In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 99-669V
Filed: December 10, 2010

DR. ROBERT G. SHARKEY and JACQUELINE K. SHARKEY, as parents and natural guardians of RYAN REID SHARKEY,	)	TO BE PUBLISHED
Petitioners,	)	
v.	)	Entitlement: Causation-in-fact; Hepatitis B Vaccination;
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	Guillain-Barré Syndrome (GBS); Differential diagnosis; Treating physician opinion
Respondent.	)	

Altom M. Maglio, Maglio, Christopher & Toale, Sarasota, Florida, for Petitioners.
Linda S. Renzi, United States Dep't of Justice, Washington, D.C., for Respondent.

DECISION[1]

LORD, Chief Special Master.

I. INTRODUCTION AND SUMMARY

On August 5, 1999, Petitioners Dr. Robert G. and Jacqueline K. Sharkey filed a claim alleging that their son, Ryan Reid Sharkey, suffered a vaccine injury under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-1 et seq. (2010). Petitioners alleged that a hepatitis B ("Hep B") vaccine administered on June 7, 1995, caused Ryan to suffer "adverse effects," including Guillain-Barré syndrome ("GBS"). This case was part of the Hepatitis B-Neurological Demyelinating Omnibus Proceeding ("Omnibus" or "Hep B Omnibus"), and was effectively stayed until 2006, when decisions were issued in the Omnibus test cases.[2] A

[1] As provided by Vaccine Rule 18(b), each party has 14 days within which to request the redaction "of any information furnished by that party (1) that is trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of a timely objection, the entire document will be made publicly available.

[2] The Omnibus proceedings are described in Stevens v. Sec'y of Dep't of Health & Human Servs., No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006). The Omnibus was divided into four test cases, one for each category of injury -- multiple sclerosis ("MS"), GBS, transverse myelitis ("TM"), and chronic inflammatory demyelinating polyneuropathy ("CIDP"). The GBS and CIDP test cases were later combined into one case. Gilbert v. Sec'y of Dep't of Health & Human Servs., No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006).

hearing was held in January 2010, and all post-hearing briefs have been filed. This case is now ripe for decision.

Before this case was assigned to me, the previously-assigned special master had reached a conclusion concerning some aspects entitlement. The primary issue remaining for decision centers on the weight to be given to the GBS diagnosis that Ryan received from Children's Memorial Hospital ("Children's Memorial" or "Children's") in Chicago, Illinois. The medical records document that Ryan underwent an extensive, six-week medical evaluation at Children's, where his condition was analyzed by a team of doctors and medical experts. The records show that the medical team performed an expansive and rigorous differential diagnosis of all the potential disorders and causal agents that could explain Ryan's condition. After six weeks of testing and care, the medical team concluded that Ryan most likely had vaccine-induced GBS.

Petitioners asserted that Ryan's diagnosis of vaccine-induced GBS was legally sufficient to prove that Ryan had GBS and to show a logical sequence of cause and effect. Further, Petitioners maintained that the Omnibus decision in Gilbert established, at least in this case, that the Hep B vaccine can cause GBS. Although Petitioners recognized that Ryan's diagnosis was not medically certain, they asserted that they had satisfied all of the legal requirements for demonstrating entitlement to compensation under the Vaccine Act.

Respondent argued that Petitioners are not entitled to compensation. Respondent claimed that Ryan's diagnosis of GBS represented the opinion of one doctor and not the entire Children's medical team. Respondent attempted to cast further doubt on Ryan's diagnosis of GBS by showing that, after Ryan left Children's, other doctors reached contrary opinions. Respondent argued that, despite the possible diagnosis from Children's, the signs and symptoms of Ryan's disorder were not consistent with GBS, and that the mostly likely explanation for Ryan's condition was a congenital muscle disorder. In addition, Respondent maintained that, because GBS cannot occur in an infant of less than one year of age, Ryan could not have had GBS, and therefore, the Omnibus decision in the GBS test case should not apply.

The medical records document the Children's team's analysis and thought processes, from admission to discharge. The records were clarified at hearing by the testimony of the nurse who coordinated the medical team's meetings and Ryan's care at Children's. Based on the testimony and my review of the medical records, I find that the medical team, and not only one physician, concluded that Ryan had vaccine-induced GBS. Although the occurrence of GBS in someone as young as Ryan is rare, the case reports submitted by Petitioners and the medical team's diagnosis are legally sufficient to satisfy Petitioners' prima facie showing under the Vaccine Act. See Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). Respondent has not demonstrated by a preponderance that an alternative factor was a substantial, much less the sole cause, of Ryan's disorder. Accordingly, I find that Petitioners are entitled to compensation.

II. BACKGROUND

A. Procedural History

This case has a long and somewhat complex procedural background. The details pertinent to this decision follow.

