

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 17-1485V
(to be published)

<p>*****</p> <p>THOMAS PELELO,</p> <p style="padding-left: 100px;">Petitioner,</p> <p style="text-align: center;">v.</p> <p>SECRETARY OF HEALTH AND HUMAN SERVICES,</p> <p style="padding-left: 100px;">Respondent.</p> <p>*****</p>	<p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p>	<p>Chief Special Master Corcoran</p> <p>Filed: August 6, 2021</p>
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James Cook, Dutton, Daniels, Hines, Kalkhoff, Cook & Swanson, PLC, Waterloo, IA, for Petitioner.

Catherine Stolar, U.S. Dep’t of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION¹

On October 10, 2017, Ann Pelelo, mother of Thomas Pelelo, filed a petition on his behalf for compensation under the National Vaccine and Injury Compensation Program (the “Vaccine Program”).² (ECF No. 1) (“Petition”). The Petition alleged that Mr. Pelelo experienced Parsonage-Turner syndrome, a/k/a brachial neuritis, after receipt of a human papillomavirus (“HPV”) vaccine on December 29, 2015. Petition at 1. The caption was changed once Mr. Pelelo became 18 years

¹ This Decision shall 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).

old, and hence the proper petitioner/party in interest. Order, dated September 19, 2019 (ECF No. 44).

I determined that this matter could be most efficiently resolved via ruling on the record. Based on that record and the parties' other written submissions, I find that Petitioner has not carried his evidentiary burden. Insufficient evidence supports the conclusion that the HPV vaccine can cause brachial neuritis, or did so to Petitioner in this case.

I. Factual Background

Mr. Pelelo was born on August 6, 2001. Ex. 2 at 1. His prior medical history included lumbar, right foot, and left lower extremity pain. Ex. 6 at 1-2 (December 2015 appointments with chiropractor for lumbar and right foot pain); *see also* Ex. 15 at 191, 193. Petitioner received his first dose of HPV vaccine on October 16, 2015, in his left deltoid. Ex. 2 at 1. The record does not reveal he experienced any reaction to it, and sets forth no symptoms associated with this claim before the next dose he received.

Vaccination and Initial Symptoms

Petitioner received his second HPV vaccine dose on December 29, 2015, again in his left deltoid. Ex. 2 at 1; Petition at 1. Petitioner has reported awakening the morning after he received this dose, with numbness and disability of the left arm. *Id.* Petitioner has also stated in another declaration that he "attended swim practice the day after" receiving his second HPV vaccination, but at that time "had great difficult[y] moving [his] left shoulder." Letter, filed as Ex. 32 on Sept. 1, 2020 (ECF No. 56-1), at 1.

Less than two weeks later, on January 11, 2016, Mr. Pelelo presented to his existing chiropractor. Ex. 6 at 3. At this time, Petitioner appears to have complained of tightness between his shoulder blades, worse on the left side, with the "date of the condition" identified as "1/8/16 – swim." *Id.* He was referred to his pediatrician for follow-up. *Id.* Later that same day, Ann Pelelo phoned Petitioner's pediatrician's office (as reflected in a note of the call memorialized in the record), stating that her son could not move his arm, and was self-treating with ibuprofen but without relief. Ex. 3 at 25-26. She also reported that Petitioner had been "evaluated by [a] swim coach and [an] athletic trainer as well as a chiropractor and felt there was nerve damage" relating to Petitioner's December 29, 2015 HPV vaccine dose. *Id.* Petitioner was now referred to an orthopedist. *Id.* at 26.

On January 12, 2016, Mr. Pelelo underwent an orthopedic assessment with Dr. Steven Rock to evaluate his left shoulder pain, which was reported to have begun "shortly after receiving his HPV vaccine on December 29, 201[5]." Ex. 3 at 15. The history of present illness noted that Petitioner's pain was "more periscapular and in the area of the upper trapezius," with weakness and associated difficulty "forward flexing or abducting the shoulder." *Id.* The pain associated with his symptoms made it difficult to for him to swim competitively. *Id.*

Upon examination, Petitioner displayed tenderness “over the supraspinatus, infraspinatus and upper trapezius on the left,” with mild tenderness in the deltoid area and reduced left upper extremity strength. Ex. 3 at 16. Dr. Rock opined that “[p]resumptively,” Petitioner had Parsonage-Turner syndrome, “which [was] felt to be a potential autoimmune response or inflammatory disorder [that] can occur post immunization, post illness or sometimes after injury.” *Id.* Dr. Rock added, however, that specific testing—an electromyography (“EMG”) and/or nerve conduction study (“NCS”)—could help “solidify the diagnosis.” *Id.* Dr. Rock prescribed a Medrol Dosepak and ordered physical therapy. *Id.*

On January 19, 2016, Mr. Pelelo went back to Dr. Rock, now reporting that his pain had not improved. Ex. 3 at 14. On exam, he revealed “no obvious scapular winging, although there [wa]s potentially some subtle winging on the left developing.” *Id.* Dr. Rock referred Petitioner to a neurologist to obtain a definitive diagnosis, and to “evaluate for any other potential possibilities.” *Id.* at 15. A week later (January 28th), Mr. Pelelo saw neurologist Dr. Marsha Horwitz. *Id.* at 8. The history from this visit reports that Petitioner was experiencing “left shoulder numbness, pain and unable to lift arm since 2 weeks after HPV injection,” although it also stated he has felt “a feeling of tightness in his left shoulder the following day” after vaccination. *Id.* On exam, Petitioner’s left upper extremity weakness was confirmed. *Id.* at 9. Dr. Horwitz’s diagnosis was “[l]eft brachial plexopathy, autoimmune, consistent with [PTS].” *Id.* at 10.

Subsequent Treatment and Evaluation

On February 24, 2016, Mr. Pelelo was evaluated at the University of Iowa’s Sports Medicine Clinic (the “Sports Medicine Clinic”). Ex. 3 at 40. The history of present illness section of the record from this visit is consistent with Petitioner’s initial witness statement, both of which report a reaction within a *day* of vaccination. Thus, this record’s history states that after the HPV vaccine dose at issue, Petitioner had “proceeded to swim practice that night with no problems,” but awoke the next day with numbness, and could not thereafter swim. *Id.* The history also noted, however, that Petitioner’s PTS initial diagnosis had been arrived at “without an EMG.” *Id.* His examination showed “severe scapular winging during forward flexion and extension indicating serratus anterior dysfunction.” *Id.* at 42. He also had “[m]ild sensation loss of [his] dorsal hand and fingers” on the left. *Id.*

EMG and NCS studies were performed at the Sports Medicine Clinic (now approximately eight weeks post-vaccination), but they did not corroborate the brachial neuritis diagnosis. Rather, they showed “no electrophysiologic evidence of either left brachial plexopathy, long thoracic neuropathy, or other neuropathy typically involved in scapular winging.” Ex. 4 at 129. In particular, Petitioner’s needle EMG was deemed “essentially normal.” *Id.* By contrast, his “left median distal latencies were slightly prolonged” in the NCS, leading to an “incidental finding of very mild median neuropathy at the wrist,” but his median motor and sensory studies were otherwise normal. *Id.* The EMG/NCS was signed by neurologist Dr. Heather Bingham, who certified that she was “present during the examination and concur[ed] with the findings and interpretation of th[e] report.” *Id.*

In the subsequent months, Mr. Pelelo was extensively treated for his presumed brachial neuritis. In March 2016, he began receiving intravenous immunoglobulin (“IVIG”) therapy, after failing to improve with physical therapy. Ex. 3 at 47. The admission note indicated that Petitioner had received an HPV vaccine dose on December 29, 2015, and “[t]hat night, he attended swim practice and noted mild discomfort and weakness.” *Id.* Petitioner reported that “his pain gradually ended but that he continues to have intermittent decreased sensation and tingling down his arm and to his central three fingers.” *Id.* Petitioner’s treating physicians had expressed confidence in the brachial neuritis diagnosis, even though their notes specifically acknowledged that on EMG Petitioner had displayed “no electrophysiologic findings for left brachial plexopathy, long thoracic neuropathy, or other neuropathy.” *Id.* at 47-48. Petitioner received two IVIG infusions that month. *Id.* at 45.

