,* Del. Supr., No. 363, 2005, at ¶ 11 (December 21, 2005)(ORDER).

by Employer's expert, Dr. Rushton, thereby satisfying element two of the *Daubert* analysis. Element three requires that the material at issue have been tested and subject to peer review and publication. Admittedly, even the FDA, as pointed out in this matter, believes that more in depth research on stem cell use for spinal conditions is warranted to better inform regulatory bodies working to ensure patient safety, however that advisement does not mean that the technology has not been studied and peer reviewed in some capacity. The mere fact that Dr. Rushton maintains that it is so controversial suggests that it is and has been subject to some rather intense peer review. Ultimately, the review may not be as thorough as Dr. Rushton may desire, however *Daubert* requires peer review and publication but does not require FDA approval. As it relates to this element, it appears to the Board that any legitimate concern Employer has regarding the opinion is adequately preserved by virtue of the Board's ability to consider the same information in determining what weight, if any, to give to the testimony of Dr. Zaslavsky on this topic. And finally, the last element of the analysis, which asks whether the topic is generally accepted, seems more open to debate and therefore, once again, more appropriate for consideration on the issue of credibility rather than admissibility. Dr. Zaslavsky pointed out that a number of techniques and products used every day in spinal surgeries are not specifically FDA approved or even being used as originally intended. While clinical trials clearly have benefits, as laid out persuasively by Dr. Rushton, the fact that even the FDA allows for special permitting for the performance of these injections suggests that they are more widely accepted than the FDA warning might suggest when considered alone. Admittedly, Dr. Zaslavsky was not involved in any special permitting with regard to the use of stem cells for Claimant, but he testified repeatedly that much of that would be the work of Spine Center Delaware and not something crucial to his mission of diagnosis and recommending treatment, particularly given his comfort level with the technical methodologies carried out by the actual provider completing the treatment.

Accordingly, the Board is persuaded that any concerns regarding the testimony of Dr. Zaslavsky go towards the credibility of that testimony and the weight it is to be afforded rather than the actual admissibility of his opinions. As such, Employer's Motion to Exclude is DENIED.

Petition to Determine Additional Compensation Due

When an employee has suffered a compensable injury, the employer is required to pay for reasonable and necessary medical services connected with that injury.[7] What constitutes "reasonable medical services" for purposes of Section 2322 is undefined by statute and ultimately left to be determined by the Board on a case-by-case.[8] As such, the issue of "[w]hether medical services are necessary and reasonable or whether the expenses are incurred to treat a condition causally related to an industrial accident are purely factual issues within the purview of the Board."[9]

Spinal injections: Dr. Zaslavsky testified that after Claimant failed to get relief for his low back symptoms via use of physical therapy and medical massage, based on his history of injury, physical examination findings, and diagnostic imaging, injections were attempted for both therapeutic and diagnostic purposes at the L4-5 level both into the disc and later the joint, hoping to provide Claimant some relief and corroborate identification of what was thought to be his pain generator: an annular tear at L4-5, clearly identifiable, says Dr. Zaslavsky, on Claimant's low back MRI. Dr. Rushton, by contrast, suggests that Dr. Zaslavsky targeted various aspects of Claimant's anatomy, none of which correlated with diagnostic or examination findings. He suggests that the injections administered would not in any way be used to treat the diagnosis of radiculopathy that Claimant carried with Dr. Zaslavsky. Moreover, Dr. Rushton opines that injections and other minimally invasive procedures are not only clinically unproven as diagnostic tools but that the utilization of such mechanisms is generally questionable.

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[7] DEL. CODE ANN. tit. 19, § 2322.
[8] *See Meir v. Tunnell Companies*, Del. IAB Hearing No. 1326876 (November 24, 2009); *Willey v. State*, Del. Super., C.A. No. 85A-AP-16, Bifferato, J., 1985 WL 189319 at *2 (November 26, 1985).
[9] *Bullock v. K-Mart Corporation*, Del. Super., C.A. No. 94a-02-002, 1995 WL 339025 at *3 (May 5, 1995).

