In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 3, 2024

LARI TALBERT,	*	
	*	Special Master Sanders
Petitioner,	*	
v.	*	No. 18-699V
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

David A. Tierney, Rawls Law Group (Richmond), Richmond, VA, for Petitioner.
Zoe Wade, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On May 17, 2018, Lari Talbert ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner later filed an amended petition on October 9, 2018. Petitioner alleged that the administration of the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine she received on October 19, 2016, caused her "debilitating pain, suspension tremor, restricted range of motion, and impingement of her right shoulder and arm[.]" Am. Pet., ECF No. 17. Petitioner alleged a Table injury claim as well as a causation-in-fact claim. *Id.*

After carefully analyzing and weighing all of the evidence presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has not met her legal burden.

[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), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act," "the Act," or "the Program"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

Petitioner failed to provide preponderant evidence that the Tdap vaccine she received on October 19, 2016, caused her to sustain a Table shoulder injury related to vaccine administration ("SIRVA") or an off-Table right shoulder injury. Accordingly, Petitioner, is not entitled to compensation.

I. Procedural History

Petitioner filed eight exhibits on May 18, 2018, including affidavits of Petitioner and her family members, immunization records, and medical records. *See* Pet'r's Exs. 1–8, ECF No. 6. Petitioner later filed an additional medical record and a statement of completion on June 26, 2018. Pet'r's Ex. 9, ECF No. 9-1; ECF No. 10.

On October 9, 2018, Petitioner filed her amended petition, adding a "Table injury" claim to her pleadings, in addition to the "causation-in-fact" claim. Am. Pet. The alleged injury is "debilitating pain, suspension tremor, restricted range of motion, and impingement of her right shoulder and arm." Amended Pet. at 1. Petitioner also filed three additional medical records. Pet'r's Exs. 10–12, ECF No. 18. On November 7, 2018, Petitioner filed one additional medical record and an amended statement of completion. Pet'r's Ex. 13, ECF No. 22-1; ECF No. 23.

Respondent filed a Rule 4(c) report on April 16, 2019, in which he recommended against compensation. *See* Resp't's Report, ECF No. 30.

On August 14, 2019, Petitioner filed an expert report from Daniel E. Carr, MD. Pet'r's Ex. 14, ECF No. 37. Respondent filed his expert report from Jennifer J. Winell, MD and Dr. Winell's curriculum vitae ("CV") on October 9, 2019. Resp't's Exs. A–B, ECF No. 38. On November 1, 2019, Petitioner filed Dr. Carr's supplemental expert report. Pet's's Ex. 15, ECF No. 39. On November 8, 2019, Respondent filed medical literature. Resp't's Ex. A, Tabs 1–7, ECF No. 41.

On August 22, 2022, the parties indicated that they would like to proceed with a ruling on the record. Informal Comm., docketed Aug. 22, 2022. Petitioner filed a motion for a ruling on the record on September 21, 2022. Pet'r's Mot., ECF No. 45. Respondent filed a response on November 21, 2022. Resp't's Resp., ECF. No. 47. Petitioner filed a reply on December 13, 2022. Pet'r's Reply, ECF No. 49. Petitioner also filed Dr. Carr's CV on December 16, 2022. Pet'r's Ex. 16, ECF No. 50-1.

This matter is now ripe for consideration.

II. Summary of the Relevant Evidence

A. Medical Records

i. Pre-vaccination History

Petitioner was 52 years old at the time of vaccination and her past medical history is significant for right arm and neck pain stemming from a fall at work in November 2009, right

carpal tunnel syndrome,[4] and mild degenerative disc disease[5] at L5-S1. Pet'r's Ex. 5 at 22, 27, 51, ECF No. 6-5; Pet'r's Ex. 10 at 7, 27, 30, 38, ECF No. 18-1. Petitioner also self-reported that she has been previously diagnosed with "disorders of the peripheral nerves,[6] neuromuscular junction and muscles." Pet'r's Ex. 5 at 66.

Petitioner sustained work-related injuries on November 16, 2009, which caused nerve damage to her right side, carpal tunnel syndrome in her right wrist, and back and neck problems. Pet'r's Ex. 10 at 5–7. The injuries were caused when Petitioner fell down wet stairs at her workplace, bracing herself with her right hand and arm. Pet'r's Ex. 10 at 6. A Workman's Compensation Initial Evaluation was performed by Dr. William P. Sanders at Green Clinic in Ruston, Louisiana on July 22, 2010. *Id.* Petitioner reported injury "to right shoulder, arm, side, and upper leg." *Id.* at 5. In the history of present illness, Dr. Sanders noted that Petitioner "has been under a physician[']s care for this previously." *Id.* at 6. Petitioner reported "pain in her right shoulder and into the wrist that it moves down her right side and into her right hip and leg . . . she describes a burning[-]type pain. She denies numbness or tingling." *Id.* Dr. Sanders referred Petitioner to radiology for an MRI and x-ray on her cervical spine,[7] as well as a physical therapy evaluation for possible rotator cuff[8] pathology. *Id.* at 7. On July 26, 2010, the MRI indicated "mild degenerative disc disease at C5-6 with mild narrowing of the bilateral neural foramina."[9] *Id.* at 12.

On August 25, 2010, Petitioner saw Dr. Michael Elias Ehrlich, a neurologist at Green Clinic in Ruston, Louisiana, upon referral from Dr. Sanders. Pet'r's Ex. 10. at 22. Dr. Ehrlich's plan included continuing Petitioner's physical therapy with modalities and requesting an MRI of the lumbar spine, EMG/nerve conduction studies ("EMG/NCS") of the neck, back, right arm, and leg, and an MRI of the right shoulder. *Id.* at 24. On November 19, 2010, Petitioner underwent an EMG/NCS. *Id.* at 29. Dr. Ehrlich's impression included "trace right carpal tunnel syndrome" and "earliest findings to herald a right lumbar radiculopathy."[10] *Id.* On December 15, 2010, Petitioner

[4] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." *Dorland's Illustrated Medical Dictionary* at 1794 (33rd ed. 2020) [hereinafter "*Dorlands*"].

[5] Degenerative disc disease "occurs when the cushioning in [the] spine begins to wear away." *Cleveland Clinic* (Mar. 27, 2024, 2:48pm), https://my.clevelandclinic.org/health/diseases/16912-degenerative-disk-disease. These spinal discs are "rubbery cushions between [ ] vertebrae . . . [which] act as shock absorbers and help [to] move, bend and twist comfortably." *Id.*

[6] The peripheral nervous system is "part of the nervous system consisting of nerves and ganglia outside the brain and spinal cord." *Dorland's Medical Dictionary Online* (Mar. 29, 2024, 2:01pm), https://www.dorlandsonline.com/dorland/definition?id=111878&searchterm=peripheral+nervous+system.

[7] The cervical spine is "the part of the spine comprising the cervical vertebrae." *Dorlands* at 1720.

[8] The rotator cuff is a "musculotendinous structure about the capsule of the shoulder joint, formed by the inserting fibers of the supraspinatus, infraspinatus, teres minor, and subscapularis muscles, blending with the capsule and providing mobility and strength to the shoulder joint." *Dorlands* at 436.

[9] A neural foramen "is an opening where a spinal nerve exits [the] spine and branches out to other parts of [the] body." *Cleveland Clinic* (Mar. 27, 2024, 2:59pm), https://my.clevelandclinic.org/health/diseases/24856-foraminal-stenosis.

[10] Lumbar radiculopathy is "any disease of lumbar nerve roots, such as from disk herniation or compression by a tumor or bony spur, with lower back pain and often paresthesias." *Dorlands* at 1547.

had an MRI of the lumbar spine, which revealed "mild degenerative disc disease at L5-S1 with mild narrowing of the spinal canal and bilateral neural foramina." *Id.* at 37.

Dr. Ehrlich continued as Petitioner's treating neurologist for Petitioner's worker's compensation injury, with regular follow-up appointments. On December 20, 2010, Dr. Ehrlich noted that Petitioner stated that physical therapy did not really help, and he advised Petitioner to obtain a right carpal tunnel wrist splint. Pet'r's Ex. 10 at 41. During a follow-up on January 24, 2011, Dr. Ehrlich noted that Petitioner reported the majority of her pain was "centered around the left forearm and arm around the elbow." *Id.* at 43. Dr. Ehrlich remarked that, "[f]or some reason we checked the right arm and both legs. [He did not] know why we didn't check the left arm." *Id.* Dr. Ehrlich continued, "[p]erhaps we didn't have approval to check four extremities." *Id.* He repeated that he did not know why they did not check the left arm but that they found right carpal tunnel syndrome. *Id.* Moving forward, Dr. Ehrlich's plan included a request to worker's compensation to refer Petitioner to Dr. Richard Ingram Ballard, an orthopedist, as well as conducting an EMG/NCS of only the left upper extremity. *Id.* Worker's compensation denied the request for the EMG/NCS. *Id.* at 48.