As part of the Hep B Omnibus proceeding, this case was assigned to then Special Master Sweeney. On January 11, 2006, this case was reassigned to Special Master Millman, who was handling the Omnibus test cases. In March 2006, Special Master Millman issued a decision in the test case Gilbert. She found that the Hep B vaccine could cause GBS and CIDP. Gilbert, 2006 WL 1006612, at *12.[3]

In August 2007, Special Master Millman issued an order to show cause why this case should not be dismissed because the medical records did not support a finding that Ryan had GBS or a demyelinating disorder. Order, Aug. 23, 2007. In response, Petitioners filed the expert report of Marcel Kinsbourne, M.D. Dr. Kinsbourne opined that Ryan suffered from GBS as a result of his Hep B vaccination. Subsequently, Special Master Millman, who apparently was satisfied that the Omnibus ruling applied to this case, allowed the case to proceed and ordered Respondent to file her Rule 4(c) report. Over the next two years, Special Master Millman held numerous status conferences, but she did not issue a final decision on any causation issue.

On June 22, 2009, this case was transferred to me.

In September 2009, Petitioners moved for a ruling that prong 1 of Althen was satisfied under the doctrines of law of the case and collateral estoppel. I denied the motion because those doctrines are not applicable to Vaccine cases. Order, Oct. 26, 2009. After Petitioners filed another motion for a ruling that prong 1 was satisfied, I held a status conference so Petitioners could more fully explain their concern. At the status conference, I discussed the applicability of the Omnibus decisions and whether Special Master Millman already had made a decision regarding prong 1 of Althen in this case. Based on my review of the record and the parties' responses at the status conference, I ruled that Special Master Millman evidently had been persuaded that the Hep B vaccine could cause GBS in the general population. In addition, I noted that it appeared that Special Master Millman was prepared to accept that, if Ryan had GBS, his Hep B vaccination could have caused his disorder. See Order, Apr. 26, 2010; see also Order, Feb. 8, 2007, at 5 (demyelinating disorders can occur during a 3 to 30 day window following a Hep B vaccination). As I stated in the April 26, 2010, Order, the fortuity of re-assignment to a different special master should not substantively disadvantage any party. Therefore, I ruled that Petitioners would be required only to prove that Ryan had GBS, a logical sequence of cause and effect connected the GBS with his vaccination, and the onset occurred within an appropriate time period.

In the same order, I also noted that Respondent asserted that the Hep B vaccine could not cause GBS in a person of Ryan's age. I requested that the parties submit evidence on whether Ryan, "who was less than one year of age when the alleged injury occurred, could have contracted GBS as a result of his vaccination." Order, Apr. 26, 2010. In response, Respondent filed an expert report from John MacDonald, M.D. Petitioners filed a supplemental expert report

[3] GBS is a peripheral polyneuropathy that typically involves the demyelination (destruction of the protective cells that surround a nerve) of motor nerves. Nelson's Textbook of Pediatrics (Robert Kliegman, M.D., et al. eds., 18th ed. 2007) at 2565. The condition is characterized by a symmetrical weakness that usually begins in the lower extremities and progresses into the trunk and upper limbs. Id. Other clinical manifestations may include acute weakness, irritability, paresthesias (sensation of tingling, prickling, or numbness), muscle pain and tenderness, respiratory failure, and loss of tendon reflexes. Id. CIDP is a chronic variety of GBS that recurs intermittently or does not improve for a period of months or years. Id.

from Dr. Kinsbourne, medical literature, and evidence from the Omnibus proceedings. The record is now closed, and this case is ripe for decision.

B. Medical History

By the time this case was filed, Ryan had a long and complicated medical history, which is summarized in more detail in the August 23, 2007, Order to Show Cause. The pertinent history follows.

Ryan was born at term on May 28, 1995. Pet'r Ex. 10 at 1015. At birth, Ryan's Apgar scores were nine and ten at one and five minutes. Pet'r Ex. 9 at 850; Pet'r Ex. 10 at 1015.

On May 31, 1995, Ryan was examined by his pediatrician, Irwin Kash, M.D., at Associates in Pediatrics ("Associates") in Ft. Myers, Florida. Pet'r Ex. 2 at 19. His weight was seven pounds. Id. Ryan returned to Associates on June 7, 1995, for a well-child visit and received his first Hep B vaccination without incident. Id. at 16.

On June 26, 1995, Ryan presented at Associates because he had been crying continuously for six days, except when sleeping or eating. Pet'r Ex. 2 at 15. On examination, Ryan was alert and calm, and his head, neck, lungs, ears, eyes, and throat were reported as normal. Id. The assessment was probable colic. Id. Ryan's father recalled that around the time of this visit, Ryan's behavior changed and he started to become weak and "floppy." Hearing Tr. at 66-71, Jan. 7-8, 2010.