By the end of March 2016, it appeared Mr. Pelelo had largely recovered, with resolution of his pain and a return to his former strength. Ex. 3 at 35. At most, he displayed “slightly diminished muscle bulk” of his left shoulder, as compared to his right, and mild scapular winging. *Id.* He was now able to return to swimming, and although he continued to pursue physical therapy, he could pursue athletic activities without pain. Ex. 5 at 4-5. As of May 2016, however, Petitioner reported a plateauing in his recovery, with “decreased ROM and more weakness with manual muscle testing.” *Id.* at 5. To gain a better understanding of the presentation, Dr. Andrew Peterson at the Sports Medicine Clinic ordered an MRI, but the results were deemed normal. Ex. 3 at 30, 33.

Into the summer of 2016, Petitioner continued to pursue competitive sports without pain, “but fe[l]t limited in some of the movements.” Ex. 5 at 3. Then, on July 14, 2016, Mr. Pelelo informed his physical therapist that his left shoulder pain had worsened “over the past 7-10 days,” although his physical therapist associated it with over-exertion and effort rather than related to Petitioner’s earlier brachial neuritis diagnosis. *Id.* By the fall of 2016, Petitioner’s physical therapy was discontinued. *Id.* at 2.

Subsequent evaluations revealed some persistent/lingering left shoulder pain, confirming the sense that Mr. Pelelo’s overall condition had plateaued since May, although his range of motion was near normal. Ex. 3 at 117-18. By early November 2016, Petitioner received a release from his pediatrician to return to “swim team and swimming in P.E.” *See* Ex. 3 at 112. Thereafter, Mr. Pelelo continued to report left shoulder pain that he said interfered with his athletic pursuits, and he pursued chiropractic treatment from 2017 to 2019. Ex. 6 at 15 (December 23, 2016 appointment with chiropractor reporting radiating pain from thoracic region into left shoulder); *see also* Ex. 19. Records from his more recent medical history do not shed light on the claims asserted herein.

II. Expert Reports

A. *Petitioner's expert: Alan J. Fink, M.D.*

Dr. Fink, a neurologist, filed three reports. Report, dated August 14, 2018, filed as Ex. 9 (ECF No. 22-1) (“First Fink Rep.”); Report, dated December 13, 2019, filed as Ex. 22 (ECF No. 46-1) (“Second Fink Rep.”); Report, dated August 16, 2020, filed as Ex. 36 (ECF No. 36-001) (“Third Fink Rep.”). Dr. Fink endorsed brachial neuritis as the proper diagnosis for Petitioner’s injury, and that the HPV vaccine had likely caused it. First Fink Rep. at 3-5.

Dr. Fink is a neurologist in private practice in Greenville, Delaware, and an examiner for the Social Security Administration. *See* Ex. 10 (ECF No. 22-2) (Dr. Fink’s Curriculum Vitae (“CV”)) at 2. He received his medical degree in 1970 from State University of New York – Buffalo School of Medicine, and did a residency in medicine at Nassau County Medical Center, followed by a neurology residency at Yale-New Haven Hospital. CV at 1-2. He also held MRI-related fellowships thirty-plus years ago. *Id.* at 1. He has received several “best doctor-neurology” awards from a Delaware regional magazine, and is board certified in neurology. *Id.* at 2-3. He holds the position of Clinical Assistant Professor of Neurology at Thomas Jefferson Medical College in Philadelphia, Pennsylvania. *Id.* at 3. Over his 47 years of practice, Dr. Fink recalls encountering “the neurological complications of vaccines” presenting as brachial neuritis twice, although he also treated the same condition twice where it did not arise in connection with vaccination. First Fink Rep. at 1.

First Report

Dr. Fink began his first report with a brief review of Mr. Pelelo’s medical history consistent with the medical record, beginning well prior to vaccination. First Fink Rep. at 1-3. He specifically accepted the conclusion that Petitioner’s onset occurred within 24 hours of his receipt of a second HPV vaccine dose. *Id.* at 3.

Dr. Fink then characterized brachial neuritis as “a condition that causes pain and weakness of the shoulder girdle muscles and/or of the upper extremity muscles.” First Fink Rep. at 3. He noted that “[a]utoimmune and immunizations” are an understood cause for brachial neuritis, and maintained it was reasonable to view it as immune-mediated. J. Van Eijk et al., *Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment*, 53 *Muscle Nerve* 337-50 (2016), filed as Ex. 25 on Dec. 16, 2019 (ECF No. 46-4) (“Van Eijk”), at 339-40. Another article Dr. Fink had offered showed that between 30 to 85 percent of all case involving assumed immune-mediated responses occurred three to fourteen days after vaccination, and thus somewhat acutely (although obviously less so than Petitioner avers occurred in his case). First Fink Rep. at 3; P. Debeer et al., *Brachial Plexus Neuritis Following HPV Vaccination*, 26 *Vaccine* 4417-19, 4418 (2008), filed as Ex. 11 on Aug. 28, 2018 (ECF No. 22-3) (“Debeer”) (describing brachial neuritis as presenting with “sudden severe pain”). Debeer, however, is a single-subject case report, observing one case of brachial neuritis in a

19 year-old woman that manifested *one month* after the second HPV dose—not one day. Debeer at 4417.

Regarding causation, Dr. Fink observed that post-vaccination brachial neuritis had been observed in connection with a number of vaccines, and specifically noted that case reports existed suggesting the HPV vaccine was associated with 16 incidents of brachial neuritis (although Dr. Fink’s report provides no citation for this assertion). First Fink Rep. at 4.³ He proposed, however, that these occurrences were likely under-reported, since “neuritic pain is often related to a shoulder joint problem.” *Id* He provided no other explanation in this report for *how* the HPV vaccine might trigger or cause brachial neuritis.

Dr. Fink also provided some examples from the medical record that he maintained supported his opinion that the HPV vaccine caused Mr. Pelelo’s brachial neuritis. He observed that Petitioner’s treaters had made the diagnosis based on the evidence of “sudden and severe pain followed by atrophic weakness of the shoulder muscles and dyskinesia.” First Fink Rep. at 4-5. Mr. Pelelo also did not see a return to normal muscle function, which Dr. Fink said is characteristic in more than half of all brachial neuritis cases. *Id.* at 4. And Petitioner had experienced some recurrence as well, which also was not unusual. *Id.*; Van Eijk at 339.

Dr. Fink admitted that some important diagnostic criteria—in particular, Petitioner’s MRI or EMG results—did not confirm the brachial neuritis diagnosis. First Fink Rep. at 4. However, he discounted the importance of such findings, arguing that this was not an unusual outcome and did not *per se* rule out the diagnosis. *Id.*

Second Fink Report

Dr. Fink’s second report responded both to challenges raised in the report of Respondent’s expert, as well as questions posed to him directly by the special master previously presiding over the case. First, Dr. Fink noted other aspects of the medical record that he maintained supported the brachial neuritis diagnosis. In particular, scapular winging (which he deemed a potential result of brachial neuritis) was observed at a May 2016 exam conducted by the University of Iowa Sports Clinic. Second Fink Rep. at 1. Mr. Pelelo’s lack of complete recovery even as late as the fall of 2016 was also consistent with the diagnosis. *Id.* at 1, 4. And the kind of ongoing “prolonged weakness” Petitioner had experienced was seen in at least a quarter of brachial neuritis cases. *Id.* at 3.