By May 4, 2011, Dr. Ehrlich prescribed a sample of Lyrica[11] for neuropathic pain at varying levels. *Id.* On June 16, 2011, Dr. Ehrlich added Zanaflex[12] for Petitioner's neuropathic pain. *Id.* at 54. Petitioner continued to see Dr. Ehrlich for follow-up appointments with complaints of neck, back, right arm, leg, and shoulder pain, with some alterations to her medications on August 8, 2011, November 1, 2011, February 1, 2012, May 4, 2012, August 13, 2012, November 13, 2012, March 13, 2013, July 1, 2013, November 11, 2013, February 10, 2014, March 10, 2014, and August 27, 2014. *See id.* at 61–120; Pet'r's Ex. 5 at 11–21. Throughout these appointments, the treatment plan remained mostly unchanged, besides slight alterations to Petitioner's medication. *See id.* On July 1, 2013, Petitioner discontinued Lyrica after expressing dissatisfaction. Pet'r's Ex. 10 at 115-120. Dr. Ehrlich prescribed a sample of Gralise[13] to be taken in conjunction with Zanaflex. *Id.* On November 11, 2013, Dr. Ehrlich discontinued Gralise and Zanaflex, with Petitioner to try samples of Trokendi XR.[14] Pet'r's Ex. 5 at 4. On February 10, 2014, the Trokendi XR was increased to 100 mg and the Zanaflex was resumed at 4 mg. *Id.* at 9.Throughout these appointments, the assessment generally stayed the same and included shoulder joint pain,

[11] Lyrica is the trademark name for "a preparation of pregabalin." *Dorlands* at 1074. Pregabalin has "anticonvulsant and antinociceptive effects, used in the treatment of neuropathic pain in diabetic neuropathy and postherpetic neuralgia" which is "administered orally." *Id.* at 1486.

[12] Zanaflex is the trademark name for "a preparation of tizanidine hydrochloride." *Dorlands* at 2060. Tizanidine hydrochloride is "used as a short-acting agent to manage the increased muscle tone associated with spasticity, as that related to multiple sclerosis or spinal cord injury" which is "administered orally." *Id.* at 1903.

[13] Gralise is the trademark name for "a preparation of gabapentin." *Dorlands* at 792. Gabapentin is "an anticonvulsant . . . used as adjunctive therapy in the treatment of partial seizures and the management of postherpetic neuralgia" which is "administered orally." *Id.* at 745.

[14] Trokendi XR is the trademark name for a preparation of an "extended-release version of topiramate." *Supernus Pharmaceuticals* (Mar. 27, 2024, 3:22pm), https://www.trokendixr.com/. Topiramate is "a substituted monosaccharide used as an anticonvulsant in the treatment of partial seizures" which is "administered orally." *Dorlands* at 1910.

orthopedic disorders of the spine, backache, lumbago,[15] cervical spondylosis,[16] pain in limb, carpal tunnel syndrome, cervicalgia (pain in neck), shoulder joint pain, chronic pain syndrome, right arm pain, and fibromyalgia.[17] *Id.* at 70, 80, 88, 110.

However, during a follow-up on January 19, 2015, Dr. Ehrlich noted that Petitioner's pain was "slowly getting worse with neck pain radiating to the arms with numbness and tingling of the hands as well as back pain radiating to the legs with numbness and tingling of the legs worse when she is sitting down at work." Pet'r's Ex. 5 at 21. Dr. Ehrlich also noted that Petitioner had not received an updated workup since 2010 and indicated that he would request worker's compensation approval for a new MRI of the cervical and lumbar spine, EMG/NCS, and a new desk chair at work. *Id.* at 25. During Petitioner's next follow-up on April 20, 2015, Dr. Ehrlich noted that worker's compensation denied the request for an updated MRI and EMG/NCS. *Id.* at 29. Dr. Ehrlich prescribed Tramadol,[18] and he advised Petitioner to secure the supportive desk chair, which was approved but not yet delivered. *Id.* at 29. Petitioner continued to see Dr. Ehrlich for follow-ups and pain management, with no reported changes on July 20, 2015, October 19, 2015, January 18, 2016, and July 27, 2016. *See id.* at 34–35, 39–40, 44, 49. Petitioner continued to see Dr. Ehrlich regularly for pain management, primarily through medication, including Topamax 100 mg, Zanaflex 4 mg, and Tramadol 50 mg. *Id.*

ii. Post -Vaccination Medical History

On Wednesday, October 19, 2016, Petitioner presented to her primary care physician ("PCP"), Dr. Bridgett Dawn Foreman, at University Health-Shreveport in Shreveport, Louisiana., to follow-up for asthma and worsening shortness of breath. Pet'r's Ex. 6 at 90–99, ECF No. 6-6. Petitioner also received a flu vaccine in her left deltoid and the Tdap vaccine in her right deltoid during this visit. *Id.* at 99.

Eight days later, on October 27, 2016, Petitioner followed up with Dr. Ehrlich regarding her worker's compensation injury. Pet'r's Ex. 5 at 51. Dr. Ehrlich reiterated that Petitioner required a new workup for her neck and back pain, including an MRI and EMG/NCS, because it had not been updated since 2009. *Id.* Dr. Ehrlich also noted that worker's compensation had not approved the previous requests for a workup and that he would send another request. *Id.*

Nearly a month later, on November 17, 2016, Petitioner messaged Dr. Foreman reporting right arm pain and stiffness since the vaccination via MyChart Communication, an online patient portal. Pet'r's Ex. 7 at 1, ECF No. 6-7. After no response, Petitioner sent another message on November 28, 2016. *Id.* at 2. On December 5, 2016, Dr. Foreman replied to Petitioner, indicating that this pain was unusual and that an examination of Petitioner's shoulder was needed. *Id.* at 3.

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[15] Lumbago is "a nonmedical term for any pain in the lower back." *Dorlands* at 1062.

[16] Cervical spondylosis is a "degenerative joint disease affecting the cervical vertebrae, intervertebral disks, and surrounding ligaments and connective tissue, sometimes with pain or paresthesia radiating along the upper limbs as a result of pressure on the nerve roots." *Dorlands* at 1725.

[17] Fibromyalgia is "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." *Dorlands* at 696.

[18] Tramadol is "an opioid analgesic used for the treatment of moderate to moderately severe pain following surgical procedures and oral surgery" which is "administered orally." *Dorlands* at 1920.

On December 12, 2016, Dr. Ehrlich performed an EMG/NCS on Petitioner for "neuropathic pain." Pet'r's Ex. 5 at 57. The studies revealed "mild right carpal tunnel syndrome" and "absent bilateral sural[19] and superficial peroneal[20] nerve responses." *Id*.

Petitioner returned to Dr. Foreman on February 1, 2017. Pet'r's Ex. 6 at 124. Petitioner reported that she "still ha[d] pain in her right shoulder after receiving [Tdap] in that arm." *Id.* Petitioner noted that she was seeing a neurologist, Dr. Ehrlich, for her previous nerve damage. *Id.* Upon a physical examination, Dr. Foreman further found Petitioner to have "[l]imited [range of motion] of right shoulder due to pain[]" and tenderness to palpation but no swelling or erythema. *Id.* at 125. Dr. Foreman advised Petitioner that if her shoulder pain continued and no etiology was found with Dr. Ehrlich, then imaging may be required. *Id.* at 130. Dr. Foreman further advised Petitioner to return in two months and to take Tylenol in the meantime. *Id.*

Two days later, on February 3, 2017, Petitioner followed-up with Dr. Ehrlich. Pet'r's Exhibit 5 at 65. Petitioner reported that her right shoulder pain was "now worse" and that "when she moves her shoulder[,] she has severe pain at the top of the shoulder joint." *Id*. Dr. Ehrlich noted that Petitioner's December 12, 2016 EMG/NCS showed mild abnormalities, and he observed no musculoskeletal abnormalities during a physical exam. *Id.* at 65, 69. Dr. Ehrlich ordered an MRI of Petitioner's right shoulder for possible rotator cuff injury and advised Petitioner to follow-up in a month. *Id.* at 69. The MRI request was denied by worker's compensation. *Id.* at 71–75. Dr. Ehrlich further ordered Petitioner to begin physical therapy three times a week for six weeks, for her back and neck. *Id.* at 69. However, Petitioner did not begin this physical therapy until May 22, 2017. [21] *See* Pet'r's Ex. 6 at 266.