At Ryan's two-month well-child visit on August 2, 1995, Dr. Kash noted that Ryan was sleeping for long periods of time at night and that his muscle tone had decreased. Pet'r Ex. 2 at 14. He had an increase in head lag but normal deep tendon reflexes ("DTRs"). Id. The assessment was hypotonia and failure to thrive. Id.[4] Dr. Kash deferred Ryan's two-month immunizations. Id. Ryan had three follow-up visits with Dr. Kash in August 1995, and at each visit, Ryan was still noted to have poor muscle tone. Pet'r Ex. 2 at 13.

Starting in August 1995, Ryan's parents began taking him to various doctors in an attempt to obtain a diagnosis. On August 10, 1995, Ryan had a neurology consultation with John Osterman, M.D., at Nemours Children's Clinic ("Nemours") in Ft. Myers, Florida. Pet'r Ex. 9 at 895-97. Dr. Osterman reviewed Ryan's medical history and noted that he appeared to be normal for the "first eight weeks or so of life," and following that time, he "[became] sleepy, hypotonic, and stopped sucking and feeding well" over a two-day period. Id. at 895. Dr. Osterman ordered laboratory tests and concluded, "At this point, there appears to be no clear involvement of the central nervous system, but rather a disorder of the motor unit." Id. at 897. He suggested that "[a] diagnosis of exclusion would be benign congenital hypotonia." Id.

Ryan returned to Associates on August 14, 1995. Pet'r Ex. 2 at 12. Dr. Kash noted persistent hypotonia and agreed that Ryan might have congenital hypotonia. Id. On August 22, 1995, Ryan received his second Hep B vaccination. Id. at 20.

On October 16, 1995, Ryan was seen at the Pediatric GI clinic at Nemours for poor feeding and bloody stools, and he was prescribed Carafate for possible gastroesophageal

[4] Hypotonia is a condition of diminished tone of the muscles. Dorland's Illustrated Medical Dictionary (30th ed. 2002) at 900.

reflux. Pet'r Ex. 9 at 879-80. On October 17, 1995, following a dose of Carafate, Ryan presented at the emergency room and was observed to be diffusely cyanotic and diaphoretic, with nasal flaring, grunting, and choking. Pet'r Ex. 7 at 667.[5] He was transferred and admitted to the pediatric intensive care unit at Lee Memorial Hospital and intubated for respiratory failure. Id. at 658, 671. The neurological exam was remarkable for "pronounced weakness and hypotonia having a proximal distribution, pronounced about the neck and trunk, with arm greater than leg involvement." Id. DTRs were absent in the upper extremities, but throughout Ryan's stay, they increased in the lower extremities "to the point of being normal to somewhat increased." Id.

While at Lee Memorial Hospital, Ryan underwent many tests, all of which were unremarkable. Pet'r Ex. 9 at 889. A muscle biopsy was taken and sent to Brigham and Women's hospital ("Brigham") in Boston, Massachusetts. Pet'r Ex. 7 at 659. The results revealed "nonspecific myopathic findings, including small muscle fiber size, muscle size variation, and poor fiber typing." Id. Ryan's discharge summary from Lee Memorial Hospital suggested a working diagnosis of congenital myasthenic syndrome. Pet'r Ex. 7 at 657.[6]

On December 10, 1995, Ryan's care was transferred to the Mayo Clinic in Rochester, Minnesota. Id. at 655, 735. At the Mayo Clinic, the muscle biopsy from Brigham was reviewed again and the diagnosis was "[m]uscle fiber atrophy, cause undetermined." Pet'r Ex. 8 at 752. An additional muscle biopsy sample was taken from the bicep, revealing an active inflammatory myopathy. Id. at 756.[7] An electromyography test ("EMG") was abnormal and "most consistent with generalized myopathy." Id. at 759.[8] Ryan was discharged from the Mayo Clinic on December 15, 1995. Andrew Engel, M.D., diagnosed Ryan with inflammatory myopathy and ventilator-dependent respiratory failure. Id. at 812. Ryan was transported to Lee Memorial Hospital, where he remained ventilator dependent. He was treated with Prednisone, but due to a lack of response, he was also given a five-day course of intravenous gamma gobulin ("IVIG"), and subsequently placed on a weekly dose of IVIG. Pet'r Ex. 9 at 910.

On February 4, 1996, Ryan was transferred to Children's Memorial, where he underwent an extensive, multidisciplinary work-up that lasted six weeks. See Pet'r Ex. 25. Ryan was evaluated by a medical team including Wes McRae, M.D. (neurology), Lauren Pachman, M.D. (immunology), Denise Goodman, M.D. (critical care), Lisa Clock, M.D. (ICU resident), Stephen Sheldon, D.O. (sleep disorders), L. K. Gallo, M.D. (genetics), Julia Bateman (social work intern), Laurie Surgis (occupation therapist), and Barb Taylor (physical therapist). Pet'r Ex. 24 at 64; Tr. at 103. A number of other physicians took an active role in his treatment and evaluation, including Dr. Holinger (ENT), Thomas Green, M.D. (critical care), Dr. Klein, and David

[5] Cyanotic means a bluish discoloration of the skin, usually indicating a lack of oxygen in the blood. Dorland's at 455. Diaphoretic means characterized by sweating. Id. at 509.

