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

KIMBERLY PENDLETON,	*	
	*	No. 22-39V
Petitioner,	*	Special Master Christian J. Moran
v.	*	Filed: November 14, 2024
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ying Zhou, Law Office of Ying Zhou, Philadelphia, PA, for petitioner;
Emily Hanson, United States Dep't of Justice, Washington, D.C., for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

Kimberly Pendleton alleges that the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine she received on July 31, 2019, caused her to suffer from an on-Table Shoulder Injury Related to Vaccine Administration ("SIRVA"). Am. Pet., filed Oct. 4, 2024, at 4. Alternatively, Ms. Pendleton claims that her shoulder injuries were caused-in-fact by the vaccine. Id. However, Ms. Pendleton has not presented a theory to support her allegation that the vaccine was the cause-in-fact

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted in the website.

of her shoulder injury. Ms. Pendleton also has not established her claim alleging an on-Table SIRVA.

I. Medical History

Ms. Pendleton was born in 1970. Exhibit 8 at 5. On July 31, 2019, when Ms. Pendleton was 49 years old, she visited her primary care provider ("PCP"), Norriton Family Medicine, for an annual exam. Id. at 1. Her ongoing problem list included obesity, foot calluses, hot flashes, IBS, perimenopausal symptoms, and tobacco use. Id. She had no acute complaints, and there is no mention in the record of arm pain. Id. Ms. Pendleton received the Tdap vaccination. Id. at 5.

Thirty-four days later, on September 3, 2019, Ms. Pendleton returned to her PCP with a chief complaint of left arm pain going up her neck. Exhibit 2 at 34. (This appears to be an error, as most other records, including further notes from this same visit, report right arm pain). She stated that, "since the day of the shot," she had pain that was shooting in nature from the site of injection to the top of her shoulder in neck. She had not had any neck, shoulder, or arm issues prior to the vaccine. Id. Dr. Aysha Jilani recorded that Ms. Pendleton had "Pain from cervical spine to upper right arm with range of motion limited due to pain line." Id. She assessed Ms. Pendleton as having brachial neuritis and started her on a trial of baclofen, steroids, and physical therapy. If Ms. Pendleton did not respond to this treatment, Dr. Jilani planned to refer her to a physical medicine & rehabilitation ("PMR") specialist for an electromyography ("EMG") study and treatment. Id. at 35.

Ms. Pendleton returned to Dr. Jilani on September 17, 2019. Exhibit 2 at 37. Her chief complaint was right arm pain, and she reported that her arm had not "felt right" since her vaccination six weeks prior. Id. She had not improved with treatment, and stated that she felt worse. She had not been able to set up a physical therapy appointment. Ms. Pendleton described the pain as going down her shoulder to her neck, down to the right scapula, and now completely down her right arm. She also reported weakness in her arm. Id. Dr. Jilani's assessment was cervical radiculopathy with a possible brachial plexus injury. She wrote that Ms. Pendleton needed physical therapy to prevent a frozen joint, and that she should get a PMR evaluation for a definitive diagnosis. Id. at 38. She prescribed cyclobenzaprine and referred her to physical therapy and a PMR evaluation. Id.

On September 19, 2019, Ms. Pendleton had a physical therapy evaluation. Exhibit 2 at 56. Ms. Pendleton recounted that she did not have pain immediately following her vaccination, but "by the next day she was having severe [right] arm pain." Id. The pain worsened over time, and her symptoms were worse with movement of her right upper extremity or neck. She had taken to holding her right upper extremity at her chest, and she avoided turning her head to drive or talk to people. The pain began at the base of her neck and spread into her right upper extremity and down to her fingers and down her scapula. She described the pain as shooting, burning, tingling, and throbbing, and pain medications did not help. Id. Ms. Pendleton reported that she had no prior issues with her right upper extremity or neck, but was now unable to grip, lift, carry, reach, clean, do dishes, or cook. Id. at 57. She rated her pain as an 8 out of 10. Id.