Petitioner sent another message via MyChart Communication to Dr. Foreman on March 8, 2017, reporting continued post-vaccination pain and requesting that Dr. Foreman examine her right shoulder at her upcoming visit, scheduled for March 22, 2017. Pet'r's Ex. 7 at 4–5. On March 22, 2017, Dr. Foreman performed a physical examination of the shoulder, which revealed "[l]imited [range of motion] of right shoulder due to pain[, l]imited abduction and extension[,]" and tenderness to palpation. Pet'r's Ex. 6 at 238. Dr. Foreman diagnosed Petitioner with right shoulder impingement. *Id.* Dr. Foreman instructed Petitioner to receive a steroid injection into her right shoulder, which she received on March 29, 2019. *Id.* at 248–250. Dr. Foreman further referred Petitioner to physical therapy for evaluation and treatment. *Id.* at 228–241.

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[19] The sural nerve is the "medial sural cutaneous nerve and sural communicating branch of lateral sural cutaneous nerve" located on the "skin on back of leg, and skin and joints on lateral side of heel and foot." *Dorlands* at 1242.

[20] The superficial peroneal nerve is "a mixed nerve that carries sensory information from the anterolateral aspect of the leg and the greater part of the dorsum of the foot (except for the first web space)." Superficial Peroneal Nerve Block, *National Library of Medicine* (Mar. 27, 2024, 4:57pm), https://www.ncbi.nlm.nih.gov/books/NBK537363/#:~:text=The%20superficial%20peroneal%20nerve%20(superficial,for%20the%20first%20web%20space).

[21] Petitioner did not begin her physical therapy treatment until May 22, 2017, after Dr. Foreman also referred Petitioner to Jason Copelin at University Health-Shreveport. Pet'r's Ex. 6 at 267. It is unclear why Petitioner did not immediately begin physical therapy.

Later that month, on March 29, 2017, Petitioner followed up with Dr. Ehrlich, who noted that Petitioner "had severe shoulder pain since she fell around 2009 or 2010 . . . ." Pet'r's Ex. 5 at 70. He continued that Petitioner reported worsening right shoulder pain since her October 2016 Tdap vaccination. *Id.* He noted that Petitioner had developed a suspension tremor and pain with right shoulder movement. *Id.* Dr. Ehrlich also indicated that he would attempt to refer Petitioner to an orthopedist, Dr. Ballard. *Id.* at 74.

Later that day, Petitioner presented to Dr. Foreman's office and saw Dr. Edward Allan Griffin, an internist, and Dr. Foreman, who diagnosed her with subacromial impingement of her right shoulder. Pet'r's Ex. 1 at 5; Pet'r's Ex. 6 at 240–54. Petitioner received a steroid injection in her right subacromial joint. *Id.* On April 24, 2017, Petitioner had a follow-up visit with Dr. Ehrlich, who noted that Petitioner had received a steroid "shot in her right shoulder which didn't really help." Pet'r's Ex. 5 at 75–80.

Petitioner attended nine physical therapy sessions with physical therapist Jason Copelin for her right shoulder pain from May 22 to July 25, 2017. Pet'r's Ex. 6 at 262–272. Initially, PT Copelin noted Petitioner's presentation was:

> [C]onsistent with subacromial impingement in the [right] shoulder. Tenderness to palpation was [noted] in the . . . supraspinatus, [Line Hops] of the biceps, and infraspinatus. [Petitioner] lacks [right] shoulder [range of motion] in all planes with elevation being the most limited. Special testing of the [right] shoulder was positive for hawkin[]s,[22] neer,[23] empty can,[24] and [Petitioner] demonstrated a painful arc. Decreased strength noted in the right shoulder and scapular stabilizers."

Id. at 271. After nine sessions, Petitioner experienced "slightly better [range of motion], although she continued to report pain." *Id.* at 400. Petitioner also requested a discharge from physical therapy because of upcoming medical events, with Mr. Copelin noting that "[s]he had not met all of her goals set at initial eval, but has made good progress." *Id.*

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[22] The Hawkins/Kennedy test is "commonly used to identify possible subacromial impingement syndrome." *Physiopedia* (Oct. 30, 2023, 2:43pm), https://www.physio-pedia.com/Hawkins / Kennedy Impingement Test of the Shoulder. To perform the test, "[t]he examiner places the patient's arm shoulder in 90 degrees of shoulder flexion with the elbow flexed to 90 degrees and then internally rotates the arm. The test is considered to be positive if the patient experiences pain with internal rotation." *Id.*

[23] The Neer Test is "commonly used to identify possible subacromial impingement syndrome." *Physiopedia* (Oct. 30, 2023, 2:43pm), https://www.physio-pedia.com/Neer_Test. To perform the test, "[t]he examiner should stabilize the patient's scapula with one hand, while passively flexing the arm while it is internally rotated. If the patient reports pain in this position, then the result of the test is considered to be positive." *Id.*

[24] The Empty Can Test is "used to assess for lesions of the supraspinatus muscle and supraspinatus tendon." *Physiopedia* (Oct. 30, 2023, 2:43pm), https://www.physiopedia.com/Empty_Can_Test. To perform the test, "[t]he patient's arm should be elevated to 90 degrees in the scapular plane, with the elbow extended, full internal rotation, and pronation of the forearm. This results in a thumbs-down position, as if the patient were pouring liquid out of a can. The therapist should stabilize the shoulder while applying a downwardly directed force to the arm, the patient tries to resist this motion. This test is considered positive if the patient experiences pain or weakness with resistance." *Id.*

Petitioner presented to Dr. Ballard at Green Clinic on July 20, 2017. Pet'r's Ex. 5 at 81–87. Petitioner's chief complaint was a right shoulder injury after she "fell down stairs at work" in 2009. *Id.* at 81. Petitioner described the pain as "an achy pain that has a pulling and ripping sensation" that is "worse at night." *Id.* Petitioner also reported that she had "difficulty reaching, holding, and lifting objects" and that she had "little relief with [over the counter] meds and prescription meds." *Id.* Petitioner rated her pain as an 8/10. *Id.* Dr. Ballard noted that Petitioner "had a recent fall downstairs at work resulting in a jamming type of injury to her shoulder." *Id.* Dr. Ballard also noted that Petitioner's shoulder seemed weak but not unstable. *Id.* Dr. Ballard diagnosed Petitioner with a rotator cuff strain, refilled her Zanaflex, directed Petitioner to begin vigorous physical therapy, and directed her to return in 4 to 6 weeks. *Id.* Petitioner returned to Dr. Ballard on August 3, 2017. *Id.* at 87-88. Dr. Ballard noted that Petitioner had continuing pain despite medication and therapy and suggested an MRI of the shoulder. *Id.*

On August 23, 2017, Petitioner followed up with Dr. Foreman for primary care and noted that she "still has pain in her right should[er]" and is planning to get an MRI. Pet'r's Ex. 6 at 429.

On September 1, 2017, December 15, 2017, March 16, 2018, and June 15, 2018, Petitioner was seen by Dr. Brian Larry Stucki, a neurologist at Green Clinic, for carpal tunnel flares and continued pain in her right shoulder, neck, and back following her fall in 2009. Pet'r's Ex. 5 at 90, 100, 107, 333. Petitioner received a right carpal tunnel release from Dr. Jorge Alvernia-Silva at Green Clinic on July 30, 2018. Pet'r's Ex. 11 at 341–42, ECF No. 18-2.

On September 7, 2017, Petitioner followed up with Nurse Practitioner ("NP") Robert Garrett at Green Clinic for her "right rotator cuff strain." Pet'r's Ex. 5 at 95. The treatment plan included direction to "seek approval for right shoulder MR and X-ray from work[ers] comp[ensation]" for a muscle or tendon strain of the right shoulder rotator cuff. *Id.*

On May 30, 2018, Petitioner followed up with Dr. Foreman for primary care. Pet'r's Ex. 9 at 28. Dr. Foreman ordered a shoulder MRI. *Id.* at 36. On September 7, 2018, Petitioner had a shoulder MRI without IV contrast. Pet'r's Ex. 13 at 5. The MRI impression was "[f]raying of bursal surface and undersurface of the supraspinatus[25] with no full thickness perforation nor tear.

[25] Supraspinatus is "the smallest of the [four] muscles which compromise the rotator cuff of the shoulder joint specifically in the supraspinatus fossa. It's considered as the most superiorly located of the rotator cuff muscles." *Physiopedia* (Mar. 29, 2024, 1:44pm), https://www.physio-pedia.com/Supraspinatus.

