In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

RICHARD McCONNELL,	*	No. 18-1051V
	*	Special Master Christian J.
Petitioner,	*	Moran
	*	
	*	Filed: August 19, 2022
v.	*	
	*	Entitlement; pneumococcal
	*	13-valent conjugate ("Prevnar
SECRETARY OF HEALTH	*	13") vaccine; Guillain-Barré
AND HUMAN SERVICES,	*	syndrome ("GBS"); disputed
	*	diagnosis; theory; timing.
Respondent.	*	

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner;
Jennifer L. Reynaud, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Richard McConnell claims that the pneumococcal 13-valent conjugate ("Prevnar 13") vaccine he received on August 1, 2016, caused him to develop Guillain-Barré syndrome ("GBS"). The parties have submitted reports from experts and argued their positions through legal briefs. Mr. McConnell has not provided a reliable mechanism by which the Prevnar 13 vaccine can cause GBS. Accordingly, Mr. McConnell has not met his burden of establishing that the Prevnar 13 vaccine caused his GBS. Thus, his case is dismissed.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

I. Facts

Mr. McConnell received the Prevnar 13 vaccination on August 1, 2016, at the office of his primary care physician, Robert Cramer, M.D. Exhibit 1 at 1-2; exhibit 5 at 36, 53. At the time of vaccination, Mr. McConnell was a 78-year-old retiree. Id. at 31. Before vaccination, Mr. McConnell had a history of type 2 diabetes, coronary artery disease, dyspnea on exertion, degenerative disc disease with spinal stenosis, and glaucoma. Exhibit 2 at 2, 47-51; exhibit 5 at 31-36, 48-52.

On September 15, 2016, 45 days after vaccination, Mr. McConnell went to the emergency department ("ED") at St. John's Hospital for leg weakness, difficulty walking, balance problems, and low right back pain. Exhibit 2 at 122-24. Upon presentation to the ED, Mr. McConnell reported "sudden onset of lower extremity weakness." Id. at 122. He informed the ED doctor, Sayeeda Jabeen, M.D., that he noticed weakness in his bilateral lower extremities and had difficulty walking the day prior. Id. Additionally, Mr. McConnell reported experiencing "back pain 2 weeks ago . . . after lifting a heavy object, but [said] it resolved quickly." Id. at 127. Dr. Jabeen's examination revealed decreased strength in Mr. McConnell's lower extremities and an "unsteady and shuffling" gait. Id. at 123. Dr. Jabeen noted that Mr. McConnell had received the pneumococcal conjugate vaccine "in the recent past[,] probably 4-8 weeks ago." Id. Additionally, Dr. Jabeen recommended Mr. McConnell "hold off" on the flu vaccine. Id. at 286. Mr. McConnell was admitted to the hospital for concerns of GBS. Id. at 123-24.

While at the hospital, Mr. McConnell underwent a cervical, thoracic, and lumbar spine MRI, which revealed mild disc disease and moderately severe central stenosis. Id. at 126. Orthopedist Ryan O'Rourke, M.D., reviewed Mr. McConnell's MRI images and determined that it was "highly unlikely" that his acute symptoms were due to spinal, skeletal, or disc issues. Id. at 132. Instead, Dr. O'Rourke suggested that Mr. McConnell's symptoms were more likely due to a neurological issue. Id. Given Mr. McConnell's history of diabetes, a lumbar puncture was not performed due to the common finding of elevated protein in cerebral spinal fluid in both GBS and diabetes. Exhibit 5 at 295.

Neurologist Todd Elmore, M.D., also examined Mr. McConnell during his hospital stay. Exhibit 2 at 133-38. Upon examination, Dr. Elmore observed that Mr. McConnell had full strength (5/5) in all his extremities except his left leg (4/5). Id. at 136. Mr. McConnell underwent a bedside electromyography ("EMG") / nerve conduction study ("NCS"), which was consistent with "[p]robable GBS

superimposed upon subclinical P[eripheral] Neuropathy due to diabetes." Exhibit 2 at 283; exhibit 6 at 26-29 (report). Dr. Elmore diagnosed Mr. McConnell with "[p]robable GBS superimposed upon subclinical P[eripheral] Neuropathy due to diabetes" and started him on intravenous immunoglobulin ("IVIG") therapy. Exhibit 2 at 283-86; exhibit 6 at 26-29.

On September 16, 2016, while still at the hospital, Mr. McConnell developed left arm weakness. Exhibit 2 at 292. During examinations on September 17, 2016, and September 18, 2016, Mr. McConnell's extremity weakness was more pronounced on the left side. Id. at 295, 303. When Dr. Elmore examined Mr. McConnell on September 19, 2016, he noted Mr. McConnell's extremity weakness was still worse on the left than the right. Id. at 308.

