In the United States Court of Federal Claims

No. 15-1553V
(Filed: November 22, 2021)[1]

JONATHAN PATTON, **Petitioner,** **v.** **SECRETARY OF HEALTH AND HUMAN SERVICES,** **Respondent.**	**National Childhood Vaccine Injury Act, 42 U.S.C. §§300aa-1 et seq.; Brachial Neuritis; Causation-in-fact; Althen Prong One; Burden of Proof; Case Reports; Remand.**

Michael Andrew London, Douglas & London, P.C., 59 Maiden Lane, 6th Floor, New York, NY 10038, for Petitioner.

Brian M. Boynton, C. Salvatore D'Alessio, Heather L. Pearlman, Darryl R. Wishard, Claudia B. Gangi, United States Department of Justice, Civil Division, Torts Branch, P.O. Box 146, Benjamin Franklin Station, Washington, DC 20044, for Respondent.

OPINION AND REMAND ORDER

WILLIAMS, Senior Judge.

In the underlying action before the Special Master, Petitioner claimed that he developed two neurological disorders, radiculomyelitis and brachial neuritis, as a result of receiving an influenza ("flu") vaccine. The Special Master ruled that Petitioner suffered from brachial neuritis,[2]

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[1] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, the Court's issued its Opinion under seal to provide the parties an opportunity to submit redactions. The parties did not propose any redactions. Accordingly, the Court publishes this Opinion.

[2] Brachial neuritis or Parsonage Turner Syndrome is a peripheral nerve disorder, which is "characterized by severe onset of regional pain and muscle weakness and wasting." ECF No. 65-1 at 4.

which is also known as Parsonage Turner Syndrome, but that he failed to establish that the flu vaccine caused his condition. Petitioner timely filed the instant petition for review.[3]

Background[4]

On January 11, 2013, Petitioner received a flu vaccine at his primary care provider's office. At the time of the vaccination, Petitioner was 15 years old and had no significant recorded health concerns other than an ankle laceration and a history of nosebleeds. On January 17, 2013, six days after receiving the flu vaccine, Petitioner woke up with a heavier-than-normal nosebleed and was unable to move his arms, describing them as "dead weight." ECF No. 83 at 5; ECF No. 12-2 at 59. He also experienced neck pain and bilateral shoulder pain. Petitioner alerted his parents and was immediately taken to the emergency room at All Children's Hospital ("ACH"). Petitioner's arm weakness was so severe that he was unable to fasten his seat belt, and he developed an occipital headache on the way to the hospital.

Dr. Ricardo Jiminez, M.D., examined Petitioner at around 3:42 a.m. on January 17, 2013, at the ACH Emergency Department and recorded differential diagnoses of central nervous system mass, carbon monoxide poisoning, dehydration, electrolyte abnormality, unspecified headache, migraine, tension headache, intracranial hemorrhage, meningitis, post-concussion syndrome, shunt malfunction, and stroke. Petitioner was later examined by Dr. Leslie Carrol who listed differential diagnoses of spinal cord compression, spinal cord ischemia, acute demyelinating process, Guillain-Barre Syndrome, and carbon monoxide toxicity.

The following morning, neurologist Steven Winesett, M.D. evaluated Petitioner at ACH. Dr. Winesett noted "[p]ossible Parsonage-Turner Syndrome with an autoimmune brachial plexitis" and that the "weakness in his shoulders predominantly 3 days after the flu shot could be consistent with an autoimmune process related to a reaction to the influenza vaccine," however "other autoimmune processes are also possible." ECF No. 12-2 at 74.

During his three-day hospitalization at ACH, Petitioner was also evaluated by attending physician Dr. Ronald M. Ford, M.D., who noted "[b]rachial plexus MRI pending to observe for brachial plexopathy secondary to influenza vaccine; most likely etiology of this patient's symptoms." Id. at 78, 80. After Petitioner underwent the MRI, Dr. Jordan R. Larsen, a Doctor of Osteopathic Medicine, evaluated Petitioner and recorded that the most likely differential diagnosis was "brachial plexopathy secondary to flu vaccination." Id. at 80, 83. Petitioner underwent physical and occupational therapy while admitted, and his occupational therapist noted Petitioner's "significant loss of function to both [upper extremities] due to recent diagnosis of Parsonage Turner Syndrome." Id. at 47, 162. Petitioner's condition continued to improve, and he was discharged from ACH on January 20, 2013, with Parsonage Turner Syndrome and neuropathic pain.