More of Dr. Fink’s second report was devoted to explaining why he did not consider the normal MRI and EMG results to be inconsistent with a brachial neuritis diagnosis. He noted literature stating that only about six percent of brachial neuritis cases featured abnormal MRI

³ At most, one of the case reports filed in the matter states that 17 instances of “brachial plexopathy” were reported by passive surveillance systems of reported adverse effects after the HPV vaccine. Taras et al., *Brachial Neuritis Following Quadrivalent Human Papilloma Virus (HPV) Vaccination*, 6 Hand 454-456 (2011), filed as Ex. 12 on Aug 28, 2018 (ECF No. 22-4) at 456. As discussed herein, however, that kind of data does not receive significant weight in Program cases.

results. Second Fink Rep. at 2; Van Eijk at 339. The same was generally true of EMGs, even though they admittedly were often relied upon by neurologists to confirm the diagnosis. Second Fink Rep. at 2; Van Eijk at 343. EMGs were in fact often “fraught with sampling error,” and thus might well fail to demonstrate abnormalities demonstrated in clinical evidence, and thus optimally two should be performed (although that did not occur here). Second Fink Rep. at 2, 3; Van Eijk at 342 (“[a] normal motor nerve conduction study examination does not exclude brachial plexitis as a diagnosis”). Dr. Fink also observed that in Petitioner’s case, it appeared the EMG/NCS was performed not by a neurologist but by a technician less skilled at the task. Second Fink Rep. at 3.

In response to questions raised by the special master about the likely pathophysiology of Petitioner’s injury attributable to vaccination—a matter not explored in any detail in his the first report—Dr. Fink proposed a multi-factored process. A genetic predisposition carried by the injured party would, in his view, likely interact with (a) a mechanical injury to a nerve (in this case, Mr. Pelelo swimming the day after receipt of the second HPV dose), and (b) a vaccine-instigated immune system reaction, producing an autoimmune process. Second Fink Rep. at 3; N. van Alfen et al., *Treatment for Idiopathic and Hereditary Neuralgic Amyotrophy (Brachial Neuritis) (Review)*, (3) Cochrane Database of Systematic Reviews, Art. No.: CD006976, 1-6 (2009), filed as Ex. 28 on Dec. 16, 2019 (ECF No. 46-7) (“van Alfen I”); M. Martinez-Lavin, *Hypothesis: Human Papillomavirus Vaccination Syndrome—Small Fiber Neuropathy and Dysautonomia Could be its Underlying Pathogenesis*, 34 *Clin. Rheumatol.* 1165-69 (2015), filed as Ex. 26 on Dec. 16, 2019 (ECF No. 46-5) (“Martinez-Lavin”).

Martinez-Lavin does not specifically address brachial neuritis. Rather, it puts forth the hypothesis that small fiber neuropathy and dysautonomia (both of which it deems manifestations of “[s]ympathetic nervous system dysfunction”) could constitute the underlying pathogenesis for a group of rare overlapping reactions (complex regional pain syndrome, postural orthostatic tachycardia syndrome, etc.), that often are reported in passive surveillance as adverse responses to receipt of the HPV vaccine. Martinez-Lavin at 1165. Indeed, Martinez-Lavin notes that adverse reactions appear to be more frequent after HPV vaccination when compared to other types of immunizations, although the article does not flesh out a causal relationship. *Id.* Brachial neuritis could, therefore, in Dr. Fink’s view plausibly reflect the same kind of “HPV syndrome.” Evidence that the process causing brachial neuritis was likely immune-mediated was also provided by other literature suggesting “[t]he presence of multimodal mononuclear infiltrates . . . and antiganglioside antibodies” in the blood serum of patients with the condition. Second Fink Rep. at 3.⁴

Third Fink Report

⁴ Dr. Fink’s report cites a particular article for this assertion. Z. Simmons, *Electrodiagnosis of Brachial Plexopathies and Proximal Upper Extremity Neuropathies*, 24 *Phys. Med. Rehabil. Clin. N. Am.* 1-20 (2013), filed as Ex. 29 on Dec. 16, 2019 (ECF No. 46-8) (“Simmons”). Respondent filed the same article. *See* Ex. C. However, I cannot locate in Simmons *where* the autoimmune nature of brachial neuritis is discussed. The sections of Simmons highlighted by Petitioner do not at all deal with the subject, and the more general focus of Simmons is on the utility of the use of EMG and NCS testing.

Dr. Fink’s final report, the longest of the three, endeavored to answer several additional questions posed by the special master formerly presiding over the matter about Petitioner’s causation theory. First, Dr. Fink discussed what he would deem a “medically acceptable” onset for HPV vaccine-caused brachial neuritis. Third Fink Rep. at 2. Dr. Fink noted that some literature supported an onset of 3-14 days, and hence a timeframe longer than what Petitioner alleges to have experienced, but added that the “consensus current working opinion” is that onset occurs “acutely” —which, in his view, supported a single-day onset. *Id.*; M. Bromberg, *Brachial Plexus Syndromes – UpToDate* (Aug. 8, 2018), <https://www.uptodate.com/contents/brachial-plexus-syndromes/print?search=...>, filed as Ex. 14 on Aug. 28, 2018 (ECF No. 22-6) (“Bromberg”). Bromberg briefly reviews the underlying anatomy, pathogenesis, and general clinical features of brachial plexopathies, and discusses a number of specific plexopathies classified by clinical setting. Bromberg at 1. Bromberg distinguishes between acute and insidious onset of symptoms from brachial plexopathies. *Id.* at 3. However, no actual timeframe (measuring from trigger to symptoms manifestation of brachial neuritis) is discussed in this article. Acute and insidious onset are distinguished in terms of pain occurring in the shoulder or upper arm, versus progressive pain and evolving weakness. *Id.* It is thus not self-evident from Bromberg that “acute” can be interpreted as Dr. Fink proposes, since the term’s usage seems intended to describe degree and temporal intensity of pain (i.e. coming on unexpectedly and severely), rather than the timeframe from trigger to symptoms.

Second, Dr. Fink disputed that certain sports activities relevant in this case could be the cause of brachial neuritis independent of vaccination. He felt instead that “thoracic outlet syndrome” would be the proper diagnostic descriptor for such a sports-related injury arising from Petitioner’s pursuits (swimming and baseball). Third Fink Rep. at 3. But in any such case, the symptoms would be “significantly different” from what Petitioner experienced. *Id.* Brachial plexus injuries do not appear associated with swimming or baseball, but instead with other kinds of contact sports (football, rugby) or biking. *Id.* And they would feature secondary clinical indicia reflective of their severity (broken bones, collapsed lungs). *Id.* At bottom, the kind of neurologic symptoms characterizing Mr. Pelelo’s injury were not akin to the orthopedic-in-nature symptoms common to a swimming injury. *Id.*

Dr. Fink also provided further explanation for the biological process through which he contended the HPV vaccine would theoretically cause brachial neuritis. Third Fink Rep. at 4. He proposed it would occur either via “direct antigenic attack” on brachial plexus nerves, or through “focal inflammation of vessels of the nerve” resulting in axonal damage. *Id.*; G. Chavada & H. Willison, *Autoantibodies in Immune-Mediated Neuropathies*, 25(5) *Current Opinions – Neurology*, 550-55, 555 (Oct. 2012), filed as Ex. 30 on Dec. 16, 2019 (ECF No. 46-9). The fact that Petitioner had already received the HPV vaccine (two months before) had effectively “primed” his immune system to respond more quickly after a second dose. Third Fink Rep. at 4.

Besides the above, Dr. Fink repeated his prior contentions that the absence of EMG abnormalities in Petitioner’s case was not significant, especially since the test appeared not to have

been performed by a physician capable of performing the test or interpreting the results properly. Third Fink Rep. at 4-5, 7. He also again referenced medical record evidence supporting his view that Petitioner's condition had persisted (despite some contrary evidence suggesting improvement). *Id.* at 5-7.

B. Respondent's expert: Peter Donofrio, M.D.

Dr. Donofrio acted as Respondent's expert and filed three written reports. Report, dated June 11, 2019, filed as Ex. A (ECF No. 34-1) ("First Donofrio Rep."); Report, dated April 23, 2020, filed as Ex. L (ECF No. 51-1) ("Second Donofrio Rep."); Report, dated December 17, 2020, filed as Ex. P (ECF No. 60-1) ("Third Donofrio Rep."). He contested the accuracy of Petitioner's diagnosis, and otherwise disputed the assertion that the HPV vaccine can cause brachial neuritis.