After four rounds of IVIG, Mr. McConnell's symptoms improved. Id. at 324; exhibit 3 at 4. Accordingly, he was discharged from the hospital and transferred to the Springfield Clinic for inpatient rehabilitation on September 21, 2016. Id. Mr. McConnell's diagnoses at discharge included GBS and acute kidney failure related to diabetic chronic kidney disease. Exhibit 2 at 113.

Upon arrival to the Springfield Clinic on September 22, 2016, Mr. McConnell reported that the strength was improving on his right side, but not his left side. Exhibit 2 at 324. The physical therapist noted that Mr. McConnell had diminished strength in all four extremities, his lower extremities were weaker than his upper extremities, and his left side was weaker than the right. Id. at 9.

After five weeks of inpatient rehabilitation, Mr. McConnell could walk with a wheeled walker and perform activities of daily living ("ADLs") involving his arms "with standby assistance." Exhibit 3 at 4. However, Mr. McConnell needed "maximal assistance" when performing ADLs involving his legs. Id. Due to safety concerns related to his wife being unable to care for him, Mr. McConnell was transferred to a long-term rehabilitation facility, The Bridge, for continued care on October 27, 2016. Id.; exhibit 5 at 26; exhibit 7 at 38-66.

While at The Bridge, Mr. McConnell saw Dr. Cramer on November 2, 2016. Exhibit 5 at 26-29. At the time of his visit with Dr. Cramer, Mr. McConnell was wearing an ankle-foot orthosis ("AFO") on his left foot. Id. at 30. Mr. McConnell reported intermittent pain in his left arm and hands, which Dr. Cramer believed was related to the "rejuvenation of the nerves." Id. Dr. Cramer also observed that Mr. McConnell's weakness was mainly limited to his left side, while his right side

was "normal." Id. Dr. Cramer recorded, "I spoke with his wife recently . . . about [GBS] and the relationship to vaccinations, prior infection, and that it can occur without any trigger also." Id. at 26. Dr. Cramer's impression was "Guillain-Barre syndrome following vaccination." Id. at 30.

Mr. McConnell visited Dr. Elmore on November 7, 2016. Exhibit 6 at 22-25. Dr. Elmore noted that Mr. McConnell was getting better and had recently been able to ambulate farther when using a wheeled walker in therapy. Id. at 22. However, Dr. Elmore observed that Mr. McConnell's left side continued to be much weaker than his right. Id.

On November 28, 2016, Mr. McConnell visited Dr. Cramer to discuss his GBS and a recent episode of pneumonia. Id. at 7. Dr. Cramer indicated that Mr. McConnell was suffering from GBS "following vaccination." Id. He also noted that Mr. McConnell had "Hemiparesis, left." Id.

Mr. McConnell's balance, strength, and endurance continued to improve over the following months. On December 5, 2016, Dr. Elmore noted, "He still has a lot more left-sided weakness than right which is a bit odd. Also, he has developed a little bit of a flexion contracture in his left wrist and fingers." Exhibit 6 at 18. Dr. Elmore's assessment was that Mr. McConnell "had severe Guillain-Barre syndrome." Id. at 21. Dr. Elmore further stated that it was "a bit odd" that Mr. McConnell's GBS was "rather patchy and asymmetric," but concluded that his "workup was pretty classic" for GBS. Id.

On December 14, 2016, Mr. McConnell was discharged from The Bridge. Exhibit 7 at 49-50. Mr. McConnell had reached nearly all his short-term occupational therapy goals and was independent in most ADLs. Id. at 46, 50. However, he continued to struggle with limited mobility. Id.

After his discharge from The Bridge, Mr. McConnell began working with a physical therapist at his home. See exhibit 4 (Great Lakes Caring records). Based on records from Dr. Cramer, Mr. McConnell's physical therapist noted that his primary diagnosis was GBS. Id. at 4-12, 53. Other diagnoses included hemiplegia following cerebral infarction affecting the left dominant side, type 2 diabetes with diabetic chronic kidney disease, and hypertensive chronic kidney disease. Id.

Mr. McConnell returned to Dr. Cramer on January 25, 2017. Exhibit 5 at 10-14. At the time of his visit, Mr. McConnell had developed a contracture in his left hand. Id. Mr. McConnell's left foot drop had resolved, and he no longer

needed the AFO. Id. However, Dr. Cramer observed that Mr. McConnell had an abnormal gait and could not stand without help. Id. Dr. Cramer noted that Mr. McConnell's "[l]eft arm and leg are still mildly weak." Id. at 13. Dr. Cramer recommended that Mr. McConnell follow up in three months. Id.

Mr. McConnell was discharged from his in-home physical therapy and occupational therapy program on February 1, 2017. Exhibit 4 at 11-18, 188.

Mr. McConnell returned to Dr. Elmore on March 6, 2017. Exhibit 6 at 14-17. Dr. Elmore noted that Mr. McConnell continued to experience weakness and was still using a walker. Id. Dr. Elmore suggested aggressive therapy and stretching and told Mr. McConnell to follow up in four months. Id. Mr. McConnell returned for follow-up appointments with Dr. Elmore on July 6, 2017, and January 4, 2018. Id. at 10-13; exhibit 15 at 7-8, 14-17. At the time of those visits, Mr. McConnell reported experiencing ongoing weakness and using a walker. Exhibit 15 at 7-8, 14-17.

