In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-2044V

MARGARET ACHANZAR, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: November 25, 2024

Phyllis Widman, Widman Law Firm, LLC, Linwood, NJ, for Petitioner.

Naseem Kourosh, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING TABLE SIRVA CLAIM AND ORDER OF REASSIGNMENT[1]

Margaret Achanzar seeks compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act") for injuries following her receipt of a human papillomavirus ("HPV") vaccine which she received on October 21, 2019. I hereby conclude that she has not established a shoulder injury related to vaccine administration ("SIRVA") corresponding to a listing on the Vaccine Injury Table ("the Table"), *see* 42 C.F.R. § 100.3(c)(10). Her Table SIRVA claim must therefore be **DISMISSED**, and the matter is transferred out of the Special Processing Unit (the "SPU") and reassigned randomly to a Special Master for further proceedings.

[1] Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling 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] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

I. Procedural History

Petitioner originally alleged "a left shoulder injury (SIRVA) and/or significan[t] aggravat[ion]… in the alternative, [a] shoulder injury that was caused-in-fact by the vaccination." Petition filed Oct. 20, 2021 (ECF No. 1).

Respondent did not invite any settlement discussions. In formally opposing compensation, Respondent disputed the threshold severity requirement, as well as the Table SIRVA requirements for onset, reduced ROM, and lack of an alternative explanation for Petitioner's symptoms. *See generally* Rule 4(c) Report filed Mar. 24, 2023 (ECF No. 33) at 12 – 14.

Petitioner maintained that her claim should proceed – but revised her injury allegation to SIRVA "and/or axillary nerve mononeuropathy," Amended Petition filed July 12, 2023 (ECF No. 43) at Preamble; *see also* Brief filed July 13, 2023 (ECF No. 46); Response filed Aug. 23, 2023 (ECF No. 47); Reply filed Sept. 6, 2023 (ECF No. 48).

The parties were encouraged to explore informal resolution centering on Petitioner's showing of an axillary nerve injury persisting for over six months post-vaccination, but not a Table SIRVA. Scheduling Order filed Aug. 12, 2024 (ECF No. 50) (memorializing status conference). Petitioner requested to pursue "concurrent" claims for a Table SIRVA and a nerve injury (despite my warning that those seemed to be incompatible), and she conveyed a settlement demand to Respondent. Status Report filed Sept. 23, 2024 (ECF No. 54).[3] However, Respondent declined to enter into settlement discussions, and requested that the case proceed on a litigation track. Status Report filed Oct. 29, 2024 (ECF No. 56). The matter is ripe for adjudication.

II. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). Compensation may not be awarded "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of

[3] Petitioner also mentioned "talk[ing] with her expert." Status Report filed Sept. 12, 2024 (ECF No. 51). She was "reminded that the parties should not retain a medical expert, life care planner, or other expert without consulting each other and the Chief Special Master. Engaging experts is not routine in SPU cases and may not be found to be a reasonable cost depending on the circumstances of the case." Scheduling Order filed Sept. 20, 2024 (Non-PDF), citing SPU Initial Order filed June 10, 2022 (ECF No. 15) at 1.

petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical 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).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

A potential petitioner must demonstrate that he or she "suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." Section 11(c)(1)(D)(i)[4]; *see also Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied,* 132 S.Ct. 1908 (2012); *Wright v. Sec'y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

Beyond severity and other requirements concerning the vaccination received, and the lack of other award or settlement, *see* Section 11(c)(1)(A), (B), (D), and (E), a petitioner must establish that he or she either suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). 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

[4] Section 11(c)(1)(D) presents two alternative grounds for eligibility to compensation if a petitioner does not meet the six months threshold: (ii) death from the vaccine, and (iii) inpatient hospitalization and surgical intervention. Neither alternative is alleged or implicated in this claim.

> injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). 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 C.F.R. § 100.3(c)(10) (2017).

