In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1312V

WILLIAM RECORD,	*	Chief Special Master Corcoran
Petitioner,	*	
	*	Filed: September 3, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Brian Arnold, Brian R. Arnold & Assoc., Richardson, TX, for Petitioner.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On April 29, 2021, William Record (initially as a *pro se* litigant) filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Program").[2] Petition (ECF No. 1) at 1. Petitioner alleges that he suffered from a shoulder injury related to vaccine administration ("SIRVA," a Table claim), as a result of Hepatitis A ("Hep A") and B ("Hep B") vaccines he received on April 30, 2018, and/or that these vaccines caused some other constellation of injuries. *Id.* The matter went to trial on March 13, 2024. Now, having reviewed the record, trial testimony, expert reports, and other briefing, I find Petitioner is not entitled to compensation, for the reasons set forth below.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Vaccination and Treatment through August 2018

Petitioner was born on January 28, 1957, and had a medical history significant for (among other things) spinal stenosis, sciatica, and bilateral carpal tunnel syndrome ("CTS"). Ex. 2 at 8, 10, 18–20.

On April 26, 2018, Petitioner visited registered pharmacist Lori Luyk in preparation for an upcoming trip to Brazil. Ex. 2 at 16. Ms. Luyk recommended that Petitioner make a pre-travel immunizations appointment to receive Hep A, Hep B, and yellow fever vaccines. *Id.* On April 30, 2018, Petitioner received the Hep A and Hep B vaccines, and further consented to receive the European yellow fever vaccine.[3] (only the Hep A and B vaccines are at issue in this case). There is no record evidence of any immediate vaccine reaction.

More than two months later, on June 14, 2018, Petitioner went to his primary care physician Dr. Robert Beeson complaining of bilateral shoulder pain for one month (which would place onset in mid-May). Ex. 3 at 3. Petitioner specifically reported pain with lifting his arms and rolling onto his shoulders, adding that the pain was worse in the morning but improved throughout the day, and claiming his symptoms began after being vaccinated in April. *Id.* Upon examination, Petitioner demonstrated pain with abduction, external rotation, and internal rotation of the shoulders. *Id.* Dr. Beeson's assessment was bilateral shoulder pain and lumbar radiculopathy, and he recommended physical therapy ("PT"), which Petitioner declined, and further laboratory testing.[4] *Id.*

On July 12, 2018, Petitioner returned to Dr. Beeson complaining of persistent bilateral shoulder pain. Ex. 3 at 5. Petitioner also raised a new complaint of bilateral wrist and hand pain (left more than right), with numbness in the first four fingers along with swelling (although he did not identify precisely when these new symptoms began). *Id.* Petitioner's previous lumbar radicular pain was seen as improved, and he exhibited positive results on Phalen's testing.[5] *Id.* Dr. Beeson's assessment was bilateral CTS. *Id.* He recommended prednisone and referred Petitioner for additional testing.

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[3] Ms. Luyk reviewed with Petitioner that the yellow fever vaccine approved for use in the United States was currently unavailable, and that he would be required to sign a consent form to receive the European yellow fever vaccine, which has not yet been approved by the FDA. Ex. 2 at 20.

[4] Petitioner's lab results revealed mildly elevated C-reactive protein, which in Dr. Beeson's view was not high enough to indicate polymyalgia rheumatica. Ex. 2 at 25.

[5] "Phalen test" is where "the size of the carpal tunnel is reduced by holding the affected hand with the wrist fully flexed or extended for 30 to 60 seconds, or by placing a sphygmomanometer cuff on the involved arm and inflating to a point between diastolic and systolic pressure; appearance of numbness or paresthesias indicates carpal tunnel syndrome." *Phalen test*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112848 (last visited Sept. 3, 2024).