Partial thickness under surface tear at insertion of infraspinatus.[26] Type III acromion.[27] Significant [acromioclavicular arthritis[28]]. Deltoid muscle lipoma."[29] *Id.*

Petitioner submitted a letter dated September 14, 2018, from Dr. Stucki. Pet'r's Ex. 12 at 1, ECF No. 18-3. Dr. Stucki wrote, "[t]hough [Petitioner] did have pain in her shoulder[prior to her injection,] she is reporting today that it did not become focal pain like it currently is until she had an injection in her right lower deltoid muscle in October 2016." *Id.* He noted that Petitioner "was being treated for cervical radiculopathy[]" and that he had been treating her since 2017. *Id.* Dr. Stucki wrote that he had "not treated her for focal shoulder/upper arm pain as it appeared to be unrelated to her previous worker's comp claim." *Id.*

On September 14, 2018, Petitioner followed up with Dr. Stucki for "neck pain and low back pain for workman's comp." Pet'r's Ex. 10 at 195. As of this date, Petitioner was still prescribed Tramadol HCL 50 MG tablets twice daily as needed for pain. *Id.* at 197.

B. Affidavits

i. Petitioner's Affidavit

Petitioner's affidavit was executed on May 16, 2018. Pet'r's Ex. 1 at 7, ECF No. 6-1. Petitioner recalled her vaccinations on October 19, 2016, where she "received the influenza vaccine in [her] left deltoid first and did not experience any discomfort." *Id.* at 1. Petitioner was then "given the Tdap vaccination in [her] right deltoid . . . [She] noticed that the Tdap vaccination was administered at a somewhat higher location in comparison to the influenza vaccination [she] had just received in [her] opposite arm." *Id.* Further, Petitioner recalled "flinching from the discomfort [she] felt when the Tdap vaccination was administered and Nurse Carson asking [her] why [she] made the jumping motion." *Id.* Petitioner "replied that [she] had felt a strange sensation upon administration of the vaccine, or something to that effect." *Id.* She also asserted that during this medical visit, she was "told to expect some pain and discomfort for approximately three days to a week" and use her arms as much as possible. *Id.* Petitioner averred that upon administration of the vaccine, she "felt discomfort in [her] right shoulder that has not subsided since." *Id.* at 2.

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[26] Infraspinatus is a "thick, triangular muscle; one of the [four] muscles which compromise the rotator cuff of the shoulder." *Physiopedia* (Mar. 29, 2024, 1:46pm), https://www.physio-pedia.com/Infraspinatus?utm_source=physiopedia&utm_medium=search&utm_campaign=ongoing_internal.

[27] A type III acromion is one of four shapes of the acromion, also known as a "hooked" acromion, characterized by a "hooked shape" of the most anterior portion of the acromion, "down-sloping in the anterior-third of the acromion[,]" and "associated with increased incidence of shoulder impingement." *Radiopaedia* (Mar. 29, 2024, 1:50pm), https://radiopaedia.org/articles/acromial-types?lang=us.

[28] Acromioclavicular arthritis "develops when the cartilage in the [acromioclavicular] joint begins to wear out. With this condition, there usually [is] pain that limits the motion of the arm." *UC Davis Health, Department of Orthopaedic Surgery* (Mar. 29, 2024, 1:56pm), https://health.ucdavis.edu/orthopaedics/specialties/sports-medicine-info/ac-joint-rehab.html.

[29] Lipoma is "a benign, soft, rubbery, encapsulated tumor of adipose tissue, usually composed of mature fat cells[.]" *Dorlands* at 1049.

Petitioner further alleged that in the days following the vaccination, she noticed "that the pain in her right shoulder and arm were progressively getting worse, that she was losing range of motion, and that her arm would often lock in place if she reached above shoulder-height and would have to be coaxed back to its resting position." *Id.* Petitioner stated that the "pain began to radiate to [her] neck and even across her body to her left arm." *Id*. Petitioner was unable to reach around her body to wash, buckle her bra, raise her arm above her shoulder to comb her hair, put on or take off tops, or extend to wipe after a bowel movement. *Id.* Petitioner did not find relief with acetaminophen or opioid pain medication and muscle relaxants, which were prescribed for her 2009 work injury. *Id.* Petitioner attested that she made involuntary audible groans and screams at any given moment due to shoulder pain and had difficulty sleeping. *Id.* By November 17, 2016, the pain became unbearable, and Petitioner reached out to Dr. Foreman via MyChart. *Id.*

Petitioner stated that, as of the date of this affidavit, she rated her pain as a four out of ten on a regular basis. *Id.* at 4. Petitioner stated that "[s]ince receiving the Tdap vaccination in October of 2016[, her] professional, personal, and family life has changed drastically." *Id.* As an executive assistant, Petitioner experienced pain from prolonged typing. *Id.* at 5. Tasks that Petitioner previously completed either required more time and effort or were no longer possible. *Id.* Such tasks include carrying supplies upstairs from storage and setting up traffic barricades. *Id.* Petitioner further stated that her injury has impacted her involvement at church, where she can no longer clap or play tambourine in the choir or participate in semi-annual cleanings. *Id.*

Additionally, Petitioner no longer participates in her various extracurricular activities, including running, mountain climbing, dancing, bowling, and playing basketball and volleyball. *Id.* at 6. Petitioner also struggles to play with her five-year-old granddaughter, plan family gatherings, and take care of her elderly mother. *Id.* Further, Petitioner struggles to take care of household chores and find comfortable sleeping positions. *Id.* Petitioner concluded her affidavit by stating:

> [She] truly believe[s] that if [she] had not received the Tdap vaccination on October 19, 2016, [she] would not have suffered from right shoulder impingement; [she] believe[s she] would still be able to work in the same manner [she] used to, fill all of the roles within [her] family and community that [she] previously have filled, and be able to live a healthy and active lifestyle.

Id. at 7.

ii. Affidavit of Brenda Berry

Petitioner submitted an affidavit executed on April 20, 2018, by Brenda Berry, Petitioner's first cousin. Pet'r's Ex. 2 at 1–2, ECF No. 6-2. Ms. Berry stated that Petitioner is like a "sister" and that they speak on the phone nearly every day. *Id.* at 1. Specifically, Ms. Berry spoke to Petitioner both before and after the October 19, 2016 appointment where Petitioner received the Tdap vaccine. *Id.* Ms. Berry stated, "[Petitioner] told [her after the appointment] that the Tdap vaccination that was administered in [Petitioner's] right arm was very painful and that her shoulder was still hurting." *Id.* Petitioner spoke to Ms. Berry about her worsening pain, including difficulty raising and using her right arm and shoulder, inability to sleep comfortably, and involuntary

screams and cries due to pain with movement. *Id.* Ms. Berry advised Petitioner to contact her doctor because of the symptoms. *Id.* Further, Ms. Berry recalled Petitioner describing how difficult it was to function in everyday life, including "getting in and out of her car, putting on her seatbelt, combing her hair, dressing and undressing, typing while at work, etc." *Id.* at 2. Finally, Ms. Berry concluded that "[Petitioner] is limited as a result of this vaccination []" and that Ms. Berry had "never known [her] cousin to be this incapacitated in any way whatsoever." *Id*.

iii. Affidavit of Katrina Malone

Petitioner submitted an affidavit executed on April 20, 2018, by Katrina Malone, Petitioner's niece. Pet'r's Ex. 3 at 1–2, ECF No. 6-3. Ms. Malone recalled Petitioner complaining of pain one week after the vaccination and reporting that she felt no relief from Tylenol and her prescribed opioid medicine. *Id.* Further, Petitioner was always "full of energy and full of fun . . . [but since the vaccine,] she cannot play with [her nephews, ages ten and five-years-old] like she used to." *Id.* at 1. Ms. Malone also recalled how Petitioner used to help wash and style her hair but can no longer do so because of the shoulder pain. *Id.* at 2. Ms. Malone described Petitioner since the vaccination as "no longer the outgoing and happy-go-lucky person that [she] has known all [of her] life – her pain and fear of causing additional pain have been debilitating to her." *Id.* Ms. Malone stated that "[p]rior to [the vaccination], [she] had not once ever heard [Petitioner] complain of any shoulder pain." *Id.*

C. Expert Review

i. Expert Backgrounds

1. Petitioner's Expert, Daniel E. Carr, M.D.

Dr. Carr received his medical degree from the University of Vermont in 1980. Pet'r's Ex. 14 at 1. He then completed a yearlong surgical internship at the University of Utah followed by orthopedic residency at the University of Vermont. *Id.* While Dr. Carr has retired from active operations, he continues to see patients at a local free medical clinic. *Id.* Dr. Carr is an orthopedic surgeon who was board certified for 30 years with a sub-specialization in sports medicine and injuries of the shoulder. *Id.*

Dr. Carr began his practice in sports medicine at the Scott Orthopedic Center in Huntington, West Virginia in 1985. *Id.*; Pet'r's Ex. 16 at 1, ECF No. 50-1. He also served as head team physician at Marshall University with a practice concentration in sports injury, trauma, and injuries of the shoulder. *Id.* In this role, Dr. Carr was the designated regional expert for injuries of the shoulder region, "enabling [him] to treat thousands of them during [his] 9[-]year tenure in West Virginia." *Id.* In 1994, Dr. Carr moved to Williamsburg, Virginia to begin a private practice while also serving as team physician at the College of William and Mary and Christopher Newport University. *Id.* Dr. Carr was also involved with the U.S. Olympic Medical Program, including Head Physician at the 2002 Winter Olympics and the 2009 Pan American Games. *Id.*

