

Carrie Harriman
Board No. 3590910

COMMONWEALTH OF MASSACHUSETTS

ESSEX, SS.
1274

DEPARTMENT OF INDUSTRIAL ACCIDENTS
NO: 3590910

CARRIE HARRIMAN
Employee

v.

DECISION OF THE ADMINISTRATIVE JUDGE
(Hon. Douglas A. Bean)

SMITH & NEPHEW Inc.
Travelers Ins. Co.

The parties in the above captioned matter appeared before the Administrative Judge of the Department of Industrial Accidents on January 22, and May 6, 2016, pursuant to Chapter 152 of the General Laws of the Commonwealth of Massachusetts. Testimony was heard for 6 hours and 27 minutes.

Appearances: John A. Finbury, Esq. for the employee.
Scott E. Richardson, Esq., for the insurer.

Issues presented: The reasonableness and necessity of Scrambler Pain Mitigation Therapy and a §8(5) penalty.

Claims: Payment for scrambler therapy pursuant to §§13 & 30 and a §8(5) penalty.

Stipulations: Employment and the employee suffered an industrial injury on January 26, 2011.

Stenographer: Maryellen Moulaison January 22, 2016
Linda Walsh May 6, 2016

Witness: Carrie Harriman
Dr. Stephen J. D'Amato
Robert Smith
Frances Perry

EXHIBITS:

1. The employee's biographical data sheet.
2. The insurer's issue sheet.
3. The impartial medical examiner's report.
4. The notes of Dr. Crawford Campbell.
5. The Calmar Pain Relief Therapy treatment notes.
6. A list of 33 peer reviewed articles on scrambler therapy.
7. Pilot Evaluation of Scrambler Therapy for the Treatment of Chemotherapy-Induced Peripheral Neuropathy.
8. Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial.
9. Noninvasive Treatments for Pediatric Complex Regional Pain Syndrome: A Focused Review.
10. Scrambler Therapy for the management of chronic pain.
11. Billing/Payment summary spreadsheet for Calmar Pain Relief Therapy.
12. Calmar medical bills.
13. Employee's out of pocket payments to Calmar.
14. Employee's out of pocket lodging expenses.
15. Employee's mileage log expenses.
16. Calmar's insurance company reimbursement 2014-2015.
- 16A. Calmar's insurance company reimbursement 2016.
17. Explanation of Calmar Pain Mitigation Therapy.
18. The curriculum vitae of Dr. Stephen J. D'Amato.
19. My hearing decision of January 28, 2012.
20. The report of Dr. Amin Sabra.
21. The curriculum vitae of Robert Smith, J.D.

*Exhibits 7-10 are peer reviewed articles on Scrambler Pain Mitigation Therapy.

PROCEDURAL HISTORY

This case was first brought before Administrative Judge Dennis Maher on August 31, 2011 on the employee's initial claim for compensation. Judge Maher ordered the insurer to pay §34 temporary total disability compensation. The insurer's appeal of that order presented the matter to me at hearing for *de novo* determination. Judge Maher had been transferred to the Worcester Court and the case was re-assigned to me. I tried the case on September 10, 2012, the record closed on November 26, 2012 and my decision issued on November 28, 2012. See exhibit 19.

A second claim concerning this matter came before me for conference on March 25, 2015. The employee sought ongoing medical treatment in the form of Scrambler Therapy. Disability is not at issue. My conference order of March 26, 2015 directed the insurer to pay for the requested Scrambler Therapy, pursuant to §§13 and 30. The insurer paid for past Scrambler Therapy treatment as ordered but did not continue to pay for the treatments, leading the employee to add an additional claim for §8(5) penalties. The employee was examined on May 14, 2015 by Dr. Julien Vaisman, an impartial medical examiner retained by the Commonwealth pursuant to §11A. His report has been entered into evidence as exhibit 3. He was not deposed. I allowed additional medical evidence to be submitted as the impartial doctor did not comment on the reasonableness and necessity of Scrambler Therapy. The hearing was held on January 22 and May 6, 2016. Four witnesses testified, the employee, Dr. Stephen J. D'Amato who administered the Scrambler Therapy treatments, Robert Smith, the business manager of the Scrambler Therapy provider, and Frances Perry, the insurance adjuster for this case. Ms. Perry, who lives and works in Florida, testified by agreement, over the telephone. The record closed at the conclusion of testimony on May 6, 2016.