[6] Myasthenia is a neuromuscular disorder characterized by muscular debility and weakness. Dorland's at 1205.

[7] Myopathy is any disease of the muscle. Dorland's at 1215.

[8] An EMG measures the electrical conduction of motor and sensory nerves. Dorland's at 598. A nerve conduction velocity test ("NCV") measures the speed of electrical conduction through nerves, and it is often performed at the same time as an EMG. National Library of Medicine, Nerve Conduction Velocity, Medline Plus (last updated: June 24, 2009), http://www.nlm.nih.gov/medlineplus/ency/article/003927.htm.

Rozansky, M.D. (resident). Pet'r Ex. 25 at 61, 103.[9] He also was evaluated by other medical professionals. See Pet'r Ex. 24 at 70 (evaluated by endocrinology, hematology/oncology, pulmonology, and speech pathology). Ryan underwent numerous tests while at Children's, including MRIs of the muscles, brain, and cervical and thoracic spine; sleep studies; an EEG; a BAER; nerve conduction studies; and an EMG. Pet'r Ex. 24 at 70.[10] On February 9, 1996, Ryan's physicians held a care conference to discuss diagnostic progress and to compose a diagnostic plan.

On February 23, 1996, another care conference was held. Pet'r Ex. 25 at 61. One doctor told the team that she had spoken with a doctor at the FDA about Ryan's vaccination and reported to the FDA a possible vaccine reaction. Id. At that time, the team had narrowed the differential diagnosis to two possibilities: "G.B. syndrome r/t [related to] vaccine reaction possible sequelae" and myopathy. Pet'r Ex. 25 at 61.[11] The records show that the team carefully considered and ruled out various alternative causes for Ryan's condition. See Pet'r Ex. 24 at 64; Pet'r Ex. 25 at 63. The records also note that the team saw no evidence of inflammatory myopathy. Pet'r Ex. 25 at 64. The team recognized that Ryan's symptoms were atypical and that some factors weighed against a finding of GBS. Pet'r Ex. 24 at 64; see also Pet'r Ex. 25 at 107. The team reached a consensus that "no diagnosis can be given with complete certainty, but that [GBS] is the most likely diagnosis." Pet'r Ex. 25 at 69. The team also considered the cause of Ryan's GBS, and they explored a variety of causal agents. Pet'r Ex. 25 at 64-65. In the end, they felt that Ryan's Hep B vaccination was the most likely causal agent. Id.[12]

Following the February 23, 1996 care conference, multiple progress notes indicated that GBS was the most likely diagnosis. See, e.g., Pet'r Ex. 24 at 67 (a progress note on March 11, 1996, stated that Ryan was an "8 month old with hypotonia and probable Guillain Barre [sic]").

On March 12, 1996, Ryan's physicians conducted their final care conference. Pet'r Ex. 24 at 71. The differential diagnosis summary included GBS, congenital myasthenia syndrome, congenital myopathy, inflammatory myopathy, and steroid myopathy. Pet'r Ex. 25 at 109-11. The work-up had ruled out congenital myopathies, myasthenia gravis, and mitochondrial enzyme abnormalities.

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[9] The first names of some of the doctors do not appear in the medical records.

[10] BAER means brainstem auditory evoked response, which is a test that measures brain activity in response to sound. National Library of Medicine, Brainstem Auditory Evoked Response, Medline Plus (last updated: Aug. 3, 2010), http://www.nlm.nih.gov/medlineplus/ency/article/003926.htm. The test can help diagnose nervous system problems and hearing loss. Id.

[11] Differential diagnosis is a standard scientific technique used to identify the cause of a medical problem by eliminating the potential causes until the most probable cause is identified. Westburry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999). Differential diagnosis "generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is most likely." Id.

[12] At hearing, Petitioners offered the testimony of Elizabeth Schwarm, RSN, who took notes during the care conferences and helped coordinate Ryan's care at CSH. To the extent that the medical records are unclear, I adopt the facts as described in her testimony.