On January 16, 2019, Mr. McConnell began seeing neurologist Atul Syal, M.D. Exhibit 13 at 11-13. Upon examination, Dr. Syal found that Mr. McConnell's weakness was worse on the left side and that his deep tendon reflexes were normal. Id. at 12. Dr. Syal's impression was that Mr. McConnell's presentation did not fit with GBS, diabetic neuropathy, or chronic inflammatory demyelinating polyneuropathy ("CIDP"). Id. However, Dr. Syal noted that a repeat EMG/NCS "reveal[ed] severe neuropathy in his upper and lower extremities." Id. at 6. Mr. McConnell continued to see Dr. Syal for follow up visits in 2019. See generally exhibit 13.

Mr. McConnell established care with a new neurologist, Kumaraswamy Sivakumar, M.D., on November 15, 2019. Exhibit 16 at 1-10. Dr. Sivakumar's examination revealed that Mr. McConnell's "spasticity [was] more on the left upper and lower extremities than on the right." Id. at 3. He stated that the "slowing" evidenced in Mr. McConnell's NCS may have been caused by his diabetes and related kidney issues. Id. He elaborated, "The slowing in NCV of diabetes may have been mistaken for demyelination, thus the diagnosis of GBS." Id. Dr. Sivakumar opined that transverse myelitis was a more appropriate diagnosis than GBS and suspected that Mr. McConnell also had diabetic polyneuropathy. Id. While Dr. Sivakumar noted that Mr. McConnell "could have GBS followed by new spasticity due to a cervical cord problem," id., subsequent imaging of the cervical spine ruled out a cervical cord problem. Exhibit 26 at 1.

The most recently filed medical record is a visit with Dr. Sivakumar on October 29, 2019. Exhibit 26 at 1-3. At the time of this visit, Mr. McConnell's condition remained unchanged. Id. Dr. Sivakumar again stated that Mr. McConnell's more likely diagnosis was transverse myelitis. Id. at 1.

II. Procedural History

Mr. McConnell filed a petition for compensation on July 18, 2018. Pet., filed July 18, 2018, at 1. Contemporaneous with his petition, Mr. McConnell filed initial medical records. The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., filed July 12, 2019.

The parties then proceeded to the expert report stage. To support his case, Mr. McConnell presented an initial report from Frederick Nahm, M.D., Ph.D., on March 20, 2020. Exhibit 17. In response, the Secretary submitted a report from Subramaniam Sriram, M.D., on June 16, 2020. Exhibit A. Mr. McConnell then submitted a rebuttal report from Dr. Nahm on October 7, 2020. Exhibit 19. On January 22, 2021, the Secretary provided a responsive report from Dr. Sriram. Exhibit B. The parties also filed several medical articles their experts cited.

Following the completion of the expert report stage, the parties were instructed to file briefs advocating for their positions. Order, issued Mar. 9, 2021. After submitting updated medical records, Mr. McConnell filed his brief in support of entitlement on July 13, 2021. On October 15, 2021, the Secretary submitted his responsive brief. Mr. McConnell did not file a reply.

After reviewing the parties' entitlement briefs, the undersigned determined that the briefs did not engage with the critical issue of timing. Accordingly, the parties were ordered to submit supplemental briefs addressing Mr. McConnell's onset of symptoms and the appropriate time interval for which to infer vaccine-vaccination. Order, issued Feb. 17, 2022. Mr. McConnell filed his supplemental brief on March 4, 2022. The Secretary filed his supplemental brief on March 17, 2022.

The initial order for briefs explained that any additional medical literature must be accompanied by a signed statement from an expert providing an explanation for the article's relevance. Order, issued Mar. 22, 2021, at 2. However, contemporaneous with his supplemental brief on timing, Mr. McConnell filed the Schonberger article as exhibit 27 without an accompanying statement from an expert. Thus, Mr. McConnell was ordered to file a statement from an

expert explaining the significance of the Schonberger article, which he submitted on June 30, 2022. Exhibit 28 (Dr. Nahm's signed statement). The Secretary provided a response to Dr. Nahm's signed statement regarding the Schonberger article on July 28, 2022. The case is now ready for adjudication.

III. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When pursuing an off-Table claim, the petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] 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." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Furthermore, as a threshold matter, a petitioner must establish she suffers from the condition for which she seeks compensation. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). When a petitioner fails to establish her diagnosis, there is no need for an analysis pursuant to Althen, 418 F.3d at 1278. See Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

IV. Analysis

This section will first resolve the threshold issue of whether Mr. McConnell has established that he suffers from GBS, the injury for which he seeks compensation. Next, this section will discuss whether Mr. McConnell has met his burden under each Althen prong.