Throughout Dr. Carr's career, he has "treat[ed] numerous injection (vaccine and non-vaccine) injuries . . . and personally administered innumerable injections about the shoulder." *Id.*

His practice has continued to surround sports medicine and the shoulder. *Id.* At Dr. Carr's current practice with the local free medical clinic, he "routinely sees injuries and chronic issues involving the shoulder. This frequently involves giving injections about the shoulder[,] ordering and reviewing MRI's[, and] . . . prescribing Physical Therapy." *Id.* In his practice, "[o]ne of the most common diagnoses is impingement of the shoulder." *Id.*

2. Respondent's Expert, Jennifer J. Winell, M.D.

Dr. Winell is a board-certified orthopaedic surgeon. Resp't's Ex. A at 1, ECF No. 38-1. Dr. Winell received her medical degree from New York University School of Medicine in 1996, followed by residency in Orthopaedic Surgery at the New York Orthopedic Hospital. Resp't's Ex. B at 1, ECF No. 38-2; Resp't's Ex. A at 1. During residency, Dr. Winell trained under Dr. Louis Bigliani, "one of the fathers of modern shoulder surgery," where she "directly cared for hundreds of patients with multitudes of shoulder pathology." Resp't's Ex. A at 1. Dr. Winell also has specialty training in pediatric orthopaedics and currently practices at the Children's Hospital of Philadelphia. *Id.* Additionally, Dr. Winell is an assistant professor of orthopaedic surgery at the Perelman School of Medicine, University of Pennsylvania. *Id.* at 1–2.

Currently, Dr. Winell's practice is in general pediatric orthopaedics, including a large sports medicine component. *Id.* at 2. Dr. Winell "routinely treat[s] patients with upper extremity trauma both acute and chronic in nature." *Id.* Additionally, Dr. Winell has published articles in general pediatric orthopedics and sports medicine in peer-reviewed journals. *Id.* She also gives regular lectures to local pediatricians, family practice physicians, and orthopaedic surgery residents. *Id.*

ii. Expert Reports

1. Dr. Carr's Expert Report

Petitioner filed Dr. Carr's expert report on August 14, 2019. Pet'r's Ex. 14. Dr. Carr opined that Petitioner "sustained a clear new right shoulder injury as a consequence of an adverse reaction to a Tdap vaccine administration." *Id.* at 3. Specifically, Dr. Carr noted that Petitioner's "pain began immediately on administration and worsened over the next few days, until she was diagnosed with impingement syndrome and bursitis." *Id.*

Dr. Carr opined that Petitioner's injuries were not related to her 2009 fall, stating, "[Petitioner] was neither complaining about her shoulder nor being treated for a shoulder injury at the time of the subject vaccine administration." *Id.* He continued that "by the time of the [vaccine], [Petitioner's] work-related injury treatment was concentrated on her neck and nerve damage." *Id.* Dr. Carr further noted that the "remoteness of any prior shoulder complaints" negates a relationship between the 2009 fall and the post-vaccination symptoms and diagnoses. *Id.*

Dr. Carr also wrote that once Petitioner "presented with objective evidence of a shoulder disorder after her vaccine administration, [Dr. Ehrlich] immediately referred her to Dr. Ballard, an [o]rthopedic [s]urgeon." *Id.* Dr. Carr noted that Dr. Ehrlich had cared for Petitioner's work-related injury "for several years without referring her out for more expert advice earlier." *Id.* Dr. Carr

opined that Dr. Ballard's request for an MRI in July 2017 when previous MRIs had been performed for Petitioner's work-related injury "indicates a new injury." *Id.* at 2. Dr. Carr further opined that Petitioner's "prior [work-related injury] diagnoses were neurological in nature and could not cause impingement syndrome or bursitis." *Id.* at 3. He concluded that:

> [T]here is no evidence to support any other causative agent than the adverse TdaP vaccine reaction in regard to [Petitioner's] right shoulder impingement and bursitis. The symptoms of pain began immediately on vaccine administration and required at least fourteen months of treatment, medication, and injection[,] and multiple physician visits. [He] opine[d] none of these would have been necessary if not for the vaccine administration.

Id.

2. Dr. Winell's Expert Report

Respondent filed Dr. Winell's expert report on October 19, 2019. Resp't's Ex. A. In her report, Dr. Winell opined that Petitioner's shoulder impingement is not related to her adverse vaccine response. *Id.* at 8. Specifically, Dr. Winell noted that Petitioner's PCP, Dr. Foreman, never documented in her medical assessment or plan that the diagnosis of subacromial impingement was caused by the vaccine. *Id.* at 6. Further, Dr. Winell stated that subacromial impingement is a common condition seen in women of Petitioner's age. *Id.*

Dr. Winell also noted an alternative cause, Petitioner's 2009 fall. *Id.* at 6–7. Specifically, Dr. Winell pointed to Dr. Ehrlich's medical records, which document Petitioner complaining of right shoulder pain before the vaccination. *Id.* at 6. Dr. Winell opined that "the fact that a right shoulder MRI was requested is a testament to the fact that the pain must have been bad enough that Dr. Ehrlich felt an MRI was needed." *Id.* Additionally, Dr. Winell pointed to Dr. Ehrlich's March 29, 2017 note, which stated that Petitioner "had suffered from severe right shoulder pain dating back to a fall in 2009 or 2010 which was 'never addressed' and got worse after the vaccine," such that Petitioner's shoulder was not symptom free prior to the vaccine. *Id.* at 6–7 (citing Pet'r's Ex. 5 at 70).

Next, Dr. Winell rebutted Dr. Carr's opinion that Petitioner's right shoulder pain could not date back to 2009 because she temporarily responded to a subacromial injection in the shoulder. *Id.* at 6. Instead, Dr. Winell stated:

> This is simply not true. Subacromial impingement, AC /glenohumeral arthritis, and rotator cuff pathology are conditions that can wax and wane with age. Individuals can be symptom free for years and then have a flare up due to movements that might even seem inconsequential, like reaching high up for an object. The pain can improve quite well with an injection no matter when the symptoms appear, how long they have lasted, or if they disappeared and reappeared.

Id. Dr. Winell also rebutted Dr. Carr's assessment that Dr. Ballard's July 20, 2017 note and the fact that he ordered a right shoulder MRI must indicate a new injury. *Id.* Rather, Dr. Winell asserted

that there are no medical records to support this opinion and that Dr. Ballard did not specify that the injury was new. *Id.* In fact, Dr. Winell highlighted that Dr. Ballard stated Petitioner's history included that she "had a recent injury work-related fall in 2009" and the vaccine was not mentioned. *Id.*

Dr. Winell further disagreed with Dr. Carr's contention that because Petitioner's prior diagnoses were neurological in nature, her pre-existing conditions could not cause impingement syndrome or bursitis. *Id.* at 7. Rather, Dr. Winell opined that cervical spine pathology, which is neurological, "can cause pain which can mimic [Petitioner's] diagnoses as well." *Id.* Dr. Winell further pointed to Petitioner's MRI which showed "significant osteoarthritis of the right AC joint, degenerative changes in the glenohumeral joint and degenerative issues of the rotator cuff muscles," which are findings that could cause Petitioner's pain complaints. *Id.* (citing Pet'r's Ex. 13 at 5.) Further, Dr. Winell noted that the MRI has "no sign of fluid or bursitis in the subacromial or subdeltoid bursae." *Id.* Lastly, the MRI showed degenerative changes on the cervical spine. *Id.*

Dr. Winell then turned to the four criteria required for a SIRVA Table claim pursuant to the Table's Qualifications and Aids to Interpretation[30] ("QAIs"), and she opined that only one of the four criteria is met. *Id.* at 8. Regarding the first criterion, which requires no history of pain or dysfunction of the affected shoulder prior to the intramuscular injection to explain the symptoms, Dr. Winell pointed to Petitioner's long history of right shoulder pain, which is well-documented in Petitioner's worker's compensation appointments. *Id.* at 7. Dr. Winell flagged that Petitioner sought worker's compensation approval for a shoulder MRI as late as 2017. *Id.* Dr. Winell also asserted that the second criterion, pain within 48 hours, was not met because Petitioner did not reach out to her doctor until almost a month after the vaccination and was not seen until almost four months after the vaccination. *Id.* Dr. Winell opined that the third criterion, pain and reduced range of motion limited to the shoulder in which the injection was administered, is met with respect

[30] Table injury cases are guided by statutory "Qualifications and Aids in Interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition: SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). 42 CFR §100.3(c)(10).

to Petitioner's right shoulder. *Id.* For the fourth and final criterion, that no other condition could explain the petitioner's symptoms, Dr. Winell averred that Petitioner has several other conditions that could explain the symptoms, including AC joint arthritis, glenohumeral degenerative changes, and rotator cuff pathology (all part of the general aging process), as well as degenerative changes in Petitioner's neck with bulging discs and narrowing of foramina for existing nerve roots. *Id.* at 9.

