In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-848V

(to be published)

HOLLY D. PATEL,	*	
	*	
Petitioner,	*	Filed: May 1, 2020
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza vaccine; *Althen* prong three; Timeframe; Chronic inflammatory demyelinating polyneuropathy; Headaches and fatigue
	*	
	*	
Respondent.	*	
	*	

Andrew D. Downing, Van Cott & Talamante, Phoenix, AZ, for Petitioner.

Robert Coleman III, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On July 19, 2016, Holly D. Patel filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] alleging that she experienced Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") because of vaccines that she received on August 20, 2013, and November 13, 2013. Petition (ECF No. 1). Petitioner later amended her claim to the allegation that the influenza ("flu") vaccine she received in November 2013 was causal of her CIDP. Joint Status Report at 1, filed on August 1, 2018 (ECF No. 47).

[1] This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a 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." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

The parties acceded to my proposal that the matter be resolved by a ruling on the record. Now, after review of all submissions in the case, I **DENY** an entitlement award. As discussed in greater detail below, Petitioner has not successfully established that onset of her CIDP occurred in a medically acceptable timeframe when measured from her November 2013 vaccination.

I. Factual Background

A. *Pre-Vaccination History & Status After Receipt of Flu Vaccine*

Two months before the vaccination at issue, Ms. Patel gave birth to her second daughter on September 22, 2013, while living in England. Hertfordshire Community Records at 1, filed on Jan. 8, 2019 as Ex. 61 (ECF No. 69-1). Before this time, she had a medical history of Grave's disease, hyperthyroidism, goiter, and a benign systolic mummer. Lister Hospital Records at 3, filed on March 3, 2017 as Ex. 17 (ECF No. 13-2). Her labor was difficult, and in it she lost a significant amount of blood and declined transfusion. Hertfordshire Community Records II at 1, filed on Oct. 25, 2018 as Ex. 59 (ECF No. 64-1). On October 4, 2013, Petitioner was advised of the symptoms of anemia and prescribed iron and ferrous sulphate supplements. *Id.* at 2. Right around this time, Petitioner reported feeling "tired, emotional, and some dizziness", symptoms which persisted for several days. *Id.* at 1, 2.

On November 18, 2013, Petitioner received a seasonal flu vaccination in the United Kingdom.[3] Vaccination Record, filed on Oct. 17, 2016 as Ex. 1 (ECF no. 7-2). She returned to the United States at the end of that month. Pet'r's Aff. at 1, filed on Mar. 13, 2018 as Ex. 20 (ECF No. 30-1). The medical record does not suggest that Ms. Patel experienced any reaction to the receipt of this vaccine. Indeed, there is a subsequent gap of a few months in the medical records revealing no treatment history at all. But Petitioner attributes this gap to the fact that she was then arranging for health insurance, and had to wait for an appointment to see her new primary care provider. Pet'r's Aff. at 1–2. Petitioner also maintains that beginning the first week of December 2013, she "began experiencing dizziness, fatigue, and headaches." *Id.* at 1. To treat these symptoms she started taking various over-the-counter medications (e.g., Tylenol, Ibuprofen, and Dramamine) but they did not help. *Id.*

B. *2014 and Headache/Dizziness Symptoms*

The next medical record is from February 10, 2014, when Ms. Patel visited Elizabeth O'Connor, D.O., at Abrazo Healthcare in Scottsdale, Arizona. Abrazo Healthcare Records, filed as Ex. 15 on February 3, 2017 (ECF No. 11-2) ("Abrazo Healthcare") at 69; *see also* Pet'r's Aff. at 1. The purpose of the visit was to establish a new treatment provider. Abrazo Healthcare at 69. At this initial visit, Ms. Patel raised only three problems: gestational diabetes mellitus, hypothyroidism (for which she reported taking medication), and an iron deficiency. *Id.* at 69–70.

[3] The parties have agreed that this vaccine is covered under the Vaccine Act. Joint Status Report at 1, filed on August 1, 2018 (ECF No. 47).

The history section of these records does not mention headaches, lightheadedness, or dizziness, however. *Id.*

A review of Ms. Patel's symptoms by Dr. O'Connor did not note headaches, lightheadedness, or a change in an any preexisting headache pattern. Abrazo Healthcare at 70. The physical exam section also noted that Petitioner was ambulating normally and had normal muscle strength and tone. *Id.* Petitioner was assessed with gestational diabetes mellitus, hypothyroidism, and iron deficiency, and labs were ordered in reference to these problems. *Id.* Test results obtained on February 25, 2014, at a follow-up visit showed normal iron levels and low TSH levels. *Id.* at 95–98. As with the first visit, these records reference no neurologic problems, headaches, dizziness, or fatigue, and no neurologic consult was proposed. *See generally id.* at 69–70.

On February 27, 2014, however, Petitioner called Abrazo Healthcare complaining of dizziness. Ex. 53, filed on September 25, 2018 (ECF No. 56-1), at 1. Her blood sugar levels came back normal, ruling out diabetes mellitus as an explanation for dizziness. In response to Ms. Patel's request to look for alternative etiologies for her symptoms, she was given a neurology referral. *Id.*

Petitioner followed up with Dr. O'Connor at Abrazo Healthcare the next month, on March 21, 2014. Abrazo Healthcare at 67–68. Her chief complaints at this visit were dizziness, lightheadedness, and headaches which she now reported occurred almost daily, plus fatigue, malaise, and some vision issues. *Id.* at 67–68. These records set forth her presenting issues as hypothyroidism, iron deficiency, obesity, gestational diabetes mellitus, and dizziness. *Id.* at 67. A review of systems reflected Petitioner's symptoms, although a physical exam noted normal muscle tone and strength. *Id.* at 68. Ms. Patel also stated that she had a consult scheduled with a neurologist in a few weeks, but wanted to see if there was anything Dr. O'Connor could do for her before then. *Id.* at 68. There is no evidence that Petitioner followed up thereafter with Dr. O'Connor.

There is then another medical records gap of a month. Then on April 23, 2014, Petitioner visited Jack Anderson, M.D., for an injury she claimed to have sustained in mid-February to her jaw and right side of her face when a shelf in her home fell off the wall and struck her. Arizona Pain Institute Records, filed as Ex. 51 on September 19, 2018 (ECF No. 53-1) ("Arizona Pain") at 11. Notably, the medical treatment Petitioner *did* obtain in this gap period says nothing about any such injury (despite the fact that clearly she could have sought medical intervention in this March-April timeframe). Nevertheless, Ms. Patel informed Dr. Anderson that she had experienced several weeks of pain since the incident, along with more frequent headaches. Previously she reported suffering headaches in the occipital[4] area, but since the injury those headaches had shifted to the right temporal area. *Id.* At this visit she denied any vision problems, other facial sensitivity, or

[4] "Occipital" refers to the occiput or occipital bone located at the back of the skull near the base. *Dorland's Illustrated Medical Dictionary* 1292 (33d ed. 2020) (hereinafter "Dorland's").

other medical problems. *Id.* A physical exam showed normal motor strength, reflexes, and sensitivity. *Id.* at 13. Petitioner was diagnosed with an unspecified TMJ disorder. *Id.* at 14.

