

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 01-0707V

Filed: May 24, 2013

TO BE PUBLISHED

MICHAEL STEPHEN SHAW,

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Petitioner,

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Hepatitis B Vaccine; Small Nerve
Fiber Neuropathy; Finding of
Entitlement to Compensation

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v.

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SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

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Respondent.

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Ronald Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for petitioner.

Voris R. Johnson, Department of Justice, Civil Division, Torts Branch, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

This case is before the undersigned on remand. The issue before the undersigned is whether the hepatitis B vaccines that petitioner, Michael Shaw, received on May 5, 1999,

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will delete such material from public access.

and June 11, 1999, caused him to suffer a small nerve fiber neuropathy.² The undersigned finds, by a preponderance of the evidence, that petitioner's vaccinations caused his injury. In so finding, the undersigned notes that this ruling represents a "close call" and should accordingly be resolved in favor of petitioner. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005) (citing Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir.1994) (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program")); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006) (citation omitted).

PROCEDURAL HISTORY

On December 20, 2001, petitioner filed a petition pursuant to the National Vaccine

² "Small fiber neuropathy is a disorder of the peripheral nerves." Pet's Ex. 67, Tab F, Jinny Tavee & Lan Zhou, Small Fiber Neuropathy: A Burning Problem., 76 (5) Clev. Clin. J. Med. 297, 298 (May 2009).

Small-fiber neuropathy is a subtype of sensory neuropathy. It has a small number of known causes and requires special diagnostic investigation; thus it is useful to separate this entity from other forms of neuropathy. Small-fiber neuropathy can be defined physiologically or anatomically as a sensory neuropathy that exclusively or predominantly affects small fibers and their functions. . . . Because many patients with predominantly small-fiber neuropathy have mild, often subclinical large-fiber involvement, a practical working definition allows the presence of mild large-fiber dysfunction.

Pet's Ex. 67, Tab D, David Lacomis, Small-Fiber Neuropathy, 26 Muscle & Nerve 173 (Aug. 2002) ("Lacomis").

More broadly defined, a neuropathy is "a functional disturbance or pathological change in the peripheral nervous system." Dorland's Illustrated Medical Dictionary 1268 (30nd ed. 2012) ("Dorland's"). Among the various types of neuropathies, petitioner's alleged injury--small fiber neuropathy--is a subtype of sensory neuropathy. Lacomis at 173. Primarily, affecting sensory nerves, a sensory neuropathy can create either a heightened or a dulled sensation in the patient to the sensations of touch and temperature. Transcript of July 28, 2010 Hearing (Tr. 2) at 13-14. A sensory neuropathy can affect one (neuropathy) or several (polyneuropathy) sensory nerves in the peripheral nervous system. Dorland's at 1268.

Injury Compensation Program (Vaccine Program or Program),³ wherein he alleged that his hepatitis B vaccinations caused him to suffer a neuropathy. See Petition (Pet.) at 2-8.⁴ 42 U.S.C. §§ 300aa-1 to -34 (2006). Thereafter, petitioner submitted an expert report opining that he either suffered the condition of transverse myelitis (“TM”) or of chronic inflammatory demyelinating polyneuropathy (“CIDP”) as a result of his vaccinations. Petitioner’s Exhibit (Pet.’s Ex.) 45 at 3-4.

An evidentiary hearing was convened on March 12, 2008, to elicit the testimony of Sherri Tenpenny, D.O., an osteopathic physician,⁵ on behalf of petitioner, and Thomas Leist, M.D., a neurologist, on behalf of respondent. In a decision filed August 31, 2009, the undersigned found that petitioner failed to demonstrate entitlement to compensation. Shaw v. Sec’y of Health & Human Servs., No. 01-707V, 2009 WL 3007729 (Fed. Cl. Spec. Mstr. Aug. 31, 2009), review granted in part, cause remanded by 91 Fed. Cl. 715 (2010) (“Shaw I”). Specifically, the undersigned found that petitioner did not suffer from either of the conditions TM or CIDP as his expert, Dr. Tenpenny, had asserted in her theory of vaccine-related causation. Accordingly, the undersigned found that petitioner failed to establish a logical sequence of cause and effect as then presented, and denied compensation. Shaw I at *27.

Pivotal to the undersigned’s finding of no entitlement in Shaw I was the finding, after a careful review, that to the extent petitioner’s injury was a neurologic one, petitioner’s medical records indicated that the more likely consensus diagnosis was a small fiber neuropathy. Shaw I at *25. But, as Dr. Leist testified at the March 12, 2008 hearing, “small nerve fibers lack the myelin sheaths that would be harmed by the [petitioner’s] proposed demyelination process.” Shaw I at *26. Petitioner did not rebut this testimony. Thus, relying on the unrefuted testimony of Dr. Leist, the undersigned found that petitioner’s proposed theory of causation, demyelination, failed when applied to

³ The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. § 300aa-10 et seq. (2006) (Vaccine Act or the Act). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

⁴ Unrepresented by counsel at the time he filed his petition, petitioner filed with the petition an unnumbered collection of medical records and a summary of his medical records. The unnumbered pages are cited in sequential order.

⁵ Dr. Tenpenny explained that as an osteopathic physician, she received medical school training as well as training in manipulation, such as a chiropractor receives. Transcript of March 12, 2008 hearing (Tr.) at 31.

an injury of small fiber neuropathy. Id.

On September 21, 2009, petitioner filed a Motion for Reconsideration of Shaw I, asserting that the undersigned's Decision was not in accordance with the law and seeking to introduce evidence, previously available but not filed, that small nerve fibers "may well" be myelinated. Motion for Reconsideration at 6. The undersigned denied the Motion for Reconsideration explaining that the evidence concerning small fibers was available to the petitioner two years prior to the filing of the expert report by Dr. Tenpenny and at the time of the hearing. Shaw I at *31.⁶ The undersigned observed that the inability of petitioner to rebut the testimony of Dr. Leist was attributable "directly to Dr. Tenpenny's acknowledged lack of expertise in neurological matters." Id. at 32. Moreover, the undersigned noted that the newly presented information regarding myelinated small nerve fibers was not persuasive "in the absence of any evidence presented by petitioner regarding how this evidence supports the theory of causation proposed by petitioner in this case for the specific injuries of TM and CIDP that Dr. Tenpenny's opinion contemplated." Id.

Petitioner moved the United States Court of Federal Claims to review the undersigned's decision. Motion for Review filed September 30, 2009. On review, the court determined that the Shaw I decision--was "thorough and well reasoned"-- in finding that petitioner neither suffered TM or CIDP, but rather a small fiber neuropathy. Shaw v. Sec'y of Health & Human Servs., 91 Fed. Cl. 714, 720 (Fed. Cir. 2010). The reviewing judge upheld the undersigned's finding that the un rebutted testimony at hearing established that "Mr. Shaw's medical theory, demyelination, was incapable of causing [small fiber neuropathy]." Id. However, the court concluded that "[i]n light of the purposes and structure of the Vaccine Act, we find it in the interest of justice for the [undersigned] to consider the effect of the newly offered evidence." Id. at 721. The court left to the discretion of the undersigned the decision whether to re-open the record beyond allowing consideration of the new evidence and permitting respondent's expert Dr. Leist an opportunity to comment on that evidence. Id.

On remand and after consultation with the parties, the undersigned afforded petitioner an opportunity to retain an expert in neurology to explain how the newly offered evidence supported petitioner's theory of the case. Respondent's expert, Dr. Leist, also was offered an opportunity to address the newly presented evidence. Order filed March 12, 2010. Petitioner ultimately offered the opinion of Thomas Morgan, M.D., a neurologist, in support of his vaccine claim. Respondent again offered the neurologic expertise of Dr. Leist, who challenged petitioner's newly asserted theory of causation.

⁶ The undersigned notes that Westlaw published the ruling on Petitioner's Motion for Reconsideration at the same cite, which appeared directly following the undersigned's first decision in this case.

Another expert hearing was conducted on July 28, 2010 in Washington, D.C. The undersigned sought the testimony of Drs. Morgan and Leist on the issue of whether or not petitioner developed a small fiber neuropathy as a result of his hepatitis B vaccine series.

On remand, Mr. Shaw continued to rely on a theory of causation in fact. In support of his claim, he has filed: (1) an affidavit; (2) medical records; (3) the medical opinion of Dr. Morgan, (4) supporting medical literature, and (5) post-hearing briefs. Respondent offered: (1) the expert opinion of Dr. Leist; (2) a number of medical articles; and (3) a post-hearing memorandum to rebut petitioner's claim.

I. Facts

The facts set forth below are largely derived from the undersigned's recitation of the facts in Shaw I. In general, the parties do not dispute the facts of this case, but rather the medical and legal conclusions to be drawn therefrom. As directed by the Vaccine Act, the undersigned has carefully considered, "in addition to all other relevant medical and scientific evidence contained in the record" the diagnoses, conclusions, and medical judgments contained in the record regarding the nature, causation and aggravation of petitioner's condition as well as the results of diagnostic tests contained in the record. 42 U.S.C. § 300aa-13(b)(1). Declining to review here the entirety of petitioner's voluminous medical records, the undersigned focuses on the records upon which the parties have relied most heavily.