The examination found that Ms. Pendleton's right upper extremity active range and passive range were limited, and that there was significant muscle guarding in her right shoulder. Exhibit 2 at 57. Her right upper extremity strength was within functional limits. Id. at 58. The assessment stated that her presentation was most consistent with cervical radiculopathy, although there were "no hard neuro[logical] signs present." Id. at 59. It was also noted that Ms. Pendleton had impairments in her cervical range of motion and motor control, and muscle guarding and limited neural/soft tissue mobility throughout the cervical and thoracic spine and right upper extremity. Her rehabilitation prognosis was fair, and it was predicted that she would benefit from skilled physical therapy with an eventual discharge to a home exercise program. Id.

On October 2, 2019, Ms. Pendleton had an EMG on her right arm. Exhibit 5 at 367. Ms. Pendleton recounted that after her vaccine, she had increased pain in her right arm, fever, and difficulty moving her arm. Id. It was now better, but she still had pain into her scapula and difficulty moving her neck and shoulder. She also reported tingling down her arm and into her fingers, migrating from her elbow to her hand. She reported that she sometimes had throbbing pain that could last 15-20 minutes and was worse at night in her shoulder and arm. She did not have symptoms on her left side, and she did not have previous injuries to her arm or neck.

The EMG study was abnormal. Exhibit 5 at 367. The impression noted evidence of right median neuropathy of the wrist of mild to moderate severity, with similar findings on the left.

After four visits, Ms. Pendleton was discharged from physical therapy on January 20, 2020. Exhibit 4 at 323. The reason given was: "because the patient did not return / dropped out." The Secretary notes that this discharge was five months and 20 days post-vaccination. Resp't's Rep. at 3.

Ms. Pendleton saw Dr. Abim Esrick at her PCP office on June 16, 2020 with a primary complaint of back pain that had started three days prior. Exhibit 2b at 403. The symptoms had started after work with no particular inciting or aggravating event. It was located in her right lower thoracic back. She described the pain as moderate-severe intensity, constant, and aggravated by prolonged standing, rotation, and using the stairs. Dr. Esrick assessed her as having a spasm of the thoracic back muscle. He and advised her to continue gabapentin and Tylenol, to do home exercises, to take time off work/return with restrictions, and to refrain from bending, twisting, lifting weights over 20 pounds, and standing from more than ten minutes at a time. Id. at 404.

A follow-up appointment with Dr. Esrick took place ten days later. Exhibit 2b at 408. Ms. Pendleton's symptoms had greatly improved, but not yet fully resolved. She could stand for longer than ten minutes, twist, and bend, but did not think she could lift more than 20 pounds. She was taking gabapentin and Advil but was not doing home exercises. Id. Ms. Pendleton was advised to continue her treatments and to return to work on light duty. Id. at 409. On July 15, 2020, Ms. Pendleton advised Dr. Mahalakshmi Srinivasan at her PCP office that her lower back pain had resolved a week prior, and she returned to full duty at work. Id. at 413-14.

Ms. Pendleton had another appointment with her PCP on September 5, 2020. Exhibit 2b at 418. Her chief complaint was "recurrent right arm pain/numbness/tingling" beginning "after a vaccine." It was noted that she improved after a lot of physical therapy. Gabapentin helped, but she had run out. Id. Dr. Srinivasan assessed her as having radiculopathy and right arm pain, and referred her to physical therapy and restarted the gabapentin. Id. at 419.

Ms. Pendleton went to Moss Rehab for physical therapy on October 7, 2020. Exhibit 4 at 324. Her history of present illness listed a one-month history of right neck, scapular, and upper extremity pain "that began when temperatures dropped." Id. at 327. It was noted that she was first seen nine months prior for the same condition "which she states began after receiving a tetanus shot." Id. She had no complaints during the summer, but now her pain was worse with use of her upper

right extremity. It had been diagnosed as radiculopathy. The assessment found that she had "impairments in CT mobility, CT soft tissue pain, and mild upper limb tension." Id. at 329.[2] The plan was for her to do one session per week for three weeks. Id. at 330.