Dr. Donofrio is a professor of neurology and director of the MDA and ALS clinics at the Vanderbilt University Medical Center. First Donofrio Rep. at 1; *See* Ex. B (ECF No. 34-2) (Dr. Donofrio's Curriculum Vitae ("Donofrio CV")) at 2. He received his B.S. at the University of Notre Dame, and then attended the Ohio State University School of Medicine for his M.D. Donofrio CV at 2. He is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular disorders. *Id.* Dr. Donofrio is experienced in treating peripheral neuropathies like GBS and CIDP, as well as brachial neuritis, and is a member of organizations focusing on these kinds of neuropathic conditions. First Donofrio Rep. at 1. Among his publications is a textbook on the specific topic of peripheral neuropathy. Donofrio CV at 21. He is not an immunologist—although neither is Dr. Fink.

First Report

Dr. Donofrio's initial report included a detailed review of Mr. Pelelo's medical history. First Donofrio Rep. at 1-5. He then provided an overview of brachial neuritis, deeming it an "inflammatory condition of the nerves within the brachial plexus." First Donofrio Rep. at 6. The brachial plexus⁵ is a "clustering of nerve fibers" whose branches form the primary nerves for the shoulder, arms, and hands. First Donofrio Rep. at 6; Z. Simmons, *Plexopathies and Proximal Upper Extremity Neuropathies*, 24 *Phys. Med. Rehabil. Clin. N. Am.* 1-20 (2013), filed as Ex. C on July 23, 2019 (ECF No. 39-1) ("Simmons"). Injuries to the brachial plexus will, therefore, inherently "produce weakness, sensory changes and commonly deep tendon reflex abnormalities." First Donofrio Rep. at 6. And the fact that the brachial plexus is comprised of nerve fibers also means that injuries to it will be detectible through EMG/NCS testing. *Id.* This kind of condition should also be visible to an extent on MRI, since brachial neuritis will usually lead to "neurogenic atrophy" of the muscles served by the brachial plexus. *Id.*

⁵ Dr. Donofrio thus distinguished brachial neuritis from injuries to peripheral nerves connected to, but distal from, the plexus. First Donofrio Rep. at 6.

Brachial neuritis is understood in some cases to have an infectious origin or trauma (whether from surgical interventions or some external accident), but is also commonly idiopathic, meaning no triggering explanation can be identified. First Donofrio Rep. at 6, 8. Although Dr. Donofrio admitted that case reports exist purporting to observe an association between some vaccines and brachial neuritis, he opined that there was no reliable scientific/medical proof connecting the two. *Id.* He noted in particular that the Institute on Medicine's report regarding proposed adverse effects of various vaccines had found no reliable link between the HPV vaccine and brachial neuritis. *Id.* at 8; Institute of Medicine of the National Academies, *Adverse Effects of Vaccines: Evidence and Causality, Chronic Inflammatory Disseminated Polyneuropathy*, 512-13 (Kathleen Stratton, et al.), filed as Ex. D on July 23, 2019 (ECF No. 39-2) (the "IOM Report I").

Based on his overall review of the record, Dr. Donofrio concluded that Mr. Pelelo likely had not experienced brachial neuritis. First Donofrio Rep. at 9. He based this conclusion on a number of different factors. He allowed for the fact that Petitioner's presentation, from the late December 2015 vaccination until February 2016, was at least "suggestive of a brachial plexus process." First Donofrio Rep. at 6. But Dr. Donofrio deemed the negative/normal EMG and NCS results almost dispositive of the issue, since the timing of the performance of this testing (approximately two months after alleged onset in late December) meant they should have detected "even subtle neurogenic abnormalities" by that time, if in fact injury to the brachial plexus had previously occurred. *Id.* Indeed, Dr. Donofrio questioned later treater support for the brachial neuritis diagnosis in the face of these normal results. *Id.* at 7 (discussing Ex. 3 at 47).

In highlighting the normal EMG/NCS results, Dr. Donofrio stressed his disagreement with Dr. Fink that brachial neuritis could exist even without confirmation by such nerve testing. First Donofrio Rep. at 7-8. He noted that medical literature filed in the case (by both sides) strongly supported the conclusion that EMG/NCS testing were understood as critical to the diagnosis. *Id.* at 8; J. Aymond et al., *Neuralgic Amyotrophy*, 28(12) *Orthopaedic Rev.* 1275-1279 (1989), filed as Ex. F on July 23, 2019 (ECF No. 39-4); Bromberg at 3. Indeed, the more reputable studies focusing on persons with brachial neuritis all involved individuals whose diagnosis had been confirmed via EMG/NCS testing. *See, e.g.*, A. Martinez-Salio et al., *Neuralgia Amiotrofica: Revision de 37 Casos*, 27(159) *Rev. Neurol.* 823-826 (1998) (original in Spanish), filed as Ex. G on July 23, 2019 (ECF No. 39-5). This was also true of many of the case reports filed by Petitioner that purported to associate the HPV vaccine with brachial neuritis. *See, e.g.*, Debeer at 4418; J. Taras et al., *Brachial Neuritis Following Quadrivalent Human Papilloma Virus (HPV) Vaccination*, 6 *Hand* 454-456 (2011), filed as Ex. 12 on Aug. 28, 2018 (ECF No. 22-4) ("Taras") at 455 (female subject's brachial neuritis began three days after receipt of second HPV vaccine dose; diagnosis confirmed by EMG/NCS results, although initial results were normal).

Other facts gleaned from the medical record persuaded Dr. Donofrio that Petitioner's brachial neuritis diagnosis was not tenable. The May 2016 MRI scan of Mr. Pelelo's left shoulder, for example, produced normal results, and thus did not reveal the kind of denervation-related muscle atrophy that should have been present. First Donofrio Rep. at 7; *citing* Ex. 3 at 32. Scapular winging was not observed in January 2016, although it should have in Dr. Donofrio's opinion been evident in a case of brachial neuritis that began in late December. First Donofrio Rep. at 9. Petitioner also showed marked improvement after treatment with IVIG and steroids (contrary to assertions in Dr. Fink's report), and seemed largely recovered by the end of March. First Donofrio Rep. at 7, 9. And Dr. Donofrio noted a number of factual inconsistencies about Petitioner's treatment progress, noting instances where improvement of symptoms was not acknowledged in certain records. First Donofrio Rep. at 7, *citing* Ex. 3 at 17-18, 30. Dr. Donofrio overall seemed to find (although his report did not say so directly) that the totality of Petitioner's treatment course—looking at the record between early December 2015 (before the second HPV vaccine dose was administered) and August 2017—revealed he suffered from a host of “musculoskeletal symptoms” that might better explain the symptoms complained of in this case. First Donofrio Rep. at 9.

Second Report

Dr. Donofrio's next report endeavored to answer Dr. Fink's attacks on his initial opinion. Dr. Donofrio devoted considerable attention to the importance of the EMG/NCS testing results. Second Donofrio Rep. at 1-3. First, he defended the results obtained for Petitioner as trustworthy, over Dr. Fink's objections that a physician had not literally performed the tests on Petitioner, emphasizing that Dr. Bingham (the neurologist who approved the results) would have well-understood how to perform such testing and whether the results were reliable, and thus her endorsement of the results was reasonable even if a technician had been actually responsible for the tests. *Id.* at 1. Dr. Donofrio's review of the specific records pertaining to the testing underscored for him the reliability of the results, since the testing was thorough and involved the muscles most likely to be abnormal in cases of scapular winging (and thus essentially undercut conclusions by treaters about the significance of the presence of scapular winging). *Id.* at 1, 2-3.

Second, Dr. Donofrio reiterated points in his first report supporting the overall importance of EMG/NCS results in diagnosing brachial neuritis. He noted that literature filed in the case stood directly for the proposition that such testing was virtually required to confirm the diagnosis. Second Donofrio Rep. at 2-3; Simmons at 10-11; N. van Alfen, et al., *Sensory Nerve Conduction Studies in Neuralgic Amyotrophy*, 88 Am. J. Phys. Med. Rehabil. 941-946, 942 (2009), filed as Ex. N on Apr. 28, 2020 (ECF No. 51-3) (“van Alfen II”). In response to Dr. Fink's arguments that literature like Van Eijk acknowledged that the diagnosis was tenable without an abnormal EMG result, Dr. Donofrio attempted to clarify EMG as a term, noting that it “is often used to describe only the needle examination whereas other health care providers use the term EMG to describe all parts of the electrodiagnostic exam,” including the NCS component. Second Donofrio Rep. at 2.