If, the petitioner's injury does not fit within a Table listing, the petitioner must prove that the administered vaccine was the cause in fact of the injury. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove the claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.*

III. Contemporaneous Evidence

- Petitioner had a preexisting diagnosis of Ehlers-Danlos syndrome,[5] and repeated exam findings of hypermobility. *See, e.g.*, Ex. 18 at 3 – 5; Ex. 9 at 5 – 6; Ex. 3 at 2 – 3; Ex. 3 at 5 – 6; *id.* at 7 – 9. Born in 2003, she was a high school student on the swim team and color guard. *See, e.g.*, Ex. 15 at 6; Ex. 3 at 2 – 3.

- Petitioner received the at-issue vaccine in her left arm on October 21, 2019, at her pediatrics office in New Jersey. Ex. 1 at 1; Ex. 15 at 4; Ex. 19 at 3.

- Petitioner did not mention the vaccine or any shoulder/arm complaints at a gynecological appointment fifteen days post-vaccination. Ex. 5 at 188 – 91.

- But twenty-nine (29) days post-vaccination, on November 19, 2019, Petitioner sought an initial orthopedics evaluation for "[l]eft shoulder pain which began about 4 weeks ago. She denies any specific history of trauma… She does participate in the color guard and has been swimming over the past week with exacerbation of symptoms." Ex. 3 at 2. The pain was persistent despite taking ibuprofen and "working with the athletic trainer at school." *Id.* at 3. On exam, the left shoulder had full range of motion ("ROM "), but pain on extremes; hypermobility; instability; and "grossly intact" sensation. *Id.* at 3. A labral tear was suspected. *Id.* Petitioner declined x-rays due to concerns about radiation. *Id.* At a December 3, 2019, follow-up appointment, the orthopedist reviewed that an MRI arthrogram did not show labral or rotator cuff tearing. *Id.* at 7 – 9.

- At a November 26, 2019 physical therapy ("PT") initial evaluation, Petitioner reported an onset in "mid-September," denied trauma, but acknowledged "participating in color guard at the time." Ex. 3 at 5. The pain currently rated 3/10, and she was only kicking during swim team practice. *Id.* The physical therapist documented normal passive ROM with pain at extremes and 4/5 strength; did not offer any specific assessment, and instructed Petitioner on home exercises. *Id.* at 5 – 6.[6]

[5] Ehlers-Danlos syndrome is defined as: "A group of inherited disorders of connective tissue… Prominent manifestations include hyperextensible skin and joints, easy bruisability, and friability of tissues with bleeding and poor wound healing… Called also *cutis hyperelastica*." *Dorland's Medical Dictionary Online*, https://www.dorlandsonline.com/dorland/definition?id=110561 (hereinafter "*Dorland's Online*") (last accessed Nov. 21, 2024).

[6] No further records of formal PT sessions have been filed. *See generally* Ex. 3, 18; *but see* Ex. 12 at 2, 5 (December 10, 2019, physiatry record stating that Petitioner had completed about 4 PT sessions, which she should continue"); *id.* at 7 (December 18th record stating that Petitioner should discontinue PT as of that date).

- Around this time, Petitioner's mother learned about SIRVA from internet research, *see* Ex. 23 at ¶ 18, and/or an acquaintance, Ex. 12 at 2. She contacted Marko Bodor, M.D., who "stated that it is possible that [Petitioner] may have SIRVA",[7] and referred her to a physiatrist at the Rutgers – State University of New Jersey medical school and health system. Ex. 12 at 2.