SUBSIDIARY FINDINGS OF FACT

Carrie Harriman, hereinafter the employee is a 57 year old high school graduate, and the mother of one adult child, who lives alone. She worked at a job that required much office work including typing, emailing and other computer work. This caused her to suffer an industrial injury to her right upper extremity. She underwent surgery and subsequently developed complex regional

Carrie Harriman
Board No. 3590910

pain syndrome. She has been out of work, collecting workers' compensation benefits since January 2011. Exhibit 19.

Today the employee's complex regional pain syndrome causes her significant pain, swelling, burning sensations and temperature variations in her right hand. Her hand gets cold easily. She testified wearing a glove on the hand. She wears a sling to cradle her right arm if she has to walk significant distances.

The employee has treated her condition with surgery, physical therapy, ganglion blocks, opioids and Scrambler Therapy. She has had six ganglion blocks which helped but the effects dissipated within seven to ten days. Opioids suppressed her pain but "knocked her out". She was incoherent and could not drive. She now takes over the counter pain medications and gabapentin. The gabapentin leaves her lethargic and tired and unable to concentrate well.

The employee sought Scrambler Therapy at the suggestion of her mother. She traveled to the State of Rhode Island from her home in Hampstead, New Hampshire to consult with Dr. Stephen J. D'Amato of Calmar Pain Relief Therapy Co. (Calmar), who administers Scrambler Therapy as part of his medical practice. Dr. D'Amato found the employee to be a good candidate for the treatment.

Scrambler Therapy is a controversial new treatment modality for chronic neuropathic pain. This non-invasive, non-opiate treatment modality is used to treat chronic neuropathic pain from several sources including phantom pain experienced by amputees, pain associated with cancer, and pain associated with chronic regional pain syndrome. It does not treat non-neuropathic pain. It does not cure the underlying condition, but reduces or eliminates the pain associated with the condition. The insurer argues that the treatment modality is new and not widely accepted within

Carrie Harriman
Board No. 3590910

the medical community. The employee argues that while new, it is accepted by many physicians and it works.

Scrambler Therapy is administered by a doctor using a Scrambler Therapy device, a microprocessor that is attached by wires near to the patient's painful areas but not directly on them. The device uses transcutaneous electrical stimulation of pain fibers with the intent of re-organizing maladaptive signaling pathways. The device produces 16 different electrical currents to stimulate normal nerve action potentials. This changes pain signals to the brain into non-pain signals, relieving the pain. Exhibits 7, 10. The author of a peer reviewed article on the subject wrote "The Scrambler Therapy device is composed of five electrical stimulation channels that through the surface receptors of C fibers replace endogenous pain information with a synthetic one of 'non-pain' or normal self that travels through the same pathways to the brain. Through plasticity within brain networks mediating the perception of pain, a series of treatments 'retrain' the brain so that the area of concern is no longer considered painful." Exhibit 10 page 3. Through the end of 2015 "20 reports of varying scientific quality, have been published regarding (the Scrambler Therapy) device; all but one small study, published only as an abstract, provided results that appear positive." The one negative study may have been hampered by the inexperience of the device operators. The amount of relief experienced by a patient can be dependent on the skill of the Scrambler Therapy device operator. The author concluded that "(t)he positive findings from preliminary studies with Scrambler Therapy support that this device provides benefit for patients with refractory pain syndromes." Exhibit 10, page 1. The device has been cleared by the FDA.

The therapy is administered in five one hour sessions, five days in a row, typically Monday through Friday, with a second series of five one hour sessions in five days after a single intervening weekend. Patients must be free of certain medications, (anticonvulsants) such as gabapentin,

Carrie Harriman
Board No. 3590910

Lyrica and Neurontin, which interfere with the therapy. Some patients are pain free quickly, while others take more time. People's brains learn at different rates. Some patients experience a significant reduction in neuropathic pain, but continue to experience some residual pain after the treatments. The therapy is ineffective for about ten percent of patients. The doctor knows when the treatment is ineffective in just four or five one hour sessions. Whether successful or not there are no side effects. Some patients need follow up "booster sessions" from time to time. These booster sessions, often another single series of five one hour sessions in five days, but sometimes only one or two sessions, are needed every three to twelve months or longer, as the effects of the prior treatment wear off and the neuropathic pain returns. But most patients experience permanent pain relief.