On May 6, 2014, Ms. Patel finally had her previously-scheduled neurology consult with Andrew Gorman, D.O., at Arizona Neurological Institute. Core Records, filed as Ex. 28 on May 24, 2018 (ECF No. 38-1) ("Core") at 29. She now reported a six-month history of dizziness, "a characterized by a spinning sensation like [a] 'drunk type feeling'" that could occur on standing or walking around. *Id.* Petitioner added that she felt her symptoms had begun within two to three weeks of her delivery of her daughter (which would have been prior to receipt of the flu vaccine)[5], noting that she had taken supplements in this period for an iron deficiency. *Id.* Petitioner also reported a history of migraine headaches in the past, and relayed her reported February 2014 accident with a falling shelf, stating that she had experienced headaches more frequently since then. *Id.* Episodes would occur a few times per month, but she could not identify any particular trigger. *Id.*

A physical exam proved largely normal. Petitioner's cranial nerves showed normal visual fields and extraocular movements and corneal reflexes. Core at 30. She also displayed full (5/5) motor abilities and strength, her reflexes were 2/4 and symmetric with flexor plantar responses, her sensory exam was intact to light touch, and her gait was normal with no shuffling. *Id.* Ms. Patel was assessed with vertigo, common migraine, abdominal pregnancy with intrauterine pregnancy, and unspecified head injury. *Id.* at 30. As a result, Dr. Gorman could propose no etiology for her symptoms *Id.* at 31. Instead, he favored a diagnosis of peripheral vestibulopathy but would need to rule out intracranial abnormality given the onset of symptoms after giving birth. *Id.* Basilar migraine events could also explain Petitioner's symptoms. *Id.* Regarding Petitioner's increasing headaches, he informed her that worsening headaches after head injury is known to occur. *Id.* A follow-up visit was requested in six weeks. *Id.*

Two weeks later, Petitioner returned to Dr. Anderson at Arizona Pain Institute on May 15, 2014. Arizona Pain at 6. She again reported associated headaches in the right temporal side of her head, along with an inability to fully open her mouth. *Id.* However, she denied dizziness, numbness, tingling, and instability while walking. *Id.* at 7–9. On physical exam Petitioner had full strength, reflexes, and sensation—the only abnormalities noted were specific to her reported jaw injury. *Id.* at 8–9.

C. *Increasing Evidence of Peripheral Neuropathic Injury*

On June 30, 2014, Petitioner returned to Abrazo Healthcare reporting the onset of a new and more recent kind of symptom - slight aches in both arms accompanied by muscle tenderness, beginning two weeks before. Abrazo Healthcare at 59–63. The aching was mild, aggravated by

[5] Petitioner delivered her daughter on September 22, 2013. This would put the onset of her dizziness around early October 2013—at least a month before her November 18, 2013 flu vaccination.

lifting and carrying things; but was not associated with numbness, tingling, swelling, or redness. *Id.* at 60–61. A physical exam revealed "no tenderness to her forearms on palpation," normal motor strength, and normal tone. *Id.* The treating nurse practitioner was unsure what might be causing Petitioner's muscle pain and ordered several tests. *Id.* at 64.

A month later, on July 28, 2014, an MRI was taken of Petitioner's head. Abrazo Healthcare at 81. The results were normal except for a mild Chiari-I malformation.[6] *Id.* The same day Ms. Patel visited Dr. O'Connor for muscle weakness and loss of feeling and numbness in her fingers. *Id.* at 57. Petitioner now specifically reported that "something is wrong with me." *Id.* at 58 (internal quotations omitted). In particular, she claimed to have "difficulty with lifting things, different than 6 months ago," felt "heavy," and could not "get through the day without a nap." *Id.* A neurological exam revealed bilateral numbness in two or three fingers of both hands but was otherwise normal. *Id.*

Then, on August 12, 2014, Petitioner visited Dr. O'Connor again because of her progressively worsening symptoms. Abrazo Healthcare at 51. She felt that she was getting worse every day, had muscle twitching, and decreased strength. *Id.* at 52. Additionally, Petitioner noted she was fatigued, had shortness of breath, was lightheaded, and had abdominal pain and appetite changes. *Id.* Dr. O'Connor assessed Petitioner with fatigue, ordered labs and specialist referrals, but did not opine on what could be causing the fatigue. *Id.*

The next day, August 13, 2014, Petitioner was hospitalized at Scottsdale Healthcare at Thompson Peak for fatigue, weakness, and numbness in her extremities. Scottsdale Healthcare Records, filed as Ex. 9 on Oct. 17, 2016 (ECF No. 7-10) ("Scottsdale Healthcare") at 26. Triage notes taken on intake stated that Ms. Patel had noticed her symptoms began six weeks before, or the end of June 2014 at the earliest, starting bilaterally in her upper extremities and then progressing to her biceps and thighs.[7] *Id.* at 25–26. Petitioner could no longer open containers, hold her child, or ambulate normally. *Id.* at 26–27. Petitioner also reported that she had ocular weakness with fuzzy vision that occurred with an intermittent headache. *Id.* A physical exam noted that Petitioner had an abnormal gait, decreased tone and weakness in the upper and lower extremities, abnormal deep tendon reflexes, and no abnormalities on inspection of the eyes. *Id.* at 27.

At the same visit, the attending physician's notes recorded a similar onset and problems. Scottsdale Healthcare at 28. Petitioner reported "weakness that has been going on for a number of

[6] This refers to a "prolapse of the cerebellar tonsils into the spinal canal without elongation of the brainstem; it is often asymptomatic." Chiari I Malforamtion, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=119469 (last visited April 16, 2020) ("Dorland's Online").

[7] The same note also records that "10.5 months ago pt gave birth and had large blood loss." Scottsdale Healthcare at 25. This indicates that, at this visit, Petitioner was considering her health history from at least 10 months ago—around October 2013.

months, however, has worsened in recent weeks." *Id.* Petitioner also reported "weakness and tingling of her extremities that progressed over the past 6 weeks." *Id.* The attending doctor also took note that Petitioner "gave birth 11 months ago" and lost a significant amount of blood. *Id.*

Petitioner had a neurology consultation on August 14, 2014, at which time she repeated her prior assertions about onset and also recounted her history of headaches. Scottsdale Healthcare at 37. The consulting physician, Jeffery Becker, D.O., also noted that Petitioner had a mild Chiari malformation type I. *Id.* Petitioner denied any previous history of neurological symptoms, or "episodic symptoms such as visual loss, double vision, numbness, tingling, weakness, [or] clumsiness." *Id.* Her father was present at Petitioner's bedside and affirmed there was no previous history or family history of any neurologic disorders." *Id.*

At the same consultation Dr. Becker performed a neurologic examination on Petitioner. Scottsdale Healthcare at 38. He examined Petitioner's cranial nerves II–XII and no abnormalities were noted. *Id.* Funduscopic[8] exam revealed no hemorrhages or papilledema. *Id.* Exam also showed normal facial sensation, visual fields, and no facial weakness, although it reflected the weakness and numbness that Petitioner reported. *See id.* Dr. Becker thus proposed that Petitioner likely had Guillain-Barré syndrome ("GBS"), and noted that plasma exchange or IVIG could both treat her condition. *Id.* A lumbar puncture performed the next day showed high cerebrospinal fluid ("CSF") protein count. *See id.* at 182, 188. Over the next several days Petitioner received plasma exchange therapy to treat her symptoms. Scottsdale Healthcare at 13, 40–41, 441. Eventually she recovered enough to be discharged on August 23, 2014. *Id.* at 13. The discharge summary report stated that Petitioner "began having dizziness and headaches approximately eight weeks ago." *Id.* at 13. Her discharge diagnoses were GBS, weakness, and hypothyroidism. *Id.*

D. *Subsequent Treatment and Proposal of CIDP Diagnosis*

After a brief recovery, Petitioner's symptoms returned in September 2014. On September 16, 2014, Petitioner again visited Dr. Gorman at Arizona Neurologic Institute. Core at 16. Petitioner reported that her "symptoms began in [M]ay [and became] progressively worse." *Id.* She had recovered since receiving plasma exchange but recently began to decline again with increasing weakness, more sensory symptoms, and some blurred vision. *Id.* Dr. Gorman noted Petitioner's lumbar puncture and presumptive GBS diagnosis, and ordered labs to assess how to treat her relapsing symptoms. *Id.* at 18.

On September 20, 2014, Petitioner was hospitalized again at Scottsdale Healthcare at Thompson Peak when her symptoms of dizziness, lightheadedness, worsening peripheral vision, and proximal muscle weakness returned. Scottsdale Healthcare Records II, filed as Ex. 55 on Oct.

[8] This refers to the examination of the interior of the eye with the ophthalmoscope—an instrument containing a perforated mirror and lenses used to examine the interior of the eye. Ophthalmoscope, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=35274 (last visited April 16, 2020) ("called also funduscope").