- At the December 10, 2019[8] physiatry initial evaluation, Petitioner reported that the HPV vaccine had been administered "towards the back of the left shoulder with the needle pointing downwards," and was followed by initial discomfort, which "persisted and worsened over the next two weeks." Ex. 12 at 2.[9] The exam findings included trace reflexes (1+) in both upper limbs; decreased sensation to light touch/ pinprick at the left deltoid – corresponding to the axillary nerve; and decreased active ROM and a positive crossed adduction sign in the left shoulder. *Id.* at 3. An ultrasound found "subacromial, sub-deltoid bursa fluid collection anterior to [left] deltoid head." *Id.* at 5. The physiatrist endorsed: "Left shoulder pain immediately s/p IM deltoid muscle vaccination thus SIRVA." *Id.* at 5 – 6 (noting that SIRVA was first proposed by Bodor and Montalvo). The physiatrist's more specific diagnoses in Petitioner's case were "subacromial subdeltoid bursitis[10] [and…] axillary nerve mononeuropathy." *Id.* 5. The physiatrist planned a subacromial bursa aspiration and steroid injection, noting "If the symptoms persist, consider a procedure targeting the left axillary nerve." *Id.* at 6.

- The physiatrist performed the subacromial bursa aspiration and steroid injection on December 18, 2019. Ex. 12 at 7 – 8. At a follow-up 16 days later, Petitioner reported that those procedures were painful and "did not provide significant relief," and her pain was increased following New Year's Eve festivities. *Id.* at 9. A repeat ultrasound found "mild to moderate effusion[11] in the subacromial subdeltoid bursa." *Id.* at 10. The physiatrist administered a second steroid injection. *Id.* at 11.

[7] There are no medical records or other evidence or allegation that Dr. Bodor, who is based in California, *evaluated* Petitioner, who was living in New Jersey in 2019.

[8] Petitioner incorrectly recalls establishing with the physiatrist on December *12*, 2019. Ex. 2 at ¶ 11.

[9] Both parties cite copies of the physiatry records which do not include the physical exam findings. *See* Rule 4(c) Report at 3 – 4 and Brief at 3 – 4, citing Ex. 4 at 4 – 11.

[10] Bursitis is defined as inflammation of a bursa, which is "a sac or saclike cavity filled with a viscid fluid and situated at places in the tissues at which friction would otherwise develop." *Dorland's Online*.

[11] Effusion is defined as "the escape of fluid into a part or tissue." *Dorland's Online.*

- At a January 23, 2020 pediatrics appointment, Petitioner reported the post-vaccination immediate onset of acute left shoulder pain, which the physiatrist had diagnosed as bursitis and SIRVA. Ex. 7 at 5. An exam found normal active and passive ROM and strength, but decreased sensation on the superior/ lateral shoulder/ deltoid; Petitioner reported that the area "felt weird" with light touch. *Id.* at 6. The pediatrician did not offer any new diagnoses or treatment – stating that that Petitioner should follow her specialist's recommendations. *Id.* at 6.[12]

- Three months and thirteen (13) days post-vaccination, on February 3, 2020, Petitioner reported "0% relief" despite the steroid injections and rest; she "continued to have 8/10 achy pain with associated intermittent 'electrical sensation' sharp throbbing pain over the anterior and posterior left shoulder." Ex. 12 at 12.[13] On a repeat ultrasound, three views were negative for bursitis or effusion, compared to only one view finding "equivocal" effusion. *Id.* at 13. The physiatrist believed that bursitis "may not be [Petitioner's] primary pain generator." *Id.* Instead, based on the clinical history, exam findings of decreased sensation, and "100%" pain relief from the nerve block, Petitioner's ongoing condition was "probably due to axillary nerve mononeuropathy." Petitioner was instructed not to resume PT, not to engage in physical activities such as swimming and softball, and call to schedule a pulsed radiofrequency ablation ("RFA")[14] of the left axillary nerve. *Id.*

- At a February 27, 2020 neurology initial evaluation,[15] Petitioner recounted that an improperly-administered HPV vaccine had caused her injury, which involved "pain, numbness, weakness in the left arm." Ex. 6 at 2. A neurological exam was apparently normal (including sensation "within normal limits"). *Id.* at 2 – 3.