In a letter that accompanied Ryan's transfer file, Dr. McRae, the treating neurologist, summarized the physicians' findings. Pet'r Ex. 25 at 107-11. Dr. McRae indicated that evidence for GBS without full recovery was the most compelling. Id. Dr. McRae listed the evidence for GBS as: an acute onset; a possibility that the six-day colic episode, reported on June 27, 1995, was neuropathic pain; an occurrence after immunization as seen with GBS; initially abnormal BAERs as seen in GBS; tachy/bradycardia and blood pressure irregularities, which may have been autonomic neuropathy; and a complete loss of reflexes. Id. He also listed the evidence against GBS: nerve conduction velocity studies remained normal, but 20% of GBS patients have normal NCVS in non-acute phase; muscle biopsy showed inflammation; mild increase in muscle enzymes, but this would be expected with increased muscle use following chronic weakness and disuse; CSF (cerebrospinal fluid) protein normal (not increased in all GBS patients, and then only in acute phase); and EMG showed myopathy (this was questionably due to disuse). Id. The letter recognized that the diagnosis was subject to some uncertainty, and in the absence of direct proof, it remained a diagnosis of exclusion. Id.

The treating physicians advised Ryan's parents that he should never again have any Hep B or live virus immunizations. Pet'r Ex. 24 at 72.

Both Petitioners and Elizabeth Schwarm, the Clinical Care Coordinator from Children's Memorial, testified that they had been present for the care conferences and that the conclusions documented in the medical records were consensus conclusions, not the opinion of one doctor with whom the other team members disagreed. The consensus conclusion that Ryan had contracted GBS from his June 7, 1995, Hep B vaccine was made after all involved disciplines worked through exhaustive processes and after discussions among those doctors at multiple and spirited care conferences. See Tr. at 26-31 (Mrs. Sharkey's testimony); Tr. at 82-85 (Dr. Sharkey's testimony); Tr. at 96-118 (Mrs. Schwarm's testimony).

Ryan was discharged from Children's on March 13, 1996, with a diagnosis of hypotonia of unknown etiology. Pet'r Ex. 25 at 10.[13] Although hypotonia was coded as the diagnosis, the transfer note referred Dr. McRae's letter. Pet'r Ex. 24 at 74. Ryan was transferred back to Lee Memorial Hospital on March 13, 1996. He was again examined by Dr. Osterman, who noted that no specific diagnosis was confirmed at Children's, although he noted the "possibility of a Guillain-Barre [sic] variant or some mixture of this and an inflammatory myopathic process due to an autoimmune response was posed." Pet'r Ex. 9 at 884. Dr. Osterman's impression was non-progressive neuromuscular disease of unknown origin. Id. at 885. Ryan was discharged from Lee Memorial Hospital on March 21, 1996, with the diagnosis of idiopathic myopathy. Id. at 904.

C. Testimony and Expert Opinion

1. Fact Witnesses

At hearing, both Robert and Jacqueline Sharkey testified as to the progression of Ryan's condition and the diagnosis of the medical professionals. Their testimony was consistent with the medical records.

[13] Mrs. Schwarm explained that his disorder had to be coded as hypotonia because, without conclusive evidence, GBS could not be the discharge summary diagnosis. See Tr. at 122-25. However, GBS was indicated as the diagnosis in the record of general assessment. Tr. at 124-25.

Petitioners also offered the testimony of Elizabeth Schwarm, RSN, who was Ryan's Care Coordinator at Children's Memorial. Mrs. Schwarm testified that she coordinated the logistics of the clinical care meetings about Ryan, and she took notes at the meetings. Tr. at 97-98. Mrs. Schwarm recalled that Ryan underwent an unusually large number of diagnostic tests and was evaluated by numerous medical professionals. Tr. at 98. Based on her review of her notes, she testified that, in addition to herself and the parents, at least different nine medical professionals (six doctors and three therapists) participated in the care meetings. Tr. at 102-03.

Mrs. Schwarm then read portions of her notes into the record to clarify any ambiguities introduced by her handwriting or through reproduction. She testified that, due to the complexity of the discussion at Ryan's care meetings, the amount of note taking required was unusual. Tr. at 119. Mrs. Schwarm testified that she did her best to keep up, but she admitted she may have missed relevant details of the discussion. Tr. at 119-20. She testified that the team reached a collective diagnosis of GBS. Tr. at 111-14. She also stated that the letter from Dr. McRae was a much better summary of what the team agreed upon than her notes were. Tr. at 120-21.

2. Dr. Kinsbourne

Dr. Kinsbourne's opinion was that Ryan's muscular weakness was caused by GBS or a GBS-type condition, and that he largely agreed with the careful assessment performed by the doctors at Children's Memorial. Tr. at 141-42. His testimony primarily addressed the conflicting facts and opinions in the medical records.

Dr. Kinsbourne opined that, after the June 7, 1995, Hep B vaccination, Ryan's condition gradually deteriorated over the following two to four weeks, with increasing weakness in the muscles in his trunk, arms, and legs. Tr. at 136. Dr. Kinsbourne admitted that Ryan's condition was not perfectly consistent with GBS. See, e.g., Tr. at 172-74 (no positive CSF findings). He also admitted Ryan's condition was possibly consistent with other disorders, such as myopathy. Tr. at 189 (biopsy and enzymes consistent with muscle inflammation). Dr. Kinsbourne addressed each inconsistency and explained why he still felt Ryan had GBS. Dr. Kinsbourne's opinion and reasoning on this topic was substantially the same as that of the medical team at Children's Memorial, but he stated that he did not form his opinion by adopting the findings of any other doctors. Tr. at 141-42.