On this issue, the Board finds Dr. Zaslavsky more credible than Dr. Rushton. This finding is supported by not only the strength and logic of the treatment approach explained by Dr. Zaslavsky as it relates to Claimant but by the credible testimony of Claimant as well. Dr. Zaslavsky explained in great detail the nature of the annular tear discovered in Claimant's low back, including the risk of chemical radiculopathy. He confirmed, as do Claimant's records, that at least at various times throughout his treatment following the motor vehicle accident, Claimant had lower extremity radiation of symptoms. He also confirmed that Claimant's credible subjective complaints were concordant with all other relevant findings lending credibility to the diagnosis and treatment plan moving forward. Of further import is the fact that Claimant, as is required by the Delaware Worker's Compensation Guidelines for ongoing use of such a modality, demonstrated significant improvement from each injection, albeit short lived. Claimant underwent a right-sided transforaminal injection localized to the L4-5 level, allowing it to be both diagnostic and therapeutic after which he reported 50% relief two weeks after the injection and produced improved physical examination findings. A second injection was administered on April 9, 2021, where in addition to injecting the actual tear itself, they proceeded with an injection for the joints. According to Dr. Zaslavsky, when the injection for the joints helped temporarily, the decision was made to burn the nerves to the joints hoping for more permanent relief, also known as ablation. As Dr. Zaslavsky explained, even such short lived relief can be diagnostic in working to confirm that the correct area of the spine is being targeted. If an individual gets relief from the numbing of a certain area, the physician can theoretically corroborate clinical exam and diagnostic findings that the correct anatomy is being impacted. This does not eliminate the possibility of a multi-faceted problem which may require more than one approach or injection to thoroughly assess the precise nature and extent of the damage done.

The Board rejects Dr. Rushton's global suggestion that injections and other minimally invasive treatment modalities cannot be considered diagnostic in nature. Dr. Zaslavsky's explanation to the

contrary is far more consistent. Moreover, the Board accepts Dr. Zaslavsky's suggestion that injections are routinely used for such purposes, as acknowledged under the Delaware Worker's Compensation Guidelines.

Furthermore, there is little room to suggest that Claimant ever recovered from the injuries sustained in the motor vehicle accident sufficient to break the causal nexus between the accident and his ongoing symptomatology. There is no question that Claimant had a low back history that included a 2006 low back fusion with hardware. There is also no dispute that if he overdid it or engaged in activity too physically demanding, Claimant would occasionally have low back pain that he largely treated with over the counter medications. The most recent such flare up, however, as indicated by Claimant's medical records, appears to have been in February 2020, almost eight months prior to the work accident. There is no evidence that Claimant required any formal ongoing low back treatment after February 2020 so as to maintain his pre-work accident baseline of occasional low back flares. There is also little room to find that after the October 2020 work accident that Claimant ever returned to his pre-injury low back baseline, at least until later in his treatment with the removal of his preexisting hardware.

The Board also takes issue with the suggestion that the MRI findings made after Claimant's motor vehicle accident and most specifically the annular tear are degenerative in nature. Instead, the Board is persuaded by the testimony of Dr. Zaslavsky that the new tear was induced in the motor vehicle accident. While Dr. Rushton may not favor use of the term high intensity zone, Dr. Zaslavsky's explanation that the annular tear at L4-5 had marked inflammation as evidenced by its high intensity appearance on MRI makes sense when considered in terms of the rest and remainder of the chronology of events detailed herein. Dr. Zaslavsky testified that Claimant would likely have required active treatment for the tear had it degeneratively occurred over time but instead did not present with concordant symptomatology and MRI findings until after the motor vehicle accident. The Board does not believe that Claimant's sudden

onset of low back symptomatology far worse than his baseline was a coincidence. In fact, it appears far more likely than not that the accident caused the tear and the symptoms. As such, the Board is persuaded that Claimant sustained his injuries in the October 2020 work accident.