[12] The pediatrician may have notified the Vaccine Adverse Reporting System ("VAERS") of Petitioner's injury in January 2020, *see* Ex. 7 at 5; Ex. 22 at 8, but that report has not been filed.

[13] Of note, the exam findings are identical in the December 2019 physiatry initial evaluation and the February 2020 follow-up – raising the possibility that those were carried forward in the electronic medical records. *Compare* Ex. 12 at 3, *id.* at 14.

[14] The Cleveland Clinic explains: "During a radiofrequency ablation [RFA] procedure, a small hollow needle is inserted into the targeted nerve that is causing pain. An electrode is inserted into the top of the needle, which sends the radio waves through the needle to the targeted nerve. The heat causes a lesion that prevents the nerve from sending pain signals to your brain." Cleveland Clinic, *Radiofrequency Ablation for Pain Management*, https://my.clevelandclinic.org/health/treatments/17411-radiofrequency-ablation (last accessed Nov. 21, 2024).

Additionally, "pain relief following a nerve block injection[…] tells your provider that that particular nerve is the source of your pain and is an appropriate target for RFA." *Id.*

[15] *See also* Ex. 15 at 16 and Ex. 6 at 2 – 3 (reflecting that Petitioner's pediatrician had arranged the referral to the neurologist).

Regardless, the neurologist endorsed that the vaccine had "directly injured the left axillary nerve due to swelling," for which Petitioner would "continue to follow up with her physiatrist." *Id.* at 3.

- In a March 3, 2020 VAERS report, Petitioner's mother wrote: "Feb. 3rd nerve block confirmed that pain is coming from nerve in shoulder. [The] physiatrist recommended ablation. [Petitioner] has been in pain every day since the shot was given. Never a day less than 2 – 3/10 pain scale, and about 2 -3 days per week of pain over 7/10 pain scale." Ex. 22 at 8.

- However, there are no recorded complaints, exam findings, or treatment for a left shoulder injury over the next thirteen (13) months – despite intervening medical encounters.

    - Specifically at a November 5, 2020 pediatrics annual evaluation, Petitioner was noted to be exercising, swimming, walking, and playing football – but the same record notes a 7-pound weight increase "due to decreased activity and exercise." Ex. 7 at 9. The medical record does not address the presence or absence of any left shoulder injury. *Id.* at 10. Her mother requested "1 vaccine at a time d/t previous bursitis from HPV vaccine in 10/2019," and did not consent to the 2nd HPV vaccine dose *Id.* Accordingly, Petitioner received a Menactra vaccine, in her right arm. *Id.*

    - Petitioner's left arm was used for administration of vaccines on February 25, and April 2, 2021. Ex. 7 at 14, 16. She attended pediatric appointments for unrelated concerns on April 5, April 26, July 13, and October 8, 2021, as well as January 27, 2022. *Id.* at 18 – 32. The pediatric records do not address the presence or absence of a left shoulder injury – but they reflect Petitioner's requests for referrals to an epidemiologist, *id.* at 23, and to "immunology – reason: HPV vaccine reaction," *id.* at 26.

- At an April 4, 2022, telemedicine physiatry appointment, Petitioner reported a "similar" but "worsened" left shoulder injury in the last two months ("February 2022… further in March 2022"). Ex. 12 at 16. Her pain rated 5 – 6/10. Ex. 12 at 16. She had been "active and working out and believe[d] multiple factors contribute[d] to the exacerbation." *Id.*

- At an April 20, 2022 in-person physiatry evaluation, on exam, the left shoulder had normal ROM, reflexes, and strength; the only abnormal finding was decreased

sensation at the left axillary nerve. Ex. 12 at 18.[16] An ultrasound's findings were normal (with "no evidence of impingement," "no atrophy teres minor"). *Id.* at 18 – 19. The physiatrist administered another axillary nerve block injection, which delivered "significant improvement of the achy quality pain." *Id.* at 19 – 20. However, the nerve block "unmasked" a different "stabbing" pain. Ex. 12 at 21 – 23. The physiatrist considered that this *new* pain "may be associated with possible impingement," but that was not corroborated by a limited ultrasound performed on April 26, 2022. *Id.* at 24. In May 2022, the physiatrist prescribed gabapentin, and administered a steroid injection to the subacromial bursa. *Id.* at 25 – 28.