8, 2018 (ECF No. 59-1) ("Scottsdale Healthcare II") at 2, 6–7. The history from this hospitalization notes that "[t]here was no obvious precipitating infectious illness," and [p]rior to her symptoms starting in June [2014] she had never had anything like this before." *Id.* at 6–7. Throughout her September hospitalization Petitioner had several consultations with specialists—one of whom recorded that Petitioner's recurrence was odd for GBS, and proposed consideration of other diagnoses, including CIDP. Scottsdale Healthcare II at 26. And an infectious disease consult identified no other possible antecedent illnesses. *Id.* at 20. At most, Ms. Patel reported "an illness that began [December 2013] which was characterized by dizziness and 10–12 episodes between December [and] March of this year which prompted a neurologic work-up and MRI," but no diagnosis was made, and the symptoms went away "spontaneously and did return on this admission, not so much on the recent admission of August." *Id.* Petitioner received another round of plasma exchange treatment and was eventually well enough to be discharged on September 29, 2014. Scottsdale Healthcare II at 2.

On October 13, 2014, Petitioner visited Dr. Gorman again. Ex. 5, filed on Oct. 17, 2016 (ECF No. 7-6), at 5. She now presented with numbness in her limbs and extremities which improved with plasma exchange treatment (plasmapheresis)—although she had started to feel weaker in the last few days. *Id.* at 5. Dr. Gorman discussed the possibility of CIDP, opining that Petitioner's overall course made GBS unlikely. *Id.* Petitioner returned to Arizona Neurology Associates on October 20, 2014. Ex. 5 at 8. At this visit, the history section states Petitioner was "symptomatic since December 2013 when she started to have dizzy spells." *Id.* Lab results obtained later that month were now consistent with a demyelinating neuropathy. *Id.* at 16–17.

From October 27 to November 1, 2014, Petitioner's symptoms recurred and she was hospitalized again. Dignity Health Records, filed as Ex. 13 on Oct. 17, 2016 (ECF No. 8-5) ("Dignity Health"), at 114. Her history now reported both onset of headaches in December 2013, with different kind of neurologic symptoms (characterized by fingertip numbness) presenting in June 2014, with more severe symptoms plus fatigue and weakness after that. *Id.* at 116, 128; *see also id.* at 131–32, 177. In this time period, she obtained an EMG[9] from Erik Ortega, M.D. Barrow Neurological Institute Records, filed as Ex. 12 on Oct. 17, 2016 (ECF No. 8-4) ("Barrow Neurological Institute") at 57. Notes from this visit state that Petitioner presented with "a history of an evolving sensorimotor symptoms that began in June of this year." *Id*. Based on his interpretation of EMG labs and other tests, Dr. Ortega expressed the view that Petitioner likely had CIDP. *See id.*

[9] Electromyography, or EMG, is "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." Electromyography, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited April 16, 2020).

Around the same time, treaters proposed other possible explanations for some of Petitioner's symptoms, some of which were thought to reflect pregnancy complications. Thus, she was evaluated for Sheehan syndrome,[10] reporting in connection therewith her pregnancy-associated blood loss the prior year. Dignity Health at 122. Since that time, Petitioner had experienced trouble nursing her child and instances of "intermittent positional dizziness/lightheadedness accompanied by nausea without vomiting." *Id.* In addition, two weeks before her hospitalization she had seen an endocrinologist and "reportedly failed ACTH stim testing for these symptoms, and was placed on hydrocortisone and fludrocortisone."[11] *Id.* The consulting physician diagnosed Petitioner with Sheehan's syndrome with possible panhypopituitarism, in addition to her CIDP diagnosis. *Id.* at 112.

On November 8, 2014, Ms. Patel had a consultation visit for her CIPD. Dignity Health at 729. The history section of the records from this visit mostly place her presentation of neurologic symptoms as having begun June 2014. *Id.*; *see also id.* at 731, 1216 (onset of symptoms in June 2014); *id.* at 739, 748, 754, 758, 770 (noting that CIPD symptoms began June 2014—note in "impression and plan" section). Some, however, placed onset far earlier, at the start of the time Petitioner reported experiencing headaches. *Id.* at 1143 (reporting in the HPI section that Petitioner's "lightheadedness and numbness in the extremities began in 12/2013"). A neurological consultation at Barrow Neurological Associates from February 2015 took the onset issue a step further, placing it as not long after giving birth in September 2013, with Petitioner's symptoms progressing to headaches, then numbness and tingling of her fingers in 2014, although the "onset of problem" section stated that the problem started in June 2014. *Id.*

Petitioner's CIDP diagnosis does not appear since then to have been revised or reexamined, and she has responded well to IVIG treatment. Ex. 4, filed on Oct. 17, 2016 (ECF No. 7-5), at 4.

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[10] Sheehan syndrome references "hypopituitarism developing postpartum as a result of pituitary necrosis; caused by ischemia due to a hypotensive episode during delivery." Sheehan syndrome, Steadman's Medical Dictionary, https://1 next.westlaw.com/Document/Idbaf520070ec11e4b9b9ea2bcc83d096/View/FullText.html?navigationPath=Search%2Fv1%2Fresults%2Fnavigation%2Fi0ad740110000171849387d2fc862dd8%3FNav%3DANALYTICAL%26fragmentIdentifier%3DIdbaf520070ec11e4b9b9ea2bcc83d096%26parentRank%3D0%26startIndex%3D1%26contextData%3D%2528sc.Search%2529%26transitionType%3DSearchItem&listSource=Search&listPageSource=1ae87afcbc757f4945c0142eb8551482&list=ANALYTICAL&rank=3&sessionScopeId=f9cfd325ef76ed70d8f254fc76de9b1716fea7ad6bacf315daa9e166f52edb88&originationContext=Search%20Result&transitionType=SearchItem&contextData=%28sc.Search%29, (last visited on April 16, 2020) (available on Westlaw).

[11] The ACTH stimulation test is used to diagnose adrenal insufficiency, a condition known as Addison's disease. It is also used to determine if the pituitary gland is not working properly due to hypopituitarism. Deficient cortisol could alternately be a cause of secondary adrenal insufficiency. *See* ACTH Stimulation Test, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=112396&searchterm=ACTH%20stimulation%20test (last visited on April 22, 2020).

II. Expert Reports and Other Evidence

A. *Petitioner's Expert – Dr. Laura Boylan*

Dr. Boylan, a neurologist, submitted two expert reports on behalf of Petitioner. Boylan Rep., filed on June 11, 2018 as Ex. 31 (ECF No. 44-1); Boylan Supp. Rep., filed on February 7, 2019 as Ex. 63 (ECF No. 70-1). Dr. Boylan opines that (1) Petitioner's November 2013 vaccination caused her CIDP; and (2) Petitioner's initial symptoms of CIDP emerged in December 2013, which is in a medically acceptable timeframe measured from vaccination one month prior. Boylan Rep. at 20.

Dr. Boylan earned a B.A. in political science at Barnard College, Columbia University. Boylan CV at 1, filed on June 4, 2018 as Ex. 29 (ECF No. 42-1). She took pre-medical courses at City College of New York from 1988 to 1989. *Id.* Then she earned her M.D. at Columbia University in 1994. *Id.* After graduating medical school she interned at St. Vincent's Hospital in New York City from 1994 to 1995. *Id.* at 2. From 1995 to 1998 she was a neurology resident at The Neurological Institute, Columbia-Presbyterian Medical Center ("the Neurological Institute") in New York City. *Id.* Following her residency, from 1998 to 2000, she completed a post-doctoral clinical research fellowship at the Neurological Institute. *Id.* From 1998 to 2000 Dr. Boylan completed a post-doctoral clinical research fellowship in affective disorders at New York State Psychiatric Institute. *Id.*

Dr. Boylan is board certified in neurology and is licensed to practice medicine in New York and Minnesota. Boylan CV at 1. She is currently an attending neurologist at Bellevue Hospital Center, New York City. *Id.* She also serves as an adjunct professor of neurology at New York University School of Medicine. *Id.* at 2. Dr. Boylan has diagnosed and treated dozens of cases of CIDP in her career. Boylan Rep. at 2. Although she has written and published on several medical topics no of them appear to be related to a demyelinating disease. *See generally* Boylan CV.