Petitioner thereafter saw neurologist Dr. Peter Bergman on July 30, 2018, for an evaluation of his hand numbness and to undergo EMG[6] and NCS[7] testing. Ex. 3 at 7. Testing results revealed bilateral severe median neuropathy at the wrist, with active denervation of the abductor pollicis brevis ("APB") muscle present on the left. *Id.*

Treatment in Second Half of 2018 and Suspicion of Different Explanations

On August 10, 2018, Petitioner visited family medicine specialist Dr. Emily Masterson for ongoing bilateral shoulder pain and hand swelling, with the former identified to have begun approximately twenty-four hours after Petitioner's April receipt of the Hep A and Hep B vaccines, and the latter developing "the end of June to July." Ex. 3 at 12. Dr. Masterson noted Petitioner's assertion that the prednisone he had taken had reduced the shoulder pain but not helped with his hand issues. *Id.*

Upon examination, Petitioner exhibited a painful arc bilaterally, decreased internal rotation bilaterally, negative empty can test bilaterally, and mild impingement signs on the left side but with none on the right. Ex. 3 at 12. It was proposed that Petitioner's CTS pain was likely secondary to swelling from a possible vaccine reaction, although Dr. Masterson allowed that Petitioner may have had some mild pre-existing CTS. *Id.* at 13. She also proposed the possibility of reactive arthritis, and did not rule out a vaccine reaction. *Id.* Dr. Masterson referred Petitioner to orthopedics, rheumatology, and immunology/allergy, for further consultation. *Id.*

Dr. Masterson initially conferred with an in-network rheumatologist, Dr. Matthew Husa. *See generally* Ex. 2 at 60–61, 66. Dr. Husa disclaimed expertise to comment on vaccine causation, however, referring Dr. Masterson to allergy/immunology. *Id.* at 66. Otherwise, he proposed testing relevant to rheumatologic conditions, and characterized the attempt to identify an explanation for Mr. Record's presentation to come down to either some form of "atypical reaction" to his vaccinations or "just an odd occurrence of inflammatory arthritis." *Id.* at 60.

Next, on August 20, 2018, Petitioner saw allergy and immunology specialist Dr. Jatinder Aulakh. Ex. 3 at 14. Dr. Aulakh reviewed Petitioner's prior lab results and noted that Petitioner showed signs of elevated C-reactive protein and total complement (biomarkers for active inflammation), but deemed the rest of the findings normal. *Id.* Dr. Aulakh further noted a family history of arthritis, and observed some synovial thickening over Petitioner's metacarpophalangeal

[6] "Electromyography" is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needles electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited Sept. 3, 2024).

[7] Nerve Conduction Studies "involve eliciting nerve action potentials at sites along a peripheral nerve and recording the response from another site along the nerve or from a muscle innervated by that nerve." R. O'Bryan & J. Kincaid, *Nerve Conduction Studies: Basic Concepts and Patterns of Abnormalities*, 39 Neurol Clin. (2021) (available at https://pubmed.ncbi.nlm.nih.gov/34602218/) (last visited Sept. 3, 2024).

("MCP") joints. *Id.* His assessment was possible reactive arthritis, but noted that "[a]t this time[,] suspicion of seronegative rheumatoid arthritis is higher." *Id.* Dr. Aulakh ordered additional immunological work-up. *Id.* at 16.

On August 23, 2018, Petitioner saw rheumatologist Dr. Tyson Hagen for an evaluation of his shoulder, wrist, and hand pain and stiffness. Ex. 3 at 18. Petitioner again reported shoulder pain beginning the day after his April vaccinations, adding that it had worsened significantly over the next nine days, moving down to his elbows over the course of several weeks. *Id.* Petitioner also noted that he had previously experienced sciatica, plus hip and buttock pain the week prior to receiving the vaccinations in question, but that the pain resolved quickly. *Id.* at 19. Petitioner stated that he began experiencing symptoms in his hands in early July, and since then had completed two courses of prednisone. *Id.*

Dr. Hagen's assessment included inflammatory polyarthritis and bilateral CTS, but noted that "[i]t is not clear at this time if this is just a reactive arthritis from the vaccinations or if this is an onset of a more chronic inflammatory condition." Ex. 3 at 20. Dr. Hagen also considered polymyalgia rheumatica, seronegative rheumatoid arthritis, and other seronegative inflammatory polyarthritis as diagnostic possibilities. *Id.* He further documented that "[Petitioner] had pre-existing carpal tunnel syndrome in both hands. The inflammation of the wrists seems to have exacerbated his carpal tunnel symptoms." *Id.* Dr. Hagen advised Petitioner to continue wearing his CTS braces and to return in three months or soon if necessary. *Id.* at 20–21.