Petitioner was born on June 15, 1959. Petitioner's Exhibit (Pet.'s Ex.) 1 at 1. His medical history is most notable for a couple of concussive head injuries, a cracked pelvis, a chipped tailbone, a fractured nose, and broken hands and feet. Pet.'s Ex. 4 at 5; Tr. at 12, 16. He also has a history of herpes. Pet.'s Ex. 2 at 4.

Prior to receiving the vaccinations at issue in this case, petitioner traveled extensively in his professional capacity as the corporate general manager for a large, multi-national trading firm. Pet.'s Ex. 43 at ¶ 1. He had responsibilities for approximately 30 offices throughout the Asian Pacific region. Id.

Recreationally, Mr. Shaw enjoyed extreme sports activities, including motorcross riding, mountain biking, roller blading, hang gliding, parachuting, rafting and mountain climbing. Id. He also enjoyed golf, tennis, skiing, softball and basketball. Id.

In anticipation of scheduled business travel and as part of an employment-related immunization program, Mr. Shaw received his first hepatitis B vaccination on May 5, 1999. Pet.'s Ex. 2 at 67; Tr. at 5. He did not recall experiencing any effects after that

vaccination. Tr. at 5.

The next month, on June 11, 1999, he received his second hepatitis B vaccination and a polio vaccination. Pet.'s Ex. 2 at 67; Pet.'s Ex. 43 at ¶ 2. The medical records indicate that on June 21, 1999, 10 days after receiving the hepatitis B vaccination of interest, petitioner visited his primary care physician, John Roberts, M.D., of Blackhawk Medical Group, complaining of recurring numbness in his right leg below the knee. Pet.'s Ex. 1 at 31; Petitioner's Post-Hearing Brief filed May 28, 2008 (P's Brief) at 2. Petitioner reported that the numbness had begun on June 17, 1999, four days prior to his visit to Dr. Roberts and six days after he had received his second hepatitis B vaccine.⁷ The numbness was "now progressing to a throbbing pain." Pet.'s Ex. 1 at 31. Dr. Roberts noted a patient history of "lots of trauma" associated with his motorcross riding. Id. Dr. Roberts diagnosed petitioner with lumbar strain and nerve compression. Id. Dr. Roberts prescribed prednisone⁸ and urged petitioner to obtain x-rays and magnetic resonance image (MRI) of his back.⁹ Id.

Petitioner began an international business trip on June 23, 1999. Pet.'s Ex. 43 at ¶ 3. In his affidavit, prepared on October 17, 2006, he recalled that:

By the time I reached my first stop in England, both my feet [and] legs were affected. During business meetings in India, I began to experience tremors in my limbs, cognitive memory/speech problems, and coordination difficulties. Prior to returning home from the two-week trip, my arms were also affected. The symptoms now included, not only, numbness and tingling but also sharp, shooting, burning, and throbbing pain. I managed to

⁷ The pertinent medical record indicates that the numbness began on the Thursday preceding the office visit. Pet's Ex. 1 at 31. According to the June 1999 calendar, the referenced Thursday was June 17, 1999. See id.; see also Year 1999 Calendar, [timeanddate.com](http://www.timeanddate.com), <http://www.timeanddate.com/calendar/index.html?year=1999&country=1> (last visited May 15, 2013).

⁸ Prednisone belongs to a class of drugs called steroids. See Prednisone Information, [Drugs.com](http://www.drugs.com/prednisone.html), <http://www.drugs.com/prednisone.html> (last visited May 15, 2013). A synthetic glucocorticoid, it is used as an anti-inflammatory and as an immunosuppressant. See Dorland's at 1509.

⁹ Magnetic resonance imaging (or an MRI) is "a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments." Dorland's at 916.

complete the trip in defiance of significant pain.

Once home, the pain continued. I experienced numbness in both of my hands and legs and had spasms in my back.

Id. at ¶¶ 3-4.

Petitioner underwent imaging of his spine on July 6, 1999. Pet.'s Ex. 1 at 95. The MRI of his cervical spine produced an impression of “[e]arly disc degeneration without extrusion.” Id. The MRI of his lumbar spine was normal. Id. at 95-96. On July 9, 1999, three days after his spinal MRIs, petitioner returned to his primary care provider. See Pet.'s Ex. 1 at 29. He complained of flu-like symptoms and of continued numbness in his right leg. Id. Although the office notes reflect a history of numbness in petitioner's left leg and hands, only a general time frame of symptom onset is specified. Id.; but see Pet.'s Ex. 1 at 25 (petitioner reporting, during a visit to his primary care physician on October 27, 1999, that his numbness had progressed to all of his extremities in late June). The diagnostic impression at the July 9, 1999 visit was sinusitis and strain in the lumbar and cervical regions of the spine. See Pet.'s Ex. 1 at 29. The examining physician prescribed Lorabid and Xanax¹⁰ and ordered physical therapy. Id.

Treatment Sought During the First Six Months after the Hepatitis B Vaccination.

Five weeks later, on August 18, 1999, petitioner visited Samuel Jorgenson, M.D., an orthopedist. Pet.'s Ex. 4 at 11. Petitioner reported a two-month history of right foot pain and intermittent numbness and tingling in his arms, hands, and feet. Id. Petitioner also reported that he did not continue to take the Xanax he had been prescribed because it caused drowsiness. Id. at 10. Dr. Jorgenson's physical examination revealed a “decreased sensation to sharp pin prick” in petitioner's right foot when compared with his left one. Id. at 12. It was the orthopedist's assessment that petitioner had a possible entrapment neuropathy in his lower right extremity. Id.

¹⁰ Lorabid is an antibiotic indicated for the treatment of mild to moderate infections. See Lorabid (Loracarbef) Drug Information, RxList, <http://www.rxlist.com/lorabid-drug.htm> (last reviewed Dec. 8, 2004).

Xanax is indicated for the treatment of anxiety and panic disorders which can include symptoms of paresthesias (specifically, numbness or tingling sensations). See Xanax (Alprazolam) Drug Information, RxList, <http://www.rxlist.com/xanax-drug/indications-dosage.htm> (last reviewed Sept. 7, 2011).

Dr. Jorgenson referred petitioner for an electromyogram¹¹ that was conducted on September 2, 1999. See Pet.'s Ex. 1 at 66. The electromyogram (or EMG) revealed no evidence of "acute or chronic lumbosacral radiculopathy, plexopathy¹² or peripheral neuropathy." Id. at 67. Petitioner had described symptoms of progressive burning pain and intermittent numbness from his foot to his ankle that, at times, emanated to his knee. Pet.'s Ex. 1 at 66. The physician interpreting the EMG results noted that "[t]he patient is most likely exhibiting very early symptoms of idiopathic peripheral neuropathy" and recommended a trial of Neurontin¹³ to reduce the burning parasthesias. Id. at 67.

Approximately two months later, on November 9, 1999, petitioner saw Janet Lin, a neurologist, on referral from Dr. Roberts, his primary care physician. Pet.'s Ex. 2 at 1, 3. Dr. Lin noted that petitioner's neurologic exam was normal "except for some minimal sensory abnormalities in his hands and feet." Pet.'s Ex. 2 at 3. Although petitioner reported feeling fatigued, there was no evidence of muscle weakness. Id. Dr. Lin believed that petitioner was "suffering [due to] a post-inflammatory neuropathy related to immunizations." Id. During her examination nearly five months after petitioner received the subject vaccination, Dr. Lin surmised that the "culprit" might be the hepatitis B immunization that petitioner received because petitioner had received all the other immunizations previously. Id.

Treatment Sought Over the Next Two Years

Petitioner sought treatment from a variety of specialists over the next two years.

¹¹ An electromyogram (or EMG) "is a test that is used to record the electrical activity of muscles. When muscles are active, they produce an electrical current. This current is usually proportional to the level of the muscle activity. . . . EMGs can be used to detect abnormal electrical activity of muscle that can occur in many diseases and conditions, including . . . inflammation of muscles, pinched nerves, [and] peripheral nerve damage (damage to nerves in the arms and legs)." William C. Shiel, Jr., EMG (electromyogram) Test Information, MedicineNet.com, <http://www.medicinenet.com/electromyogram/article.htm> (last visited May 24, 2013).

¹² A plexopathy is any disorder of a network of nerves. See Dorland's at 1462.

¹³ Neurontin is an anticonvulsant. See Neurontin Information, Drugs.com, <http://www.drugs.com/neurontin.html> (last visited May 15, 2013). Because it affects chemicals and nerves in the body that are involved in the cause of seizures and some types of pain, it may be used in the treatment of epilepsy. Id. It also may be used to treat nerve pain caused by the herpes virus or shingles. Id.