A. GBS Diagnosis

Mr. McConnell alleges that he suffers from GBS. However, the Secretary contends that his presentation and test results were inconsistent with GBS. Resp't's Br., filed Oct. 15, 2021, at 11. This section first discusses the diagnostic criteria for GBS. Then, it evaluates Mr. McConnell's clinical presentation and electrodiagnostic testing. Next, it examines statements from Mr. McConnell's treating physicians regarding diagnosis. Finally, this section weighs the evidence and concludes that Mr. McConnell has met his burden in establishing that he suffers from GBS.

1. Diagnostic Criteria

To assess whether Mr. McConnell met his burden in establishing that he suffered from GBS, it is necessary to set forth the diagnostic criteria. In Dr. Sriram's first report, he provided the following clinical criteria used in diagnosing GBS: (1) "Bilateral and flaccid weakness of the limbs," (2) "decreased or absent tendon reflexes in weak limbs," (3) "symmetrical weakness . . . in over 50% of patients," (4) "flaccid" tone, (5) "[m]onophasic pattern disease with maximal deficit occurring in 28 days with gradual recovery," and (6) "albumin-cytological dissociation" as shown by cerebrospinal fluid ("CSF"). Exhibit A at 7. Dr. Nahm did not contest these criteria in his responsive report but added that clinical features of GBS "include progressive weakness in the legs and arms, at times presenting only in the leg[s]." Exhibit 19 at 4 (citing exhibit 18, tab B (Hugh J. Willison et al., Guillain-Barré Syndrome, 388 Lancet 717 (2016))). Dr. Nahm elaborated, "There are many examples of GBS cases that do not meet these criteria, and many publications showing atypical presentations are not uncommon such as asymmetry in weakness and longer periods of weakness." Dr. Sriram responded that the articles on which Dr. Nahm relied, Willison (exhibit 18, tab B) and Leonhard (exhibit 23),[2] noted that "[m]arked, persistent asymmetry of weakness" cast doubt on a GBS diagnosis. Exhibit B at 1-3.

[2] Sonja E. Leonhard et al., Diagnosis and Management of Guillain-Barré Syndrome in Ten Steps, 15 Nature Revs. Neurology 671 (2019).

2. Mr. McConnell's Presentation and Electrodiagnostic Testing

Dr. Nahm opined that Mr. McConnell's "initial clinical presentation of acute bilateral lower extremity weakness, reduced deep tendon reflexes and gait impairment, as documented by [his] initial neurological evaluation . . . support [Mr. McConnell's] GBS diagnosis." Exhibit 19 at 1 (citing exhibit 2 at 283).

The Secretary, through Dr. Sriram, argues that Mr. McConnell's clinical presentation and electrodiagnostic testing are inconsistent with a GBS diagnosis. Resp't's Br. at 11. Dr. Sriram noted that "Mr. McConnell's weakness was abrupt and involved primary lower extremities, left greater than right." Exhibit A at 7. He added, "At the onset of the illness, reflexes were present in the weak left leg, but absent in the right leg." Id. He concluded that Mr. McConnell's asymmetrical weakness is inconsistent with the clinical feature of bilateral weakness seen in GBS patients. Id. Regarding Mr. McConnell's muscle tone, Dr. Sriram noted it was "variable" with "increasing spasticity and contractures," while GBS patients are expected to have flaccid muscle tone. Id. Dr. Sriram also opined that Mr. McConnell's course was "protracted and last almost three months before partial recovery," which did not fit with a monophasic pattern and gradual recovery. Id.

Mr. McConnell underwent a bedside electromyography EMG/NCS on September 16, 2016, which Dr. Elmore reported was consistent with "[p]robable GBS superimposed upon subclinical P[eripheral] Neuropathy due to diabetes." Exhibit 2 at 283; exhibit 6 at 26-29 (report). Regarding Mr. McConnell's electrodiagnostic testing, Dr. Sriram opined that the results of his EMG/NCS from September 16, 2016, "overall were more suggestive of a diabetic polyneuropathy." Exhibit A at 7-9. Conversely, Dr. Nahm concluded that his NCS from September 16, 2016, "showed a pattern consistent with a demyelinating and axonal polyneuropathy." Exhibit 17 at 10.

3. Statements from Treating Doctors

Although statements from some of Mr. McConnell's treating physicians contradict each other, both Dr. Elmore and Dr. Cramer, who treated Mr. McConnell early in his course, supported a GBS diagnosis. Mr. McConnell's treating neurologist, Dr. Elmore, diagnosed Mr. McConnell with GBS during his hospital stay. Exhibit 2 at 283-86; exhibit 6 at 26-29. Although Dr. Elmore stated that there was "some focality," he concluded that Mr. McConnell's presentation

was "classic" for GBS. Id. at 199; see also exhibit 7 at 21. Additionally, Mr. McConnell's primary care physician, Dr. Cramer, endorsed his GBS diagnosis. See, e.g., exhibit 5 at 30; exhibit 6 at 7.