On January 21, 2013, Petitioner was seen by his primary care physician, Dr. Lynne Ellis, M.D., who noted that Petitioner "had a reaction to our flu vaccine," went to the ER and was

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[3] The Special Master determined that Petitioner did not suffer from radiculomyelitis, and Petitioner did not challenge this finding.

[4] This background is derived from the record before the Special Master and this Court.

diagnosed with Parsonage Turner Syndrome. ECF No. 8-1 at 2. Dr. Ellis referred Petitioner to physical therapy for clinically diagnosed Parsonage Turner Syndrome that was the "[r]esult of flu shot 1.11.13." ECF No. 8-4 at 4. Petitioner underwent physical therapy from January 22, 2013 until September 24, 2013.

After his discharge, Petitioner returned to his neurologist, Dr. Winesett, for several follow-up examinations. At the first follow-up visit on January 30, 2013, Dr. Winesett noted Petitioner's "probable Parsonage Turner Syndrome after influenza vaccine with bilateral shoulder and arm weakness." ECF No. 8-3 at 6. After the second follow-up visit on April 15, 2013, Dr. Winesett reported to Petitioner's primary care physician that Petitioner's shoulder weakness "took months, but eventually did resolve, and he says he is back to normal except . . . his right leg has continued to be numb." Id. at 1. Dr. Winesett stated that his impression was "[d]ecreased sensation with a right T4 level," and his treatment plan was to "proceed with doing a MRI of the entire spine with an[d] without contrast to look to see if [he could] find a cause of this." Id. at 2.

The results of the MRI were normal, apart from some bulging of the C5-C6 disc as previously observed in an earlier MRI. Id. at 3; ECF No. 12-2 at 63, 71. After Petitioner's final follow-up on November 13, 2013, Dr. Winesett wrote to Dr. Ellis that "[f]or the most part, things have gotten better, although he still has some numbness in his mid chest." ECF No. 12-3 at 17. Dr. Winesett recorded that Petitioner suffered from "Parsonage Turner syndrome, slowly recovering." Id. Dr. Winesett concluded that Petitioner could be seen in the future as needed and that "[u]nfortunately, he may have to live with the area of numbness in his mid chest." Id. at 18.

Discussion

Jurisdiction and Standard of Review

This Court has jurisdiction under the Vaccine Act to review the decision of a special master and:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (B) set aside any of the findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)-(C); Doe 93 v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 553, 564-65 (2011).

"Findings of fact of the special master are reviewed under the arbitrary and capricious standard, conclusions of law are reviewed under the not in accordance with law standard, and discretionary rulings are reviewed under the abuse of discretion standard." Broekelschen v. Sec'y of Health & Hum. Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, 618 F.3d 1339 (Fed. Cir. 2010) (citations omitted).

The Court's role is not to "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357, 1360 (Fed.

Cir. 2000) (citation omitted). However, the Court has "a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, 'considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision.'" Paluck v. Sec'y of Health & Hum. Servs., 786 F.3d 1373, 1380 (Fed. Cir. 2015) (quoting Hines ex rel. Sevier v. Sec'y of Health & Hum. Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Conclusions of law are reviewed de novo by this Court. See 42 U.S.C. § 300aa–12(e)(2)(B); Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278-79, 1281 (Fed. Cir. 2005).

Burden of Proof under the Vaccine Act

In the seminal case of Althen v. Secretary of Health & Human Services, the Federal Circuit articulated the petitioner's burden to demonstrate causation-in-fact as follows:

> [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278.

Petitioner must prove causation-in-fact "by a preponderance of the evidence." 42 U.S.C. § 300aa–13(a)(1)(A). The Federal Circuit "has interpreted the preponderance of the evidence standard referred to in the Vaccine Act as one of proof by a simple preponderance, of more probable than not causation." Althen, 418 F.3d at 1279 (citation omitted). Petitioner's claim must be "substantiated by medical records or medical opinion." Id.

The Federal Circuit "adopt[ed] the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) (citing Restatement (Second) of Torts § 431)).

Causation is determined on a case-by-case basis, as follows:

> Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain. Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms.

Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994) (citations omitted).