First Report

Dr. Boylan's first report addresses (a) what a medically acceptable time frame is for initial onset of vaccine mediated CIDP; (b) how Petitioner's December 2013 symptoms (headache, lightheadedness, and fatigue) were her first manifestations of CIPD; (c) whether vaccines can cause CIDP; and (d) why Petitioner's other medical conditions cannot explain her December 2013 symptoms. *See generally* Boylan Rep. Because this Decision turns on the onset of Petitioner's CIPD symptoms and whether those symptoms occurred in a medically acceptable timeframe, I will only discuss portions of Dr. Boylan's reports that address this specific question - although I have considered all of her reports and associated literature.

Dr. Boylan opines that "[p]ost-vaccine and post-infectious syndromes are considered to typically occur following a variable period of delay within 6 weeks following exposure." Boylan Rep. at 3. Later, she states that "in Ms. Patel's case I do think her initial symptoms of CIDP fell

within the traditional onset of post vaccine demyelinating polyneuropathy but her course was not typical." *Id.* at 14. She explains that CIDP has a variable course that can present with non-motor, non-specific symptoms. Boylan Rep. at 14–15. This can make its true onset difficult to diagnose. *Id.*

To support the contention that CIDP could manifest it non-obvious ways, Dr. Boylan referenced a study in which 47 of 87 participants (54 percent) displayed distinct symptomatic features outside the typical clinical presentation of CIDP. Boylan Rep. at 14–15 (citing F. Rotta et al., *The Spectrum of Chronic Inflammatory Demyelinating Polyneuropathy*, 173 J. Neurol. Sci. 129–139 (2000), filed on Aug. 8, 2018 as Ex. 43 (ECF No. 49-2) ("Rotta")). Four of the Rotta study participants (5 percent) displayed "predominant cranial nerve involvement." *Id.* (citing Rotta at 136). In particular, "[c]ranial nerves (CNs) III, IV, and VI were affected in three patients, CN VII in two, and CNs IX, X, and XI in one patient each."[12] Rotta at 136. The patients also displayed some degree of limb weakness and one had decreased sensation in the limbs. *See id.* at 136–37. In making such points, Dr. Boylan underscored her view that the diagnosis of CIDP is "notoriously difficult" and that the medical/scientific understanding of the spectrum of demyelinating diseases is continuously changing as more understood about the disease process. Boylan Rep. at 15.

[12] The cranial nerves control various functions:

I. Sense of smell. *See* nervus olfactorius, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92354.

II. Vision. *See* nervus opticus, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92356.

III. Pupillary constriction, opening eyes, some extraocular movements. *See* nervus oculomotorius, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92353.

IV. Downward, inward movement of eye. *See* nervus trochleasris, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92429.

V. Motor - temporal and masseter muscles (jaw clenching), lateral movement of jaw
Sensory - Three divisions: (1) ophthalmic, (2) maxillary, (3) mandibular. *See* nervus trigeminus, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92428.

VI. Lateral deviation of eye. *See* nervus abducens, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92220.

VII. Motor - facial movements (facial expression, closing eye, closing mouth). *See* nervus facialis, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92293.

VIII. Hearing (cochlear division) and balance (vestibular division). *See* nervus vestibulocochlearis, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92439.

IX. Motor – pharynx.
Sensory - posterior portions of eardrum and ear canal, pharynx, and posterior tongue, including taste (salty, sweet, sour, bitter). *See* nervus glossopharyngeus, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92300.

X. Motor - palate, pharynx, and larynx
Sensory - pharynx and larynx *See* nervus vagus, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92435.

XI. Motor - the sternomastoid and upper portion of trapezius. *See* nervus accessories, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92221.

XII. Motor – tongue. *See* nervus hypoglossus, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=92304.

Next, Dr. Boylan opined that Petitioner's headaches and visual problems "may have been directly due to problems with spinal fluid pressure caused by CIDP." Boylan Rep. at 15. However, Dr. Boylan was only "able to identify two case reports of CIDP presenting with headache." *Id.* (referencing A. Altinkaya et al., *Chronic Inflammatory Demyelinating Polyradiculoneuropathy Associated Intercranial Hypertension*, 34 J. Neurol. Sci. 1027–29 (2013), filed on Aug. 8, 2018 as Ex. 32 (ECF No. 48-1) ("Altinkaya"); K. Morrison & P. Davies, *Chronic Inflammatory Demyelinating Polyneuropathy Presenting with Headache and Papilledema*, 39 Headache 299–300 (1999), filed on Aug. 8, 2018 as Ex. 41 (ECF No. 48-10) ("Morrison")). Each of these case reports involved a man in his mid-50s suffering from headaches, vision problems, and CIDP, and each acknowledged that the additional symptoms rarely were present with CIPD. *See generally* Altinkaya; Morrison. In addition, both patients had papilledema[13] and a high opening pressure when taking a lumbar puncture, and experienced improvement in their headaches when treated with cortisone or prednisone. Altinkaya at 1028; Morrison at 299–300.

Dr. Boylan claims that the headaches and visual problems experienced by the subjects of these two case reports were comparable to what Petitioner experienced. Boylan Rep. at 15. Thus, in her view Petitioner's headaches were likely attributable to abnormal CSF pressure or flow. *Id.* at 15–16. Dr. Boylan did not see formal testing of visual fields in the records, however, and noted that testing of Petitioner's intracranial pressure was not performed—which can be done in connection with a lumbar puncture. *Id.* In the absence of CSF pressure testing evidence, she speculated that: (i) Petitioner had findings of enhancement of spinal roots that is sometimes seen in CIDP; (ii) enhancement of spinal roots can cause an abnormal or decreased CSF flow; (iii) abnormal CSF flow can sometimes be mistaken for Chiari I malformations; (iv) Petitioner's MRI had been interpreted as "consistent with" a Chiari I malformation; (v) the words "consistent with" means there are other things that could cause the same images; and (vi) therefore Petitioner likely had abnormal CSF pressure which caused her headaches. *See id.* at 15–16.

Dr. Boylan did not claim to have viewed the MRI images of Petitioner's Chari malformation, such that she could conclude that a mistaken diagnosis was made. *See* Boylan Rep. at 4–5, 16. In the record, only the notes and impressions of the images are available, rather than the images themselves. *See generally* Simon Med. Imaging, filed as Ex. 16 on Feb. 3, 2017 (ECF No. 11-3) (showing only notes and impressions of MRI images); *see also id.* at 5 (MRI imaging taken July 28, 2014, and noting mild Chiari I malformation). Dr. Boylan instead suggests that the doctor interpreting the images likely did not find abnormal CSF flow because he did not know of any abnormalities in the spinal roots when the images were taken. Boylan Rep. at 16.

Finally, Dr. Boylan concluded her first report by opining that "[i]internal inconsistency of records is the rule not the exception." Boylan Rep. at 18. In this regard, she speculated from review

[13] Papilledema is "edema of the optic disk (papilla), most commonly due to increased intracranial pressure, malignant hypertension, or thrombosis of the central retinal vein." Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=36673&searchterm=papilledema (April 17, 2020).

of certain records of an August 2014 treatment visit that a medical student with the initials "AA" might have mischaracterized Petitioner's symptoms. *Id.* (citing Scottsdale Healthcare at 67) ("AA found no weakness on Ms. Patel's examination while other doctors were able to identify it."). Ms. Patel's primary treaters, however, were ultimately able to identify weakness on examination, and that "[n]eurologists are better at the exam and detailed neuromuscular exams are typically more sophisticated when done by neuromuscular specialists." *Id.* Then, in the next paragraph of her report, Dr. Boylan discussed how Dr. Gorman—a neurologist—also likely missed or mischaracterized Petitioner's symptoms. *Id.* at 18–19. She overall expressed the view that treaters had likely failed to recognize the full nature of Ms. Patel's presentation as early as February 2014. *Id.* at 19.