On referral from his primary care doctor, petitioner consulted on February 28, 2000 with Benedict Villanueva, M.D., an infectious disease specialist. See Pet.'s Ex. 6 at 1- 4. As reflected in the notes from the consultation, Dr. Roberts had referred petitioner to Dr. Villanueva for an evaluation of whether his symptoms of diffuse sensory neuropathy were a “[p]ossible post vaccine adverse reaction.” Id. at 1. The particular vaccine under examination was the polio vaccine--not the hepatitis B vaccine--that petitioner had received in June 1999. Id. Dr. Villanueva noted that petitioner had a normal EMG, a “basically” normal MRI of his cervical and lumbar area and, with the exception of a slightly elevated protein level, a normal spinal tap.¹⁴ Id. In Dr. Villanueva’s assessment, among the “[p]ossible etiologies” for petitioner’s “subjective diffuse sensory polyneuropathy” would be a “rare/remote adverse reaction to the polio vaccine.” Id. at 3. But, Dr. Villanueva observed, such reactions occur within a few weeks after immunization and, to his knowledge, do not last for several months after the inoculation. Id.

Approximately one month later, petitioner underwent further neurologic examination by Catherine Lomen-Hoerth, M.D., at the University of California in San Francisco. See Pet.'s Ex. 9 at 107. He returned to Dr. Lomen-Hoerth on May 10, 2000, for a follow-up of continuing pain and numbness. Id. Dr. Lomen-Hoerth noted that petitioner’s discomfort had progressed and was worse than when she had examined him for the first time one month earlier. See id. It was Dr. Lomen-Hoerth’s impression that petitioner had “a progressive small fiber neuropathy rather than a static neuropathy related to his vaccinations last summer.” Id.

On referral from his neurologist Dr. Lomen-Hoerth, petitioner saw David Martin, M.D., a rheumatologist, on July 31, 2000. Pet.'s Ex. 2 at 9. The purpose of the referral was to evaluate petitioner’s severe fatigue, weight loss, intermittent burning rash on both arms and joint pain. Id. at 10. It was Dr. Martin’s impression that extensive laboratory work and physical examination failed to produce any clear evidence of connective tissue disease. Id. at 11-12. In his view, petitioner suffered from “an idiopathic syndrome associated with chronic fatigue and . . . possibly related to a vaccine exposure or possibly a toxin.” Id. at 12. Dr. Martin suspected that petitioner’s condition had an underlying psychiatric component with possible depression. Id.

On referral from Dr. Lomen-Hoerth, petitioner was examined by Nicholas Maragakis, M.D., a neurologist at John Hopkins Hospital on August 21, 2000, for evaluation of a possible small fiber neuropathy. Pet.'s Ex. 13 at 174. Dr. Maragakis

¹⁴ A spinal tap or cerebrospinal fluid (CSF) examination that yields an elevated protein level may be indicative of an underlying infectious or inflammatory process. See Mosby’s at 682, 686.

noted that petitioner's "exam [was] normal, with the exception of some mild decreased pinprick sensation in the hands and feet, which is often typical for a small fiber neuropathy. Of note, quantitative sensory testing at an outside hospital was essentially normal. I think this most likely represents some form of small fiber neuropathy." Id. at 175-176. In an addendum to his August 21, 2000 report, Dr. Maragakis noted that petitioner's skin biopsy "demonstrate[d] a normal range of epidermal nerve fiber density;" however, he found the biopsy was "suggestive of early nerve fiber degeneration" and that a later biopsy "may be useful." Id.

Over four months later, on January 3, 2001, petitioner presented to the emergency room "[a]cting strange and confused" and complaining of worsening pain in his extremities. Pet.'s Ex. 3 at 25. The admission notes indicate that petitioner has a neuropathic condition that has waxed and waned, but is slowly progressive. Id. The admission notes also indicated that petitioner had experienced some changes in mental status, including poor memory, decreased alertness, and diminished concentration. Id. The diagnosis on discharge was "[a]cute severe exacerbation of chronic neuropathy pain." Id. at 27.

On May 8, 2001, petitioner saw Rex Chiu, M.D., an internist at Stanford Hospital and Clinics, on referral from Dr. Lomen-Hoerth. Pet.'s Ex. 5 at 13. Dr. Chiu noted that petitioner experienced an onset of numbness and tingling in his left toe six days after receiving a polio vaccination and a hepatitis B vaccination in anticipation of business travel to India. Id. Petitioner's developing symptoms produced "concern for a postinflammatory reaction to the immunizations," but a trial course of prednisone provided no relief. Id. Following a series of visits to diverse medical specialists, the "consensus diagnosis" appears to be small fiber neuropathy. Id. Dr. Chiu wrote that because petitioner's neurologic changes seem to have arisen after his immunization in 1999, "there is question as to whether there is some type of autoimmune or other reaction to this vaccination, which may now be worsening in a progressive fashion." Id. at 16. Dr. Chiu noted: "[T]he patient is hepatitis B negative," referring to the lack of hepatitis B antibodies that might be expected to appear. Id. Dr. Chiu planned to refer petitioner for further neurologic and rheumatologic examination at Stanford. Id.

On referral from Dr. Chiu, Yuen So, M.D., a neurologist at Stanford, examined petitioner on July 12, 2001. Pet.'s Ex. 5 at 21. Dr. So noted that petitioner had seen a number of neurologists over a two-year period. Id. Dr. So further noted that the "most disabling" feature of petitioner's illness was his diffuse pain. Id. Based on a physical examination of petitioner and a review of petitioner's laboratory test results, Dr. So wrote: "It is conceivable that [petitioner] had an acute, predominantly sensory polyneuropathy back in 1999." Id. at 22. But without the records of petitioner's medical evaluation during that time period, Dr. So found it "difficult" to ascribe petitioner's complaint of

progressive symptoms since 1999 to the received vaccinations. Id. at 22. Disturbing to Dr. So about petitioner's condition was the "very diverse nature" of petitioner's symptoms. Id. Also disturbing to Dr. So was the lack of objective evidence of neuropathic abnormality in a patient who has had ongoing disease for a course of two years. Id. Contrary to normal expectations for a patient suspected of having a prior acute neuropathy, petitioner did not demonstrate a slow and steady course of improvement. See id. Dr. So described the case as a "very difficult" one to diagnose and to treat. Id.

In September 2001, petitioner and his wife moved from northern California to Delaware. See Pet.'s Ex. 18 at 46. Approximately, two months later, on November 8, 2001, petitioner visited Gail Berkenblit, M.D., an internist at Johns Hopkins, for ongoing chronic pain. Pet.'s Ex. 13 at 161; see also Gail Valerie Berkenblit, MD, PhD, Johns Hopkins Medicine <http://www.hopkinsmedicine.org/doctors/results/directory/profile/0010383/gail-berkenblit> (last visited May 15, 2013). Dr. Berkenblit conducted a physical examination and reviewed the records that petitioner presented regarding his extensive laboratory work. See Pet.'s Ex. 13 at 161-165. Dr. Berkenblit took an extensive patient history and noted that petitioner's evaluations have been essentially normal, including his autonomic function testing. See id. Petitioner's initial diagnosis was a possible postinflammatory neuropathy. Id. at 162. Subsequently, petitioner received evaluations for a possible small fiber neuropathy. Id. Repeated testing, however, had not disclosed any "definite evidence of a small fiber neuropathy." Id. Rather, swelling noticed in the distal leg sites during a neurologic examination at Johns Hopkins by Dr. Nicholas Maragakis was suggestive of "early possible nerve fiber degeneration." Id. During the office visit, Dr. Berkenblit addressed concerns expressed by petitioner and his wife that petitioner's symptoms resulted from his hepatitis B vaccination. Id. at 165. Dr. Berkenblit observed that there is no clear link between hepatitis B vaccination and progressive neuropathic pain, but noted that "[i]f [petitioner] did develop symptoms of a sensory neuropathy as a consequence of the vaccine it would most likely be as an autoimmune type mechanism" and not a vaccine contamination issue as petitioner's wife speculated. Id.

Petitioner filed his vaccine claim on December 20, 2001. See Pet. at 1.

On January 15, 2002, a second skin biopsy was taken from several different places on petitioner's leg. Pet.'s Ex. 13 at 145. The test result again showed a normal range of epidermal nerve fiber density, offering "no definitive evidence" of a small fiber neuropathy and "no clear progression compared to the August 2000 biopsies." Pet.'s Ex. 13 at 145 (emphasis added). Three weeks later, on February 7, 2002, petitioner visited Lee Dresser, M.D., a neurologist, for an evaluation. Pet.'s Ex. 18 at 44. Dr. Dresser noted that previous evaluations by neurologists included an assumption that petitioner had developed a sensory neuropathy as a response to his vaccination, but that diagnosis was modified as

extensive testing has returned negative results. Id. at 45. It was Dr. Dresser's impression that petitioner suffers from "[d]iffuse dysesthetic pain following remote vaccinations." Id. at 47. Of interest to Dr. Dresser was the finding of a mild elevation of petitioner's spinal fluid protein following petitioner's extensive and otherwise unremarkable testing. Id. Dr. Dresser observed that petitioner's symptoms were "essentially 100% subjective with no significant objective findings on . . . testing or examination." Id. Dr. Dresser found petitioner's case to be a "very complicated" one. Id.