The Vaccine Act permits proof of causation through "the use of circumstantial evidence envisioned by the preponderance standard." Capizzano v. Sec'y of Health & Hum. Servs., 440

F.3d 1317, 1325 (Fed. Cir. 2006) (citation omitted). As the Federal Circuit has consistently reiterated, under the Vaccine Act, "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280; Capizzano, 440 F.3d at 1325-26; Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009).

If the petitioner proves by a preponderance of the evidence that the vaccine caused petitioner's injury, the burden then shifts to the Government to prove, by a preponderance of the evidence, that a factor unrelated to the vaccination actually caused the injury. de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008); 42 U.S.C. § 300aa–13(a)(1)(B). If the Government fails to meet this burden, the petitioner is entitled to compensation. de Bazan, 539 F.3d at 1352. "So long as the petitioner has satisfied all three prongs of the Althen test, [he] bears no burden to rule out possible alternative causes." Id. (footnote omitted) (citation omitted).

Under Althen's prong one, a petitioner must provide a sound and reliable medical theory demonstrating that the vaccine can cause the petitioner's injury. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019). A petitioner must provide a reputable medical or scientific explanation of his theory. Id.; see Doe 11 ex rel. Estate of Doe. v. Sec'y of Health & Hum. Servs., 83 Fed. Cl. 157, 172-73 (2008), aff'd, 601 F.3d 1349 (Fed. Cir. 2010).

Here, the Special Master concluded that Petitioner did suffer from brachial neuritis, adopting the opinion of Dr. Salvatore Napoli, Petitioner's expert.[5] Dr. Napoli opined that after receiving the flu vaccine, Petitioner had an autoimmune reaction causing muscle weakness and wasting in his upper extremities, which was diagnosed as brachial neuritis. Dr. Napoli opined that Petitioner's body began attacking his nerves as a result of molecular mimicry, brought on by the flu vaccine. He supported his opinion by relating brachial neuritis, a peripheral nerve disorder, to Guillain-Barre syndrome ("GBS"), another peripheral nerve disorder, that has been linked to various types of vaccines.

Respondent's expert, Dr. Vinay Chaudhry,[6] opined that because Petitioner's clinical presentation did not fit neatly into any single diagnosis, his condition was not caused by either radiculomyelitis or brachial neuritis. However, Dr. Chaudhry was unable to offer an opinion on what Petitioner's diagnosis was. Tr. 254. According to Dr. Chaudhry, Petitioner's clinical presentation was inconsistent with either brachial neuritis or radiculomyelitis because he did not

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[5] Dr. Napoli is a board-certified neurologist who completed his neurology residency at Albany Medical Center in 2003. ECF No. 86 at 7. He is licensed to practice in Massachusetts and certified by the American Board of Psychiatry and Neurology. Id. at 8. Dr. Napoli regularly treats individuals suffering from brachial neuritis, including cases of vaccine-induced brachial neuritis. He has participated in 17 clinical trials and research projects focused on a variety of neurological disorders. Id.

[6] Dr. Chaudhry is a professor of neurology at Johns Hopkins University School of Medicine. ECF No. 40-1 at A-1. He is board certified in Neurology, Neuromuscular diseases, Electrodiagnostic Medicine, and Clinical Neurophysiology. Id. He evaluates over 2,000 patients a year, mostly related to peripheral nerve disease. Id. He is also involved in clinical research and has had over 120 publications. Id.

believe Petitioner had pain in his upper extremities, only weakness.[7] The Special Master credited Dr. Napoli's opinion that Petitioner suffered from brachial neuritis.

The Special Master determined, however, that Petitioner had not met Althen's prong one as he failed to show that the flu vaccine "can cause" this condition, reasoning:

> Dr. Napoli has acknowledged that he has provided no evidence -- no study apart from anecdotal case reports (Exs. 28-31) -- directly indicating that the flu vaccine can cause brachial neuritis. (Tr. 93, 97) Instead, Dr. Napoli relies on the notion that brachial neuritis is theorized to be an autoimmune condition associated with multiple triggers, both known and unknown, including infections. (Tr. 16.) Thus, Dr. Napoli opined that the flu vaccine can cause brachial neuritis via molecular mimicry. (ECF No. 77, pp. 35-39; Tr. 38-39.)
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> However, special masters have repeatedly held in varying contexts that it is insufficient for petitioners to merely invoke molecular mimicry without more. See, e.g., W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1361 (Fed Cir. 2016) (finding that the "special master reasonably considered the lack of evidence connecting the cross-reactivity observed by Wuncherpfenning to the facts of petitioner's case to weigh 'against finding that Dr. Tornatore's opinion is perusaisve [sic].'"); Issac v. Sec'y of Health & Human Servs., No. 08-601V, 2012 WL 3609993, at *3-5, *21-22 (Fed. Cl. Spec. Mstr. July 30, 2012), mot. for rev. denied, 108 Fed. Cl. 743 (2013), aff'd, 540 Fed. Appx. 999 (Mem.) (Fed. Cir. 2013); Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020).

ECF No. 83 at 28 (emphasis added) (footnotes omitted).

But the record here contains "more" than Petitioner's superficial invocation of molecular mimicry as a mechanism for causing brachial neuritis. Dr. Napoli characterized the theory of molecular mimicry as a "well-known response in immunology" and explained:

> And to me, the immune system is really the military of your body. You have an innate and an adaptive immune system. The innate . . . immune system is your frontline defense, so when you stub your toe, you have macrophages, cytokines that attack the potential bacteria on that nail where you stub your toe.
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> But then there's an adaptive immune system which is a little bit more eloquent, and what happens with the adaptive immune system is that tends to then memorize what you've been exposed to in the past. So for a vaccine, it's not your innate immune system that's really in overdrive. It's your adaptive immune system. The adaptive immune system involves your T cells, your B cells, and there's an interplay between those cells to develop an immune response, so that it memorizes

[7] The record, however, indicates that Petitioner experienced neck pain and bilateral shoulder pain when he awoke on January 17, 2013, the day he was admitted to ACH. ECF 12-2 at 59. Upon admission to the ACH Emergency Department, Petitioner's pain scale score was a 7. Id. at 58.

> a protein that you've been exposed to, say, a vaccine or any virus you've been exposed to, and then it creates these memory military members that when it gets exposed to a foreign substance or what it perceives to be a foreign substance, it then attacks.
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> . . .
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> So, you've developed that military in your body, and the way I like to describe it to patients, including my [multiple sclerosis] patients, to, Why did this happen, Doctor, well, you know, there's five members of the military that have gone rogue and believe that the protein that's actually normal to yourself, your self antigen, is similar to an antigen that it's been exposed to that thinks it's foreign. So it creates a friendly fire scenario in your own body. What they think is foreign is actually yourself, and it creates friendly fire. And that's basically what happened, I believe, to [Petitioner].

Tr. 38-39; see ECF No. 65-1 at 21-5.

Dr. Napoli opined that the flu vaccine can cause brachial neuritis via molecular mimicry because brachial neuritis is an autoimmune condition associated with multiple triggers, including infections.[8] In support of his opinion Dr. Napoli relied upon his actual experience treating patients with brachial neuritis caused by the flu vaccine. Dr. Napoli testified that every three to six months he treats individuals suffering from brachial neuritis and that some cases he saw were induced by the flu vaccine. ECF No. 86 at 8.[9]

Dr. Napoli supported his theory that the flu vaccine can cause brachial neuritis with four case reports finding that vaccines, including the flu vaccine, actually caused brachial neuritis. A case report is a report written and published by a medical professional to document a patient's case. As Dr. Napoli explained:

> And the importance of these case reports isn't necessarily to say that there is kind of this huge incidence of this occurring. The importance of the case report is to say it can occur, though I can't prove that the flu vaccine will cause this 3 percent of the time it's given because incidences are so rare. But what this is helpful in is when I'm seeing a patient, I can say, yes, this has happened in a rare situation, and it can happen.

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[8] The Special Master's wholesale rejection of molecular mimicry as a theory linking the flu vaccine to brachial neuritis based upon earlier Vaccine Program cases with different experts and different records was not warranted. See ECF No. 83 at 28. A different evidentiary record can lead to different outcomes. Compare Andreu, 569 F.3d at 1370 with Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1325-26 (Fed. Cir. 2010). Changing technological advances and medical breakthroughs can alter the viability of a particular theory. Cf. Rickett v. Sec'y of Health & Hum. Servs., 468 Fed. App'x 952, 959 (Fed. Cir. 2011).