Dr. Kinsbourne also testified regarding the conflicting diagnoses by different treating physicians. Although various doctors diagnosed Ryan with some form of myopathy, Dr. Kinsbourne opined that none of those doctors performed an analysis as thorough as the medical team at Children's Memorial, and none reached a diagnosis that was more probable than GBS. Tr. at 192-94. Dr. Kinsbourne stated that, following Ryan's visit to Children's Memorial, Ryan's physicians focused on treating him, not diagnosing him, which accounts for the fact that he was not treated strictly for GBS. Tr. at 192.

After the hearing, Petitioners filed a supplemental expert report by Dr. Kinsbourne and some supporting medical literature. Dr. Kinsbourne's report addressed case studies documenting the occurrence of GBS in infants less than one year of age.

3. Respondent's Experts

At hearing, Respondent presented the testimony of Gerald Raymond, M.D.[14] Dr. Raymond described the typical symptoms and progression of GBS. When attempting to diagnose GBS, physicians often look for hypotonia, areflexia, and weakness. Tr. at 330-31, 383.[15] Some findings that can help confirm the presence of GBS include elevated protein in the CSF, abnormalities in nerve conduction studies by EMG, and evidence of nerve inflammation in an MRI with gadolinium. Tr. at 330-33.

It was Dr. Raymond's opinion that Ryan never showed evidence of GBS, and that a Hep B vaccine did not cause Ryan's condition. Tr. at 335. Dr. Raymond interpreted Ryan's medical history as being more consistent with some form of myopathy than with GBS, but Dr. Raymond stated he was not making a diagnosis because, on this medical record, any diagnosis would be speculative. Tr. at 337-40. Dr. Raymond then addressed many of the features of Ryan's condition and explained why he felt they were not consistent with GBS: Ryan was too young to have GBS, the symptoms fluctuated instead of presenting acutely, the alleged initial symptoms of GBS could have been just colic, some reflexes were only diminished and not completely absent, Ryan did not respond to IVIG treatment, Ryan's CSF was negative, the EMG nerve conductions were normal, and an MRI did not show demyelination. Tr. at 341-53, 361-65. Although Dr. Raymond opined that inflammatory myopathy was a more likely diagnosis than GBS, he admitted that the results of the muscle biopsies are inconsistent with the severity of Ryan's condition. Tr. at 357-58.

Dr. Raymond also questioned whether the letter written by Dr. McRae represented the Children's medical team's opinion or Dr. McRae's own opinion. He interpreted the letter as Dr. McRae's opinion and asserted that the other doctors never accepted the diagnosis. Tr. at 365.

Post-hearing, Respondent filed an expert report from Dr. MacDonald that addressed the occurrence of GBS in infants. Dr. MacDonald opined that, "There have been only a few case reports of newborns with a clinical picture similar to [GBS]." Resp't Ex. S. "Due to the incomplete myelin development in the normal newborn infant, clinical symptoms in mild to moderate cases would be difficult to identify since neurological exam is limited in this age group." Id.

III. DISCUSSION

A. Findings of Fact

To the extent the facts are in dispute, I adopt the facts set forth in Petitioners' post-hearing brief and those described by the fact witnesses at hearing. In relevant part, I find that the diagnosis of GBS at Children's Memorial represented the medical team's opinion. Not only did the medical records contain multiple notations that Ryan had probable or likely GBS, but the fact was further clarified by the corroborating testimony of Mrs. Schwarm and Petitioners.

I also find that Ryan more likely than not had GBS. Although Ryan's condition did not present as a typical case of GBS, the Children's medical team considered every feature of his condition, both consistent and inconsistent, before reaching its conclusion. It is rare for the

[14] Dr. Raymond also prepared an expert report, which Respondent filed prior to hearing. See Resp't Ex. B.

[15] Areflexia means the absence of reflexes. Dorland's at 130.

medical records in a vaccine injury case to reflect such extensive attention and evaluation from a team as numerous and well-qualified as the one at Children's Memorial. The medical records document the medical team's exhaustive investigation into Ryan's condition, and show the team's thought processes along the way. In light of the medical team's rigorous analysis and combined expertise, I place great weight on its conclusions.

B. Legal Standard

To receive compensation under the Vaccine Act, a petitioner must prove that either: 1) he suffered a "Table Injury"-- that is, an injury falling within the Vaccine Injury Table corresponding to one of his vaccinations, or 2) he suffered an "off-Table" injury that was actually caused by or "caused-in-fact" by a vaccine. See §§ 300aa-13(a)(1)(A), 300aa-11(c)(1); Shalala v. Whitecotton, 514 U.S. 268, 270 (1995); see also 42 C.F.R. § 100.3(a). In this case, Petitioners have alleged that Ryan suffered an off-Table injury.