Applying the broader understanding of the term (which Dr. Donofrio appeared to endorse), it could not be said that a normal EMG result was common to brachial neuritis. *Id.*⁶ In fact the relevant literature did not actually consider in studied brachial neuritis cases whether full EMG diagnostic tests had been performed. *Id.*; van Alfen II at 942.

Dr. Donofrio also defended certain record evidence as supportive of his diagnostic contentions. He continued to embrace Petitioner's MRI results as inconsistent with brachial neuritis, although he agreed that an additional MRI, performed with gadolinium contrast,⁷ would have helped confirm the significance of the initial findings. Second Donofrio Rep. at 3. He disputed the importance of the fact that Petitioner had been treated with steroids or IVIG, maintaining that their use was commonplace when neurologic injury was suspected, and hence such treatments did not particularly corroborate the diagnosis. *Id.* Indeed, he deemed their alleged effectiveness as further undermining the diagnosis, since such immunomodulating treatments are not understood to have such a positive impact on brachial neuritis. *Id.* at 3-4. And he identified numerous other discrepancies in the record that he felt did not corroborate the diagnosis, such as inconsistency in observing scapular winging over the course of Petitioner's treatment. *Id.* at 4-5.

Regarding Petitioner's onset, Dr. Donofrio took issue with Dr. Fink's contention that a 2-20 day onset was reasonable, observing that (a) one of the very case reports relied upon for an HPV vaccine-brachial neuritis association observed that this timeframe had *not* been confirmed for the HPV vaccine, and (b) it was not consistent otherwise with Petitioner's one-day onset, which had not itself been substantiated by any reliable evidence. Second Donofrio Rep. at 5. In fact, the timeframe for onset of *any* form of brachial neuritis was not in Dr. Donofrio's view likely to be so short, given what was known about how long it would take for an immune response to occur after antigenic exposure. *Id.*; Institute of Medicine of the National Academies, *Adverse Effects of Vaccines: Evidence and Causality, Evaluating Biological Mechanisms of Adverse Events*, 57-58, 58 (Kathleen Stratton, et al.), filed as Ex. O on April 28, 2020 (ECF No. 51-4) (the "IOM Report II"). Indeed, even re-exposure to the same antigen (which would inherently be faster, as was arguably the case here, since Petitioner's second HPV dose is alleged causal of his injury) would not produce an immune reaction sooner than three to five days post-vaccination. *Id.*

⁶ In so asserting, Dr. Donofrio also noted that Van Eijk relied on an earlier item of literature for the conclusion that an EMG could be normal and not preclude a brachial neuritis diagnosis, but that this earlier-published item did not consider the combination of nerve testing that Dr. Donofrio deemed to be included under the EMG heading. Second Donofrio Rep. at 2; van Alfen at 7.

⁷ In some cases, a contrast material (typically gadolinium) will be injected through an intravenous line during an MRI scan. Mayo Clinic, *MRI Overview*, <https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768> (last visited July 20, 2021). The contrast material enhances certain details in the imaging, and in particular can reveal the existence of ongoing or present inflammation. *Id.*

Third Report

Dr. Donofrio's final report reacted to some of Dr. Fink's responses (in his own third report) to the special master's questions, although he limited his commentary to diagnostic issues. He first discussed whether it was accurate to characterize the onset of brachial neuritis after vaccination as "acute," questioning the reliability of one of the items of medical literature supported in behalf of this assertion. Third Donofrio Rep. at 1. Dr. Donofrio then noted that to the extent "acute" was meant to support the medical acceptability of a one-day onset, this contention was not consistent with other medical literature filed by Petitioner, which supported only a longer onset timeframe. *Id.*; Taras at 454 (stating that in 30-85% of the cases, an antecedent event can be found 3-14 days before the initial onset of pain). He also deemed such a short onset "highly unusual for an immunological vaccine reaction," adding that three days or more for a reaction was far better supported by medical science. Third Donofrio Rep. at 4.

Next, Dr. Donofrio reviewed the distinction he drew between literature pertaining to the common clinical features of brachial neuritis and what a young athletic person like Mr. Pelelo might experience. Third Donofrio Rep. at 1. Although he disclaimed specialized expertise in sports injuries, Dr. Donofrio did identify (based on some literature research he performed to respond to the issue) a small study of 22 swimmers that did not reveal brachial plexopathy, or some other neurologic source, to be the cause of their shoulder complaints. S. Rupp et al., *Shoulder Problems in High Level Swimmers – Impingement, Anterior Instability, Muscular Imbalance?*, 16(8) J. Sports Med. 557-565 (1995), filed as Ex. Q on Dec. 17, 2020 (ECF No. 60-2) ("Rupp"). He added that scapular winging was not itself specific to brachial neuritis, despite Dr. Fink's suggestions to the contrary. Third Donofrio Rep. at 1.

Dr. Donofrio's third report also spent additional time arguing with Dr. Fink about the legitimacy/adequacy of Petitioner's February 2016 EMG testing, and whether its findings were trustworthy, as well as the greater question of whether a "normal" EMG test result was consistent with brachial neuritis. Third Donofrio at 2. And he commented on several exhibits that (at the time of the preparation of this final report) had been recently filed. Many of these newly-filed exhibits were simply additional medical records or witness statements, although Dr. Donofrio did highlight one—a case report purportedly linking the HPV vaccine to brachial neuritis—that he found involved a different injury (proximal median nerve palsy), and that moreover had been *confirmed* by an abnormal EMG. *Id.* at 3; Taras at 455.

III. Procedural History

After filing this action in October 2017, Petitioner began gathering documents relevant to his claim and filing them into the record, completing the process the same month as filing. The petition was initially assigned to the Special Processing Unit of the Office of Special Masters (the "SPU") based on the supposition that it might be readily settled. However, after Respondent's Rule 4(c) Report (filed June 2018 (ECF No. 17)) revealed the intent to defend the claim, Petitioner filed

Dr. Fink's first expert report that August, prompting a responsive report from Dr. Donofrio in June 2019. The matter was thereafter transferred out of SPU. ECF No. 36.

Additional expert reports were filed by both sides thereafter, with the matter subsequently being reassigned to me in the summer of 2020. ECF No. 55. I allowed a final round of additional expert reports to be filed, and then informed the parties of my view that the case could properly be resolved on the papers. Petitioner's Motion for Ruling on the Record was filed in January 2021 (ECF No. 61) ("Mot."), and Respondent's Opposition filed in March 2021 (ECF No. 63) ("Opp."). No reply was filed, and the claim is now ripe for resolution.

IV. Parties' Respective Arguments

Petitioner offered a succinct brief arguing in favor of entitlement in this case, addressing in succession each of the three causation prongs from *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). First, he noted the other kinds of vaccines that have been associated with brachial neuritis, adding that case reports (some of which were filed in this matter) have also linked the HPV vaccine to the injury. Mot. at 1. He further reiterated the potential mechanisms outlined by Dr. Fink for how the vaccine could initiate the injury—either “direct antigenic attack” on the brachial plexus nerves, or “a focal inflammation of vessels of the nerves” that indirectly would cause nerve damage. *Id.* at 2. The fact that Petitioner had received one dose of the HPV vaccine already also impacted his exaggerated immune reaction to the second dose. *Id.*

Second, Petitioner endeavored to demonstrate how his medical history was consistent with the vaccine causing his brachial neuritis. He recalled the one-day onset of pain and weakness, observing this was consistent with the sudden/acute nature of brachial neuritis onset, as well as his subsequent course. Mot. at 2-4. Finally, Petitioner devoted the remainder of his brief to defending the time in which his onset began as medically acceptable, although in so doing he revisited Dr. Fink's attacks on the legitimacy of the normal EMG findings. *Id.* at 5-6. He otherwise maintained that the course of his injury reflected brachial neuritis despite some evidence of improvement, and disputed Dr. Donofrio's points that Petitioner's athletic endeavors could have played a role in causation. *Id.* at 7-9.