[9] Dr. Napoli was not asked precisely how many brachial neuritis cases he found to be vaccine-induced.

Tr. 96.

One case report published in 2019, described a 61-year-old male who received two flu vaccines, one in 2010 the other in 2013. ECF No. 65-11 at 31-1. Within six weeks of the second flu vaccine, he began to experience shoulder and neck pain and weakness in his upper left extremity, which was eventually diagnosed by a neurologist as brachial neuritis. Id. "Using accepted standard rules for determining causation in the vaccine industry and the [Food and Drug Administration], the author has determined that this rare neurologic event adverse (AE) was probably causally related to the influenza vaccination." Id.

The other three case reports also described the onset of brachial neuritis within several weeks after the patient's receipt of a flu vaccination. A 2000 case report, authored by a private physician who completed a residency in neurosurgery, described a 66-year-old male patient who had received a flu vaccination and was diagnosed several weeks later with acute brachial plexus neuritis. ECF No. 65-8 at 28-1. A 2012 case report published by three physicians in the Department of Rheumatology at Whipps Cross University Hospital in London detailed a finding of "[a]cute brachial neuritis following influenza vaccination." ECF No. 65-9 at 29-1. Finally, in a 2005 case report, "[a] case of acute brachial neuropathy in a male person, age 65, with severe pain, muscle weakness and atrophy of the shoulder and arm muscles six days after influenza vaccination with Vaxigrip is described." ECF No. 65-10 at 30-1.

Dr. Napoli also submitted medical literature identifying other peripheral nerve disorders, such as GBS as being causally related to the flu vaccine, and opined that the evidence linking GBS to flu vaccinations is broadly applicable to the context of brachial neuritis. In support of his theory, Dr. Napoli relied on an article by Haber et al. that relates the flu vaccine to the Acute Inflammatory Demyelinating Polyneuropathy (AIDP) form of GBS, which results from an autoimmune process believed to involve a cross-reaction affecting myelin tissue, resulting in demyelinating damage. ECF No. 83 at 29. In addition, the Haber article cited case reports of GBS following the administration of vaccines for influenza, rabies, polio, and hepatitis. Id. at 15.

In response to Dr. Napoli's expert opinion, Dr. Chaudhry opined that even if Petitioner did have brachial neuritis, it could not have been caused by the flu vaccine because the case reports cited by Petitioner were unreliable,[10] and brachial neuritis and GBS are too dissimilar for there to be similar autoimmune reactions. Dr. Chaudhry noted that GBS results in demyelinating nerve damage while brachial neuritis overwhelmingly results in axonal nerve damage.

Petitioner submits that the Special Master erred in his Althen prong one analysis by giving little weight to the case reports and medical literature submitted by Dr. Napoli, basing his decision in part on the fact that no epidemiological studies currently exist linking brachial neuritis to the flu vaccine, and disregarding the opinions of four of Petitioner's treating physicians. ECF No. 86 at 2-3.

[10] Dr. Chaudhry admitted that case reports can be helpful if they "are very typical and detailed." Tr. 195. However, Dr. Chaudhry only read two of these case reports and did not give them much weight saying that it was difficult to tell whether the case reports would be helpful because "they didn't even mention what nerves were damaged." Id.

In considering Petitioner's case reports, the Special Master concluded that "Dr. Napoli has acknowledged that he has provided no evidence -- no study apart from anecdotal case reports (Exs. 28-31) -- directly indicating that the flu vaccine can cause brachial neuritis," ECF No. 83 at 28 (footnote omitted), and stated:

> "[C]ase reports 'do not purport to establish causation definitively, and this deficiency does indeed reduce their evidentiary value' . . . . [but] 'the fact that case reports can by their nature only present indicia of causation does not deprive them of all evidentiary weight." See Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 475 (2012) (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2001), aff'd, 786 F.3d 1373 (Fed. Cir. 2015)).

ECF No. 83 at 28 n. 20 (alterations in original). It thus appears that the Special Master accorded these case reports little weight, noting that Petitioner's expert had not cited any "study" except for these "anecdotal" case reports.