Some of Mr. McConnell's treating neurologists who provided care to him later in his course questioned his GBS diagnosis. Dr. Syal opined that Mr. McConnell's presentation did not fit with GBS, diabetic neuropathy, or CIDP. Exhibit 13 at 6. Dr. Syal did not appear to propose an alternative diagnosis. Further, Dr. Sivakumar indicated that transverse myelitis may have been a more appropriate diagnosis. Exhibit 16 at 3. Regarding Dr. Sivakumar's suggestion that transverse myelitis was a more likely diagnosis, Dr. Nahm noted that Mr. McConnell's cervical MRI from October 9, 2019, did not show any evidence for transverse myelitis. Exhibit 17 at 13. Dr. Nahm elaborated that Mr. McConnell may have developed cervical cord disease or experienced a stroke in the years after his vaccination and GBS diagnosis, which may explain why Dr. Syal and Dr. Sivakumar doubted Mr. McConnell's GBS diagnosis. Id. He explained, "Neither condition can be used to retrospectively negate the overwhelming evidence for a vaccine induced polyneuropathy as the cause of [Mr. McConnell's] neurological disability starting in 2016." Id.

4. Resolution

Although Mr. McConnell's presentation was unusual, the evidence preponderates in favor of a finding that he suffered from GBS. As Dr. Sriram and some of Mr. McConnell's treating physicians pointed out, Mr. McConnell's extremity weakness was asymmetrical with more weakness on the left side and primarily weakness in the lower extremities. However, as Dr. Sriram acknowledges, symmetric weakness occurs in over 50% of GBS patients, but not all. Exhibit A at 7. Also, while Mr. McConnell experienced primarily lower extremity weakness, the EMG of his upper and lower extremities conducted on September 16, 2016, was consistent with a sensorimotor polyneuropathy. Exhibit 2 at 283; exhibit 6 at 26-29 (report). Further, the medical records from September 22, 2016, noted that Mr. McConnell was experiencing upper extremity weakness, albeit not as severe as his lower extremity weakness. Exhibit 2 at 9.

Moreover, Dr. Elmore's and Dr. Cramer's statements in support of Mr. McConnell's GBS diagnosis are entitled to consideration. Dr. Elmore believed, despite the asymmetrical weakness, Mr. McConnell's presentation was "classic for GBS." Exhibit 6 at 21. Although Dr. Cramer is not a neurologist, and his statements regarding Mr. McConnell's diagnosis carry less weight than that of a

treating neurologist, he also endorsed Mr. McConnell's GBS diagnosis. Exhibit 5 at 30; exhibit 6 at 7. Dr. Syal's and Dr. Sivakumar's contradictory statements do not overcome the support from Dr. Elmore and Dr. Cramer, who treated Mr. McConnell closer in time to his diagnosis. Additionally, Dr. Syal did not propose an alternative diagnosis, and Dr. Nahm noted that the medical records do not support a diagnosis of transverse myelitis as Dr. Sivakumar suggested. Additionally, Dr. Nahm aptly pointed out that Dr. Syal's and Dr. Sivakumar's statements were retrospective and years after his GBS diagnosis. Exhibit 17 at 13. Accordingly, Mr. McConnell has met his burden of establishing that he suffered from GBS.

B. Althen Prong One: A Causal Theory Connecting the Vaccine to Mr. McConnell's GBS

1. Parties' Arguments

The first Althen prong requires the petitioner to provide a "sound and reliable" medical theory demonstrating that the vaccine can cause the alleged injury. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). The petitioner must also offer "a reputable or scientific explanation that pertains specifically to [his] case." Moberly, 592 F.3d at 1322.

Through Dr. Nahm, Mr. McConnell offers molecular mimicry as the mechanism by which the Prevnar 13 vaccine can cause GBS. Exhibit 17 at 7. Dr. Nahm explained that GBS can develop "in response to some environmental antigen that then triggers an immune/inflammatory response," which then causes injury to the nerves and myelin. Id. (citing exhibit 18, tab B (Willison)). He elaborated that molecular mimicry occurs because of "similarities between certain pathogenic elements" contained in the Prevnar 13 vaccine and certain proteins found in human tissues. Id. Dr. Nahm added that anti-ganglioside antibodies can trigger the membrane attack complex, which affects the axons and the endplate on myelin. Id. He concluded that the Prevnar 13 vaccine can create an immune cross-reaction, which damages peripheral nerves and myelin, thus leading to GBS. Id. at 14.