In conclusion, Dr. Winell asserted that Petitioner did not meet the requirements for a SIRVA diagnosis. *Id.* Specifically, Dr. Winell opined that Dr. Carr's expert report relies solely on Petitioner and her family's accounts of her pain and timeline. *Id.* Dr. Winell found no objective evidence to prove that the vaccine caused Petitioner's injury. *Id.* Further, Dr. Winell opined that Dr. Carr is unable to refute that Petitioner had right shoulder complaints prior to 2016, which is well-documented in the worker's compensation medical records. *Id.* Lastly, Dr. Winell pointed to the MRI pathology as a more likely cause of Petitioner's pain. *Id.*

3. Dr. Carr's Supplemental Expert Report

Petitioner filed Dr. Carr's supplemental expert report on November 1, 2019. Pet'r's Ex. 15. Dr. Carr first acknowledged the work-related injury, highlighting that it was six years prior to the vaccination. *Id.* at 1. Dr. Carr further stated that Petitioner underwent an EMG of her right upper extremity when the work-related injury first occurred, which indicated no objective evidence of right shoulder pathology. *Id.* (citing Pet'r's Ex. 5 at 57). Dr. Carr noted that, as treatment of the work-related injury continued, the focus of treating doctors was Petitioner's neck and arm, not her shoulder. *Id.*

Dr. Carr indicated that soon after Petitioner's vaccination in October 2016, Petitioner made her shoulder pain known to Dr. Ehrlich, who referred her to Dr. Ballard, a shoulder specialist, after seeing "objective symptoms clearly distinct from her chronic residual neck and nerve injuries from six years prior, including not only pain, but stiffness." *Id.* Dr. Carr opined that Petitioner's "signs and symptoms after her October 2016 vaccination were distinct from her prior symptoms, and not related to her neck and nerve injury." *Id.*

Additionally, Dr. Carr opined that Petitioner's MRI suggested "the type of chronic right shoulder wear and tear that we see every day in our practice: Arthritis, bone spurs, partial rotator cuff tears and inflammation." *Id.* Dr. Carr "concur[red with Dr. Winell] that an adverse vaccine reaction would not cause arthritis or bone spurs and that these could have been exacerbated by her 2010 injury." *Id.* Dr. Carr further opined that these findings are common and not necessarily a source of pain and that an impingement test can provide further insight. *Id.* at 1–2. An impingement test is a "subacromial injection of steroid and novacaine," and "[i]f symptoms almost completely resolve, then the radiographic findings can be assumed to be the culprits." *Id.* at 2. Dr. Carr noted that Petitioner "underwent these subacromial injections, but her stiffness and pain did not respond in any way." *Id.* He asserted that this "would suggest that the radiographic findings were the cause of her shoulder pain, as they rarely improved with any significance at all." *Id.* Thus, Dr. Carr opined that Petitioner's "signs and symptoms were not related to her radiologic findings, impingement, or arthritis." *Id.*

Further, Dr. Carr opined that while signs and symptoms of impingement can and do wax and wane over the years, "[his] operating experience on impingement syndrome suggests that waxing signs and symptoms are usually due to an acute or subacute event." *Id.* Dr. Carr concluded that in Petitioner's case, the only potential event is the Tdap vaccine on October 19, 2016, which resulted in "the sudden increase in pain, loss of motion and weakness." *Id.* Dr. Carr opined that because of the sudden and dramatic nature of Petitioner's signs and symptoms without any other immediate acute or subacute event besides the vaccination, "they were not caused by a waxing impingement syndrome." *Id.*

Dr. Carr then turned to the four criteria required for a SIRVA Table claim, and he asserted that all of the four factors are met. *Id.* at 2–3. Regarding the first criterion, Dr. Carr noted that Petitioner's worker's compensation "injury to the right neck, shoulder, and arm region six years prior to the vaccination" had "no objective evidence of shoulder pathology." *Id.* He contended that this criterion is met because of the "remoteness of the injury, the lack of attention to her shoulder by her treaters, and the difference in the nature of her post-vaccination symptoms from her prior symptoms." *Id.* Dr. Carr also found that the second criterion is met because Petitioner immediately told the administering nurse of her pain and promptly followed up with her doctor when the symptoms did not resolve. *Id.* Dr. Carr and Dr. Winell agreed that the third criterion is met. *Id.* at 3. Finally, Dr. Carr asserted that the fourth criterion is met. *Id.* Dr. Carr opined that Petitioner's signs and symptoms were new after her vaccination and there is "no other documented or identified causes could explain [Petitioner's] acute shoulder symptoms." *Id.*

Dr. Carr concluded that because Petitioner's October 2016 symptoms "were sufficiently distinct from her remote injury to prompt a shoulder MRI and involved a dramatic and sudden increase in pain and new onset stiffness, . . . they were not likely related to her 2010 injury." *Id.* Also, Dr. Carr found that "because [Petitioner's] signs and symptoms did not resolve significantly with subacromial injections, it is [his] opinion that they were not related to arthritis and related radiological findings." *Id.* Lastly, Dr. Carr opined that "more likely than not, the cause of Ms. Talbert's pain and stiffness was an adverse reaction to the October 19, 2016 vaccine." *Id.* at 5.

III. Ruling on the Record

A. Petitioner's Motion

In Petitioner's motion for a ruling on the record, filed on September 21, 2022, Petitioner argues that she is entitled to compensation. Pet'r's Mot. at 2. Petitioner relies on her affidavit, in which she stated that "from the instant of the [Tdap] vaccine administration, she felt discomfort in her right shoulder that has not subsided since." *Id.* at 1 (quoting Pet'r's Ex. 1 at 2). Petitioner pointed to her messages with Dr. Foreman via MyChart Communications as evidence of onset and timeline. *Id.* 1–2. Although Petitioner acknowledges her previous work-related injuries, she asserts that the medical records from Dr. Ehrlich provide evidence that her shoulder pain was worse since the vaccination and resulted in a distinct diagnosis of shoulder joint pain. *Id.* at 3. She cites Dr. Foreman's notes that Petitioner had limited range of motion in her right shoulder and that the shoulder was tender to palpation, both symptoms to support a finding of a distinct post-vaccination injury. *Id.* at 3. Petitioner further cites the March 2017 diagnosis from Dr. Griffin and Dr. Foreman of subacromial impingement of the right shoulder as evidence of a vaccine-caused injury. *Id.* at 4.

Additionally, Petitioner asserts the injury has extended beyond six months since the vaccine administration, evidenced by Dr. Ehrlich's notes of continuing treatment. *Id.*

Finally, Petitioner argues that Dr. Carr's opinion that there was no evidence to support any other cause for Petitioner's post-vaccination pain supports a ruling in her favor. *Id.* at 4–5. Specifically, she notes that Dr. Carr opined that Petitioner's 2009 fall was remote and asymptomatic by the time of the vaccine injury, which caused acute trauma. *Id.*

B. Respondent's Response

On November 21, 2022, Respondent filed his response to Petitioner's motion, and Respondent argues that Petitioner has not established that she is entitled to compensation. Resp't's Resp. at 2. He asserts that Petitioner has not presented preponderant evidence that she suffered a Table SIRVA or that she suffered an injury that was caused-in-fact by her vaccination. *Id.* at 7.

Regarding the Table injury claim, Respondent argues that Petitioner has not claimed to suffer from SIRVA. *Id.* at 7. Even if Petitioner did plead a Table SIRVA, Respondent argues that Petitioner's claim fails because she has not presented preponderant evidence that her injury fulfills the Table criteria. *See id.* Respondent notes that Petitioner had pre-vaccination right arm and shoulder pain stemming from the 2009 injury, there is no objective evidence of onset and limited motion of the right shoulder within forty-eight hours of vaccine administration, the post-vaccination pain was not limited to the right shoulder, and there are several other conditions that could explain Petitioner's pain. *Id.* These conditions include "AC joint arthritis, glenohumeral degenerative changes, rotator cuff pathology, degenerative changes, bulging discs, and narrowing of foramina for exiting nerve roots in [Petitioner's] neck." *Id.* at 8.