Supplemental Report

Dr. Boylan's supplemental report attempts to buttress her opinion that Petitioner's December 2013 marked the onset of her CIDP, and in so doing ventures to explain why there is little record evidence of the typical CIDP symptoms before June 2014. Boylan Supp. Rep. at 1–2.

Dr. Boylan acknowledged in her supplemental report that Petitioner's December 2013 symptoms ("severe fatigue, headache dizziness and chest pain")[14] were non-specific, and thus could not be attributed at first glance to any particular disease or illness, and only appeared to be clinical indicia of CIDP on hindsight. Boylan Supp. Rep. at 2, 3. Here, such hindsight allows these symptoms to be understood as reflecting problems in the autonomic nervous system—and thus characteristic of GBS, a peripheral neuropathy comparable to CIDP. Boylan Supp. Rep. at 2 (citing Z. Zaeem et al., *Autonomic Involvement in Guillain–Barré Syndrome,* Clinical Autonomic Research (2018), filed on May 8, 2019 as Ex. 65 (ECF No. 77-2) ("Zaeem").

Zaeem discusses evidence of autonomic dysfunction in GBS—specifically, "blood pressure fluctuations, arrhythmias, vasomotor dysfunction, and gastrointestinal (GI) motility dysregulation." Zaeem at 1. Zaeem concludes that autonomic dysregulation may precede the occurrence of neurological deficits in GBS, and that early diagnosis could hasten treatment, but it does not apply its findings to CIDP. Zaeem at 9. Dr. Boylan otherwise did not explain how these various kinds of autonomic-related symptoms generally capture what Ms. Patel was experiencing as early as December 2013 (which the record reveals was mainly persistent headaches). Boylan Supp. Rep. at 1–2.

In order to address this issue, Dr. Boylan next opined that "fatigue may be the primary, initial presenting symptom of CIDP." Boylan Supp. Rep. at 2 (citing S. Boukhris et al., *Fatigue as the main Presenting Symptom of Chronic Inflammatory Demyelinating Polyradiculoneuropathy: A Study of 11 Cases,* 10 J. Periph. Nerv. Syst. 329–37 (2006), filed on May 8, 2019 as Ex. 66 (ECF

[14] Dr. Boylan repeatedly states that Petitioner suffered from chest pain in addition to her other non-specific symptoms. *See* Boylan Rep. at 5; Boylan Supp. Rep. at 2. It is unclear where chest pain appears in the record, especially as one of Petitioner's early symptoms. Chest pain is not mentioned in Petitioner's affidavit or her VAERS report.

No. 77-3) ("Boukhris"). Boukhris studied eleven patients presenting with fatigue and some sensory deficits but no weakness. Boukhris at 2. Patients in this study were selected from a pool of 60 people diagnosed with CIPD. *Id.* However, *none* of the studied patients also presented with headaches or dizziness, as the record shows Ms. Patel first experienced, and only one reported anything that arguably might cause such symptoms secondarily, like eye problems such as nystagmus.[15] *Id.* at 3.

Dr. Boylan's supplemental report also included a significant qualification limiting her opinion. Thus, she specifically admitted that "in the absence of further information and accepting the premise of *no relevant symptoms* prior to June or July 2014 the level of medical certainty regarding attribution of Ms. Patel's CIDP to her November 18th, 2013 influenza vaccination would be low." Boylan Supp. Rep. at 2 (emphasis added).

B. *Respondent's Expert – Dr. Vinay Chaudhry*

Dr. Chaudhry—like Dr. Boylan a neurologist—submitted two expert reports on behalf of Petitioner. Chaudhry Rep., filed on Nov. 16, 2018 as Ex. A (ECF No. 68-1); Chaudhry Supp. Rep., filed on June 17, 2019 as Ex. C (ECF No. 81-1). Dr. Chaudhry agrees that Petitioner has CIPD, but maintains that her November 2013 flu vaccine did not cause her CIDP, which began in June or July 2014, and therefore not in a medically acceptable timeframe. Chaudhry Rep. at 12–13.

Dr. Chaudhry completed his undergraduate education at Delhi University in India. Chaudhry CV at 1, filed on November 16, 2018 as Ex. B (ECF No. 68-2). He then earned his bachelor of medicine and bachelor of surgery at All India Institute of Medical Sciences in New Delhi, India. *Id.* In 2009 he earned his MBA (business of medicine) at John's Hopkins University. *Id.* After his formal education, from 1980 to 1981, he completed an internship and residency (in pediatric surgery) in India. *Id.* at 2. From 1982 through 1983 he was a house officer and senior house officer in internal medicine at hospitals in the United Kingdom. *Id.* From 1984 to 1987 he served as a neurology resident at the University of Tennessee Center for Health Sciences, and later the University of Alabama at Birmingham School of Medicine. *Id.* In 1987 he was the neurology chief resident at the University of Alabama at Birmingham School of Medicine. *Id.* After his residency he served as a clinical fellow, and later a clinical and research fellow, in the neurology department at Johns Hopkins University School of Medicine. *Id.*

Presently, Dr. Chaudhry is a neurology professor at Johns Hopkins University School of Medicine. Chaudhry CV at 2–3. He is licensed to practice medicine in Maryland and is board certified in Neurology, Neuromuscular diseases, Electrodiagnostic Medicine (Nerve Conduction and EMG), and Clinical Neurophysiology. *Id.* at 28–29. He serves as a reviewer and on the editorial boards of several medical journals and neurology publications. *See id.* He has also

[15] Nystagmus is "an involuntary, rapid, rhythmic movement of the eyeball, which may be horizontal, vertical, rotatory, or mixed." Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=34565 (last visited April 20, 2020).

published several pieces on CIPD and peripheral neuropathies. In his clinical practice he sees "close to 2000 patients a year (for over 25 years) mostly related to peripheral nerve disease." Chaudhry Rep. at 1.

First Report

In his initial report, Dr. Chaudhry agreed with Dr. Boylan that Petitioner has CIDP and that a medically acceptable onset for "post-vaccine and post-infectious syndromes" like it would be six weeks. Chaudhry Rep. at 13 (internal quotations omitted). But (in addition to his view that CIDP is not likely vaccine-caused), he maintained that the record only supports the conclusion that Ms. Patel's CIDP began *more* than six weeks post-vaccination—after June 2014, with fatigue or other nonspecific symptoms beginning *before* vaccination, right after the birth of her daughter in September 2013. *See* Chaudhry Rep. at 13–18. In support, he referenced a plethora of records which place the onset of Petitioner's acute CIDP symptoms (tingling and sensorimotor symptoms) in June or July 2014. *See, e.g., id.* at 16–17. By contrast, several records identify the start of Petitioner's non-specific symptoms (lightheadedness, fatigue, dizziness) in October 2013, albeit inconsistently, as she did not report them in early 2014 at all when she first began seeking medical treatment after her return to the United States. *See, e.g., id.* at 14–15.

Dr. Chaudhry also disagreed that Petitioner's headaches were, or could be, a presenting symptom of CIDP. *See* Chaudhry Rep. at 16. First, he questioned Dr. Boylan's reliance on Altinkaya and Morrison, since these case reports each documented evidence of intracranial hypertension, high opening CSF, and papilledema—features not found in Petitioner. *See id.* He also noted a "MRI cine flow study showed no signs of increased intraventricular pressure," although this finding was made in 2015 and thus long after the alleged onset periods. *Id.* (citing Simon Med. Imaging at 3). Next, Dr. Chaudhry disagreed with Dr. Boylan's assessment that Petitioner had abnormal CSF flow as an explanation for her headaches. *Id*. (characterizing Dr. Boylan's assessment as "unilateral" and "without any evidence"). Dr. Chaudhry also emphasized that CIDP and GBS, although similar, are distinct diseases with different courses and recognized causes, and thus literature on one condition does not automatically apply to the other. *Id*. at 13–14.

Supplemental Report

Dr. Chaudhry also submitted a supplemental report to address Dr. Boylan's supplemental report, associated medical literature, and new medical records. Chaudhry Supp. Rep. at 1 (addressing Exs. 60–66). He reiterated therein that the records show Petitioner's symptoms started acutely in June 2014, and that many of her non-specific symptoms started before her vaccination or have alterative explanations. *Id.* at 3–4.