To support his theory, Dr. Nahm relied on multiple case reports and studies. See id. at 10 (citing exhibit 18, tab H; exhibit 18, tab I; exhibit 18, tab J).[3] One

[3] Exhibit 18, tab H (Hassan El Khatib et al., Case Report: Guillain-Barré Syndrome with Pneumococcus – A New Association in Pediatrics, 11 IDCases 36

report describes a thirteen-year-old girl who had GBS-like symptoms following an episode of pneumococcal pneumonia. Exhibit 18, tab H (El Khatib). Another case report explores a potential link between the pneumococcal conjugate vaccine and GBS. Exhibit 18, tab I (Ravishankar). The subject of the Ravishankar case report received the Prevnar 13 vaccine and developed symptoms of polyneuropathy between 70 days and 10 months later. Id. at 1-2. During the interval between receipt of the Prevnar 13 vaccine and onset of symptoms, the subject received the Pneumovax 23 vaccine, another pneumococcal conjugate vaccine. Id. at 1. Dr. Nahm also relied on a post-licensure surveillance study that examined Vaccine Adverse Events Reporting System ("VAERS") reports of GBS following the Prevnar 13 vaccine. Exhibit 18, tab J (Haber). The authors of the study ultimately determined that the incidence of Guillain-Barre syndrome after PCV-13 vaccine was no greater than the background incidence in the population. Id.

In response, Dr. Sriram asserted that that Dr. Nahm did not offer any medical literature to demonstrate any homology or cross-reactivity between any component of the Prevnar 13 vaccine and proteins in peripheral nervous system. Exhibit A at 9. Further, Dr. Sriram questioned the utility of the literature Dr. Nahm used to support his theory. Regarding the El Khatib case report (exhibit 18, tab H), Dr. Sriram asserted that it carried little weight because the subject's symptoms, such as fever and urinary and fecal incontinence, were inconsistent with GBS. Id. at 10. With respect to Ravishankar, Dr. Sriram asserted that it did not support vaccine-causation due to the long interval between receipt of the Prevnar 13 vaccine and development of GBS symptoms. Id. at 10-11. Finally, Dr. Sriram emphasized that the Haber study (exhibit 18-J) concluded that there was no increased incidence of GBS following the Prevnar 13 vaccine. Id. at 11.

In addition to Dr. Sriram's critiques, the Secretary argued that scientific literature shows that the Prevnar 13 vaccine is safe, and no evidence supports a higher incidence of GBS following the vaccine. Resp't's Br. at 14 (citing exhibit 18, tab J (Haber)). The Secretary further argued that Dr. Nahm's use of molecular mimicry to support vaccine-causation was "overbroad" and "generic." Id. at 15 (citing Boatmon, 941 F.3d at 1360; W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013)).

(2018)); exhibit 18, tab I (Nidhi Ravishankar, Guillain-Barre Syndrome Following PCV Vaccine, 4 J. Neurology & Neurosurgery 134 (2017)); exhibit 18, tab J (Penina Haber et al., Post-Licensure Surveillance of 13-Valent Pneumococcal Conjugate Vaccine (PCV13) in Adults Aged > 19 Years Old in the United States, 34 Vaccine 6330 (2016)).

2. Resolution

Dr. Nahm opined that anti-ganglioside antibodies can cause GBS via molecular mimicry. However, Dr. Nahm did not identify any components in the Prevnar 13 vaccine that contain anti-ganglioside antibodies. See exhibit 17. Although molecular mimicry is generally accepted as a mechanism for causation of GBS, "mere invocation" of the term does not satisfy Mr. McConnell's burden under Althen prong one. See Deshler v. Sec'y of Health & Hum. Servs., No. 16-1070V, 2020 WL 4593162, at *20 (Fed. Cl. Spec. Mstr. July 1, 2020); see also Forrest v. Sec'y of Health & Hum. Servs., No. 14-1046V, 2019 WL 925495, at *3 (Fed. Cl. Spec. Mstr. Jan. 18, 2019) (citing Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 135 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012)). Dr. Nahm's failure to specifically link a component of the Prevnar 13 vaccine to anti-ganglioside antibodies makes his theory unpersuasive. Without an identified homology, Dr. Nahm's proposed cross-reaction cannot be reliably traced to the Prevnar 13 vaccine. Identifying a link between the vaccine and injury enhances the reliability of the theory of molecular mimicry. See Yalacki v. Sec'y of Health & Hum. Servs., No. 14-278V, 2019 WL 1061429, at *34 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), mot. for rev. denied, 146 Fed. Cl. 80, 91-92 (2019) (ruling that the special master did not elevate petitioner's burden on prong one).

The literature Dr. Nahm relied on does not overcome the lack of specificity. Dr. Sriram persuasively explained why the El Khatib case report (exhibit 18-H) and the Ravishankar case report (exhibit 18-I) lack relevance to Mr. McConnell's case. Additionally, case reports standing alone are too weak to carry a petitioner's burden. See Paluck v. Sec'y of Health & Hum. Servs., 104 Fed. Cl. 457, 475 (2012) ("[C]ase reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value . . . .") (quoting Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011), aff'd, 786 F.3d 1373 (Fed. Cir. 2015)). Further, although the Haber study (exhibit 18-J) reported 11 cases of GBS following the Prevnar 13 vaccine, the authors of the study concluded that there was no increased incidence of GBS following Prevnar 13.