Given the additional evidence here, the Special Master's requirement that Petitioner submit a "study" to meet Althen prong one was legal error. As the Federal Circuit concluded in Capizzano, "requiring either epidemiologic studies . . . or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect" is contrary to Althen. 440 F.3d at 1325. Such an approach is "inconsistent with allowing the use of circumstantial evidence envisioned by the preponderance standard" and "impermissibly raises the claimant's burden under the Vaccine Act." Id.

In a similar vein, the Court of Federal Claims in Paluck v. Secretary of Health & Human Services, found that it was error for the special master to discount case reports, reasoning that while this additional evidence was "not scientifically certain" it was "sufficiently worthy and reliable to merit an extensive scientific inquiry" because the standard of proof set forth in Althen and the Vaccine Act requires no more. 104 Fed. Cl. at 475 (discussing Althen prong one); see Contreras v. Sec'y of Health & Hum. Servs., 107 Fed. Cl. 280, 304 (rejecting the special master's apparent finding that case reports held no evidentiary value and stating that "epidemiological studies are not required, and that circumstantial evidence is sometimes enough to prove causation in a Vaccine Act case.") (citing Capizzano, 440 F.3d at 1325-26 and Andreu, 569 F.3d at 1378-79). Here, as in Paluck and Contreras, the Special Master erred in his prong one analysis by discounting the evidentiary value of the case reports Dr. Napoli submitted. As the Federal Circuit recognized in Andreu: "[i]n a field bereft of complete and direct proof of how vaccines affect the human body, a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery." 569 F.3d at 1379 (quoting Capizzano, 440 F.3d at 1325-26).

It also appears that the Special Master rejected Dr. Napoli's opinion that the flu vaccine can cause brachial neuritis because he adopted Respondent's expert Dr. Chaudhry's opinion "that cases of brachial neuritis overwhelmingly result in axonal damage and not demyelination." ECF No. 83 at 33 (citing Tr. 131-33, 279-80 and ECF No. 40-3 at 7). Further, it appears that the Special Master assumed that Petitioner suffered from a demyelinating injury, not axonal damage -- even though he found that Petitioner had brachial neuritis. See ECF No. 83 at 29-30.[11] The Special

[11] However, in his prong two analysis, the Special Master stated: "Petitioner has failed to show by preponderant evidence a logical sequence of cause and effect whereby the flu vaccine

Master concluded that Dr. Napoli did not provide evidence that a vaccine causing one type of nerve damage (demyelination) via molecular mimicry should be assumed capable of causing the other (axonal). See ECF No. 83 at 30. But this distinction that Dr. Chaudhry drew between demyelinating nerve damage versus axonal damage cannot be applied to Petitioner on this record. As the Special Master found, "there is no evidence on this record distinguishing whether petitioner's symptoms were caused by demyelination or axonal damage." Id. at 33. The record establishes that Dr. Napoli suspected that Petitioner had demyelinating lesions, but the EMG was done too early to tell, and there is no evidence in the record indicating whether or to what extent Petitioner had a demyelinating injury or axonal damage. Tr. 107; see also Tr. 254; ECF No. 86 at 16. Thus, the Special Master's adoption of Dr. Chaudhry's opinion based upon an apparent assumption that Petitioner had a demyelinating injury, not axonal damage, was not supported by the evidence.

The diagnoses of four treating physicians that Petitioner suffered from brachial neuritis caused by the flu vaccine further supports the reliability of Petitioner's theory that the flu vaccine can cause brachial neuritis. Dr. Winesett, a neurologist, evaluated Petitioner at ACH and noted a "possible" diagnosis of brachial neuritis three days after the flu shot that "could be consistent with an autoimmune process related to a reaction to the influenza vaccine." ECF No. 12-2 at 74. At a follow-up visit on January 30, 2013, 13 days after his initial evaluation, Dr. Winesett recorded Petitioner's "probable Parsonage Turner Syndrome [or brachial neuritis] after influenza vaccine with bilateral shoulder and arm weakness." ECF No. 8-3 at 3-6 (emphasis added). Also during his hospitalization at ACH, both Dr. Ford, an attending physician, and Dr. Larsen, an osteopathic doctor, evaluated Petitioner and concluded a likely diagnosis of "brachial plexopathy secondary to flu vaccination." ECF 12-2 at 7-78, 7-80, 7-83. Finally, Petitioner's primary care physician, Dr. Ellis, stated in Petitioner's medical record that he "had a reaction to our flu vaccine" and noted "Do not give flu vaccine" to Petitioner. ECF No. 8-1 at 1-2. The Special Master erred in failing to accord these medical records weight in analyzing prong one. Cf. Capizzano, 440 F.3d at 1326 (stating that "medical 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 shows that the vaccination was the reason for the injury.").