To prove an off-Table claim, a petitioner must provide evidence, in the form of medical records or reliable medical opinion, to establish "(1) a medical theory causally connecting the vaccination to 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.

A petitioner seeking to establish causation-in-fact must show, by a preponderance of the evidence, that but for her vaccination she would not have been injured, and that the vaccination was a substantial factor in bringing about her injury. Shyface v. Sec'y of Dep't of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Mere temporal association is not sufficient to prove causation in fact; a petitioner must present a medical theory that is supported either by medical records or by the opinion of a competent physician. Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); see also Grant, 956 F.2d at 1148 (medical theory must support actual cause).

The preponderance of evidence standard under the Vaccine Act requires proof that a vaccine more likely than not caused the vaccinee's injury. Althen, 418 F.3d at 1279. Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove her case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

A special master can find that a petitioner has established causation in fact based on the medical records alone. Id. at 1279 (quoting § 300aa-13(a)(1)) (a petitioner "must prove causation in fact by a 'preponderance of the evidence,' substantiated by medical records or medical opinion"). Causation can be supported by a treating physician's opinion that a vaccination was causally linked to the vaccinee's injury if the special master finds the opinion to be both reliable and persuasive. Moberly, 592 F.3d at 1324-25. Evidence used to satisfy one prong of Althen can overlap to satisfy another prong. Cappizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Respondent may offer evidence of an alternative theory of causation to show that a petitioner has not satisfied an element of her case. Doe 11 v. Sec'y of Dep't of Health & Human Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010). When a petitioner bases her case in part on the absence of alternative causes, it is proper for the special master to consider evidence of alternative causes that is presented by Respondent in evaluating whether the petitioner has met her burden of proof. Id.

Once the petitioner has met the initial burden of proof, "the burden shifts to the government to prove '[by] a preponderance of the evidence that the petitioner's injury is due to a factor unrelated to the . . . vaccine.'" de Bazan v. Sec'y of Dep't of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citations omitted). If the petitioner fails to establish a prima facie case of causation, however, the burden does not shift. Doe 11, 601 F.3d at 1357-58.

C. Analysis

1. Prong 1

As discussed above, the previously-assigned special master apparently determined that the Hep B vaccine could cause GBS, leaving undecided only whether the vaccine could have caused GBS in an individual who was less than one year old.

Petitioners filed Dr. Kinsbourne's report and supporting case studies. Dr. Kinsbourne's report stated that epidemiological evidence of GBS in infants was not available, but he cited to some case reports documenting instances where the onset of GBS occurred in early infancy. Pet'r Ex. 63 at 2-3. He opined that, aside from congenital forms of GBS, no evidence showed that "the mechanisms by which babies are stricken with GBS differ from those that operate in older children." Pet'r Ex. 63 at 3.

In addition, the medical team at Children's Memorial apparently was satisfied that GBS could occur in an infant like Ryan, and that it could be vaccine induced.

In rebuttal, Respondent filed the report of Dr. MacDonald. Dr. MacDonald admitted the existence of case reports of conditions similar to GBS in newborns. Resp't Ex. S. Dr. MacDonald stated that none of the case studies implicated vaccination as a primary etiology of GBS in such infants. Id. He also opined that clinical symptoms in newborns would be difficult to identify due to the incomplete myelin development in such infants. Id. Dr. MacDonald's opinion does not support a finding that GBS cannot occur in an infant. The implication of his opinion is that GBS would be difficult to corroborate in an infant, and test results could be inaccurate or incomplete.

Based on this record, I find that the Hep B vaccine could have caused Ryan to contract GBS. The case studies and Dr. Kinsbourne's opinion are legally sufficient to show that GBS can occur in an infant. Dr. MacDonald did not dispute that newborns could acquire GBS; he merely asserted that no scientific studies prove that GBS can be caused by vaccinating an infant. Accordingly, Petitioners have satisfied prong 1 of Althen.

2. Prong 2

The second prong of Althen requires a petitioner to prove "'a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury.'" Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009) (quoting Althen). The

sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Under prong 2 of Althen, petitioners are not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect . . . ." Capizzano, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Capizzano, 440 F.3d at 1325-26; Andreu, 569 F.3d at 1375-77 (treating physician testimony).

As discussed above, a medical team at Children's Memorial diagnosed Ryan with vaccine-induced GBS following an extensive evaluation. Dr. McRae's summary of the team's conclusions, which were the product of a differential diagnosis, showed that the team carefully considered and ruled out alternative diagnoses. The team recognized that Ryan's condition was not a typical presentation of GBS, but concluded that GBS was the most probable diagnosis. Dr. McRae's letter recognized that, in the absence of direct proof, the diagnosis was one of exclusion. In addition to the letter, the medical records further detailed the team's six-week analysis, and documented the team's careful consideration of Ryan's condition.