Moreover, Dr. Nahm did not provide epidemiological evidence to support a link between Prevnar 13 and GBS. See Tullio v. Secretary of Health & Human Services, No. 15-51V, 2019 WL 7580149 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). Therefore, Dr. Nahm's generic molecular mimicry theory does not satisfy Mr. McConnell's burden under Althen

prong one. See W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352 (Fed. Cir. 2013) (quoting Broekelschen, 618 F.3d at 1345 (rejecting the petitioner's theory because the evidence was too generalized to relate "specifically to the petitioner's case"); see also Pek v. Sec'y of Health & Hum. Servs., No. 16-736V, 2020 WL 1062959, at *16 (finding that the petitioner's evidence pertaining to molecular mimicry was too broad to satisfy Althen prong one).

Special masters in other cases involving Prevnar 13 and GBS have reached different outcomes regarding whether the Prevnar 13 vaccine can cause GBS. Compare Pierson v. Sec'y of Health & Hum. Servs., No. 17-1136V, 2022 WL 322836, at *27-31 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) (crediting the theory that Prevnar 13 can cause GBS via molecular mimicry because the petitioner's expert identified components of the vaccine that share a homology with GBS); with Deshler, 2020 WL 4593162, at *20 (finding that the petitioner failed to show that components of the Prevnar 13 vaccine shared sufficient homology to cause cross-reactivity).

These cases do not weigh heavily in the analysis for three reasons. First, despite an instruction for the parties to cite any similar cases, Order, issued Mar. 22, 2021, at 6-7, Mr. McConnell did not discuss any similar cases in his brief. Therefore, any arguments based on analogous cases appear to have been waived. Vaccine Rule 8(f)(1). Second, decisions of other special masters are nonbinding. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1358 (Fed. Cir. 2019). Third, the differences in outcome in these cases primarily derive from disparities in evidence. See Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1368 (Fed. Cir. 2000) (recognizing that special masters may weigh evidence differently). As explained above, the evidence in this case is insufficient to establish, more likely than not, that Prevnar 13 can cause GBS.

C. Althen Prong Two: A Logical Sequence of Cause and Effect

The second Althen prong requires a petitioner to show a logical sequence of cause and effect usually supported by the medical records. Althen, 418 F.3d at 1278; Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). With respect to the second prong, the Federal Circuit has instructed special masters to carefully consider the views of treating doctors. Capizzano, 440 F.3d at 1326.

To support a logical sequence of cause and effect, Dr. Nahm stated that before receiving the Prevnar 13 vaccine, Mr. McConnell had no neurological

issues, weakness, numbness, difficulty walking, or visual problems. Exhibit 17 at 9. Dr. Sriram responded that Mr. McConnell did have neurological issues prior to vaccination due to his long history of diabetes. Exhibit A at 10.

Mr. McConnell also derives some support from his treating physicians. When Mr. McConnell was in the hospital, Dr. Jabeen wrote that adverse reactions to Prevnar 13 "do and may happen" and recommended that Mr. McConnell "hold off on [the] flu vaccine" in the future. Exhibit 2 at 289. Furthermore, Dr. Cramer noted that Mr. McConnell received the Prevnar 13 vaccine six weeks prior to the onset of symptoms and noted that there was "no other antecedent event to cause GBS." Exhibit 5 at 26. In response, the Secretary asserts that statements from Mr. McConnell's treating physicians do not assist him because the treaters did not provide a theory for vaccine-causation. Resp't's Br. at 18. The Secretary further argues that Mr. McConnell's failure to meet his burden under prong one necessitates that he must also fail on prong two. Id. at 17.

Although Mr. McConnell has some support from his treating doctors, these statements do not bind a special master to adopt their conclusions. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). Further, in light of the finding that Mr. McConnell has not satisfied Althen prong one, the statements from his treating physicians carry little weight. See Deshler, 2020 WL 4593162, at *21. Accordingly, Mr. McConnell has not met his burden under Althen prong two.

D. Althen Prong Three: A Showing of a Proximate Temporal Relationship Between Vaccination and Mr. McConnell's GBS

The third Althen prong requires the petitioner to show a "proximate temporal relationship" between the vaccination and the alleged injury. Althen, 418 F.3d at 1281. The timing prong of Althen contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

Here, the parties dispute when Mr. McConnell's neurological symptoms first manifested. Mr. McConnell proposes that his symptoms began on or around

September 8, 2016, 38 days after vaccination. Pet'r's Supplemental Br., filed Mar. 4, 2022, at 2-3. In contrast, the Secretary asserts that Mr. McConnell first began experiencing neurological symptoms on September 14, 2016, 44 days post-vaccination. Resp't's Supplemental Br., filed Mar. 15, 2022, at 2.

Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). The medical records in this case favor a finding that Mr. McConnell's neurological symptoms began on or around September 14, 2016. Three hospital records from September 15, 2016, reported that Mr. McConnell had leg weakness or difficulty walking since "yesterday." See exhibit 2 at 127, 133, and 159.