- At a May 16, 2022 telemedicine physiatry follow-up, Petitioner reported 85% improvement from the recent steroid injection, and "good relief" from gabapentin. Ex. 12 at 29. She described only "a small pinch in her left shoulder" constituting an "impairment." *Id.* The physiatrist assessed that Petitioner had experienced a "transient delayed exacerbation status post axillary nerve block 04/20/22." *Id.* at 30. He referred Petitioner for PT. *Id.*

- At the June 17, 2022, PT initial evaluation, Petitioner reported that the 2019 vaccination had caused left shoulder bursitis and impingement. Ex. 13 at 8. She currently had "sharp pain in the posterior shoulder then an ache that radiates down the arm… some N [numbness?] in the L hand with long periods of positioning. Agg. with reaching, lifting." *Id.* She was "work[ing] as a bartender – must lift kegs, repetitively use hands…" *Id.* She also had neck pain and hypermobile joints. *Id.* at 8, 11 – 13. On exam, the left shoulder had normal ROM with the possible exception of passive flexion and abduction ("catch around 95 but reaches full 180/180 degrees"). *Id.* at 9. The therapist's assessments were left shoulder pain and cervical radiculopathy. *Id.* at 13. After 12 sessions concluding on July 29, 2022, Petitioner's pain had improved. There does not appear to be a repeat physical examination or a discharge summary. Ex. 13 at 14 – 38; Ex. 16 at 1 – 52.

- Physiatry follow-up encounters took place via telemedicine on June 27, July 11, July 25, and September 26, 2022. *See generally* Ex. 17. The last encounter's record confirms that Petitioner was "now able to lift things with her shoulder, reach overhead, and has had significant improvement." *Id.* at 8. Her current pain rated 1 – 2/10. *Id.* At The physiatrist maintained that Petitioner's left shoulder pain was "consistent with SIRVA… and transient delayed exacerbation status post axillary nerve block 4/20/22." *Id.* at 9. She had "two pain subtypes"; the first was axillary nerve pain which had been temporarily relieved by the nerve block, currently

[16] April 20, 2022, was the physiatrist's final physical examination of Petitioner's left shoulder. All subsequent encounters were either focused on therapeutic procedures or conducted via telemedicine.

managed with gabapentin, and currently rated 2/10. *Id.* The second pain subtype was "mechanical mainly lateral pain with abduction," which was "unmasked" by the April 2022 nerve block. *Id.* Petitioner's description of this second pain subtype, and the significant relief from the May 2022 were suggestive of subacromial impingement but that was not confirmed on the ultrasound. *Id.* At the final encounter in September 2022, the physiatrist recorded that Petitioner had decreased pain and increased strength; she would try to take gabapentin less often, and she could return for another steroid injection if her pain worsened. *Id.* There are no further medical records.

IV. Affidavits

- In November 2021, Petitioner recalled: "[The physiatrist] recommended a procedure that would burn the nerve away, but I have not had this procedure done because I am very young and it is very risky. For the last two years since receiving the HPV vaccine, I have been in pain every single day. The nerve-blocking experience on February 3, 2020, is the only time since receiving the HPV vaccine that I have been pain-free. That brief period of pain relief made me realize just how much pain I have been living with for the last two years." Ex. 2 at ¶¶ 12 – 16.

- In July 2022, Petitioner alleged that the vaccine had caused a neuropathy. "Over time, the muscle controlled by that nerve has grown weak and I can't move my arm properly causing the shoulder joint bones to bang together when I raise my arm. The doctor [which?] said this is called an impingement." Ex. 14 at ¶ 16.