Opinions of Possible Vaccine Related-Causation

To assist petitioner with his pending vaccine claim, Dr. Roberts, the primary care physician who examined petitioner when his symptoms first began in 1999, wrote a letter dated February 13, 2002. Pet.'s Ex. 18 at 6. Dr. Roberts stated that petitioner had no significant neurologic symptoms prior to the petitioner's receipt of the hepatitis B vaccination and that petitioner began to develop neurologic complaints shortly after his immunization. Id. It was Dr. Roberts' belief that the temporal relationship between the received vaccination and the onset of petitioner's symptoms "strongly correlate[d]" with the hypothesis that the symptoms were caused by the vaccination. Id.

Thereafter, other treating doctors offered views about what may have caused petitioner's symptoms.

On January 21, 2003, Robert Allen, M.D., an evaluator retained by the defense in connection with the workers' compensation claim filed by petitioner, examined petitioner. Pet.'s Ex. 8 at 12-24; Pet.'s Ex. 33 at 43. Dr. Allen observed that petitioner's neurologic evaluations (including biopsies) have not documented any progressive neurologic disease. Pet.'s Ex. 8 at 22. In Dr. Allen's opinion, petitioner's clinical history and physical examination, together with the extensive objective work-up, suggested "a diagnosis of fibromyalgia." Id. He explained that "[t]he diagnosis of fibromyalgia involves the presence of widespread musculoskeletal pain, as well as multiple tender points . . . that occur[] both above and below the waist." Id. He stated that "[t]he etiology of his fibromyalgia remains unclear and may have developed as a result of the June 1999 vaccination[s]." Id. But, Dr. Allen acknowledged, such causation "is impossible to confirm or deny." Id. Dr. Allen was one of two evaluators to diagnose petitioner with fibromyalgia, a diagnosis that is disputed by petitioner's treating physicians.¹⁵ See Pet.'s

¹⁵ The diagnosis of fibromyalgia was first considered by the defense evaluator, Dr. Robert Allen. Another defense evaluator, Dr. Charles Skomer, diagnosed a chronic pain condition but allowed that petitioner's symptoms were "possibly consistent with [a finding of] fibromyalgia." Pet.'s Ex. 33 at 43, 48-49. But, there is no evidence in either the multiple neurologic or rheumatologic evaluations contained in petitioner's medical records

Ex. 33 at 48.

On April 29, 2003, Harold Buttram, M.D., an internist with Woodlands Healing Research Center, examined petitioner. Pet.'s Ex. 25 at 1. Dr. Buttram noted that petitioner had become ill following chelation efforts to eliminate mercury, and subsequent testing indicated that mercury toxicity was not an issue for petitioner. Id. Dr. Buttram further noted that Dr. Tenpenny, the treating physician who testified at the first hearing on petitioner's behalf, had directed petitioner's mercury detoxification process. Id. Aware that petitioner's vaccine claim was pending, Dr. Buttram wrote: "For the records, it is my opinion that the patient's peripheral neuropathy is directly related to (was caused by) a series of two hepatitis B vaccines." Id. Noting that petitioner "ha[d] been diagnosed by neurologists as having chronic neuropathic pain," Dr. Buttram prepared an opinion letter dated June 6, 2003, stating that he agreed with the diagnosis of the neurologists and reiterating that petitioner's condition was caused by a series of hepatitis B vaccines. Pet.'s Ex. 33 at 95.

On November 4, 2004, petitioner was given a diagnosis of "[v]accine-induced neuroimmune dysfunction" by Vincent Natali, M.D., a general practitioner. Pet.'s Ex. 50 at 8. Thereafter, on December 23, 2004, David Waldman, M.D., another physician, issued an extensive report concerning petitioner's disability status. See Pet.'s Ex. 33 at 2-52. Dr. Waldman's report was informed by his review of petitioner's medical records, his review of medical literature, and a physical examination of petitioner. See id. Contained in Dr. Waldman's report was a detailed, chronological summary of petitioner's medical evaluations and laboratory results. Id. at 35-45. Also contained in Dr. Waldman's report was a summary of medical articles that he had reviewed, in connection with his evaluation of petitioner, concerning "complications from the hepatitis B vaccination." Id. at 45. Dr. Waldman concluded:

There is no evidence within the records submitted that, prior to 6/11/99, Mr. Shaw had any neurological injury and was not able to function After the vaccinations of 6/11/99, Mr. Shaw began a very complex medical history, resulting in a chronic pain disorder syndrome. . . . Mr. Shaw has a problem with pain medicine addiction, which he did not have prior to his industrial injury. As stated within his multiple medical records, as a consequence of his work related chronic pain disorder, he has developed a drug dependence. . . . There is no evidence in review of the medical records that Mr. Shaw has a fibromyalgia syndrome. . . . [Rather,] Mr. Shaw has developed a chronic neuropathic pain syndrome. Although the exact

to support a finding that Mr. Shaw has fibromyalgia.

etiology has not been determined, based on the review of the medical records and medical literature, it is with medical probability that this syndrome was a consequence of the vaccinations received on 6/11/99. This opinion that this syndrome occurred post vaccination has also been supported by multiple clinical evaluators . . . includ[ing] Dr. Janet Lin and Dr. [Catherine] Lomen-Hoerth[, two neurologists] at UCSF Medical Center. This has also been supported by recent evaluations which Mr. Shaw has sought to obtain relief from his pain syndrome . . . with multiple sequelae, including drug dependence, and these conditions are industrial in nature.

Id. at 48-49 (emphasis added)(internal enumeration omitted).

Pamela P. Palmer, M.D., an anesthesiologist at the UCSF Medical Center's Pain Management Center, examined petitioner nearly nine months later on September 20, 2005. Pet.'s Ex. 39 at 13-14. Dr. Palmer assessed petitioner as "a 46 year-old gentleman with six years of diffuse pain after vaccination, consistent with a diffuse small fiber neuropathy." Id. at 14 (emphasis added).

Four months later, on January 30, 2006, petitioner was evaluated by Phyllis A. Cullen, M.D., an anesthesiologist and pain specialist with the Chico Pain Clinic in Chico, California. Dr. Cullen reported petitioner's history as that of "a 46 year old man who suffered an intense reaction to a hepatitis B vaccine in 1999, developing a small fiber neuropathy." Pet.'s Ex. 37 at 5 (emphasis added). Dr. Cullen's impression after examining petitioner was that he had a "small fiber neuropathy." Id. at 6.

Thereafter, Robert E. Sullivan, M.D., who prescribed petitioner's medicinal cannabis, found on February 13, 2007, that petitioner's "chr[onic] polyneuropathy persists, [secondary] to [a] Hep[atitis] B adverse reaction." Pet.'s Ex. 52 at 6-7.

Petitioner testified at the 2008 hearing for his vaccine claim that he continued to experience fluctuating levels of pain. See Tr. at 13. His pain is best managed by the opiate therapy he has been prescribed. Id. at 15.

A neuropsychologic evaluation was subsequently conducted by Alfred L. Scopp, Ph.D., at the request of petitioner's disability attorney. Pet.'s Ex. 76 at 12. In a lengthy report dated June 25, 2008, Dr. Scopp concluded that petitioner suffered from a "progressive peripheral neuropathy subsequent to hepatitis B inoculation." Id. at 22.

On August 7, 2008, petitioner was seen by Oscar N. Abeliuk, M.D., a neurologist for a comprehensive neurologic consultation in connection with his disability claim. Pet.'s Ex. 71 at 1. Dr. Abeliuk prepared a lengthy report, in which he determined that

petitioner suffered from a “decreased perception of pinprick and light touch in a symmetrical distribution in the upper and lower extremities distally, suggestive of long-term polyneuropathy (in this case, small fiber type).” Id. at 16. Dr. Abeliuk offered as a diagnosis, “[c]hronic debilitating polyneuropathy, well documented by multiple tests. Doctor Lomen-Hoerth has determined the presence of small fiber polyneuropathy affecting the upper and lower extremities, as documented by a skin biopsy at Johns Hopkins, with disturbing skin sensations.” Id. at 17.

On May 18, 2009, petitioner was seen by Joel M. Rothfeld, Ph.D, M.D., for a neurologic consultation. In Dr. Rothfeld’s assessment, petitioner has a “[h]istory of distal small fiber neuropathy with chronic pain refractory to multiple medication therapies.” Pet.’s Ex. 69 at 3. Dr. Rothfeld found that petitioner’s “[n]eurological exam reveal[ed] alodynic response to sensory testing distal lower extremities consistent with small fiber neuropathy neuropathic pain.” Id.

Petitioner appears to have remained under the care of his primary treating neurologist, Dr. Catherine Lomen-Hoerth. Dr. Lomen-Hoerth found after her examination of petitioner on August 26, 2009, that

clinically [petitioner] appears to have a progressive small fiber neuropathy, with documentation on skin biopsy suggestive of an early small fiber neuropathy. These type of neuropathies typically have normal nerve conduction studies and normal neuroimaging, as was the case with Mr. Shaw. . . . He is unable to work due to an inability to stand or sit for any period of time and an inability to type well due to numbness and pain.

Pet.’s Ex. 77 at 5.