Robert Smith, J.D. is the business manager and general counsel for Calmar. He provided some statistics on the Scrambler Therapy treatment provided at Calmar. The company has treated more than a thousand patients with a success rate of "nearly 80%". Ten percent of patients do not respond to the treatment and another ten percent have some relief. The success rate of workers' compensation patients is slightly less, about 70%. About a third of Calmar's patients were treated for chronic regional pain syndrome. The peer reviewed articles entered into evidence as exhibits 8 and 10 reported similar statistics.

Scrambler Therapy is now being used in several places in the United States, including the Walter Reed National Military Medical Center, the Mayo Clinic, Johns Hopkins Medical Center and the Calmar Pain Relief Therapy Co.

The Federal government has issued Scrambler Therapy a temporary "CPT code" that allows, but does not require, payment for the therapy. Medicare does not recognize the temporary

Carrie Harriman
Board No. 3590910

code number, but has been ordered to pay for the treatment by a Federal court. Some states recognize the temporary code number and others do not.

Dr. D'Amato and Calmar charge \$600 per treatment or \$6000 for an initial series of treatments and \$3000 for five session booster treatments. These charges include professional fees for Dr. D'Amato that are charged under a different CPT code number. Travelers Insurance Company (Travelers) the insurer in this action has paid for all billed treatments except for the Scrambler Therapy charged under the temporary CPT code. Calmar has been paid for its Scrambler Therapy treatments by 25 workers' compensation insurers. Travelers classified Scrambler Therapy as comparable to mere "electrical stimulation" treatment and paid \$11.61 for some of the treatments.

Dr. D'Amato is an investor and employee of the company that sells the Scrambler Therapy device.

The employee described her experiences with Scrambler Therapy. Dr. D'Amato attached electrodes to the skin of her right arm. She felt "static" and her pain was "zeroed out". Her first treatment lasted two weeks. She received one hour long treatment five days in a row, Monday to Friday, and then five more one hour treatments the next Monday through Friday. She stayed in a hotel near the doctor's office each night, returning home for the weekend. She and her doctor claim that the treatment was a success. Her pain was an 8 on the 0-10 pain scale when she arrived. It went to zero during the treatments and rose to 2-3 over night. The next day the pain went back to zero during the treatment and again, rose to 2-3 over night. After finishing her treatment her pain was significantly diminished (2-3) but not completely relieved. After 6-7 weeks her pain returned to her pre-treatment level. She then returned to Rhode Island for a booster treatment of five daily one hour treatments. Again her pain was "zeroed out" during treatments and rose to 2-3 between

Carrie Harriman
Board No. 3590910

treatments. She also experienced a reduction in swelling and greater mobility in her arm after the treatments. She can use her arm more in the weeks after her treatments. As a result of the treatment, she reduced her intake of gabapentin.

The employee seeks to continue these treatments every six to seven weeks. She describes these treatments as more effective than ganglion blocks and opioids. The treatments cost \$600 a piece (\$3000 for each booster treatment week) plus the cost of several nights in a hotel and mileage to and from Rhode Island from her Hampstead New Hampshire home.

The results of the employee's Scrambler Therapy treatment fall below the Calmar definition for success. Success has been defined by Dr. D'Amato and Mr. Smith as significant or total pain relief with booster treatments needed every three to twelve months or longer. The employee pain relief has been significant, a drop from 8 or 6 to 2 or 3, but the pain returns to pre-treatment levels in just 6-7 weeks, which is significantly less than the 12 week minimum for success. The employee's continuing use of gabapentin has been suggested as the culprit for cutting the length of the employee's success. She would stop using gabapentin for a number of days in preparation for receiving the treatment and would resume taking the drug once the treatments were completed. Dr. D'Amato and Mr. Smith stated that the employee's meager results do constitute a success. The employee agrees.

A number of doctors have been retained to comment on the employee's medical regimen.

The employee was examined on 2016 by Dr. Julien Vaisman, an impartial medical examiner retained by the Commonwealth pursuant to §11A. His report has been entered into evidence as exhibit 3. He issued a report with the standard findings that are not at issue here. He

Carrie Harriman
Board No. 3590910

did not comment on the reasonableness and necessity of Scrambler Therapy. So, I allowed the parties to submit additional medical evidence.