In this additional report, Dr. Chaudhry specifically analyzed some of the new medical literature referenced in Dr. Boylan's Supplemental Report. *See, e.g.*, P. Zalewski et al., *Autonomic Dysfunction and Chronic Disease*, 128 British Medical Bulletin 61–74 (2018), filed on May 8,

2019 as Ex. 64 (ECF No. 77-1) ("Zalewski"). Zalewski, he notes, is a broad review of various autonomic dysfunctions[16] that does not mention CIDP. Chaudhry Supp. Rep. at 2. He also critiqued Zaeem. While Dr. Chaudhry agreed that autonomic dysfunction occurs in two thirds of GBS patients, as Zaeem observes, Petitioner did not have GBS—and indeed the symptoms that prompted any treater to consider the possibility that she might have GBS or some other form of peripheral neuropathy did not present until June 2014, rather than "months prior" as Petitioner argues. Chaudhry Supp. Rep. at 2. He also distinguished Boukhris, noting that the eleven studied patients therein presented with fatigue rather than weakness, and were thus not comparable to Petitioner, who "presented with acute onset of weakness, areflexia, and high spinal fluid protein, all beginning in June 2014 and requiring plasma exchange treatment." *Id.* And in his experience, when fatigue is observed in conjunction with CIDP, it is *consistently* present, and does not wax and wane (despite the overall relapsing/remitting character of CIDP). *Id.*

C. *Other Proof*

In addition to Dr. Boylan's reports and the associated medical literature, Ms. Patel filed two additional items of evidence. Exhibit 19, filed in March 2018, is a VAERS[17] report concerning Petitioner and this case. The VAERS report was completed on August 8, 2016, however—after the filing of this lawsuit—and thus its already diminished evidentiary value as probative of causation is lessened even more.

Petitioner has also filed a letter opinion from Dr. Ortega, the treater whose EMG study helped confirm the CIDP diagnosis. Ortega Letter, dated April 18, 2018, filed as Ex. 25 (ECF No. 34-1). This four-sentence letter states in conclusory fashion that Petitioner's CIDP developed in December 2013 following her flu vaccination the preceding November. *Id.* Dr. Ortega concludes that "[i]t is reasonable to suspect that the flu vaccination was the precipitating factor for her CIDP." *Id.* The basis for this opinion, however, is not elaborated upon, and is contradicted somewhat by certain record evidence involving contemporaneous opinions offered by Dr. Ortega. *See, e.g.*, Dignity Health at 141 (Dr. Ortega observing on October 28, 2014, that there was no likely inciting event for Petitioner's CIDP).

[16] "[C]auses of autonomic dysfunction listed including multisystem atrophy, Parkinson's disease, diabetes, familial dysautonomia, chronic fatigue syndrome, fibromyalgia, migraine, and irritable bowel syndrome. Other secondary causes due to diabetes, cardiovascular disease, multiple sclerosis, autoimmune diseases, endocrine disorders, renal failure, and spinal cord diseases are also noted." Chaudhry Supp. Rep. at 2 (citing Zalewski).

[17] VAERS stands for the "Vaccine Adverse Reporting System." It is a "national early warning system to detect possible safety problems in U.S.-licensed vaccines. . . . VAERS accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention." About VAERS, HHS, https://vaers hhs.gov/about.html (last visited April 20, 2020).

III. Procedural History

Ms. Patel filed her petition for compensation on July 19, 2016. Pet. at 1. Over the next several months medical records were slowly filed. By late 2017 it was unclear if Petitioner was going to file an expert report. *See* Order at 1, filed on December 12, 2017(ECF No. 23). Petitioner explained that she was having difficulty obtaining an expert, and if the case went forward then her counsel would withdraw. *Id.* Eventually, Petitioner decided to maintain her claim, and substituted in new counsel as well. Motion to Substitute Attorney, filed on Feb. 20, 2018 (ECF No. 26).

Petitioner filed her expert report on June 11, 2018. Boylan Expert Rep. Over the next year both parties exchanged additional expert reports, filed associated literature, and filed additional medical records. *See, e.g.*, Chaudhry Rep.; Boylan Supp. Rep.; Chaudhry Supp. Rep. On July 31, 2019, Petitioner filed a motion for decision on the record. *See* Mot. For Ruling on Record (ECF No. 87) ("Brief"). Respondent filed a brief in response and Petitioner filed a reply brief. Response, filed on Oct. 4, 2019 (ECF No. 90); Reply, filed on Oct. 24, 2019 (ECF No. 91).

IV. Parties' Respective Positions

The parties agree that post-vaccine/post-infectious syndromes can occur following a variable period of delay within six weeks of exposure. Brief at 28; Chaudry Rep. at 13. But they disagree on when Petitioner's first CIDP symptoms arose—and what constitutes CIDP symptoms in the first place. Petitioner argues that her symptoms began in December 2013, when she claims to have first experienced fatigue, dizziness, and headaches. *See* Brief at 22. Respondent counters that Petitioner's December 2013 symptoms were not her first manifestations of CIDP, which only began in June 2014. Response at 12. Respondent also maintains that certain of Petitioner's non-specific symptoms predated vaccination. Response at 11–12.

V. Relevant Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 11(c)(1), 13(a)(1)(A), 14(a); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[18]

[18] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(a)(1)(a). That is, a petitioner must offer evidence that leads the "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*, 592 F.3d at 1322 n.2; *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(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 proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant

concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has clarified that the correct standard for *Althen* prong one is a "reputable," and "sound and reliable," theory, not a "lower reasonable standard" *See Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359–60 (Fed. Cir. 2019) (internal quotations omitted); *see also Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury].") (emphasis added). Petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *see also Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, 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.'" (quoting *Althen*, 418 F.3d at 1280)). Medical records are generally viewed as particularly trustworthy evidence for the "did cause" prong, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and/or statements of a treating physician's views, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human 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."). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence present in the record—including conflicting opinions

among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (finding that it is not arbitrary or capricious for special masters to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without op.*, 475 F. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.*; *see also Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *see also Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("Given the inconsistencies between petitioner's testimony and his

contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"); *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[I]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub. nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.") (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1948)).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Lowrie*, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical

records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories."

Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). But nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("Assessments as to the reliability of expert testimony often turn on credibility determinations . . . ."); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Ruling Without Hearing or Argument*

I have opted to decide this case based on written submissions and evidentiary filings, and the parties have acceded to my determination. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions (or components of a claim) on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The Federal Circuit has recently affirmed this practice. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1365–66 (Fed. Cir. 2020).

F. *Consideration of Comparable Special Master Decisions*

In reaching a decision in this case, I have considered other decisions issued by special masters involving similar injuries, vaccines, or circumstances. I also reference some of those cases in this Decision, in an effort to establish common themes, as well as demonstrate how prior determinations impact my thinking on the present case.

There is no error in doing so. It is certainly correct that prior decision in different cases do not *control* the outcome herein.[19] *Boatmon v. Sec'y of Health & Human Servs.,* 941 F.3d 1351, 1358-59 (Fed. Cir. 2019); *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). Thus, the fact that another special master reasonably determined elsewhere, on the basis of facts not in evidence in this case, that preponderant evidence supported the conclusion that vaccine X caused petitioner's injury Y does not compel me to reach the same conclusion in *this* case. Different actions present different background medical histories, different experts, and different items of medical literature, and therefore can reasonably result in contrary determinations.

However, it is *equally* the case that special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec'y of Health & Human Servs.,* 76 Fed. Cl. 328, 338–39 (2007) ("[o]ne reason that proceedings are more expeditious in the hands of special masters is that the special masters have the *expertise and experience to know the type of information that is most probative of a claim*") (emphasis added). They would be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. This is especially so given that special masters not only routinely hear from the same experts in comparable cases, but are also repeatedly offered the *same* items of medical literature regarding certain common causation theories. It defies reason and logic to obligate special masters to "reinvent the wheel", so to speak, in each new case before them, paying no heed at all to how their colleagues past and present have addressed similar causation theories or fact patterns. It is for this reason that prior decisions can have high persuasive value—and why special masters often explain how a new determination relates to such past decisions.[20] Even if the Federal Circuit does not *require* special masters to distinguish other relevant cases (*Boatmon,* 941

[19] By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). Special masters are also bound within a specific case by determinations made by judges of the Court of Federal Claims after a motion for review is resolved.