Finally, the medical literature Petitioner submitted supports his theory that the flu vaccination can cause brachial neuritis. According to the Ferrante article, one of the consistent and documented "recognized trigger[s]" for brachial neuritis is vaccinations, and another trigger is flu-like illness. ECF No. 65-3 at 3. While vaccine-caused brachial neuritis is rare, the Ferrante article found that vaccination acts as a trigger in 5% of cases. Id. Other articles cited by Petitioner documented GBS in patients who had received the flu vaccine prior to the onset of symptoms. The article by Haber et al. published in 2009 found case reports of GBS following various types of vaccine administrations, including the flu vaccine. ECF No. 65-6 at 3. Another article by Schonberger et al. published in the 1970s found that 532 GBS patients had received a flu vaccine prior to the onset of their neurologic symptoms and GBS diagnoses. ECF No. 65-5 at 1.

In sum, Petitioner demonstrated a sound and reliable medical theory that the flu vaccine can cause brachial neuritis via molecular mimicry. This theory is supported by the expert opinion

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would have induced an autoimmune reaction that caused his axonal-loss lesion resulting in brachial neuritis." ECF No. 83 at 33.

of an experienced neurologist, four case reports, three medical articles, and the diagnoses of four treating physicians that the flu vaccine likely did cause Petitioner's brachial neuritis. By disregarding this evidence and noting the absence of studies supporting Petitioner's theory, the Special Master placed too high an evidentiary burden on Petitioner with respect to Althen's prong one.

The Special Master's imposition of a heightened burden on Petitioner as to prong one impacted his Althen prong two analysis. With respect to prong two, the Special Master stated:

> The parties agree that brachial neuritis can occur within days of an antecedent trigger. (Medlink, supra, at Ex. 23, pp. 2-7; Van Eijk, Groothuis & Van Alfen, supra, Ex. C, pp. 1-2.) Here, petitioner presented with symptoms of brachial neuritis within days of his flu vaccination. This timing of onset fits squarely within the accepted timeline for brachial neuritis to develop following an antecedent event. Standing alone, however, a temporal association is not sufficient to satisfy Althen prong two.
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> Petitioner's initial presentation seemed to confuse his treating physicians who initially listed 13 differential diagnoses including central nervous system mass, carbon monoxide poisoning, dehydration, electrolyte abnormality, unspecified headache, migraine, tension headache, intracranial hemorrhage, meningitis, post-concussion syndrome, shunt malfunction, and stroke. (Ex. 7, p. 60.) However, as petitioner was further examined, his treating physicians and physical therapists settled on a diagnosis of possible or probable brachial neuritis (referenced as Parsonage-Turner Syndrome) that they related to his flu vaccination. (Ex. 7, pp. 17, 47, 53, 85.) Importantly, however, petitioner's medical records show no evidence of any diagnostic labs such as lumbar puncture which may have helped support a casual, and not merely temporal, link between the vaccine and his injury.
>
> Thus, although petitioner's treating physicians did ultimately settle on the diagnosis of brachial neuritis, their further opinion that the condition was caused by petitioner's flu vaccination relies exclusively on the temporal relationship and the lack of any known alternative triggers. This conclusion carries little weight in light of my finding that petitioner has not satisfied Althen prong one relative to brachial neuritis.

ECF No. 83 at 32 (emphasis added) (citations omitted). Thus, the Special Master's prong two analysis was colored by his finding that Petitioner failed to satisfy Althen prong one.

Conclusion

Petitioner's Motion for Review is **GRANTED**. The decision of the Special Master is **VACATED**, and this matter is **REMANDED** to the Special Master for further proceedings. On remand, the Special Master shall reassess entitlement in particular whether Petitioner satisfied Althen's prong two in light of this Court's finding that Petitioner met Althen's prong one.

Pursuant to 42 U.S.C. § 300aa-12(e)(2), the Special Master shall complete proceedings on remand within 90 days.

The Clerk shall not disclose this decision publicly for 14 days.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Senior Judge