- In July 2023, Petitioner maintained that her left shoulder injury persisted over time; despite believing that was caused by the HPV vaccine (potentially a misadministration), she believed that vaccines overall were effective, and thus received others, including two in her still-injured left arm in 2021. Ex. 24 at ¶¶ 27 – 29. Petitioner also stated that her physiatrist "recently informed me that at this point, I may have developed a shoulder impingement issue from not using my shoulder due to my injury; this is causing a new type of pain in my left shoulder." *Id.* at ¶¶ 32 – 33.

- Also in July 2023, her mother offered similar recollections – including of the physiatrist's advice to rest the shoulder; Petitioner's decision to forego surgery due to potential side effects and lack of recovery; Petitioner's adherence to home exercises; and her experience of "daily pain for years." *See generally* Ex. 23.

V. Findings of Fact

A. Table SIRVA Claim

A Table SIRVA is not viable given the facts of this matter. First, Petitioner cannot show that her bursitis or any related musculoskeletal injury resembling SIRVA persisted for at least six months post-onset, as is required for all Program claims. Section 11(c)(1)(D)(i).

Respondent's objection on this threshold issue is reasonable, particularly in light of the over two-year gap in documentation of any left shoulder injury, despite intervening primary care encounters. It would have been helpful for Petitioner to argue more specifically about the duration of each alleged injury. *See generally* Brief at 10 – 12, Reply at 5 – 7. After I provided my preliminary assessment that there was stronger evidence of an ongoing nerve injury than any ongoing musculoskeletal injury, *see* Scheduling Order (ECF No. 50), Petitioner cited only to the *initial* assessments of bursitis (within three months post-vaccination), not to any later records. Status Report (ECF No. 53), citing Ex. 7 at 5.

The medical records support the conclusion that *initially* after the vaccination, Petitioner was identified to have bursitis. The bursal fluid was aspirated in December 2019, and a February 2020 repeat ultrasound suggested that condition was at least substantially resolved (given that three views were negative for bursitis or effusion, compared to only one view finding "equivocal" effusion). Ex. 12 at 13. Also in February 2020, the physiatrist emphasized that two steroid injections had provided "0% relief," and he believed that bursitis "may not be [Petitioner's] primary pain generator." *Id.* at 20.

However, although the bursitis diagnosis was carried forward in subsequent electronic medical records, it was eventually deleted by the physiatrist. *Compare* Ex. 12 at 27 and 28. Neither did the physiatrist endorse that any ongoing bursitis caused the suspected "impingement" documented in 2022. There is thus insufficient evidence to conclude that Petitioner's initial bursitis or any related musculoskeletal injury persisted for over six months post-vaccination. This is not cured by the physiatrist's continued use of the term SIRVA – since whether the injury meets the legal definition is a matter to be determined herein.

A second deficiency with the Table claim is Petitioner's inability to eliminate any "other condition or abnormality… that would explain [her] symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 C.F.R. § 100.3(c)(10)(iv). As the Table specifically states, "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 (even if the condition causing the neurological abnormality is not known)." 42 C.F.R. § 100.3(c)(10) at Preamble.

Respondent argues that Petitioner cannot meet this element, highlighting the physiatrist's focus shifting away from bursitis, and towards the axillary nerve injury. Rule 4(c) Report at 15 – 16. And in fact, the record reveals that the nerve injury is much more prominent in the medical records (both in 2019 – 2020, and in 2022). While it could be alleged on this record that the vaccination caused SIRVA-oriented inflammation in and around the bursa which secondarily caused a nerve injury (*see* Ex. 6 at 3 (neurologist's concern that the vaccination "directly injured the left axillary nerve due to swelling")), that has not been articulated by Petitioner – and would require further development, through medical experts on both sides. But how *both* a SIRVA and non-Table claim are viable has been inadequately explained by Petitioner – and she has failed to disentangle the alleged musculoskeletal and neurological injuries, sufficient to save the Table "side" of this claim. "Claims involving shoulder pathology in the presence of significant and potentially confounding neurologic signs and symptoms are better addressed on a causation-in-fact basis." *Durham v. Sec'y of Health & Hum. Servs.*, No. 17-1899V, 2023 WL 3196229 at *14 (Fed. Cl. Spec. Mstr. Apr. 7, 2023).[17]