On October 14, 2020, Ms. Pendleton had an appointment at her PCP office with Dr. Tejaswi Venigalla to follow-up after an ER visit for back pain. She was in significant pain after running out of cyclobenzaprine. Exhibit 2b at 424. She had "left" arm pain from vaccination (this appears to be an error). Id. She was ordered to continue cyclobenzaprine for her back spasm and continue gabapentin for her arm pain, and was referred to physical therapy. Id. at 425-26.

Ms. Pendleton returned to Moss Rehab on October 21, 2020 for another physical therapy session. Exhibit 4 at 334. She tolerated the session well but needed cueing to minimize guarding of her upper right extremity. Id. at 336. Her next session was on October 29, 2020. Id. at 338. She was described as doing well, and requiring cueing to avoid compensation and shrugging. Id. at 340.

On November 12, 2020, Ms. Pendleton had another physical therapy session. Exhibit 4 at 342. She again tolerated the session well, and was improving her right shoulder mobility and tolerance. Id. at 344.

Ms. Pendleton went to Dr. Srinivasan on June 23, 2021 for an employment physical. She reported that she had not worked for two years due to long hours and flair ups of pain in her back, but she was starting a new job soon. Exhibit 2b at 427. Her right arm pain was improving with gabapentin. Id. at 429. She was diagnosed with pain in her right arm, but there were no abnormal findings. Her gabapentin was refilled. Id.

On October 11, 2021, Ms. Pendleton went to her PCP office and saw Dr. Charles Cutler for low back pain. She rated it at a 7/10, and stated that it had started two days prior. She noted that she had pain like this "every time of this year." It was "shocklike," aggravated by movement, and relieved by sitting still and taking muscle relaxant or Tylenol. Exhibit 2b at 431. Ms. Pendleton was prescribed more gabapentin and was referred to physical therapy. Id. at 432.

[2] Given the context, "CT" may be an abbreviation for "cervicothoracic."

II. Procedural History

Ms. Pendleton filed her petition on January 11, 2022, alleging that the Tdap vaccine she received on July 31, 2019 caused her to suffer from a form of SIRVA known as shoulder impingement syndrome. She noted that she had previously received a Tdap vaccination in 2013 with no incident. Ms. Pendleton stated that "started to experience severe pain from the site of injection in her right arm to the top of her right shoulder and neck" approximately 24 hours after receiving the vaccine in July 2019. She described the pain as shooting in nature, limiting her right arm's range of motion, and putting her in moderate distress.

Along with her petition, Ms. Pendleton filed a Vocational Economic Evaluation from Gary and Katherine Young. Exhibit 6. The Youngs interviewed Ms. Pendleton on October 7, 2021 for the evaluation. Id. at 1. The Youngs explain that the Social Security Administration considers age, education, occupations, and transferable skills when adjudicating disability claims. In combination with the Social Security Administration's standards, the Youngs utilized the RAPEL methodology: Rehabilitation Plan, Access to the Labor Market, Placeability, Earnings Capacity, and Labor Force Participation. Id. at 1-2.

The Youngs reviewed Ms. Pendleton's medical history, noting that she had severe right arm pain following a tetanus shot, and stated that she was diagnosed with "a shoulder impingement injury." Exhibit 6 at 3. They opined that Ms. Pendleton's restrictions are permanent. Id. at 13. They noted that she was working towards furthering her education and becoming a Licensed Practical Nurse and then a Registered Nurse. However, the Youngs stated that she does not have enough stamina for a full day of work, and that she has lost dexterity in her right hand. These interfere with her aspirations. Id. The Youngs estimated past and future wage loss between $239,219 and $787,418. Id. at 19.