To support a finding that Mr. McConnell's symptoms of GBS began on or around September 8, 2016, Mr. McConnell cites a medical record from September 15, 2016, that noted Mr. McConnell had been experiencing lower right back pain for the past week. Exhibit 2 at 159. However, the Secretary points out that another hospital record from the same date that reported Mr. McConnell's low right back pain began two weeks prior after Mr. McConnell lifted a heavy object. Resp't's Supplemental Br. at 3 (citing exhibit 2 at 127). Additionally, the Secretary noted that Dr. Nahm never attributed Mr. McConnell's back pain to his GBS. See id. at 2. One medical record reporting back pain starting a week prior does not overcome three contemporaneous medical records that support an onset of neurological symptoms on September 14, 2016. Accordingly, Mr. McConnell's neurological symptoms began on September 14, 2016.

Mr. McConnell argues that even if onset occurred on September 14, 2016, it is still an appropriate timeframe to infer vaccine-causation. To support this contention, Dr. Nahm offered an article reporting that after receiving the swine flu vaccine, the period for increased risk of vaccine induced GBS was within five weeks but could extend to ten weeks. Exhibit 27 (Lawrence B. Schonberger et al., Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977, 110 Am. J. Epidemiology 105 (1979)). Additionally, Mr. McConnell cites a Vaccine Program case in which the special master found the timeframe for onset of GBS following vaccine could extend to two months. See Pet'r's Supplemental Br. at 3 (citing Barone v. Sec'y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014)).

The Secretary responded that the Schonberger article (exhibit 27) is irrelevant because it involves a different vaccine. Resp't's Supplemental Br. at 5. Dr. Nahm addressed the Secretary's critique in a statement explaining the relevance of the Schonberger article. Exhibit 28. In his statement, Dr. Nahm explained that the article is relevant to the Prevnar 13 vaccine because the pneumococcal conjugate vaccine produces a similar immune response to the flu vaccine. Id. at 3-4. He elaborated, "A primary immune response to an antigen, such as a vaccine or infectious agent, is thought to occur over the course of a lag, logarithmic, and a plateau phase." Id. at 3. He added that immune responses to the pneumococcal vaccine occur "within a time period consistent with other vaccine responses." Id. at 3-4.

In a previous Vaccine Program case, a special master credited the Schonberger article and found it was applicable to the timing between the Prevnar 13 vaccine and onset of GBS. See Pierson, 2022 WL 322836, at *32-38. In Pierson, the special master found that a 51-day interval between receipt of the Prevnar 13 vaccine and onset of GBS was permissible to infer causation. See id. Additionally, as Mr. McConnell notes, special masters in other GBS cases have found a time interval of two months to be appropriate. See, e.g., Barone, 2014 WL 6834557, at *13; Aguayo v. Sec'y of Health & Hum. Servs., No. 12-563V, 2013 WL 441013, at *3 (Fed. Cl. Spec. Mstr. Jan. 15, 2013); Corder v. Sec'y of Health & Hum. Servs., No. 08-228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011). Although special masters are not bound by decisions of other special masters, these cases are instructive on the timing issue.

As discussed above, Mr. McConnell has provided some literature to support an onset interval of 44 days, and Schonberger has been credited in other Vaccine Program cases. Additionally, other special masters have found that an appropriate timeframe for GBS can extend to two months. Based on this evidence, Mr. McConnell likely meets his burden under Althen prong three. However, the medical acceptable timeframe depends, at least in part, on the theory being offered. Langland v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 421, 443 (2013). As explained in section I.B, Mr. McConnell has not presented a persuasive medical theory to explain how the Prevnar 13 vaccine can cause GBS. Thus, it is not necessary to resolve the question of whether Mr. McConnell has met his burden under Althen prong three. Even if the timing were appropriate, Mr. McConnell would not necessarily be entitled to compensation. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144 (Fed. Cir. 1992) ("Temporal association is not sufficient, however, to establish causation in fact."). Mr. McConnell's failure to satisfy Althen prongs one and two prevents him from establishing entitlement.

V. A Hearing Is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Mr. McConnell has had a fair and full opportunity to present his case. After Dr. Nahm presented his initial opinion, Dr. Sriram critiqued it, persuasively pointing out gaps in Dr. Nahm's report. Mr. McConnell then presented a rebuttal opinion from Dr. Nahm, which Dr. Sriram again critiqued. Mr. McConnell's efforts to address any deficiencies in Dr. Nahm's reports during the briefing process were unpersuasive. Ultimately, Mr. McConnell was unable to offer a persuasive theory by which the Prevnar 13 vaccine can cause GBS. Therefore, a hearing would not resolve the failure to provide a sound and reliable medical theory.

VI. Conclusion

Mr. McConnell has not met his burden of demonstrating that the Prevnar 13 vaccine was the cause-in-fact of his GBS. Accordingly, the Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master