Next, Respondent asserts that Petitioner has not provided preponderant evidence that her vaccination is the but-for cause of her shoulder pain. *Id.* at 11. Respondent argues that Petitioner has not set forth a reliable medical theory of causation, illustrated a logical sequence of cause and effect, or described an appropriate temporal relationship in support of her claim. *Id.* at 11–16. Respondent asserts that Petitioner failed to provide any theory at all. *Id.* at 12. Rather, Dr. Carr simply opined that the vaccine caused Petitioner's shoulder injuries without any medical literature addressing a medical theory or "any evidence explaining why [P]etitioner's other conditions were not the cause of her pain." *Id.* Further, Respondent asserts that Petitioner failed to establish a logical sequence of cause and effect, instead relying on a "post hoc ergo propter hoc" line of reasoning, based on temporal association while failing to address other conditions that Petitioner was experiencing. *Id.* at 12–14. Lastly, Respondent argues that because Petitioner has not proposed a theory explaining how the vaccine she received could cause the alleged injuries, "there is no basis for this Court to determine a medically acceptable time frame for these alleged injuries to occur." *Id.* at 15.

Nearly every aspect of Petitioner's claim is disputed by Respondent. Respondent requests denial of Petitioner's claim for vaccine compensation and that the Amended Petition be dismissed. *Id.* at 17.

C. Petitioner's Reply

In Petitioner's reply, filed on December 13, 2022, Petitioner asserts that she has provided preponderant evidence, in the form of the medical record and Dr. Carr's expert opinions, to prove that she suffered a Table injury and a causation-in-fact injury. Pet'r's Reply at 1.

Specifically, Petitioner refutes Respondent's characterization of her history of shoulder and arm pain since the 2009 injury. *Id.* at 2. She asserts that while she "did have occasional pain in her shoulder for a period of several years after her fall, from March 13, 2014 until after [P]etitioner's vaccine administration, there is no shoulder pain complained of or assessed by [her treating neurologist]." *Id.* Petitioner also argues that, according to Dr. Carr, Petitioner's "signs and symptoms after her October 2016 vaccine administration were distinct and that no other cause of her shoulder pain could explain her signs and symptoms." *Id.* at 4. Petitioner asserts that the above evidence supports her assertion that no other condition or abnormality was present that would explain Petitioner's symptoms. *Id.* Petitioner also argues that the pain and reduced range of motion were limited to her right shoulder, as evidenced by both parties' expert reports. *Id.* at 5 (citing Resp't's Ex. A at 7; Pet'r's Ex. 15 at 3). Further, Petitioner points to her affidavit and the online message to Dr. Foreman as evidence supporting onset within 48 hours. *Id.* at 6 (citing Pet'r's Ex. 7 at 7; Pet'r's Ex. 1 at 2). In conclusion, Petitioner asserts that she has demonstrated preponderant evidence she met the requirements for a table injury claim and that her shoulder injury was caused-in-fact by the vaccine administration. *Id.* at 7.

IV. Applicable Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury-i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); § 13(a)(1)(B).

The Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table injury cases are guided by statutory "Qualifications and Aids in Interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. *See* 42 CFR § 100.3(c). To be considered a "Table SIRVA," a petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG)

> studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR §100.3(c)(10).

Alternatively, if a petitioner is unable to establish a Table claim, she may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table," or causation-in-fact, claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 300aa-13(a)(1)(A); *see* § 11(c)(1)(C)(ii)(II). A petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citations omitted).

In the seminal case of *Althen v. Sec'y of Health & Hum. Servs.*, the Federal Circuit set forth a three-pronged test to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d at 1278–79. The *Althen* test requires petitioners to set forth: "(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." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). 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 & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological

mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is also unnecessary. *Althen*, 418 F.3d at 1278-81; *Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."). 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 v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See* 418 F.3d at 1279. 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. *Id.* at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [ ] both that [the] vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *See* 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325-26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* This is because "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.'" *Id.* (quoting *Althen*, 418 F.3d at 1280). In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "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." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403-04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

Once a petitioner has established her prima facie case, the burden then shifts to Respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen*, 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B). The Vaccine Act requires Respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Hum. Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* § 300aa-13(a)(2)(B). The factor unrelated must be the "sole substantial factor[;]" therefore, Respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan*, 539 F.3d at 1354.

V. Discussion

In the present case, the parties are unable to agree on any material fact or legal conclusion, save that Petitioner's Tdap vaccination occurred on October 19, 2016. Petitioner maintains that she suffered a right shoulder injury that satisfies the QAI criteria for a Table injury. Pet'r's Reply at 1. Alternatively, Petitioner asserts that she has provided preponderant evidence that she suffered an off-Table, causation-in-fact injury. *Id.* Respondent, however, disputes Petitioner's claims for both Table and off-able injuries. *See generally* Resp't's Resp. Respondent also argues that Petitioner has not presented preponderant evidence of general or specific causation between the vaccination and the development of Petitioner's alleged injuries. *Id.* at 1. After a thorough review of the record, I find that Petitioner has not presented preponderant evidence of a Table claim or a causation-in-fact claim.

A. Table Claim

i. History of Pain, Inflammation, of Dysfunction

It is undisputed in this case that Petitioner had a pre-vaccination history of pain in her right arm and shoulder, stemming from her 2009 work-related injury. Petitioner has argued that her pre-vaccination shoulder pain was occasional for several years after her fall but has been resolved since March 13, 2014. *See* Pet'r's Reply at 2. Petitioner further argues that the post-vaccination shoulder pain is separate and distinguishable from her prior fall-related pain. *See* Pet'r's Mot. at 3. This interpretation of the QAI criteria belies a plain reading of the text: "No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms . . . occurring after vaccine injection." 42 CFR §100.3(c)(10). On several medical intake forms, Petitioner self-reported symptoms, including right shoulder and arm pain after the 2009 fall. Pet'r's Ex. 10 at 6. Specifically, Petitioner described her symptoms to Dr. Ehrlich as "pain in her right shoulder and into the wrist that it moves down her right side and into her right hip and leg . . . a burning type pain." *Id.* at 7. Throughout Petitioner's pre-vaccination treatment with Dr. Ehrlich, Petitioner's medical diagnoses have included, in part, shoulder joint pain, orthopedic disorders of the spine, cervical spondylosis, pain in limb, carpal tunnel syndrome, cervicalgia (pain in neck), shoulder joint pain, chronic pain syndrome, right arm pain, and fibromyalgia. Pet'r's Ex. 5 at 70, 80, 88, 110. As late as February 1, 2017, Petitioner reported shoulder nerve damage; Dr. Foreman's note states, "[Petitioner] still has pain in her right should[er] after receiving [Tdap] in that arm. She reports previous nerve damage there [from the 2009 fall] and is seeing a neurologist." Pet'r's Ex. 6 at 124. On March 29, 2017, Dr. Ehrlich noted that Petitioner had "severe shoulder pain since she fell in around 2009. . . ." Pet'r's Ex. 5 at 71–75. Respondent's expert, Dr. Winell, opined that "there is ample documentation in [Petitioner's] Workmen's Compensation visits that [she] suffered from right shoulder pain prior to the vaccine." Resp't's Ex. A at 8. Given the extensive shoulder pain and symptoms from the 2009 fall, Petitioner's pre-existing history would explain the continued symptoms, and Petitioner cannot satisfy this QAI criterion. As Petitioner cannot satisfy this first QAI criterion, she cannot establish that she suffered a Table SIRVA. However, for completeness, I will discuss the remaining criteria.

ii. 48-Hour Symptom Onset

While it is true that Petitioner consistently related her post-vaccination shoulder pain to her October 19, 2016 Tdap vaccination, it is also true that Petitioner first reported her injury to a medical provider approximately one month post vaccination and saw a medical provider for an exam approximately four months post vaccination. Petitioner's affidavit includes evidence that Petitioner felt immediate pain with the administration of the vaccine and that she was "told to expect some pain and discomfort for approximately three days to a week." Pet'r's Ex. 1 at 1. While Petitioner's affidavit is compelling evidence of the onset of symptoms, there is a lag in medical records verifying this timeline. Eight days post vaccination, on October 27, 2016, Petitioner failed to mention the vaccination or any vaccination-related symptoms during a routine worker's compensation follow-up with Dr. Ehrlich. *See* Pet'r's Ex. 5 at 52. While Petitioner may have still considered her post-vaccination symptoms to be routine and within the expected time range for pain and discomfort, it is odd that she did not mention the symptoms to her treating neurologist, whose focus includes Petitioner's shoulder. This timing, compounded by Petitioner's affidavit alleging extreme symptoms, including the loss of range of motion, radiating pain, and trouble sleeping, weighs against Petitioner. If Petitioner was truly experiencing such extreme symptoms, it is surprising that she would not report them to her treating neurologist who was already treating her shoulder pain.

Assuming arguendo that Petitioner believed her symptoms to be routine at the time of her visit with Dr. Ehrlich, Petitioner still waited approximately one month to report her injury to Dr. Foreman and approximately four months to be seen by Dr. Foreman. This length of time does not align with the alleged severity of Petitioner's symptoms. Petitioner does not assert any reason why she did not seek out a new medical provider or emergency treatment if Dr. Foreman was not responsive or could not see Petitioner until February of 2017.