The case remained pending in the Special Processing Unit ("SPU") as the parties entered into litigative risk settlement discussions. See Resp't's Status Rep., filed Sept. 19, 2023. After the parties reached an impasse in their settlement negotiations, the Secretary filed his Rule 4(c) Report on January 17, 2024. The Secretary argued that compensation should be denied, as Ms. Pendleton's pain and reduced range of motion were not limited to her right shoulder, and therefore she did not satisfy the third requirement of the Qualifications and Aids to Interpretation. Resp't's Rep. at 6-7. Additionally, the Secretary argued that Ms. Pendleton did not meet the six-month severity requirement, as she did not report any pain for ten months. Id. at 7.

After reviewing the Secretary's assessment, the Chief Special Master commented:

> Petitioner may be successful in establishing the six-month sequela needed to satisfy the Vaccine Act's severity requirement. More problematic is the conflicting evidence regarding the nature and cause of Petitioner's symptoms, and I agree expert reports will likely be needed in this case to pursue either a Table or causation-in-fact SIRVA.

Order, issued March 22, 2024. The Chief Special Master further noted that there was "some evidence supporting a potential brachial neuritis Table injury," but that "substantial deficiencies" would need to be addressed, specifically the too-soon onset and the lack of EMG evidence. Additionally, Ms. Pendleton maintained that the brachial neuritis diagnosis was incorrect, and expressed no desire to pursue this claim. Id. The Chief Special Master authorized Ms. Pendleton to retain an expert, and the case was transferred out of SPU and reassigned to the undersigned. Id.

Ms. Pendleton filed an expert report from Dr. Asif M. Ilyas, a board-certified orthopedic surgeon who is also certified in hand surgery. Exhibit 11 at 5. Dr. Ilyas examined Ms. Pendleton and had the impression that she had "Right shoulder impingement/bursitis, caused by 'shoulder injury related to vaccine administration.'" Id. at 4. He based this on a review of her history and medical records, an evaluation of diagnostic studies, and on his own examination. Id. He stated that her shoulder pain had "continued unimproved since the date of vaccination." Id. at 5.

The undersigned then issued a template affidavit regarding onset, which Ms. Pendleton completed and filed on June 21, 2024. Exhibit 12. On July 22, 2024, the Secretary filed an expert report from Dr. Paul J. Cagle, a board-certified orthopedic surgeon with training in shoulder surgery. Exhibit A at 1.

Dr. Cagle opined that Ms. Pendleton's case was not a demonstration of SIRVA, stating that she did not meet the Table criteria. First, he noted that the first evidence of shoulder pain was dated more than a month after the vaccination and does not state that pain occurred within 48 hours. This record also references pain in the neck with concern for a neurologic origin rather than a shoulder origin. Exhibit A at 4. Next, Dr. Cagle stated that "there is a lack of definitive evidence demonstrating a true loss of range of motion in the shoulder." Id. at 5. Dr. Cagle

also highlighted that Ms. Pendleton's symptoms were frequently attributed to radiculopathy and/or neck/cervical pathology, and that there was no attempt to separate the shoulder from the neck symptoms. Id. Finally, Dr. Cagle saw no evidence of an objective shoulder injury to constitute a SIRVA, noting that there was no shoulder-specific examination or treatment. Id.

Dr. Cagle next addressed the Youngs' vocational report. He disagreed with their use of the term "impingement injury," stating that the correct diagnostic term is "impingement syndrome." Exhibit A at 5. He saw no objective evidence of impingement syndrome in the medical history, and believed it was unsupported. Id. at 5-6. He agreed with the Youngs about several diagnoses—allergic rhinitis, alopecia, elevated blood pressure, irritable bowel syndrome, low back pain, radiculopathy, and radiculopathy of arm—but noted that these are evidence of pain outside of the shoulder. Id. at 6. Dr. Cagle stated that he was "unaware of any scientific reference that supports impingement syndrome being a permanent condition," even as he has treated thousands of patients with the diagnosis. He saw no support for the Youngs' statement that hand dexterity was a reason for the limitations. Id.