The insurer had the employee examined by Dr. Amin Sabra on March 12, 2016. The resulting report was entered into evidence by the employee without objection, as exhibit 20. In his report he recorded a history that is consistent with the one related above. He discussed her past medical treatment, concluding that "(i)t is my opinion that her treatment to date has been reasonable and necessary. It seems that the only mode of treatment that has been effective is the scrambling therapy."

Dr. Crawford Campbell is the employee's treating hand specialist. He wrote that she "suffers from severe upper extremity chronic regional pain syndrome. She has had excellent results from treatment she receives at a pain clinic in Rhode Island (Scrambler Therapy). This treatment does involve a treatment every six weeks. She notes that her pain level decreases from a level 6 to a level 2 or 3 with treatment. Also her gabapentin dosage has decreased from a high of 2200 mg daily to approximately 800 mg just at night." Exhibit 4.

My conference order of March 26, 2015 directed Travelers to pay for the Scrambler Therapy. However, the insurer has not paid for the last four booster sessions, the last of which was received by the employee in November 2015. She paid for her last two treatments herself, (see exhibits 13-14) but cannot afford to pay for more. She has not had Scrambler Therapy since November 2015. Because of Travelers continuing refusal to pay for treatments that I ordered in March 2015, the employee has claimed a penalty is due pursuant to §8(5). Section 8(5) provides that "if an insurer terminates, reduces, or fails to make any payments required under this chapter, and additional compensation is later ordered, the employee shall be paid by the insurer a penalty

Carrie Harriman
Board No. 3590910

payment equal to twenty percent of the additional compensation due on the date of such filing.”

There are a number of exceptions to this requirement contained in §8(2)(a)(b)(c) and (d). But none of those exceptions applies to this case. There was testimony by Frances Perry, the adjuster on this case for Travelers who claimed compliance by paying in full the then \$500 per treatment day bill with a check for \$11.61 as “electrical stimulation”. This complex system of 16 different, finely tunes electrical currents is not mere “electrical stimulation”. Credible testimony by other witnesses establishes that none of the last four booster treatments billed at \$3000 was paid for at even that paltry amount. Because I am ordering Travelers to pay for the four unpaid booster sessions, future booster sessions and for her mileage and hotel expenses, the §8(5) penalty of 20% of the additional compensation due as of the filing of this decision is to be assessed against the insurer.

GENERAL FINDINGS

I find that Scrambler Therapy is accepted by many physicians and hospitals including the Mayo Clinic, Walter Reed Hospital and Johns Hopkins University and is reasonable and necessary medical treatment causally related to the employee’s industrial injury. Therefore I direct the insurer to pay for past and future Scrambler Therapy sessions and the related mileage and hotel expenses. Because there are no board rates I order the insurer to pay the rate ordinarily charged for these services in 2016, \$600 per session.

In making these findings, I rely on the credible testimony of the employee and Robert Smith, and the persuasive medical opinions of Doctors D’Amato, Campbell and Sabra. The employee receives significant, although temporary relief from her complex regional pain syndrome symptoms. This relief is at the low end of the provider’s definition of successful treatment.

Carrie Harriman
Board No. 3590910

Success is generally defined as relieving all or most pain for three to twelve months or more with many receiving permanent relief. The employee's period of pain relief falls below the three month threshold of substantial relief, experiencing such relief only for six to seven weeks. But Dr. D'Amato (and his business manager Robert Smith) asserted that in the employee's case, this treatment result constituted a success. I accept this opinion on that issue, noting that surgery, physical therapy, opiate use and ganglion blocks all proved to be ineffective in addressing her pain. Scrambler Therapy benefits both the employee and the insurer as the employee's need for opiates and other treatment modalities are significantly decreased or eliminated.

For the reasons stated in the last paragraph of the subsidiary findings, I assess a §8(5) penalty against the insurer.

WHEREFORE, it is ordered:

1. That the insurer pay for all of the reasonable and necessary medical treatment including past and future Scrambler Therapy at the rate of \$600 per session and the related hotel and mileage expenses related to the January 26, 2011 industrial injury pursuant to §§13 and 30.
2. That the insurer pay to the employee a §8(5) penalty of 20% of the additional compensation ordered by this decision.
3. That the insurer pay to the counsel for the employee a fee of \$5664 plus reasonable expenses pursuant to §13A(5).



Douglas A. Bean
Administrative Judge
FILED: May 17, 2016

Carrie Harriman
Board No. 3590910