Respondent's brief was considerably longer, and included a more detailed overview of Mr. Pelelo's medical history. Opp. at 4-11. After a recitation of the legal standards governing a non-Table causation claim, Respondent attempted to demonstrate why Petitioner had not carried his burden of proof. As a general matter, Respondent contested that Petitioner had in fact been properly diagnosed with brachial neuritis, noting that the EMG testing did not corroborate the treaters' clinical symptom-oriented diagnosis, and arguing that Dr. Fink's assertion that brachial neuritis could exist even with negative EMG findings was unreliable, especially when contrasted with Dr. Donofrio's more well-founded contentions. *Id.* at 15-20. Respondent also maintained that

Petitioner’s clinical course did not reflect how brachial neuritis would commonly unfold, especially since Petitioner seemed at times to recover. *Id.* at 20-21.

Respondent next proposed that the three *Althen* prongs were unmet. Dr. Fink had not established a reliable and reputable theory regarding the HPV vaccine’s propensity to cause brachial neuritis, relying on limited items of literature that revealed how little was still known about the pathogenesis of brachial neuritis. Opp. at 21-23, 26-27. Dr. Fink otherwise relied too much on case reports or VAERS data⁸ that only established a temporal relationship between the HPV vaccine and brachial neuritis. *Id.* at 23-25. Petitioner also could not prove the HPV vaccine “did cause” his brachial neuritis, relying too heavily on the temporal association alone, without offering evidence of treater views as to vaccine causation. *Id.* at 27-29. And there were un rebutted alternative explanations for Petitioner’s injury, attributable to his physical activities as a swimmer and baseball player. *Id.* at 30. Finally, Respondent maintained that a 24-hour onset of vaccine-caused brachial neuritis was not medically acceptable, noting in particular that even the Petitioner’s most-helpful literature and case reports filed in the matter supported only an onset more than a few days—not less than one. *Id.* at 31-32.

V. Applicable Law

A. Standards for Vaccine Claims

To receive compensation in the Vaccine Program, a petitioner must prove that: (1) they suffered an injury falling within the Vaccine Injury Table (i.e., a “Table Injury”); or (2) they suffered an injury actually caused by a vaccine (i.e., a “Non-Table Injury.”) *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *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). In this case, Petitioner does not assert a Table claim.

For both Table and Non–Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(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 Enter. v. United States*, 6 Cl. Ct.

⁸ “VAERS,” or the Vaccine Adverse Event Reporting System, is a passive surveillance system maintained by the Center for Disease Control, in which anyone may file a report alleging that a vaccine caused a particular injury, illness, or death. As discussed by other special masters, the data provided by VAERS does not illustrate a causal connection; rather, VAERS exists to prompt further scientific investigation into potentially dangerous vaccines. *See, e.g., Tompkins v. Sec’y of Health & Human Servs.*, No. 10-261V, 2013 WL 3498652, at *9 n.25 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review denied*, 117 Fed. Cl. 713 (2014). VAERS reports are informal and unverified, and should not be confused with formal case reports in medical literature. *Tompkins*, 2013 WL 3498652, at *9 n.26. For these reasons, other special masters have consistently declined to rely on VAERS data as probative with regard to vaccine causation. *See, e.g., Analla v. Sec’y of Health & Human Servs.*, 70 Fed. Cl. 552, 558 (2006); *Ryman v. Sec’y of Health & Human Servs.*, 65 Fed. Cl. 35, 39–40 (2005).

476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). On one hand, proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). But on the other hand, 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*, 418 F.3d at 1278: “(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.” Each *Althen* prong requires a different showing and is discussed in turn along with the parties’ arguments and my findings.

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. However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (“[w]e have consistently rejected theories that the vaccine only “likely caused” the injury and reiterated that a “plausible” or “possible” causal theory does not satisfy the standard”); *see also Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

Petitioners may offer individual items of evidence pertaining to 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). No one “type” of evidence is required. 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 evidence standard.” *Andreu*, 569 F.3d at 1380. However, even though “scientific certainty” is not required

to prevail, the individual items of proof offered for the “can cause” prong must *each* reflect or arise from “reputable” or “sound and reliable” medical science. *Boatmon*, 941 F.3d at 1359-60.

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; *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 (“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 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, 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).

However, medical records and/or statements of a treating physician's views 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) (“there 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 also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master 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 den'd*, 100 Fed. Cl. 344, 356–57 (2011), *aff'd without opinion*, 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.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd 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 den'd* (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) (determining that 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; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven 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”), *aff'd*, *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. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United*

States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) (“[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.”)).

However, there are 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) (“like 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 (“[w]ritten 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)). Under *Daubert*, the 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).

However, in the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings—e.g., the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases 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) (“uniquely 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*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, 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 91997)); *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 den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. 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 (“[a]ssessments 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) (“this 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 numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all 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. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) (“[w]e 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) (“[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered”).

E. Standards for Ruling on the Record

I am resolving Petitioner's claim on the papers rather than via hearing (and the parties have not objected in their filings that I do so). The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Overview of Brachial Neuritis

The experts in this case agree that Parsonage-Turner syndrome and brachial neuritis interchangeably describe the same condition. *See, e.g.*, Second Fink Rep. at 1; First Donofrio Rep. at 6.⁹ The brachial plexus is located between the spinal nerve roots and the nerves of the arm, and is a bundle of nerves that relates to the sensory and motor function of the upper extremities. *Dorland's Medical Dictionary* 1440 (33rd ed. 2020). It can be injured in many ways, including trauma or infection, and such injury often leads to weakness or numbness. Donofrio First Rep. at 6. Brachial plexitis is the general term for injury to the plexus due to inflammation, while any other kind of unexplained plexitis is commonly called PTS or brachial neuritis. *Id.* Brachial neuritis often involves a finding of winged scapula due to involvement of the long thoracic nerve, and it

⁹ Literature filed in this case also refers to brachial neuritis as “neuralgic amyotrophy,” but recognizes the overlap in terminology. *See, e.g.*, VanEijk at 337.

also generally involves selective weakness of the muscles of the anterior interosseous nerve. *Id.* It is characterized by severe pain, muscle weakness, and atrophy. *Id.*

Although this case does not allege a Table claim, the requirements for the sole Table-recognized brachial neuritis injury (after receipt of vaccines containing a tetanus component) provide some useful insight into the contours of a vaccine-caused brachial neuritis injury. Under the Table (42 C.F.R. § 100.3(a)(I)(B)), causation for vaccine-caused brachial neuritis is presumed when symptoms begin within 2-28 days of the vaccination. The Table also requires corroboration from “[n]erve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus . . . before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve . . .” 42 C.F.R. § 100.3(c)(6)(i-iii). Of course, a non-Table claim is *not* subject to the same restrictions.

There are ample prior non-Table decisions associating vaccines containing a tetanus component with brachial neuritis.¹⁰ *See, e.g., Devonshire v. Sec’y of Health & Human Servs.*, No. 99-031V, 2006 WL 2970418, at *15 (Fed. Cl. Spec. Mstr. Sept. 28, 2006) (stating that it is well known that brachial neuritis can occur following a tetanus vaccination), *aff’d*, 76 Fed. Cl. 452 (2007); *DeGrandchamp v. Sec’y of Health & Human Servs.*, No. 01-413V, 2003 WL 21439670, at *7 (Fed. Cl. Spec. Mstr. May 15, 2003) (relying on IOM publications to find that in theory, the tetanus toxoid in Td vaccine can cause brachial neuritis). Literature offered in this case also supports this determination. *See, e.g., J. Miller et al., Acute Brachial Plexus Neuritis: An Uncommon Cause of Shoulder Pain*, 62(9) *Am. Fam. Physician*. 2067-2017, 2068 (Nov. 2000), filed as Ex. H on July 23, 2019 (ECF No. 39-6). However, I have identified no reasoned decisions finding that the HPV vaccine *specifically* can cause brachial neuritis.¹¹

I have previously decided two non-Table cases alleging different vaccines caused brachial neuritis, denying compensation in both—but in both instances because the claimant could not establish onset occurred in a medically acceptable timeframe. *See, e.g., Greene v. Sec’y of Health*

¹⁰ Prior decisions from different cases do not control the outcome herein. *Boatman*, 941 F.3d at 1358–59; *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). But special masters reasonably draw upon their experience in resolving Vaccine Act claims. *Doe v. Sec’y of Health & Hum. 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 therefore be remiss in ignoring prior cases presenting similar theories or factual circumstances, along with the reasoning employed in reaching such decisions. I therefore include this brief discussion to illustrate the framework for my determination—which in the end arises from a balancing of the evidence offered *in this case*.