Dr. Cagle noted that the first record mentioning the "impingement syndrome" was in the October 2, 2019 EMG report, which he stated was "a very strange place to make a diagnosis." Exhibit A at 6. He opined that the "impingement syndrome" came into the record after an EMG was performed when the treating provider "wanted to suggest that the EMG was not positive for a brachial plexus/nerve injury, and that perhaps an inflammatory pathology, such as impingement syndrome was possible." Id. at 6-7. The diagnosis was then propagated through the rest of the medical records.

Finally, Dr. Cagle addressed Dr. Ilyas's report. Dr. Cagle stated that there was a lack of evidence to support the diagnosis of right shoulder impingement/bursitis, as it would be very unusual for such to last for years given that it is a treatable condition. Exhibit A at 7. He also noted that Dr. Ilyas did not explain the "new-found change in shoulder range of motion" despite there being a full range of motion in numerous records post-vaccination. Dr. Ilyas also did not advance a literature-supported viable mechanism to explain how the vaccine could have caused these symptoms for five years. Id. Dr. Cagle concluded that this is not a demonstration of SIRVA; there is no evidence of a shoulder injury; there is no evidence of sustained loss of shoulder motion; and there is no evidence of a structural shoulder injury. Id. at 8.

A status conference was held on August 5, 2024 to discuss the parties' reports. Ms. Pendleton requested the opportunity to have Dr. Ilyas to file a rebuttal report. The undersigned advised that this would be the last opportunity for Dr. Ilyas to present a theory on causation-in-fact, and failure to do so would mean that Ms. Pendleton could only proceed on a SIRVA claim. Order, issued Aug. 5, 2024. The undersigned noted that Dr. Ilyas had examined Ms. Pendleton, and asked if the Secretary wanted Dr. Cagle to examine her as well. The Secretary stated that he was not requesting this at the time. Id.

Ms. Pendleton submitted Dr. Ilyas's second report on October 4, 2024. Exhibit 20. The majority of the report responds to Dr. Cagle's report. Dr. Ilyas reaffirmed his diagnosis and opinion. He stated that the records show that Ms. Pendleton reported pain "since the day of the shot". Id. at 1 (citing records from September 3, 2019). Dr. Ilyas strongly disagreed with Dr. Cagle's statement that there was concern for a neurologic origin of the pain rather than a shoulder origin. Id. at 2. He noted that the primary care physician who diagnosed Ms. Pendleton with brachial neuritis was not an orthopedist. Furthermore, Dr. Ilyas explained that brachial neuritis is the product of trauma to the arm or an inflammatory process, and results in a combination of pain, numbness extending into the hand, and isolated areas of muscular weakness. Dr. Ilyas opined that her symptomology was inconsistent with brachial neuritis, but consistent with shoulder impingement/bursitis related to vaccination. Id.

Dr. Ilyas also disagreed with Dr. Cagle's opinion that there is no definitive evidence of a true loss of range of motion in Ms. Pendleton's shoulder. Exhibit 20 at 2. He disputed that the records indicate she ever regained a full range of motion. He also opined that the treaters "were erroneously pursuing a neurological cause" of the symptoms and that there was never evidence of a nerve injury. Id. at 3. Rather, he stated that Ms. Pendleton's reports of shoulder pain were consistent.

Dr. Ilyas maintained his diagnosis of vaccine-related shoulder impingement/bursitis based on his exam and findings of a sore shoulder, decreased active range of motion, positive Hawkin's sign, and positive Neer sign. Exhibit 20 at 3. He also cited findings indicative of no radiculopathy, including lack of numbness in the hand and arm, full range of motion in the neck, 5/5 strength in all nerve distributions below the shoulder, and no radiation or pain distally. Id. He affirmed that there was evidence of "impingement syndrome," i.e., his own examination and the lack of evidence of a neurologic problem. Id.

Dr. Ilyas contested Dr. Cagle's reliance on the medical history provided by the Youngs, who are not medical doctors but vocational experts. Exhibit 20 at 3. He also opined that the diagnoses were inconsistent with the complaints of shoulder pain, and furthermore, contended that their vocational analysis "had nothing to do with [Ms. Pendleton's] medical diagnosis and/or injury causality."