In a letter dated November 14, 2009 to Cigna Disability Claims department, Dr. Pamela P. Palmer, the anesthesiologist who continued to treat petitioner for pain, noted that he suffers from “a clearly diagnosed small-fiber neuropathy” and urged that his disability benefits be reinstated. Id. at 8. Likewise, his primary care physician, Katherine Julian, M.D., wrote a letter requesting reinstatement of petitioner’s disability benefits. Dr. Julian explained that “it is unclear as to the . . . etiology of his neuropathy, though specialists believe the cause is likely due to a vaccine he received in the late 1990’s. . . . However, he has been evaluated by neurology, and standard office-based nerve testing does reveal neuropathy.” Id. at 9.

II. Applicable Legal Standards

The Vaccine Act provides two separate methods by which to obtain Program

compensation: (1) Vaccine Injury Table (Table) claims; and (2) causation in fact (off-Table) claims. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). When asserting a Table claim, a claimant is afforded a presumption of causation if he shows that he received a vaccine listed on the Table, 42 C.F.R §100.3(a), and suffered an injury listed on the Table within the prescribed time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i); see Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). If unable to establish a Table claim, the claimant must show that his injury was “caus[ed] in fact” by the vaccine he received. See Capizzano, 440 F.3d at 1320.

The Vaccine Act provides for the compensation of “any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine” covered under the Program. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). The Act does not require a petitioner bringing a non-Table claim “to categorize [the suffered] injury.” Kelley v. Sec’y of Health & Human Servs., 68 Fed. Cl. 84, 100 (2005). Rather, a petitioner is required only “to show that the vaccine in question caused [him] injury—regardless of the ultimate diagnosis.” Id. When, as in this case, the conditions at issue present with many of the same symptoms—but the underlying causes and required treatments are different—and when, as in this case, the evidence for causation depends on the particular diagnosis of petitioner’s condition, a special master may consider whether the record supports the diagnosis proposed by petitioner. See Broekelschen v. Sec’y of Health & Human Servs., 618 F. 3d 1339, 1346 (Fed. Cir. 2010).

A petitioner may prove entitlement to Program compensation of an off-Table case by satisfying the three-part test set forth by the Federal Circuit in Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005).

Concisely stated, [a claimant’s] burden is to show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [a claimant] satisfies this burden, [he] is entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Id. at 1278 (internal citation omitted).

To prevail, a claimant’s theory of causation must be supported by a “reputable medical or scientific explanation.” Althen, 418 F.3d at 1278 (citations and internal quotation marks omitted); see also Knudsen, 35 F.3d at 548 (requiring a “sound and

reliable medical or scientific explanation”). A claimant need not produce medical literature or epidemiologic evidence in support of his theory causation, *see Andreu*, 569 F.3d at 1379; *Capizzano*, 440 F.3d at 1325; but if such evidence is submitted, a special master may consider the scientific soundness of that evidence in reaching an informed judgment as to whether a particular vaccination more likely than not caused a particular injury, *see Althen*, 418 F.3d at 1280.

While *Althen* contemplates that the provided support for a claimant’s theory of causation is based on a “reputable medical or scientific explanation,” 418 F.3d at 1278 (citations and internal quotation marks omitted), that support need not rise to the level of medical or scientific certainty for a petitioner to prevail on a vaccine claim. In *Andreu*, the Federal Circuit made clear that submitted medical literature and epidemiologic evidence

must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard: “The standard of proof required by the [Vaccine] Act is simple preponderance of evidence; not scientific certainty. . . [I]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the court meet the standards of the laboratorian.”

569 F.3d at 1380 (quoting *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, (Fed. Cir. 1991)). When reviewing offered scientific evidence, a special master must take into account that “a finding of causation in the medical community may require a much higher level of certainty than that required by the Vaccine Act to establish a prima facie case.” *Broekelschen*, 89 Fed. Cl. 336, 343 (Fed. Cl. 2009), *aff’d*, 618 F. 3d 1339 (Fed. Cir. 2010) (internal citation omitted).

Also reiterated in *Andreu* is the importance in vaccine cases of considering medical opinions contained in the records or presented at hearing testimony. *Andreu*, 569 F.3d at 1375. Such opinions, explained the Circuit Court, can be “‘quite probative’ since ‘treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” *Id.* (quoting *Capizzano*, 440 F.3d at 1326). *See also Althen*, 418 F.3d at 1279-80 (noting that the use of “medical opinion as proof” of causation is contemplated under the Vaccine Act).”

However, consistent with the Vaccine Act, a special master is not bound by any diagnosis, conclusion, judgment, test result, report, or summary contained in the record. 42 U.S.C. § 300aa-13(b)(1). A special master must consider the entire record and the course of the subject injury when evaluating the weight to be afforded to any offered diagnosis,

conclusion, judgment, test result, report, or summary contained in the record. 42 U.S.C. § 300aa-13(b)(1).

III. Analysis

A. Opinion of Petitioner's Expert Witness, Dr. Morgan

In support of his vaccine claim, on remand, Mr. Shaw relies on the opinions of the treating physicians contained in his filed medical records, as well as, the offered expert report and remand hearing testimony of Dr. Morgan. Having obtained a medical degree from Meharry Medical College in 1970, Dr. Morgan is board-certified by the American Board of Psychiatry and Neurology, as well as by the American Board of Independent Medical Examiners. Transcript of July 28, 2010 Hearing (Tr. 2) at 7; Pet.'s Ex. 68 at 2-3. Dr. Morgan is a practicing neurologist, whose focus is neurologic injury and disability. Tr. 2 at 7; Pet.'s Ex. 68 at 3. Dr. Morgan is also an Assistant Professor at Brown University, School of Medicine in the Department of Clinical Neuroscience. Tr. 2 at 7.

It is Dr. Morgan's opinion, based on the evaluations of petitioner's treating physicians, the medical records, the medical literature, as well as his own expertise that Mr. Shaw suffers from a small fiber neuropathy. See generally Pet.'s Ex. 67; Tr. 2 at 76-77. It is the further position of Dr. Morgan that petitioner's injury resulted from a demyelination of his peripheral nerves through the biological mechanism of molecular mimicry caused by the hepatitis B vaccines he received. This theory of causation contemplates that the administered "vaccine stimulates the host[']s immune system to react to the hepatitis-B antigen and cross react with the myelinated nerve fibers of the host. This mistaken attack by the body's own immune system is secondary to the similarity between the foreign hepatitis-B antigen and the myelin component in the host." Pet's Ex. 67 at 2. In sum, Dr. Morgan posits that the hepatitis B vaccine can cause demyelination of the peripheral nerves, id., and a finding that petitioner suffers from "a small fiber neuropathy causally related to a post[-vaccinal] immune mediated peripheral nerve disorder," id. at 4, is supported by the "time [of symptom] onset," id. at 3.

B. Opinion of Respondent's Expert Witness, Dr. Leist

To address the opinion offered by Dr. Morgan, respondent offered the opinion and testimony of Dr. Leist, who serves as Chief of the Division of Neuroimmunology and Director of the Comprehensive Multiple Sclerosis (MS) Center at Thomas Jefferson University in Philadelphia, Pennsylvania. Resp.'s Ex. B at 1. Possessing a doctorate in biochemistry from the University of Zurich in 1985 and a medical degree from the University of Miami in 1993, Dr. Leist augmented his studies by pursuing postgraduate training in the areas of pathology, microbiology, immunology and neurology. Id.

Board-certified by the American Board of Psychiatry and Neurology and describing himself as a bench-trained immunologist “with strong interests in general immunology and viral immunology,” he has focused, through his training, on diseases that are immunologic in nature and affect the nervous system. Tr. at 89-90.

Dr. Leist takes issue with Dr. Morgan’s opinion. Dr. Leist notes as an initial matter, that Mr. Shaw has had two skin biopsies performed to evaluate whether he has a small fiber neuropathy. In both instances, the biopsies exhibited “normal epidermal nerve fiber density” - - a result that did not support a finding that petitioner suffer from a small fiber neuropathy. Resp.’s Ex. E at 2. Dr. Leist further notes that neither the MRIs or the electrophysiologic studies that were performed for Mr. Shaw, after the vaccinations at issue, showed evidence of a demyelinating or inflammatory process in the peripheral or central nervous system. Id. at 1-2. Additional evidence that in Dr. Leist’s view diminishes the likelihood that petitioner’s injury is vaccine-related is the negative result of the test conducted for antibodies against the hepatitis B vaccine on September 26, 2001. Id. at 2. That negative finding, according to Dr. Leist, indicates that petitioner’s hepatitis B vaccination did not result in the type of T-cell response necessary to precipitate demyelination. Id.

C. Evaluating Whether Petitioner Suffers a Small Fiber Neuropathy

Among the issues to be resolved is whether petitioner suffers from a small fiber neuropathy. For the reasons discussed below the undersigned is persuaded that petitioner more likely than not suffers from a small fiber neuropathy.

At hearing, petitioner’s expert, Dr. Morgan provided the following background information concerning small fiber neuropathy. He explained that a small fiber neuropathy is a syndrome that “primarily involves the sensory nerves.” Tr. 2 at 13. He elaborated that a “hallmark” of this condition are both “positive” and “negative” symptoms. Id. Positive symptoms are sharp pains and involve the myelinated Alpha Delta fibers; in contrast, negative symptoms are numbness and involve the unmyelinated C fibers. Id. at 17, 19. He testified that “small nerve fibers are nerves that are made up of both unmyelinated fibers, [] called C fibers; and . . . myelinated fibers called Alpha Delta [fibers]” which are “thinly myelinated.” Id. at 13.