The process of eliminating other possible causes, i.e., differential diagnosis, does not necessarily mean that a remaining factor caused the condition. See Moberly, 592 F.3d at 1323. On the other hand, a sufficiently rigorous differential diagnosis can support a finding of causation under the Vaccine Act. See Hocraffer v. Sec'y of Health & Human Servs., 63 Fed. Cl. 765, 777, 779 (2005); see also Ruggerio v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (stating that the district judge has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support a causation opinion).

I am persuaded by the thorough analysis performed by the Children's medical team. The medical records show that the Children's medical team's conclusion resulted from a rigorous and methodical differential diagnosis. I am satisfied that the team's conclusion was sound and reliable.

Respondent argued that, aside from the doctors at Children's Memorial, none of Ryan's other treating physicians agreed with the GBS diagnosis. While Respondent is correct, her argument is unpersuasive. None of the other physicians conducted as thorough an analysis of Ryan, nor did any other physician identify a more probable alternative condition or alternative cause.

Dr. Raymond examined the features of Ryan's condition and explained why he thought the medical team was incorrect. Dr. Raymond's retrospective analysis does not negate the validity of the Children's medical team's conclusion. The team considered many of the factors identified by Dr. Raymond as inconsistent with GBS, but ultimately decided those factors either actually were not inconsistent with GBS or were of less importance than other factors. The team recognized that Ryan's complex clinical picture made it impossible to make a diagnosis with certainty, but concluded Ryan most likely suffered from vaccine-induced GBS.

After an extensive, six-week evaluation of Ryan's condition, a team of medical experts concluded that Ryan's Hep B vaccine caused him to develop GBS. The medical records document the team's thought process and show that the team's conclusion was reliable. I find that Petitioners have satisfied their legal burden of demonstrating a logical sequence of cause and effect under prong 2 of Althen.

3. Prong 3

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. Pafford v. Sec'y of Dep't of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006). A temporal relationship between receipt of a vaccine and the alleged onset of symptoms, without more, however, is insufficient to establish a causal relationship in a cause-in-fact case. Grant, 956 F.2d at 1148. What constitutes an appropriate temporal association is a question of fact and will vary with the particular theory of causation advanced. Id.; de Bazan, 539 F.3d at 1352.

The experts in this case agreed that, if a vaccine-injury occurred, the timeframe from vaccination to injury was medically appropriate. Tr. at 158, 383-84. On June 26, 1995, 10 days following his Hep B vaccination, Ryan was taken to his pediatrician because he had been crying continuously for six days. At the time he was assessed with colic. The Children's medical team hypothesized that the colic episode was actually neuropathic pain, marking the onset of Ryan's GBS. Pet'r Ex. 25 at 107. The team characterized the incident as "an acute onset of irritability and inconsolability lasting a few days," and noted that, in retrospect, the parents felt this marked when Ryan's crying changed and when he started to develop feeding difficulties. Id. Dr. Kinsbourne agreed that the medical team's hypothesis was plausible. Dr. Kinsbourne opined Ryan's condition's was more serious than colic, and whether it was neuropathic pain or otherwise, the episode marked the point when Ryan's condition began to deteriorate. Tr. at 136-38. He also noted that Ryan's reflexes became diminished shortly after this incident, although the first time this was documented in the medical records was not until August 2, 1995. Tr. at 139. Dr. Kinsbourne described the progression of Ryan's condition as starting gradually shortly after vaccination, and rising to its peak in October 1995; in his opinion, the onset and progression of Ryan's condition occurred in a medically appropriate timeframe. Tr. at 135-38.

Dr. Raymond argued that Ryan's progression was inconsistent with an acute presentation. Tr. at 342-47. He stated that Ryan's hypotonia did not appear in the medical records until almost two months after vaccination, but admitted that if Ryan had hypotonia within four days of vaccination, that would be consistent with an acute onset of GBS. Tr. at 382-84. He also felt that the colic episode was not neuropathic pain. Tr. at 343. It was his opinion that the progression of Ryan's condition was not consistent with vaccine-induced GBS.

Based on all the evidence, I find that it is more likely than not that the onset of Ryan's GBS occurred within two weeks of his Hep B vaccination. It is undisputed that two weeks is a medically appropriate timeframe for vaccine injury causation, if it occurred in this case. Accordingly, I find that Petitioners have established prong 3 of Althen.

IV. CONCLUSION

Petitioners have satisfied the legal requirements for proving that Ryan's June 7, 1995, Hep B vaccination was a legal cause of GBS. Respondent has not overcome Petitioners' evidence by proving an alternative cause. Therefore, I find that Petitioners have established entitlement to compensation under the Vaccine Act.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Chief Special Master