Accordingly, the Board finds, consistent with the opinions offer by Dr. Zaslavsky, that Claimant aggravated two discs in his lumbar spine in the work accident, specifically creating an annular tear at L4-5 and a progressive disc protrusion at L3-4, and further suffered an aggravation of the L4-5 joints as the hardware impinged on the joints at the time of the accident and led to increasing inflammation in the joints which also led to worsening pain from areas of micromotion at L5-S1 that had previously not been problematic to Claimant for some time. The Board accepts as compensable the use of injection therapy as described herein.

Ablations: For many of the same reasons as those detailed relevant to the compensability of the injections at issues herein, the Board finds use of ablation reasonable, necessary, and causally related to the October 2020 industrial accident as well. As previously stated, the Board accepts that Claimant was asymptomatic prior to the work accident. As part of the work accident, he suffered injury to his lumbar spine including an annular tear at L4-5. As Dr. Zaslavsky explained, the ablation, rather than an injection or numbing agent, was a procedure to burn the nerve ends leading to more permanent relief than that obtained by the injections which themselves had been significantly helpful in short increments. Again, while Dr. Rushton maintains that there is no therapeutic value to an injection that might otherwise support moving next to an ablation, the Board rejects that contention and instead adopts the opinions of Dr. Zaslavsky as it relates to this treatment. Given the results that Claimant obtained from the initial injections at L4-5, this was a necessary and reasonable step to take in the treatment of Claimant's then ongoing low back issues.

Accordingly, the Board finds this treatment compensable as well.

Stem cell treatment: The treatment that Claimant received in the realm of orthobiologics, and more specifically the stem cell injections, raises different concerns for the Board in the context of considering what is reasonable and necessary, when compared to the other treatments at issue. While the Board accepts the logic underlying Dr. Zaslavsky's treatment strategy that lead to consideration of regenerative medicine as a means of avoiding an unwanted fusion surgery to treat conditions which the Board has already found are directly related to the October 2020 work accident, specifically the L4-5 annular tear believed to be contributing to Claimant's symptomatology, the nature of this treatment and the science underlying it is more questionable than the suggestion that injection therapy cannot be used for diagnostic purposes. Dr. Zaslavsky testified that there is a wide body of literature based on clinical research supporting the use of stem cells and regenerative medicine for the treatment of spinal conditions such as the annular tear diagnosed in Claimant's low back. He even indicated that Level 1 trials, the most stringent of clinical trials, have been completed supporting the use of this methodology as it was employed in Claimant's case. While acknowledging the role of the FDA in providing warnings such as the stem cell warning that was issued in June 2021, Dr. Zaslavsky denied having knowledge of some of the FDA concerns and clearly indicated that he left discussion of those matters to occur between Claimant and the orthobiologic experts, Dr. Rudin and Spine Center Delaware.

By contrast, Dr. Rushton testified that while stem cell use to treat many conditions is being studied, particularly as it relates to hematology, it has not been sufficiently studied in use for orthopedic spinal care. Dr. Rushton confirmed that the FDA has warned individuals that if they are using this treatment they should either be in a clinical trial or have a special use permit issued by the FDA, neither of which Dr. Zaslavsky could confirm relevant to Claimant.

As such and based on the testimony presented, the Board is satisfied that while Dr. Zaslavsky was attempting to treat conditions entirely related to the October 2020 work accident when he referred

Claimant for stem cell use in reconstruction of his disc architecture, and while that may have been necessary in the context that it was perhaps then thought to be the only remaining alternative to avoid another fusion surgery, it was less than reasonable to do so based on what appears to be a faulty appreciation for the efficacy of this use in the treatment of Claimant's condition. The Board is concerned that Dr. Zaslavsky believes that there have been proven clinical trials demonstrating the potential benefits of this treatment, which remains uncovered by private insurance, Medicare, or Medicaid, given the infancy of its development. Moreover, the FDA warnings, many of which Dr. Zaslavsky advised he was unaware of, suggest that Dr. Zaslavsky's appreciation of the body of stem cell research regarding its usefulness may be wanting. This use appears to remain experimental and relatively controversial, according to Dr. Rushton, who indicated that he is not surprised that it did not provide the relief Claimant had hoped for.