The medical records indicate that Mr. Shaw began to experience both the positive symptom of “pins and needles” and the negative symptom of “some numbness,” approximately six days after his June 11, 1999 hepatitis B immunization--as reported to his treating physician. Id. at 16; see also Pet.’s Ex. 1 at 31 (noting that his numbness began on June 17, 1999, four days prior to his visit to Dr. Roberts and six days after he received his second hepatitis B vaccine, and that numbness was “progressing to a throbbing pain.”).

Petitioner experienced the symptoms in his hands and feet (“glove and stocking”). *Id.* at 18. According to Dr. Morgan, the numbness in all four limbs reported to petitioner’s orthopedic surgeon was a negative symptom involving the unmyelinated C fibers. *Id.* at 19 (citing Pet.’s Ex. 4 at 1). Contrastingly, the reported “shooting pain in the limbs with throbbing” was a positive symptom implicating the myelinated [Alpha Delta] fibers.” *Id.*; see also *id.* at 52 (discussing petitioner’s pain history). Dr. Morgan’s testimony explaining the symptoms of small nerve fiber dysfunction was consistent with petitioner’s filed medical literature. See Pet.’s Ex. 66, Allan H. Ropper & Robert H. Brown, Adams and Victor’s Principles of Neurology 112 (8th ed. 2005) (Table 8-3 describing the “A-delta” subcategory of nerve fibers as “[s]mall, thinly myelinated” fibers that are associated with “[s]ymptoms of [d]ysfunction” consisting of “[p]ain and temperature, soma touch ([s]harp, lancinating, prickly pain”); by comparison, the “C” fiber type is “[s]mall, unmyelinated; polymodal” and associated with “[s]ymptoms of [d]ysfunction” consisting of “[s]low pain and temperature ([d]ull, burning, poorly localized pain”)); Pet.’s Ex. 67, Tab F, Jinny Tavee & Lan Zhou, Small Fiber Neuropathy: A Burning Problem., 76 (5) Clev. Clin. J. Med. 297, 298 (May 2009) (“Small fibers include myelinated A-delta fibers and unmyelinated C fibers . . . Small fiber neuropathy results from selective impairment of myelinated A-Delta and unmyelinated C fibers.”).

1. Petitioner’s Laboratory Tests

Dr. Morgan addressed petitioner’s various medical tests and the test results, asserting that they supported or, at least, did not contradict a diagnosis of small fiber neuropathy. Referring to petitioner’s skin biopsies,¹⁶ Dr. Morgan explained that petitioner’s early test results showed a “normal range of epidermal nerve fiber density,” Tr. 2 at 38, but when considered with his other skin biopsy results, revealed abnormality. *Id.* Dr. Morgan testified that petitioner’s treater, Dr. Maragakis, determined from petitioner’s first skin biopsy that the “nerve swellings . . . could be the beginning of a nerve degeneration.” *Id.* (citing Pet.’s Ex. 13 at 176 (addendum to August 21, 2000 report of Dr. Maragakis discussing the results of petitioner’s first skin biopsy)). Because petitioner’s symptoms did not improve, but progressively worsened after that biopsy, Dr. Lomen-Hoerth, petitioner’s treating neurologist, recommended repeating the skin biopsy. *Id.* at 41-42 (citing Pet.’s Ex. 9 at 57 (a letter from Dr. Lomen-Hoerth)). The second skin biopsy was taken from several different places on petitioner’s leg including proximal thigh, his distal thigh, and his distal leg. *Id.* at 47-48 (citing Pet.’s Ex. 13 at 145). The test result again showed a normal range of epidermal nerve fiber density offering “no definitive

¹⁶ A skin biopsy is considered the best method for diagnosing a small fiber neuropathy. Tr. 2 at 99-100, 126; Pet.’s Ex. 9 at 57. A skin biopsy will report an abnormal result in 67% of small fiber neuropathy cases. Tr. at 127.

evidence” of a small fiber neuropathy and “no clear progression compared to the August 2000 biopsies.” Pet.’s Ex. 13 at 145 (emphasis added). Dr. Morgan testified, however, that the result was “not normal” at the proximal thigh location because petitioner’s “nerve fiber distribution was borderline” normal with a patchy distribution and that some of the examined fibers were “fragmented and contained small swellings.” Id. at 48 (citing Pet.’s Ex. 13 at 145). Similarly at the distal leg the nerve fiber “distribution again is patchy.” Id. In Dr. Morgan’s opinion, this “patchy” distribution of nerve fiber cells is consistent with a small fiber neuropathy. Id. at 50.

Dr. Morgan also addressed the findings of petitioner’s EMG and nerve conduction exams which were documented as normal.¹⁷ Dr. Morgan explained that an abnormal EMG requires “some involvement of the . . . ventral nerve root,” id. at 42, but because small fiber neuropathy “doesn’t involve the ventral nerve root that supplies motor fibers,” an EMG would not show abnormality. Id.

Dr. Morgan also discussed petitioner’s conduction study. Dr. Morgan offered that:

[S]ensory nerve conduction, which is a little more sensitive [than motor nerve]. . . measures more . . . heavily myelinated fibers. And if that process is spared, you won’t see abnormalities on the nerve conduction and the nerve conduction velocities will be normal, particularly the sensory nerve conduction. And so . . . [the nerve conduction study] just further supports that this [petitioner’s injury involves]. . . small fibers, both myelinated and unmyelinated.

Id. at 43. Dr. Morgan further offered that small fiber sensory neuropathy does not involve sufficient heavily myelinated fibers to “create [] abnormalities in the nerve conduction testing.” Id. at 44. He added that “if there is too much involvement of the heavily myelinated fibers,” the condition no longer falls within small fiber neuropathy category.” Id. at 44. Petitioner’s treating neurologist, Dr. Lomen-Hoerth, commented, in her notes that petitioner’s “normal nerve conduction” studies “do[] not exclude a small fiber neuropathy.” Pet.’s Ex. 9 at 57. The electromyographer, Dr. James Wei, who reviewed the nerve conduction studies agreed with Dr. Lomen-Hoerth. Id. at 39.

The filed medical literature confirms the difficulty described by Dr. Morgan in

¹⁷ The undersigned notes that petitioner also underwent a functional assay, Tr. 2 at 127, a fat pad biopsy, id. at 128, and an autonomic study, id. at 131. These tests did not provide any “objective” evidence that petitioner suffers from a small fiber neuropathy. Id. at 132.

diagnosing a small fiber neuropathy. As observed in the 2002 Lacomis article, small-fiber neuropathy is a “commonly encountered disorder” that is “frustrating to clinicians because of difficulties both in proving the diagnosis and in treatment.” Pet’s Ex. 67, Tab D, David Lacomis, Small-Fiber Neuropathy, 26 Muscle & Nerve 173 (Aug. 2002) (“Lacomis”). Consistent with Dr. Morgan’s testimony, Lacomis observed that to the extent routine nerve conduction studies assess large-fiber function, they are generally normal.” Id. at 174. Lacomis also states that although “heart variability can be assessed on some EMG equipment[,] . . . it is likely that the subtle abnormalities associated with most small-fiber neuropathies will not be detected.” Id. at 177.

Respondent’s expert Dr. Leist is not persuaded that petitioner suffers from a small fiber neuropathy. In his view, petitioner’s test results-- particularly the skin biopsies--provide evidence that “weighs against” a small fiber neuropathy diagnosis. Tr. 2 at 125-33. Dr. Leist opines

I would expect that if somebody has progressive symptoms over a period of time, that there would be evidence of a progressive underlying dysfunction. . . . would I expect . . . an objectifiable finding of, for example, nerve loss over the one and a half or two years between the two skin biopsies? Yes, I would expect this. The fact that it’s not there, I would consider as less usual. . . . [T]he fact that it doesn’t show abnormality clearly doesn’t support [a finding of small fiber neuropathy].

Id. at 132-33.

2. The Opinions of Petitioner’s Treating Doctors

Dr. Morgan also relied on the opinions of petitioner’s treating physicians who variously considered a small fiber neuropathy diagnosis. Tr. at 77. Petitioner’s doctors recorded different impressions about the precise nature of his injury. What is consistently reported, however, is a condition involving a progressive and chronic pain syndrome. See Pet.’s Ex. 5 at 28; Pet.’s Ex. 9 at 107; Pet.’s Ex 13 at 165; Pet.’s Ex. 53 at 1.