B. Causation Claim Severity

As noted, a non-Table claim can be articulated based on the record evidence. Arguably, the vaccination was also followed by an axillary nerve injury which involved both pain and decreased sensation. The physiatrist believed that this was Petitioner's "primary pain generator." That was relieved only temporarily by a nerve block, so the physiatrist recommended ablation surgery. That injury was confirmed by a neurologist on February 27, 2020, and described in the mother's VAERS report five days later.

This claim likely would meet the severity requirement (unlike the Table claim). There is no evidence, or argument from Respondent, that this injury would have resolved within the next seven weeks. *See also, e.g., Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) (affirming that a radial nerve injury persisted for more than six months post-vaccination). To the contrary, when Petitioner eventually returned to the physiatrist in 2022, he recorded that the injury had "worsened," again found decreased

[17] Because Petitioner has failed to establish the Table SIRVA requirement at 42 C.F.R. § 100.3(c)(10)(iv), it is unnecessary to address the additional disputed requirements, *id.* at § (c)(10)(ii) (onset of shoulder pain within 48 hours post-vaccination); *id.* at § (c)(10)(iii) (requiring limited ROM).

sensation along the axillary nerve, maintained the same diagnosis, and relieved the pain with another axillary nerve block injection and gabapentin.

Petitioner and her mother have also explained that that in early 2020, they were concerned about the ablation surgery's risks and likelihood of success, and instead continued with rest over-the-counter pain medications. This explanation is acceptable – especially when focusing on the spring and summer of 2020, when the COVID-19 Pandemic emerged.[18] The primary care records *not* addressing the shoulder begin in *November* 2020, Ex. 7 at 9 – 10, and they are focused on other concerns. *Accord Kirby*, 997 F.3d at 1383 (holding that medical records were "silent about the existence of any lingering symptoms [but] also silent about the *non*existence of such symptoms").

Petitioner's explanation that she believed the HPV vaccine was improperly administered, but she was willing to receive additional vaccines and alternated between arms, is also a reasonable explanation. Moreover, when Petitioner finally returned in April 2022, the physiatrist endorsed that Petitioner's injury had "worsened," and found similar pain and decreased sensation at the deltoid, suggesting an axillary nerve injury, which was relieved by another axillary nerve block and gabapentin. *See, e.g.*, Ex. 12 at 18 – 19; Ex. 17 at 9. For the foregoing reasons, there is preponderant evidence of an axillary nerve injury persisting for over six months, and indeed through September 2022.[19]

VI. Conclusion and Order of Reassignment

Petitioner cannot meet the elements of a Table SIRVA claim, and it is therefore **DISMISSED.** But a causation-in-fact claim is tenable under the circumstances. To that end, and **pursuant to Vaccine Rule 3(d), the above-captioned case is hereby transferred out of SPU and reassigned randomly to a Special Master by the Clerk's Office. Further proceedings will be determined by the assigned Special Master.**

IT IS SO ORDERED.

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

[18] *See, e.g.*, Centers for Disease Control and Prevention, *CDC Museum COVID-19 Timeline*, https://www.cdc.gov/museum/timeline/covid19.html (last accessed Nov. 21, 2024) (describing the national emergency declaration, and preventative measures taken throughout the United States, beginning in March 2020).

[19] At the same time, the significant gap, despite ample opportunity to at least complain of an ongoing shoulder injury, suggests that the injury was less significant. *See also* Reply at 6 (stating that Petitioner had other "emergent priorities" in 2021).