Petitioner's failure to report her post-vaccination symptoms to Dr. Ehrlich, Petitioner's one-month delay in reporting her symptoms to any medical provider, and Petitioner's four-month delay in seeking an evaluation for her symptoms all stand against Petitioner's affidavit. I find Petitioner's failure to seek treatment or report her symptoms sufficiently persuasive. Petitioner has failed to produce preponderant evidence that she experienced pain within the specified timeframe of 48 hours.

iii. Nature of Symptoms

Prior to vaccination, Petitioner was being treated by her neurologist, Dr. Ehrlich, for injuries related to her 2009 fall. These injuries included nerve damage to Petitioner's right side, carpal tunnel syndrome in her right wrist, and back and neck problems.

Respondent's expert, Dr. Winell, agreed with Dr. Carr that Petitioner's post-vaccination complaints were limited to her right shoulder where the Tdap vaccine was administered. Resp't's Ex. A at 8. During Petitioner's initial post-vaccination visits with Dr. Foreman and Dr. Ehrlich, she consistently reported that she had limited range of motion and pain in her right shoulder. Pet'r's Ex. 6 at 124–125, 236; Pet'r's Ex. 5 at 65–87. I find that there is preponderant evidence, including opinions from both Drs. Winell and Carr, that Petitioner's complaints remained limited to her right

shoulder post vaccination. While Respondent cited Petitioner's list of injuries, including her back and neck pain, carpal tunnel syndrome, and tingling and numbness in her right hand, these symptoms do not negate the fact that Petitioner consistently identified her right shoulder as the source of the pain post vaccination. As such, Petitioner has presented preponderant evidence that her symptoms were limited to her right shoulder.

iv. Lack of Alternative Condition

The last QAI factor prohibits compensation for Table SIRVA if any alternative condition is present that could explain Petitioner's symptoms. Petitioner is also unable to satisfy this requirement. After a review of Petitioner's medical records, affidavits, expert reports, and the parties' arguments, I find that there is preponderant evidence that Petitioner's post-vaccination symptoms would be explained by her 2009 injury.

Petitioner had shoulder pain stemming from her 2009 injury and there is not preponderant evidence that she was symptom-free by the time of her vaccination. Petitioner suffered an extremely serious injury in 2009 when she braced herself with her right hand and arm while slipping down wet stairs. Since this injury, Petitioner has suffered from right shoulder pathology. Petitioner regularly saw a treating neurologist who recommended numerous courses of action and consistently prescribed significant pain medications to manage the symptoms. On February 3, 2017, over three months post vaccination, Dr. Ehrlich noted that Petitioner's right shoulder pain was "now worse" after receiving the vaccination. Pet'r's Ex. 5 at 65. While Petitioner's symptoms have evolved over time, the symptoms originated with the fall in 2009. Even post vaccination, Petitioner continued to see her worker's compensation treaters for her symptoms. Petitioner also continued to bill her post vaccination treatment through worker's compensation. While Petitioner repeatedly asserted that the vaccination was the source of her shoulder pain, the record does not support a preponderant finding that there is a lack of alternative condition. I find preponderant evidence that Petitioner's symptoms would be explained by her 2009 injury.

Petitioner has not presented preponderant evidence that she suffered from Table SIRVA. Table claims carry a presumption because they are unhindered by previous similar injury, additional symptoms indicative or other conditions, and timing concerns. They are streamlined, and often resolve without medical expert reports or opinions to rule out other diagnoses. In cases where other issues are present, cases proceed more deliberately. It is Petitioner's burden to overcome those complications using the parameters set forth in *Althen*. While it is true that the QAI criteria set the parameters for a Table claim, failure to meet the standard for presumption does not disqualify Petitioner's assertion that she did in fact suffer a vaccine-caused shoulder injury.

B. Causation-in-Fact

i. *Althen* Prong One: General Causation Theory

SIRVA is a well-known phenomenon in the Program, but petitioners must present a causation theory in all off-Table cases. Petitioner's expert, Dr. Carr, clearly opined that the Tdap vaccine caused Petitioner's symptoms. Specifically, Dr. Carr opined that the vaccine caused Petitioner's injuries because "[t]he symptoms of pain began immediately on vaccine

administration and required at least fourteen months of treatment, medication, an injection and multiple physician visits." Pet'r's Ex. 14 at 3. However, Dr. Carr failed to opine as to how SIRVA occurs, generally. Petitioner did not file any medical literature as to how the Tdap vaccine could cause Petitioner's alleged injuries, nor did she explain how the injury occurs based on her expert's knowledge, training, and experience. Dr. Carr also did not explain or provide any medical literature explaining why Petitioner's symptoms were not caused by her other conditions. Because Petitioner failed to provide an expert opinion or any medical literature to support a general causation theory, she has failed to satisfy prong one of *Althen.*

ii. *Althen* Prong Two: Specific Causation

Petitioner has failed to demonstrate a logical sequence of cause and effect between the Tdap vaccine she received on October 19, 2016 and her shoulder injury. While Dr. Carr opined that Petitioner "sustained a clear new right shoulder injury as an adverse reaction to a Tdap vaccine administration," Dr. Carr failed to provide proof of a logical sequence of cause and effect, beyond temporal association, that would explain Petitioner's injury. *See* Pet'r's Ex. 14 at 3. Without any medical literature or expert opinion regarding how SIRVA occurs generally, it is unclear what sequence of cause and effect allegedly caused Petitioner's injury.

Furthermore, Dr. Carr has not adequately accounted for Petitioner's extensive history of pre-vaccination shoulder pain. While Dr. Carr opined that Petitioner's work-related injuries had resolved and could not cause Petitioner's impingement syndrome or bursitis, the record indicates otherwise. Specifically, Petitioner's right shoulder pain pre-dated the vaccine and had not yet been resolved at the time of vaccination. On March 29, 2017, over five months post vaccination, Dr. Ehrlich noted that Petitioner "has had severe shoulder pain since she fell in around 2009" and that since the vaccination, "the shoulder pain is worse." Pet'r's Ex. 5 at 71. Respondent's expert, Dr. Winell, opined that this medical record shows that Petitioner "was not symptom free prior to the vaccination." Resp't's Ex. A at 8. Many of Petitioner's medical records show a history of neck, back, and right extremity pain. *Id.* Since 2011, Petitioner has taken various nerve pain medications, muscle relaxants, antidepressants, and anticonvulsants to manage her fall symptoms. As of the date of vaccination, Petitioner was prescribed Topamax 100 MG daily, an anticonvulsant and nerve pain medication; Tramadol 50 MG daily, an opioid pain medication; and Zanaflex 4 MG daily, a muscle relaxant. Pet'r's Ex. 5 at 46. As of the most recent medical records on file, September 14, 2018, Petitioner was still prescribed Tramadol HCL 50 MG tablets twice daily as needed for pain. Pet'r's Ex. 10 at 197. The extent of Petitioner's pain management regimen indicates that her pain was, and continues to be, extremely severe. Petitioner was relying on such pain management methods prior to and on the day of her Tdap vaccination. Therefore, it is more likely than not that the onset of Petitioner's shoulder pain was before she received the Tdap vaccination in question.

The record indicates that Petitioner's right shoulder pain pre-dated the vaccine and had not yet been resolved at the time of vaccination. Petitioner has neither alleged, nor presented evidence supporting, that her vaccination significantly aggravated her pre-existing shoulder injury. Overall, Petitioner has failed to establish by a preponderance of the evidence that the Tdap vaccine administered on October 19, 2016, caused her to develop a SIRVA. Therefore, for the numerous reasons described above, Petitioner cannot satisfy prong two of *Althen.*

iii. *Althen* Prong Three: Temporal Relationship

Petitioner failed to plead any medical theory explaining how the Tdap vaccine can cause the alleged injury of "debilitating pain, suspension tremor, restricted range of motion, and impingement of her right shoulder and arm" or SIRVA. *See* Am. Pet. at 1. As such, there is no basis to contemplate and determine a medically appropriate time frame for Petitioner's alleged injury. Dr. Winell opined that the relation of Petitioner's vaccine and alleged symptoms "was purely coincidental." Respt's Ex. A at 8. Because Petitioner failed to provide an expert opinion or any medical literature to demonstrate a medically appropriate timeframe under a theory of causation, she has failed to satisfy prong three of *Althen*.

VI. Conclusion

After careful review of the record, Petitioner has failed to prove by preponderant evidence either that her Tdap vaccination resulted in a Table SIRVA or, alternatively, was the cause-in-fact of an off-Table shoulder injury. Accordingly, Petitioner is not entitled to compensation. Therefore, her case is **DISMISSED**.[31]

IT IS SO ORDERED.

/s/ Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[31] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.