After a careful review of petitioner’s records and the expert testimony, the undersigned is persuaded that it is more likely than not that petitioner suffers from a small fiber neuropathy. See Pet.’s Ex. 1 at 67 (interpretation of the EMG results in September of 1999: “[T]he patient is most likely exhibiting very early symptoms of idiopathic peripheral neuropathy.”); Pet.’s Ex. 2 at 3 (Dr. Lin indicating that petitioner was “suffering [due to] a post-inflammatory neuropathy related to immunizations”); Pet.’s Ex. 6 at 3 (Dr. Villanueva discussing petitioner’s “subjective diffuse sensory polyneuropathy”); Pet.’s Ex. 9 at 107 (Dr. Lomen-Hoerth’s impression in May of 2000 that petitioner had “a progressive small

fiber neuropathy); Pet.'s Ex. 13 at 175-76 (Dr. Maragakis's view that "this most likely represents some form of small fiber neuropathy")¹⁸; Pet.'s Ex. 5 at 22 (Dr. So opining in July 2001: "It is conceivable that [petitioner] had an acute, predominantly sensory polyneuropathy back in 1999."); Pet.'s Ex. 33 at 48-49 (Dr. Waldman finding in December 2004 that "Mr. Shaw has developed a chronic neuropathic pain syndrome"); Pet.'s Ex. 37 at 5 (Dr. Cullen's reported patient's history as that of "a 46 year old man who suffered an intense reaction to a hepatitis B vaccine in 1999, developing a small fiber neuropathy"); Pet.'s Ex. 39 at 13-14 (Dr. Palmer describing petitioner as "a 46 year-old gentleman with six years of diffuse pain after vaccination, consistent with a diffuse small fiber neuropathy"); Pet.'s Ex. 52 at 6-7 (Dr. Robert Sullivan finding on February 2007, that petitioner's "chr[onic] polyneuropathy persists"); Pet.'s Ex. 76 at 22 (Dr. Alfred Scopp indicating that petitioner has an Axis III diagnosis of "[p]eripheral neuropathy"); Pet.'s Ex. 71 at 16 (Dr. Oscar Abeliuk found petitioner's condition to be "suggestive of long-term polyneuropathy [(in this case, small fiber type)]"); Pet.'s Ex. 69 at 3 (Dr. Rothfeld's assessment that petitioner has a "[h]istory of [and current neurologic responses consistent with] small fiber neuropathy with chronic pain"); Pet.'s Ex. 77 at 5 (petitioner's primary treating neurologist, Dr. Lomen-Hoerth, finding again in August 2009 that "clinically [petitioner] appears to have a progressive small fiber neuropathy, with documentation on skin biopsy suggestive of an early small fiber neuropathy"); *Id.* at 8 (in November of 2009, Dr. Palmer, who treated petitioner for pain, noting that he suffers from "a clearly diagnosed small-fiber neuropathy").

It is true--as respondent points out, see Respondent's Post-Hearing Brief on Remand filed November 17, 2010 at 12 ("Resp.'s Brief")--that many of petitioner's treating physicians did not make a definitive diagnosis of small fiber neuropathy. But, it is this diagnosis that his various treaters and evaluations most frequently considered based chiefly on petitioner's neurologic responses.

Recognizing that the "objective" tests and studies do not clearly demonstrate or negate a diagnosis of small fiber neuropathy, the undersigned is persuaded that petitioner's clinical presentation (as reflected in the medical records), the opinions of petitioner's treating physicians, the expert opinion of Dr. Morgan and the cited medical literature adequately support such a finding. While the undersigned cannot find with medical certainty that petitioner suffers from a small fiber neuropathy, the undersigned does find that more likely than not petitioner is afflicted with this condition, and the undersigned is mindful that "[t]he standard of proof required by the [Vaccine] Act is simple preponderance of evidence; not scientific certainty." Andreu, 569 F.3d at 1380 (quoting

¹⁸ The undersigned notes that Dr. Maragakis later indicated that he could not "make a diagnosis of peripheral neuropathy based on any of the based on any of the studies" performed. Pet.'s Ex. 13 at 136 (emphasis added).

Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991)).

D. Evaluating Petitioner's Claim under the Althen Prongs

As stated earlier, petitioner must prove causation by showing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a proximate temporal relationship between the vaccination and the injury. Althen, 418 F.3d at 1278. The undersigned addresses each of the prongs of the Althen standard in turn. For ease of discussion, the undersigned addresses the first and the third prongs of the Althen before turning to the second prong.

1. Petitioner's Offered Medical Theory

Petitioner must offer a medical theory causally connecting the vaccination and the injury. Althen, 418 F.3d at 1278.

As discussed above, Dr. Morgan opined in his written report that petitioner's small fiber neuropathy resulted from his hepatitis B vaccine causing a demyelination of his peripheral nerves through a biological mechanism of molecular mimicry. This theory contemplates that the "vaccine stimulates the host[']s immune system to react to the Hepatitis-B antigen and cross react with the myelinated nerve fibers of the host." P's Ex. 67 at 2. "This mistaken attack by the body's own immune system is secondary to the similarity between the foreign Hepatitis-B antigen and the myelin component in the host." Id. At hearing, Dr. Morgan explained his theory of molecular mimicry as follows:

[I]t starts at the dorsal root ganglion and that ganglion has unmyelinated, myelinated, heavily myelinated fibers. There is a antigen antibody reaction that occurs there, disrupts the myelin and is reflected in the peripheral nerve and small fibers, specifically, involving both the alpha thinly myelinated fibers and the unmyelinated C fibers. And that is caused by an immune mechanism which is the antigen from the vaccine that looks at the normal self myelin, cross reacts with it, [and] causes this initial inflammatory reaction. And which then leads to the gradual demyelination [a]ffecting the nerve roots which then account for the person's - - for Mr. Shaw's symptoms.

Tr. 2 at 57. Dr. Morgan pointed to Petitioner's Trial Exhibit Number 5 to further describe this mechanism:

And so you could see where if someone got an inflammatory

demyelinative reaction, how the secondary effects would [a]ffect both . . . the unmyelinated fiber, which is the C fiber, which is what we see with small fiber neuropathy; but it also [a]ffects the thinly myelinated fiber, which also is part of small fiber neuropathy. And there's some suggestion that it actually [a]ffects some of even the heavier myelinated [fibers] but not much. If it does, then it becomes no longer a small fiber neuropathy. . . .

So it's a complex understanding of it, but I think it explains why these things aren't just black and [white] . . . it's not one root, one root and everything is nicely fit. That's why these syndromes are called syndromes. And they overlap.

Id. at 60-61. Dr. Morgan testified that inflammatory cells have likewise been observed, from autopsy slides, in the dorsal root ganglion of patients with Guillain-Barre Syndrome. Id. at 75.

Dr. Morgan offered evidence supporting petitioner's theory, that molecular mimicry can cause "a post[-]vaccinal type of neuropathy," in the form of medical literature. Id. at 58. Specifically, the Lacomis article notes that "[i]n some patients with idiopathic small-fiber neuropathy, an inflammatory autoimmune basis has been hypothesized, and circumstantial evidence is available." Lacomis at 182 (emphasis in original); Tr. 2 at 74-75. Lacomis goes on to discuss this evidence concluding: "Thus, there is evidence that suggests, but does not prove, that infections or autoimmune processes may cause small-fiber neuropathy. Unfortunately, there are no good laboratory markers of this autoimmune process." Lacomis at 182.

But, Dr. Leist took issue with the lack of evidence that the hepatitis B vaccination can harm unmyelinated C fibers, and was not persuaded by Dr. Morgan's explanation that the unmyelinated C fibers experience secondary effects or bystander effects from the post vaccinal inflammatory demyelinating reaction. Tr. 2 at 137-39. At the first hearing in this case, Dr. Leist conceded that it is "potentially possible" that the hepatitis B vaccine can cause auto-immune reactions. Tr. at 117. In making this statement, Dr. Leist indicated that he was relying upon "the opinion of the Institute of Medicine (IOM), which says it's possible to put a mechanism together by which hepatitis-B could cause an [immune mediated] injury." Id. at 116. Notwithstanding this statement by the IOM, Dr. Leist found in this case there is not "a reputable theory by which one could explain a small fiber neuropathy, a theory that is accepted . . . it's not accepted with respect to the hepatitis B vaccine." Tr. 2 at 140.

Reviewing the evidence on balance, the undersigned finds preponderant evidence of a "medical theory causally connecting the vaccination and the injury." To be sure, such

evidence in this case is not scientifically certain – as respondent points out, Resp.’s Brief at 16 (citing Tr. 2 at 83-84) – the medical literature does not specifically link the hepatitis B vaccination or any vaccination to the injury of small fiber neuropathy. However, petitioner has provided a sound “medical or scientific explanation that pertains specifically to the petitioner’s case . . . [that is] ‘legally probable,[even if] not medically or scientifically certain.’” Moberly, 592 F.3d at 1322 (citing Knudsen, 35 F.3d at 548-49 (Fed. Cir. 1994)).

The undersigned will next examine the third prong of the Althen test — the temporal relationship between Mr. Shaw’s vaccination and his injury — as this evidence is pivotal to the undersigned’s analysis of the second Althen prong.

2. The Temporal Relationship between the Vaccination and the Injury

Petitioner must show more than a proximate temporal relationship between the vaccination and the injury to satisfy the burden of showing actual causation. Althen, 418 F.3d at 1278; see also Grant v. Sec’y of the Dept. of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The contemporaneous medical records indicate that petitioner’s symptoms began six days after the receipt of his second hepatitis B vaccination. Dr. Morgan testified that six days is appropriate for onset of an immune related disorder. Tr. 2 at 78. Respondent’s expert, Dr. Leist, agreed that the “temporal relationship between the administration of the vaccine and the onset of symptoms was appropriate.” Tr. 2 at 198 (“It is within a period of time that would be acceptable. . . for an immune response to appear at all.”). Because symptoms of petitioner’s injury occurred within an appropriate medical time frame for an immune-mediated injury, petitioner has satisfied the third prong of the Althen standard.