As such and while the Board does not mean to suggest that cutting edge technologies do not have a place in the treatment of injured workers, the Board does believe that it becomes less and less reasonable to afford physicians the leeway to employ such unstudied measures without, at a minimum, being able to demonstrate some likelihood of success, such as may be available if clinical testing on stem cell use in orthopedics actually takes place, or at a minimum accurately report the state of research knowledge on a topic before suggesting that a patient submit thereto. Accordingly, while the Board believes that this treatment was related to injuries sustained in the work accident and even perhaps necessary to try and avoid surgery, it was an unreasonable measure to employ without a better basis to accurately suggest a potential successful outcome.

Hardware Block and Hardware Removal Surgery: After the seeming failure of the stem cell treatment Claimant received, Claimant continued to have progressively worse symptomatology. While first raised by a physician's assistant attending to Claimant, the thought became that Claimant's prior hardware may also have been implicated in the October 2020 motor vehicle accident, though initial x-rays

did not show loosening or misplacement. Dr. Zaslavsky explained that the hardware was abutting the joint at L4-5, where most of Claimant's treatment had been directed, such that it was definitely causing some irritation. Claimant had previously received good, albeit temporary relief from injections and ablations of the joints at L4-5. Looking at the treatment history and temporary relief Claimant had sustained, Dr. Zaslavsky testified that the thought became that the hardware that was abutting the joint and causing inflammation in the joint after the motor vehicle accident was related to Claimant's ongoing low back symptoms. As such, a diagnostic hardware block was performed on March 10, 2022 which gave Claimant 100% relief initially and ongoing relief of 60 to 65 percent for two weeks. Recognizing the success of the hardware block, Dr. Zaslavsky testified that the next natural step was to remove the hardware to afford Claimant more permanent relief. Unfortunately, while completing that surgery, micromotion of the fusion was detected and come augmentation of the fusion had to occur as part of the hardware removal. Now post-surgically, Claimant credibly testified that he is essentially back to his pre-October 7, 2020 baseline, having enjoyed the benefits of almost complete resolution of his symptoms.

Again, Dr. Rushton maintains that a good result from a hardware block in insufficient to warrant hardware removal even under circumstances such as Claimant's. He testified that there should be other corroborating factors that were not present here. Dr. Rushton, also however, maintains that Claimant's long term medications may well be working with his osteopenia, comprising his spinal column. He offers this as a basis for the extensive deterioration observed on Claimant's MRIs between 2020 and 2021, suggesting that everything that Dr. Zaslavsky is concerned about relevant to Claimant is part of a long standing degenerative process that is not at all accelerated for a man of Claimant's age and one taking the medications he takes.

The Board rejects this final opinion of Dr. Rushton as well. Dr. Zaslavsky's explanation of how the prior hardware abutted the joint where Claimant's pain has been centralized since the motor vehicle

accident is persuasive. Also persuasive is the reality that Claimant credibly testified that he did not have constant pain in his low back before this accident. While he may occasionally have suffered discomfort, especially if he overdid it, prior to the work accident, he did not require injections, physical therapy, massage, ablations, discography, hardware removal and all of the care he has received since the accident. It is possible that he may have required such care some day because of his medications and osteoporosis however this accident happened and brought about significant injury that accelerated any potential need for such care in the future. Claimant's hardware was not painful before the accident and his L4-5 was not irritated and causing him to require medical care before the accident either.