[20] Consideration of prior determinations is a two-way street that does not only inure to the benefit of one party. Thus, I would likely take into account the numerous decisions finding no association between vaccination and autism when confronted with a new claim asserting autism as an injury, and have informed such claimants early in the life of their case that the claim was not viable for just that reason. But I would *also* deem a non-Table claim asserting GBS after the flu vaccine as not requiring extensive proof on *Althen* prong one "can cause" matters, for the simple reason that the Program has repeatedly litigated the issue in favor of petitioners—and I have in fact done so *in this very case.*

F.3d at 1358), it is still *wise* to do so.

ANALYSIS

I. Petitioner has not Established that Her CIDP Began in a Medically Acceptable Timeframe

Although the parties disagree on Petitioner's overall success at meeting the *Althen* test in this case, resolution of the matter primarily turns on the third prong—and thus requires me to determine onset of Petitioner's first CIDP symptoms.[21] The burden of establishing onset of a vaccine injury is subject to the same preponderant evidence test that the overall *Althen* test requires. *See de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.*

A. *Brief Overview of CIDP*

CIDP is a chronic disease that typically appears as "symmetrically, predominantly motor polyradiculoneuropathy, with weakness that was both proximal and distal, associated with hyporeflexia or areflexia, and a relapsing or chronic progressive course." Rotta at 3; *see also* Chaudhry Rep. at 8. Indeed, this is consistent with how previous Program cases have characterized CIDP. *See, e.g., Blackburn v. Sec'y of Health & Human Servs*., 10-410V, 2015 WL 425935, at *22–23 (Fed. Cl. Spec. Mstr. Jan. 9, 2015) (discussing differences between CIDP and GBS). CIDP has a course of at least eight weeks, some patients experience a slowly progressive disease while others may experience a relapsing-remitting course. R. Lewis, *Chronic Inflamatory Demylinating Polyneuropathy: Etiology, Chinical Features, and Diagnosis*, UpToDate Wolters Kluwer 4 (2017) ("Lewis"). GBS can also present with similar symptoms but is acute and monophasic. *Compare*

[21] Because the onset issue is dispositive of this case, I do not include a detailed review of Petitioner's success in meeting the other two prongs. I do acknowledge that CIDP has in other cases been found to be caused by a flu vaccine, although such cases typically involve a much shorter onset timeframe. *Daily v. Sec'y of Health & Human Servs.*, No. 07-173V, 2011 WL 2174535, at *9 (Fed. Cl. Spec. Mstr. May 11, 2011); *Glassberg v. Sec'y of Health & Human Servs.*, No. 07-303V, 2009 WL 4641696, at *7 (Fed. Cl. Spec. Mstr. Nov. 23, 2009) (finding that CIDP onset within six weeks was a medically acceptable timeframe). In addition, even if Petitioner could show that CIDP could present with preliminary symptoms of headache, fatigue, and dizziness, she would still need to establish under the second *Althen* prong that *did* happen here. *See Flores v. Sec'y of Health & Human Servs.*, 115 Fed.Cl. 157, 166–67, *aff'd*, 586 F. App'x. 588 (Fed. Cir. 2014) (upholding special master's determination that petitioner had not satisfied *Althen* prong two when petitioner's theory relied on the occurrence of a blood clot that could not be established). But testing and exams of Petitioner did not establish any connection between these earlier symptoms and her later-diagnosed CIDP, while some treater analyses suggested alternative explanations for Petitioner's symptoms (sequelae from pregnancy, iron deficiency, Sheehan's syndrome, etc.) that are distinguishable from CIDP. And the treater support for an earlier onset (such as Dr. Ortega's letter opinion) was not itself persuasive.

Zaeem at 1 (discussing GBS) *with* Lewis at 4 (discussing CIDP). Observing a patient over time can distinguish which kind of peripheral neuropathy they have. Boylan Rep. at 4.

In other cases, onset two weeks after vaccination has been deemed a medically acceptable timeframe. *Kelly v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 102 (Fed. Cl. 2005), *granting mot. for rev.*, No. 02-223V, 2005 WL 1125671 (Fed. Cl. Spec. Mstr. Mar. 17, 2005) (two weeks between tetanus toxoid vaccination and onset of CIDP); *Daily v. Sec'y of Health & Human Servs.*, No. 07-173V, 2011 WL 2174535, at *9 (Fed. Cl. Spec. Mstr. May 11, 2011) (finding that two weeks was an acceptable timeframe between influenza vaccination and CIDP onset). However, onset several months after vaccination has been deemed not to satisfy the third *Althen* prong. *Strong v. Sec'y of Health & Human Servs.*, No. 15-1108V, 2018 WL 1125666, at *21 (Fed. Cl. Spec. Mstr. Jan. 12, 2012) (Four months between flu vaccine and onset of CIDP was too long).

B. *Petitioner's Headaches and Other Non-Specific Symptoms Were Not Initial Manifestations of Her CIDP*

In this case, Petitioner's onset arguments rely on initial presenting symptoms that are uncommon to CIDP, but which she reports experiencing in late 2013 or early 2014 (and thus within a few weeks of her receipt of the flu vaccine in November 2013). But even if it is assumed she *did* experience these symptoms at the time alleged, she has not preponderantly established that they are likely manifestations of her subsequently-diagnosed CIDP.

First, as Dr. Boylan admitted, headaches are rarely associated with CIDP. *See* Boylan Rep. at 15 ("I was able to identify only two cases of CIDP presenting with headache"); Altinkaya at 1; Morrison at 1 ("[t]o our knowledge, this is the first report of headache being a prominent and early symptom of this disorder."). In fact, the filed literature in this case does not support the general conclusion that CIDP would *ever* present with headaches. *See cf.*, Morrision at 1; Altinkaya at 1; *see, e.g.*, Zalewski (not mentioning GBS or CIDP). At best, there is the suggestion that some outlier cases featured headache as a symptom.

In addition, although Dr. Boylan identified two case reports in which headaches were a clinical indicia of a patient's CIDP, these reports (which constitute a kind of evidence not naturally meriting significant weight to begin with)[22] are not factually comparable to Ms. Patel's circumstances. In particular, the studied individuals had papilledema and high-pressure CSF

[22] Although case reports can provide some circumstantial evidence supporting a claimant's causation theory, they ultimately carry little weight—especially when only one or two case reports are submitted on an issue. *See, e.g.*, *Bast v. Sec'y of Health & Human Servs.*, No. 01-565V, 2012 WL 6858040, at *38 n.104 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) *mot. for rev. denied sub nom.* M.S.B. v. Sec'y of Health & Human Servs., 117 Fed. Cl. 104 (Fed. Cl. 2014) ,a*ff'd*, 579 F. App'x 1001 (Fed. Cir. 2014).

readings. *See* Altinkaya at 1; Morrison at 1. But there no evidence in this case of what Petitioner's CSF pressure was when tested (*see* Scottsdale Healthcare at 182, 188), and (as Dr. Chaudhry has pointed out), some subsequent imaging cast doubt on Dr. Boylan's conclusion that Petitioner likely had experienced high intracranial CSF pressure. Chaudhry Rep. at 16 (citing Ex. 16 at 3 (MRI cine study performed in January 2015)). Petitioner was also examined twice for papilledema, without a positive finding. *Id.* at 38 (August 2014 exam); Scottsdale Healthcare II at 26 (September 2014 exam). At most, Petitioner reported "ocular motion weakness" that had resolved prior to arriving to the emergency room in August 2014. Scottsdale Healthcare at 26. But cranial nerves II–XII were examined twice and no abnormalities were mentioned. Scottsdale Healthcare at 38; Scottsdale Healthcare II at 26.