As to Dr. Cagle's contention that should impingement syndrome is not permanent, Dr. Ilyas conceded that it is reversable when treated, but noted that Ms. Pendleton's injury was never formally treated by an orthopedist. Exhibit 20 at 4. He agreed that shoulder impingement syndrome does not directly impede dexterity, but "it can cause generalized upper extremity dysfunction limiting work ability." Id.

Dr. Ilyas also disagreed that the EMG being used to diagnose shoulder impingement syndrome would be "strange." Exhibit 20 at 4. The neurologist who mentioned the possibility would be qualified to opine on such.

Finally, Dr. Ilyas defended against Dr. Cagle's critiques of his first report, again citing his own examination as evidence of her shoulder impingement/bursitis; pointing to the lack of treatment to explain the duration of the symptoms; disputing that the records demonstrate a return to full range of motion; and citing to two articles, which were not filed.[3]

Notably absent from Dr. Ilyas's second report was an explanation of a theory by which the Tdap vaccine could cause an impingement injury. In his conclusion, he stated that Ms. Pendleton's "injuries do satisfy the *Althen* prongs for an off-table injury." Exhibit 20 at 5. He stated summarily:

> **Althen Prong 1: A medical theory causally connecting the vaccine and injury.** The diagnosis of impingement syndrome is casually connected to the Tdap vaccination of July 31, 2019.

[3] C.T. Wood and A.M. Ilyas, Shoulder Injury Related to Vaccine Administration: Diagnosis and Management, 4 J. Hand Surg. Glob. Online 111 (2022).

A.K. Harrison and E.L. Flatow, Subacromial impingement syndrome, 19 J. Am. Acad. Orthop. Surg. 701 (2011).

> **Althen Prong 2: A logical sequence of cause and effect showing the vaccine was the reason for the injury.** The clinical data I reviewed showed clear evidence of the onset of Ms. Pendleton's right shoulder complaints and symptoms triggered by the Tdap vaccine of July 31, 2019.
>
> **Althen Prong 3: A showing proximate temporal relationship between the vaccination and the injury.** The record does reflect Ms. Pendleton's complaints of pain and discomfort in the area of the vaccine injection in the required temporal period.

Id. at 5-6. Despite the lack of a specific theory, Ms. Pendleton amended her petition to add a claim "for cause-in-fact shoulder injuries resulting from the subject vaccine." Am. Pet., filed Oct. 1, 2024.

III. Standards for Adjudication

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

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

IV. Discussion

To receive compensation under the National Vaccine Injury Compensation Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e.,

an injury falling within the Vaccine Injury Table—corresponding to her vaccination, or (2) that she suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Ms. Pendleton asserts both an on-Table injury via her SIRVA claim and an off-Table shoulder injury caused in fact by the vaccine. Am. Pet., filed Oct. 1, 2024.

A. Off-Table Claim

An off-Table claim requires a petitioner to present "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The source of this evidence must be "medical records" or "medical opinion." 42 U.S.C. § 300aa–13(a)(1).

Under the first Althen prong, a petitioner must set forth a reliable theory to explain how a particular vaccine can cause the alleged injury; scientific certainty is not required. Althen, 418 F.3d at 1279-80. However, petitioners must propose a theory or mechanism, supported by a sound and reliable medical or scientific explanation. Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994).

Here, although Dr. Ilyas's report summarily states that Ms. Pendleton's impingement syndrome "is casually connected" to her Tdap vaccination, there is no attempt to explain *how* the flu vaccine would be capable of causing the injury. The Vaccine Act does not permit a petitioner to prevail based on her claims alone, "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa–13(a)(1). Neither Dr. Ilyas nor the medical records explain how the vaccine could have caused Ms. Pendleton's impingement syndrome. Thus, Ms. Pendleton cannot satisfy the first Althen prong. See Talbert v. Sec'y of Health & Hum. Servs., No. 18-699V, 2024 WL 1675338, at *19 (Fed. Cl. Spec. Mstr. Apr. 3, 2024).