The undersigned turns now to address petitioner’s proposed sequence of cause and effect.

3. The Sequence of Cause and Effect

The Federal Circuit has observed that an offered medical theory is persuasive when accompanied by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]’ the logical sequence being supported by ‘reputable medical or scientific explanation[,]’ i.e., ‘evidence in the form of scientific studies or expert medical testimony[.]’” Althen, 418 F.3d at 1278 (quoting Grant, 956 F.2d at 1148).

The Federal Circuit has found the opinions of treating physicians to be particularly probative in evaluating the second prong of Althen, particularly “[i]f a claimant satisfies the first and third prongs of the Althen standard” as “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” Andreu, 569 F.3d at 1375 (quoting Capizzano, 440 F.3d at 1326 (Fed. Cir. 2006) (claim remanded to the special master to re-evaluate the second prong of Althen in consideration of the opinions of the petitioner’s treating physicians who concluded that the petitioner’s injury was caused by his vaccinations.)).

As discussed above, Mr. Shaw has satisfied the first and third prongs of the Althen standard. In considering whether Mr. Shaw has demonstrated a logical sequence of cause and effect the undersigned turns to the opinions of his treating physicians. As an initial matter, the undersigned notes that it is undisputed that the “leading cause” of small fiber neuropathy is idiopathic – it cannot be identified. Tr. 2 at 83. However, progress is being made toward identifying potential causes of small fiber neuropathy, to include the possibility of infections or autoimmune causes. Lacomis at 182; Tr. 2 at 74-75, 83.

Petitioner has been evaluated and/or treated by a substantial number of physicians since his symptoms began in 1999. A remarkable number, although not all, of these treating doctors have either postulated or ascribed vaccine causation to his injury. Particularly persuasive to the undersigned was the opinion of vaccine-related causation expressed by petitioner’s treating neurologists. See Pet.’s Ex. 2 at 3 (Dr. Lin, an examining neurologist, recorded that petitioner was “suffering [due to] a post-inflammatory neuropathy related to immunizations.”); Pet.’s Ex. 9 at 107 (It was Dr. Lomen-Hoerth’s, Mr. Shaw’s primary neurologist, early impression that petitioner had “a progressive small fiber neuropathy rather than a static neuropathy related to his vaccinations.”); Pet.’s Ex. 18 at 47 (a consulting neurologist, Dr. Dresser recorded his impression in 2002 that petitioner suffers from “[d]iffuse dysesthetic pain following remote vaccinations.”); Pet.’s Ex. 2 at 12 (Dr. Martin, a rheumatologist, indicated that petitioner suffered from “an idiopathic syndrome associated with chronic fatigue and . . . is possibly related to a vaccine exposure or possibly a toxin.”); Pet.’s Ex. 5 at 16 (Dr. Chiu, an internist, observed that because petitioner’s neurologic changes seem to have arisen after his immunization in 1999 “there is a question as to whether there is some type of autoimmune or other reaction to this vaccination.”); Pet.’s Ex. 13 at 165 (Dr. Berkenblit, an internist, maintained that while there is no clear link between hepatitis B vaccination and progressive neuropathic pain, “[i]f [Mr. Shaw] did develop symptoms of a sensory neuropathy as a consequence of the vaccine it would most likely be an autoimmune type mechanism.”); Pet.’s Ex. 18 at 6 (Dr. Roberts, petitioner’s primary care physician, wrote a letter in 2002 indicating his belief that the temporal relationship between the received vaccination and the onset of petitioner’s symptoms “strongly correlate[d]” with the

hypothesis that the symptoms were caused by the vaccination); Pet.'s Ex. 8 at 22 (Dr. Allen who evaluated petitioner in connection with his worker's compensation claim believed that petitioner's injury¹⁹ "may have developed as a result of the June 1999 vaccination[s]."); Pet.'s Ex. 25 at 1 (Dr. Buttram, an internist, maintained the opinion that Mr. Shaw's "peripheral neuropathy is directly related to (was caused by) a series of two hepatitis B vaccines."); Pet.'s Ex. 50 at 8 ("Vaccine-induced neuroimmune dysfunction" was the diagnosis of Dr. Natali, a general practitioner.); Pet.'s Ex. 37 at 5 (Dr. Cullen, an anesthesiologist, described petitioner in 2006 as "a 46 year old man who suffered an intense adverse reaction to a hepatitis B vaccine in 1999, developing a small fiber neuropathy."); Pet.'s Ex. 39 at 13-14 (Dr. Palmer, another anesthesiologist, assessed petitioner as "a 46 year-old gentleman with six years of diffuse pain after vaccination, consistent with a diffuse small-fiber neuropathy . . ."); Pet.'s Ex. 52 at 6-7 (Dr. Sullivan found in February 2007 that petitioner's "chr[onic] polyneuropathy persists, [secondary] to [a] Hep[atitis] B adverse reaction."); Pet.'s Ex. 76 at 22 (In a report following a neuropsychological evaluation conducted at the request of petitioner's disability attorney, Dr. Scopp concluded that petitioner suffered from a "progressive peripheral neuropathy subsequent to hepatitis B inoculation."); Pet.'s Ex. 77 at 9 (Requesting reinstatement of petitioner's disability benefits, Dr. Julian a primary care physician, wrote "specialists believe the cause [of petitioner's neuropathy] is likely due to a vaccine he received in the late 1990's").

Respondent points out that some of petitioner's treaters subsequently modified their early opinions of vaccine causation or failed to ascribe his injury to vaccine-related causation. Resp.'s Brief at 18-21. For example, Dr. Chiu noted the temporal relationship to the vaccine, but did not opine as to causation. *Id.* at 18. Dr. Villanueva doubted vaccine causation, and Dr. Lin later altered her initial diagnosis of vaccine-related post inflammatory neuropathy. *Id.* at 18-19. The undersigned takes note of these observations; but the record indicates that a number of the petitioner's treating physicians postulated that petitioner's condition was vaccine-mediated, informed--in part--by the temporal relationship between Mr. Shaw's vaccinations and the onset of his injury.

Respondent further argues that Dr. Morgan's theory of a post-vaccine immune response causing a demyelinating injury must fail because the evidence does not support a finding that Mr. Shaw experienced an immune response to his vaccination. Respondent bases this assertion on the finding that petitioner's September 26, 2001 antibody testing was negative for IgG antibodies the class of antibodies that assist in fighting against infection. Resp.'s Brief at 15 (citing Pet.'s Ex. 13 at 194). Dr. Leist testified that while IgM antibodies initially mount a response to vaccination (or any other presented antigen), these antibodies are normally converted to IgG antibodies starting at day seven or eight - -

¹⁹ It was Dr. Allen's view that petitioner was suffering from fibromyalgia.

if an effective immune response is triggered. Tr. 2 at 135-36, 186, 192-93. However, on cross-examination, Dr. Leist conceded that IgM antibodies may “play[] a role” in demyelinating disorders, *id.* at 197, that petitioner may have had a significant IgM response that never converted to an IgG response, *id.* at 193, and that petitioner was never tested for IgM antibodies, *id.* at 196-97. However, Dr. Leist maintained that while these were “theoretical[ly]” possibilities, he found them to be “[e]xceedingly improbable.” *Id.* at 193-94.

On balance, the undersigned is persuaded that petitioner has demonstrated a logical sequence of cause and effect. Petitioner has presented sound scientific testimony from a medical expert, well qualified in the field of neurology, that offers a cogent explanation of how petitioner’s hepatitis B vaccination more likely than not caused him to develop a small fiber neuropathy by way of molecular mimicry. Petitioner has presented uncontested evidence of a proximate temporal relationship between the vaccination and the injury. And finally, a number of petitioner’s treating physicians attributed Mr. Shaw’s injury to the hepatitis B vaccines he received.

IV. Conclusion

As discussed above, the undersigned finds that petitioner has established by preponderant evidence in this close case that his hepatitis B vaccination was the legal cause of his small fiber neuropathy. The undersigned further finds that there is not a preponderance of the evidence that the legal cause of Mr. Shaw’s injury was due to factors unrelated to his hepatitis B vaccination.²⁰ Accordingly, the undersigned finds Mr. Shaw is entitled to compensation under the Vaccine Act. A separate damages order will issue.

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Chief Special Master

²⁰ At the first hearing in this case, Dr. Leist testified to several alternate causes of Mr. Shaw’s injury, to include: petitioner’s chronic opioid use as part of his prescriptive therapy, his past traumatic injuries, and a possible conversion disorder. Tr. at 108-13, 128-29. However, the undersigned finds that Dr. Leist never fully developed a theory of causation for any of these possible alternate causes. Moreover, respondent concedes these possible alternate causes do not rise to the level of establishing that a factor unrelated to petitioner’s vaccinations caused his injury. Resp’s Brief at 22.