¹¹ Some cases involving the HPV vaccine and brachial neuritis have resulted in settlement. *See, e.g., Hessel v. Sec’y of Health & Hum. Servs.*, No. 11-412V, 2012 WL 3140357 (Fed. Cl. Spec. Mstr. July 9, 2012). But they are of little guidance herein, because settled matters are not only non-precedential but do not contain reasoned evaluations of the science involving the capacity of the HPV vaccine to cause brachial neuritis. *See Randazzo v. Sec’y of Health & Hum. Servs.*, No. 18-1513V, 2021 WL 829572, at *4 (Fed. Cl. Spec. Mstr. Feb. 1, 2021) (discussing low relevance of settled SIRVA claims in comparison to reasoned decisions).

& Hum. Servs., No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (41-day onset after tetanus vaccine too long to be causal), *mot. for rev. den'd*, 146 Fed. Cl. 655 (Fed. Cl. 2020), *aff'd*, 841 Fed. App'x. 195 (Fed. Cir. 2020). Admittedly, *Greene* is mostly distinguishable, since not only did it involve a vaccine closely associated with brachial neuritis, but an onset far longer than relevant herein. But it stands for the proposition that even otherwise-causal vaccines may not be found to cause injuries that occur in an unacceptable timeframe post-vaccination—whether too short *or* long. *See Aguayo v. Sec'y of Health & Hum. Servs.*, No. 12-563V, 2013 WL 441013, at *4 (Fed. Cl. Spec. Mstr. Jan. 15, 2013) (onset of GBS fourteen weeks after flu vaccine too long to satisfy *Althen* prong three).

In an earlier decision—*Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184 (Fed. Cl. Mar. 24, 2017), *mot. for review den'd*, 2017 WL 3483352 (Fed. Cl. July 31, 2017)—I considered a claim that the Hepatitis A and B vaccines caused brachial neuritis. The earliest onset possible in *Garner* was even longer than *Greene*—45 days after vaccination, based on the first record documentation of any complaints by petitioner about arm or shoulder pain. *Garner*, 2017 WL 1713184, at *1. Respondent's expert, however, argued that the outer limit for latency after vaccination was four weeks. *Id.* at *8. I found this point to be dispositive, even though the claimant's *Althen* prong one showing was persuasive. *Id.* at *16.

II. Petitioner Has Not Carried His *Althen* Burden

The experts in this case hotly contest whether Mr. Pelelo *in fact* likely suffered from brachial neuritis. On this matter, there is evidence on both sides. Petitioner can point to consistent treater support for the diagnosis, as well as symptoms that reflect the alleged injury, such as pain and weakness of the left should and arm. *See Ex. 3* at 8, 15, 40.

Respondent, however, has noted that EMG/NCS testing did not corroborate the diagnosis, and that these results are very reliable. Dr. Fink did credibly establish that brachial neuritis could be present even in the absence of such abnormal test results, and he offered reliable literature to support his contention. *See, e.g., Van Eijk* at 339, 343-44. He also cited a case report that featured an initially-normal EMG result before a brachial neuritis diagnosis was obtained. *Taras* at 454-55. However, equally-reliable evidence suggests that the condition *generally* is less likely if the diagnostic testing outcome is normal. Dr. Donofrio persuasively established (over Dr. Fink's more scattershot objections) that these results should be paid heed—and they undermine the diagnosis substantially.

The context in which Petitioner experienced the injury also bears on the diagnosis. His age and background as an athlete might provide some factual bases for his injury independent of vaccination. Also, the course of his injury, which seemed to improve then worsen (but after a time when his athletic pursuits intensified) provides a tantalizing suggestion for an alternative basis for his injuries. Petitioner's expert, Dr. Fink, stated in his second report that “a mechanical injury (swimming) of different nerve elements,” may cause an injury of the brachial plexus. Second Fink

Rep. at 3. Dr. Fink backed away from this concession in his final report, however, instead asserting that “[w]ithout specific trauma to the brachial plexus it is not possible to invoke [] repetitive motion of the arm resulting in injury to the brachial plexus.” Third Fink Rep. at 3. Dr. Fink also noted as an example that certain aspects of the injury such as “winging of the scapula” were “unique to brachial plexitis.” *Id.* However, Dr. Donofrio rebutted this assertion and cited an article from the International Journal of Sports Medicine where five of twenty-two swimmers with shoulder problems had scapular winging and, in each of these instances, brachial plexopathy was “not thought to be the cause.” Third Donofrio Rep. at 1 (citing Rupp at 1).

In many cases, evaluating the evidence offered in support of, or against, the preferred diagnosis, in order to determine how that evidence preponderates, is critical to the case’s resolution. *Broekelshen*, 618 F.3d at 1346. Here, however, I need not do so despite the attention the issue was given by the experts—for it is clear from the record and filed submissions that two of the three *Althen* prongs have not been met, *even if* there was not dispute as to diagnosis. I will thus assume for sake of argument that the brachial neuritis diagnosis has preponderant support, despite the persuasive points made by Dr. Donofrio about the reliability of this conclusion. I address the prongs in order of their significance to my determination.

A. *Althen Prong One*

Petitioner’s showing on the “can cause” prong did not preponderantly support his allegations. Indeed, it was the weakest element of his overall case, and thus is grounds for dismissal regardless of how the other prongs are resolved.¹²

It is unquestionably true that *other* vaccines are associated with brachial neuritis—with one (tetanus) so persuasively linked that the Government has added a tetanus-brachial neuritis claim to the Table. But it is an axiomatic principle in the Program that petitioners do not prevail simply by analogizing their case to what is known about other vaccines; they must instead prove the vaccine *at issue* is causal. *Monzon v. Sec’y of Health & Hum. Servs.*, No. 17-1055V, 2021 WL 2711289, at *21 (Fed. Cl. Spec. Mstr. June 2, 2021). They also cannot bulwark a non-Table claim by noting how close they come to meeting a comparable Table claim’s requirements. *W.C. v. Sec’y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017). And this case does not involve a tetanus-containing vaccine in any event.

To establish that the HPV vaccine specifically can cause brachial neuritis, Petitioner mostly relied on case reports, a type of evidence recognized in the Program to offer faint causation support. *See, e.g., Campbell v. Sec’y of Health & Hum. Servs.*, 97 Fed. Cl. 650, 668 (Fed. Cl. 2011) (case reports “do not purport to establish causation definitively, and this deficiency does indeed reduce

¹² Because Petitioner must meet *all* three *Althen* prongs to prevail, I need not address Petitioner’s success in establishing the “did cause”/second prong of the *Althen* test. *Contreras v. Sec’y of Health & Human Servs.*, No. 05–626V, 2012 WL 1441315, at *1 (Fed. Cl. Spec. Mstr. Apr. 5, 2012), *rev’d on other grounds*, 107 Fed. Cl. 280 (Fed. Cl. 2012).

their evidentiary value”). Case reports are not without *any* evidentiary value, but they are weak proof of causation—a fact that is often readily acknowledged by their authors, as is true here. *See, e.g.,* Debeer at 4419.

Dr. Fink’s reports could not make up for the deficiency in reputable scientific or medical support offered for the “can cause” prong. He provided no reliable scientific or medical evidence showing that the antigens of the HPV vaccine (or for that matter the underlying wild virus it provides immunity against) could be reliably linked to brachial neuritis, and referenced no other medical research showing a connection. In addition, he personally possessed no demonstrated immunologic expertise that could shed light on the issue (as reflected in the fact that most of his expert contentions went to diagnosis rather than the crucial issue of causation). His reports otherwise were too general in their causal assertions.