Without a showing on each Althen element, a petitioner cannot receive compensation; thus, when a petitioner fails to establish one Althen prong, additional analysis is not required. Moreover, Ms. Pendleton has not set forth a theory against which to compare the facts of her case and determine if the Tdap vaccine actually did cause her injury. Nor is there a theory against which to evaluate whether the onset occurred within an appropriate timeframe. As with the first prong, Dr. Ilyas makes conclusory statements that there is "clear evidence"

that the Tdap vaccine "triggered" her symptoms, and that there was an onset "in the required temporal timeframe," but he does not elaborate. Exhibit 20 at 5-6. In the absence of a theory, Ms. Pendleton's claim fails under the remaining Althen prongs as well. Ms. Pendleton's off-Table claim is therefore dismissed.

B. On-Table SIRVA Claim

To satisfy the elements for an on-Table SIRVA claim, a petitioner must show that (1) she had no history of shoulder pain prior to vaccination, (2) the onset of pain occurred within 48 hours after vaccination, (3) the injury is confined to the shoulder in which she received the vaccine, and (4) there is no evidence of any alternative cause of her pain. 42 C.F.R. § 100.3(c)(10)(i)-(iv).

Ms. Pendleton has had sufficient notice of potential issues with her on-Table SIRVA claim. The Secretary argued in his Rule 4(c) Report that she did not meet the criteria for SIRVA. Resp't's Rep. at 5-7. Likewise, in the Order transferring the case out of SPU, the Chief Special Master commented that Ms. Pendleton would likely have trouble meeting the third criterion.

While Dr. Ilyas discusses Ms. Pendleton's range of motion in her shoulder, he does not discuss whether the injury is confined to the shoulder. The medical records, however, consistently indicate that the injury was not confined to Ms. Pendleton's shoulder. See, e.g., Exhibit 2 at 37 (pain described as going down her shoulder to her neck, down to the right scapula, and completely down the right arm); id. at 56 (physical therapy record of pain radiating from the base of the neck into the scapula and fingers); Exhibit 4 at 324 (history of right neck, scapular, and upper extremity pain); Exhibit 5 at 1 (difficulty moving neck and shoulders, pain into scapula, and tingling from right elbow into fingers); id. at 367 (pain into scapula and tingling migrating from elbow to fingers).

These medical records, which memorialize Ms. Pendleton's contemporaneous problems, are presumptively accurate. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). The Youngs' report also discusses neck pain and a loss of dexterity in Ms. Pendleton's right hand. Exhibit 6 at 3, 6. Although given an opportunity through the submission of reports from Dr. Ilyas, Ms. Pendleton has not presented a persuasive basis for finding that her pain was limited to her shoulder. Therefore, she cannot establish that she fulfills the regulatory definition for SIRVA. See Scott v. Sec'y of Health & Hum. Servs., No. 20-1982V, 2024 WL 4544335, at *19-20 (Fed. Cl. Spec. Mstr. Sep. 25,

2024) (the presence of neck pain / cervical radiculopathy precludes a petitioner from satisfying the third SIRVA criterion).

Accordingly, Ms. Pendleton is not entitled to compensation for her on-Table claim. (Given this finding regarding the third criterion, evaluating the fourth criterion is not required. It is also not required to assess whether any shoulder injury lasted longer than six months).

V. Conclusion

Ms. Pendleton merits admiration for her perseverance through her difficult course of pain. However, Ms. Pendleton has not shown that the Vaccine Program can compensate her, as she has not presented sufficient evidence for her off-Table claim, nor has she satisfied the elements for an on-Table SIRVA claim. Thus, the case is dismissed for lack of persuasive evidence.

The Clerk's Office is instructed to dismiss this case and to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline for any such submission, is available through the Vaccine Rules posted on the website for the Court of Federal Claims.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master