As such, the Board finds that the hardware block, removal, and corresponding care have all been reasonable, necessary, and causally related to the industrial accident.

ATTORNEY'S FEE AND MEDICAL WITNESS FEES

A claimant who is awarded compensation is generally entitled to payment of a reasonable attorney's fee "in an amount not to exceed thirty percent of the award or ten times the average weekly wage in Delaware as announced by the Secretary of Labor at the time of the award, whichever is smaller."[10] At the current time, the maximum based on Delaware's average weekly wage calculates to $12,340.40. The factors that must be considered in assessing a fee are set forth in *General Motors Corp. v. Cox,* 304 A.2d 55 (Del. 1973). Less than the maximum fee may be awarded and consideration of the *Cox* factors does not prevent the granting of a nominal or minimal fee in an appropriate case, so long as some fee is awarded.[11] A "reasonable" fee does not generally mean a generous fee.[12] Claimant, as the party seeking the award of the fee, bears the burden of proof in providing sufficient information to make the requisite calculation.

[10] DEL. CODE ANN. tit. 19, § 2320.
[11] *See Heil v. Nationwide Mutual Insurance Co.,* 371 A.2d 1077, 1078 (Del. 1977); *Ohrt v. Kentmere Home,* Del. Super., C.A. No. 96A-01-005, Cooch, J., 1996 WL 527213 at *6 (August 9, 1996).
[12] *See Henlopen Hotel Corp. v. Aetna Insurance Co.,* 251 F. Supp. 189, 192 (D. Del. 1966).

Claimant has secured a finding of compensability for his lumbar spine condition and an entitlement to payment of medical expenses related to injections, ablation, hardware block and hardware removal. Claimant's counsel submitted an affidavit stating that he spent a total of 24.4 hours preparing for this hearing which itself lasted approximately three hours. Claimant's counsel has experience in workers' compensation litigation; a specialized area of the law. Counsel or his firm's first contact with Claimant was June 17, 2021, such that he has been represented by counsel or his firm for just over a year. This case was of average complexity involving no novel issues of fact or law. Claimant's attorney did not appear to have been subject to any unusual time limitations imposed by either Claimant or the circumstances, although he naturally could not work on other cases at the same time that he was working on this litigation. There is no evidence that accepting Claimant's case precluded counsel from other employment other than potential representation of Employer. There is no evidence that the employer lacks the ability to pay a fee.

Taking into consideration the fees customarily charged in this locality for such services as were rendered by Claimant's counsel and the factors set forth above, I award a total attorney's fee in the amount of $7,000.

Claimant is further awarded payment of medical witness fees for testimony on his behalf, in accordance with title 19, section 2322(e) of the Delaware Code.

STATEMENT OF THE DETERMINATION

For the reasons set forth above, Claimant's Petition to Determine Additional Compensation Due is GRANTED in part and DENIED in part. More specifically, the Board finds that Claimant did sustain injury to his lumbar spine in the underlying work-related motor vehicle accident such as to warrant the care that he has received excluding the stem cell treatment herein at issue. As such and given that there was no dispute that some or all of the bill totals have not been properly moved, Claimant shall provide the billing as required after which Employer shall, within 30 days of receipt of said materials, make payment

on all outstanding medical expenses as addressed herein, pursuant to the Delaware Health Care fee schedule, in addition to payment of attorney's fees in the amount of $7000 and medical witness fees.

IT IS SO ORDERED THIS 23rd DAY OF SEPTEMBER, 2022.

INDUSTRIAL ACCIDENT BOARD

/s/ Valencia Hayes
VALENCIA HAYES

/s/ William Hare
WILLIAM HARE

I, Angela M. Fowler, Hearing Officer, hereby certify that the foregoing is a true and correct decision of the Industrial Accident Board.

Angela Fowler
Angela Fowler, Esquire
Hearing Officer

Date 9-26-2022

Mailed Date: CR
OWC Staff

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