Dr. Fink also did not provide a reliable biologic mechanism for how the vaccine would cause this injury. Although unquestionably petitioners need not *prove* a mechanism to prevail, it is fair for a special master to evaluate the claimant’s success in so showing when an attempt to do so is ventured—as here. *Morgan v. Sec’y of Health & Hum. Servs.*, 148 Fed. Cl. 454 (Fed. Cl. 2020). But Dr. Fink’s proposed mechanisms were highly speculative. He concedes in his reports that “the cause of post-vaccinial [sic] brachial plexitis is theoretical.” Third Fink Rep. at 4. Nevertheless, Dr. Fink asserts that vaccinations may cause brachial neuritis “if not [through] a direct antigenic attack by attenuated virus on brachial plexus nerves, then, a focal inflammation of vessels of the nerve [that] causes axonal damage, with unequal severity from one nerve to another.” *Id.* He goes on to suggest that autoantibodies may be involved because “autoantibodies... directed against peripheral nerve[s] can produce a polyneuropathy.” *Id.* Dr. Fink’s main support for these theories come from a single review article, however, which acknowledges its own tentative nature. P. Seror, *Neuralgic Amyotrophy. An Update*, 84 *Joint Bone Spine* 153-58, at 156 (2017), filed as Ex. 24 on Dec. 16, 2019 (ECF No. 46-3) (“[t]he pathophysiology of [brachial neuritis] remains uncertain,” and mechanistic proposals for how it advances (which include an autoimmune hypothesis) remain until now simple presumptions,” despite some evidence supporting immune-mediation).

The proposal that brachial neuritis’s pathophysiology occurs via a generalized, innate response to vaccination is also not helpful in this case in demonstrating causation. In some circumstances, it may be true that a petitioner can experience a transient reaction to a vaccination, like malaise or situs pain. But general responses that resolve short of the six-month period required to establish the severity requirement in Program cases, and that cannot otherwise be tied to the alleged injury, do not satisfy a petitioner’s burden. *Monzon*, 2021 WL 1736816 at *20. And here, insufficient evidence has been presented that would allow me to conclude that the mere triggering of an innate response to the HPV vaccine would be enough to evolve into brachial neuritis, absent connective evidence providing insight into how this might occur. It cannot be assumed that the HPV vaccine could cause brachial neuritis simply because it *is* a vaccine, administered prior to injury. Speculative literature like Martinez-Lavin, that considered whether other neuropathic

injuries might reflect some kind of “HPV vaccine syndrome,” do not say enough about brachial neuritis to be given significant weight.

Overall, Petitioner’s case seems mostly to rely on the fact that *other* vaccines have been deemed in the Program to cause the same injury. If other vaccines can cause brachial neuritis, Dr. Fink reasons, why not HPV as well? But the association between other vaccines, such as those containing a tetanus component, and brachial neuritis appear more attributable to aberrant reactions imposed by that specific component—not the general impact of vaccination. For example, a case report cited by Dr. Fink observes that, unlike case reports of brachial neuritis following the tetanus toxoid, “the HPV vaccine... does not contain a toxoid so *it remains unclear how it could have given rise to a neuritis[.]*” Debeer at 4418 (emphasis added). Vaccines are formulated differently to provide immunologic protections against different pathogens, so their components usually cannot be theorized to have a “one size fits all” impact. While there are *a few* injuries, like shoulder injury related to vaccine administration, or “SIRVA,” that may be caused by a number of vaccines interchangeably, the same has not been found to be true for brachial neuritis.¹³

In this case, neither expert possessed specific immunologic expertise to “overpower” the other simply based on personal credentials and established, well-grounded subject-matter familiarity with the functioning of the immune system and its bearing on this kind of neurologic injury. And I do not find this is a case where this particular issue goes against Petitioner because of the overall strength of Respondent’s expert’s showing (although on matters relating to brachial neuritis more generally, I *do* find that Dr. Donofrio’s opinion arose from more demonstrated expertise and reliable science than Dr. Fink’s). But Dr. Fink himself lacked the kind of specific immunologic expertise needed to breathe life into his causation theory, and his absence of professional expertise in the topic was damaging to the theory on its own (especially since *petitioners* bear the ultimate burden of proof in vaccine cases in any event). Petitioner did not carry his burden of proof on this first prong, and that assessment can be reached simply by looking at the evidence Dr. Fink *did* offer—it did not rise to a preponderant showing.

B. *Althen Prong Three*

Another deficiency in the evidence offered to substantiate the claim is the exceedingly short timeframe in which Petitioner’s post-vaccination symptoms onset occurred. The record

¹³ Indeed, a glance at the Table illustrates the problem of broad assumptions about the scope of vaccine-associated adverse events. For example, the Table allows claimants to seek recovery for SIRVA based on *twelve different* kinds of vaccines, including HPV. *See generally* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I). But the Table includes brachial neuritis *only* after receipt of tetanus-containing vaccines. 42 C.F.R. § 100.3(a)(I)(B). This reflects Respondent’s determination that medical science supports the conclusion that many vaccines can cause SIRVA, likely due to the common impetus for the injury (injection of antigen into the bursa sufficient to cause localized inflammation), which is independent of their varying contents. The same has not been found to be true of brachial neuritis.

establishes that Mr. Pelelo first experienced pain within 24 hours of vaccination. *See, e.g.*, Ex. 6 at 3; Pelelo Aff. at 1. But this is far too soon for an immune-mediated case of brachial neuritis, which the literature suggests would take several days to manifest, since the injury requires some degree of inflammation to develop before it is felt symptomatically. *See* IOM Report II.

Dr. Fink maintained in response that other literature suggested that brachial neuritis onset is felt “acutely,” but that term seems to have been employed in the relevant literature to mean “unexpected and severe,” rather than to describe a timeframe for onset. Bromberg at 3. Indeed, the case reports Petitioner places so much reliance upon *all* involve onset of more than 24 hours post-vaccination. *See, e.g.*, Debeer at 4417 (case report of brachial neuritis with onset one month after second HPV vaccination); Taras at 454 (case reported of alleged brachial neuritis with onset three days after second HPV vaccination). Thus, even if I had found that the HPV vaccine can cause brachial neuritis, the evidence does not preponderate in favor of the determination that it would likely manifest as quickly as it did so for Petitioner. This is especially so since Petitioner’s theory depends on a determination that the vaccine triggered an autoimmune process, which would most likely require some kind of adaptive immune response. Second Fink Rep. at 3. That kind of adaptive process is understood to take several days. *See Block v. Sec’y of Health & Hum. Servs.*, No. 19-969V, 2021 WL 2182730, at *1 (Fed. Cl. Spec. Mstr. Apr. 26, 2021) (time for antibody-driven peripheral neuropathy in question takes more than three days to begin). Dr. Donofrio credibly and persuasively established in his reports that even in the event of a speedier immune response attributable to a prior exposure to the HPV vaccine, onset for an immune-mediated, adaptive response (through the production of antibodies) would take more than even two days. Donofrio Second Rep. at 5.

As noted above, Vaccine Act cases involving brachial neuritis have been dismissed where onset was not demonstrated to be medically reasonable—most often because it was too long after vaccination. *See, e.g., Greene*, 2019 WL 4072110 (41 day onset too long); *Garner*, 2017 WL 1713184 (45 day onset too long). Here, onset is *too soon*—but this equally is a basis for the determination that the claim cannot succeed. *de Bazan v. Sec’y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (“we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late; in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked”).

CONCLUSION

Other vaccines have preponderantly been demonstrated in the Vaccine Program to be associated with the capacity to trigger brachial neuritis, and it is conceivable that science may eventually expand that list to include the HPV vaccine. But not nearly enough was demonstrated *in this case* to conclude that the HPV vaccine could also cause brachial neuritis, or in the very

short timeframe at issue. Accordingly, Petitioner has not met his burden of proof, and I am compelled to dismiss this claim.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.¹⁴

IT IS SO ORDERED.

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

¹⁴ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.