Dr. Boylan's explanations for how Petitioner's headaches might have been CIDP-related were otherwise unpersuasive. Thus, Dr. Boylan proposed the potential existence of deficits in Petitioner's cranial nerves, but neither the fundoscopic exam (and associated negative results for papilledema) nor the examinations of Petitioner's cranial nerves II–XII support such that conclusion.[23] *See* Boylan Rep. at 7–9, 15. She also failed to note the extent to which the Altinkaya and Morrison case reports turned on findings of papilledema and high CSF pressure. *Compare id.* at 15–16 *with* Altinkaya at 1 ("[k]eywords headache, papilledema, chronic inflammatory demyelinating polyradiculopathy") *and* Morrison at 1 ("[k]ey words: headache, papilledema, chronic inflammatory demyelinating polyradiculopathy"). And her argument that certain MRI images thought to be Chiari malformations could actually reflect abnormal CSF flow, thus explaining Petitioner's headaches, arose largely from her speculation that Petitioner's treaters erred in interpreting certain MRIs rather than from her own review of the imaging. Dr. Chaudhry also observed inconsistency in how Dr. Boylan explained the headaches—sometimes asserting that high CSF pressure was to blame, other times saying they were due to low pressure. Chaudhry Rep. at 16; *see also* Boylan Rep. at 15–16.

Petitioner has similarly not shown that her other December 2013 symptoms were likely related to her CIDP.[24] Dr. Boylan opines that symptoms of autonomic dysfunction comparable in respects to what Petitioner experienced have been reported to occur with or even precede CIDP. Boylan Supp. Rep. at 1–2 (citing Zaeem; Boukhris). However, there is a significant gap between Petitioner's case and the cited literature. Zaeem, for example, involves GBS (which Petitioner

[23] Dr. Boylan in fact left out mention of these facts from her primary report, despite explicitly considering the August 2014 neurologic consultation (which noted no papilledema and a normal cranial nerve exam). *See* Boylan Rep. at 8.

[24] Some symptoms alleged in this case as evidence of Petitioner's CIDP are not even to be found in the record. Thus, Dr. Boylan repeatedly states that Petitioner suffered from chest pain in addition to her other non-specific symptoms. *See* Boylan Rep. at 5; Boylan Supp. Rep. at 2. But it is unclear where chest pain appears in the record, and such a symptom is not mentioned in Petitioner's affidavit or her VAERS report.

unquestionably never experienced),[25] and most of the autonomic-related symptoms it discusses were never experienced by Ms. Patel. *See, e.g.*, Pet'r's Aff.; VAERS Rep. By contrast, the primary December 2013 symptoms she *did* report experiencing (headaches, lightheadedness, and fatigue) are not mentioned in this article. *Compare* Pet'r's Aff., *with* Zaeem at 1. Thus, Dr. Boylan's reliance on it is the equivalent of trying to fit a square peg into a round hole.

Dr. Boylan's efforts to link fatigue with CIDP are more successful—but not enough to meet Petitioner's preponderant burden. Thus, Bouhkris actually discusses CIDP and fatigue—one of the symptoms that Petitioner reported suffered from before she presented with more classic CIDP symptoms in June 2014. But Boukhris's applicability to Petitioner's case is limited. The article *screened out* patients with a history of thyroid disease and other conditions (Boukhris at 2), even though Petitioner had a documented history of thyroid diseases.[26] In addition, although most of Boukhris's subjects did not display weakness (*Id.* at 2), Ms. Patel's weakness was very apparent. Finally, Table 1 on page 3 of Boukhris shows the primary and secondary reported symptoms of the study participants—none of which include lightheadedness, headache, or vision problems. *See id.* Boukhris therefore provides no more than weak support for Petitioner's claim.

The weight to be given to any expert's opinion is based in part on the size of the gap between the science and the opinion proffered. *Cedillo*, 617 F.3d at 1339 (quoting *Joiner*, 522 U.S. at 146). Here, the independent science does not preponderantly support Petitioner's contention that headaches or fatigue would be reliably deemed common precursor symptoms of CIDP, absent other factors clearly not applicable to this case, or that these kinds of symptoms would commonly present long before the usual manifestations of such a peripheral neuropathy (symmetric sensorimotor weakness longer than 8 weeks duration, absent or reduced reflexes, and relapsing or slowly progressive course). And Dr. Boylan could not persuasively establish the contrary with her own arguments. Petitioner has thus not demonstrated that any of her December 2013 symptoms were likely related to her CIDP.

C. *The Onset of Petitioner's CIDP Most Likely Began in July 2014, and Thus Did Not Occur in a Medically-Acceptable Timeframe Measured from Vaccination*

[25] The admitted overlap between GBS and CIDP as peripheral neuropathies can only get Petitioner so far—for, as Dr. Chaudhry ultimately demonstrated, their differences are not *de minimis*. Chaudhry Rep. at 13–14. Of particular importance in this case, CIDP is chronic and relapsing, meaning that its presentation lacks the acute and sudden character of GBS, as well as having a different set of post-condition sequelae. Chaudhry Rep. at 12–14.

[26] The reason for this exclusion is not made explicit. However, in a study about fatigue in CIDP patients, it would be reasonable to exclude participants from the study who have other conditions that could also cause fatigue. And one of hypothyroidism's symptoms is fatigue and muscle weakness. *See* Hypothyroidism, Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=24430 (last visited April 22, 2020) (defining hypothyroidism as "deficiency of thyroid activity, characterized by decrease in basal metabolic rate, *fatigue, and lethargy*" (emphasis added)).

Having found that Petitioner's initial symptoms were not likely manifestations of CIDP, the next issue to be resolved is when Petitioner's CIDP did most likely begin. The earliest the symptoms normally associated with CIDP, like symmetrical tingling or numbness, appear in the medical record for this case is sometime in June or July 2014, when Petitioner first reported numbness and loss of feeling in her fingertips. *See* Abrazo Healthcare 2014 at 57. But all experts offering opinions in this case have agreed that "[p]ost-vaccine and post-infectious syndromes are considered to typically occur following a variable period of delay within 6-weeks following exposure." Boylan Rep. at 3; Chaudhry Rep. at 13. This is consistent with what has ben found in other Program cases. *See, e.g.*, *Daily*, 2011 WL 2174535, at *9 (finding that onset of CIDP within a few weeks of vaccination was a medically acceptable timeframe).

Applying that timeframe,[27] it is evident that Petitioner's actual onset far exceeded six weeks from the date of her November 2013 vaccination—and thus Petitioner has not established that onset of her CIDP occurred in a medically-acceptable timeframe. Indeed, as noted above, Dr. Boylan *agreed* that her opinion could not be reliably advanced in the *absence* of a finding that Petitioner's late-2013 symptoms were CIDP-related. Boylan Supp. Rep. at 2.

II. This Matter was Properly Resolved Without Hearing

In ruling on the record, I am opting against holding a hearing. The choice of how best to resolve this case is a matter that lies generally within my discretion, and neither party objects to my choice in this case, but I shall explain my reasoning nevertheless.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to afford each party a "full and fair opportunity to present its case." *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 400–01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. at 401; *see also Kreizenbeck*, 945 F.3d at 1366. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not *itself* grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

In this case, no hearing was required to resolve fairly Petitioner's claim. I was able to evaluate the evidentiary strength of her expert's theories and opinions simply based on the written reports, and did not require credibility determinations in weighing the medical/scientific reliability

[27] I do not make a determination in this case either way as to what *would be* a proper onset timeframe for post-vaccination CIDP, based on the most likely presenting clinical symptoms. I only utilize this timeframe because it found expert agreement herein, and also because it finds reasoned support in other decisions.

of the theories espoused. The case did not otherwise turn on any fact issues (for example, the ultimate diagnosis or onset) that would have merited allowing live testimony, and the fact issues most important to my resolution (the timing of certain symptoms, and whether they constituted CIDP onset) could easily be determined from review of the filed medical records. Petitioner had a full and fair opportunity to present her claim without a live hearing.

CONCLUSION

Petitioner's claim must be dismissed because it has not been demonstrated that the flu vaccine could cause CIDP more than six months after vaccination. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.[28]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[28] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.