On August 27, 2018, Petitioner saw orthopedist Dr. Sean Haney for a consultation. Ex. 3 at 23. During examination, Petitioner exhibited 180 degrees of forward flexion, 85 degrees of external rotation, internal rotation to L1, and 5/5 cuff strength. *Id.* Dr. Haney documented Petitioner's bilateral shoulder pain as multifactorial, noting that "[h]e clearly has an element of reactive arthritis." *Id.* Dr. Haney recommended PT and prednisone, and discussed the possibility of surgical release for his CTS. *Id.* at 24. Petitioner elected to proceed with surgery, and on October 16, 2018, Petitioner underwent carpal tunnel release of his left hand. Ex. 3 at 24; Ex. 2 at 114.

Subsequent Treatment

Petitioner returned to see Dr. Hagen for a follow-up appointment on October 29, 2018. Ex. 3 at 26. He now reported improved symptoms from his CTS release ten days prior, with his left forearm pain now gone, although his MCP joints were still swollen. *Id.* Dr. Hagen stated that "[Petitioner] has some active inflammatory arthritis" and recommended repeat labs and to start Methotrexate (a rheumatic drug) in four weeks if the lab results were sufficient. *Id.* at 27. On December 14, 2018, Petitioner underwent carpal tunnel release of his right hand. Ex. 2 at 151.

Petitioner had an orthopedic follow-up appointment on February 14, 2019, at which time he reported that he was no longer having symptoms at night, his sensation was gradually improving, and that it had been recommended for him to return to activity as tolerated. Ex. 3 at 28. Six days later, on February 20, 2019, Petitioner saw Dr. Hagen. *Id.* at 29. He reported that he still

had swelling in his MCP joints, but was otherwise tolerating the Methotrexate well. *Id.* Dr. Hagen recommend increasing Petitioner's dosage in order to get better control of the inflammation. *Id.*

The filed records indicate that Petitioner saw Dr. Hagen on three other occasions, with his last documented visit occurring on February 13, 2020. Ex. 2 at 211. At that time, Dr. Hagen observed no synovitis on examination and noted that Petitioner was tolerating his methotrexate well and there had been no major flares of joint pain or swelling since his last visit. *Id.* Petitioner reported some intermittent soreness in his shoulders and some mildly decreased sensation in his left thumb, index and middle fingers that was stable. *Id.* No further records have been filed in this case.

II. Witness Testimony

A. Fact Witnesses[8]

1. *William Record* – Petitioner offered testimony at the hearing. Tr. at 9–39. At the time of vaccination, Petitioner was working for a medical supply company in Colorado. *Id.* at 11. He confirmed receipt of the Hep A and B vaccines (along with a vaccine not covered in the Program) in Colorado on April 30, 2018—with one administered in each arm. *Id.* at 10. He was at that time planning a trip to South America for his daughter's wedding. *Id.* at 11. Petitioner had no pre-vaccination history of shoulder injury, and felt well the day of vaccination. *Id.* at 11–12.

A nurse practitioner was responsible for administering the vaccines, and Petitioner recalled sensing that they were given too high in his shoulder. Tr. at 13–14. He did not, however, feel more than some soreness immediately after, consistent with what he expected from a vaccination. *Id.* at 14. However, the soreness sensation grew by the day after, and he also began to experience problems with moving his arm and discomfort during sleep. *Id.* at 15–16.

Petitioner thereafter travelled abroad as originally planned, but continued to notice issues with pain and arm movement. Tr. at 17–18. He took some over-the-counter anti-inflammatory medications, which provided limited relief, but did not seek medical treatment. *Id.* at 18. By the time of his return to the U.S., Petitioner was still assuming the problem was transient in nature, but started to notice his symptoms "migrate a little bit down my arm," leading him to call his medical provider for an in-person treatment (set for mid-June). *Id.* at 19. There, Petitioner reported his severe pain and the range of motion limitations he was experiencing, but he was told to self-medicate with more anti-inflammatories, and to return for more care if improvement was not observed. *Id.* at 20–21.

[8] Petitioner also offered an affidavit from his stepdaughter, Paige Nicole Lopez. *See generally* Ex. 13 (ECF No. 52-1). However, Ms. Lopez did not testify at trial—and because the subjects she addresses in her witness statement were adequately covered at hearing, and are otherwise not dispositive of the case. I do not summarize the contents of that statement.

A month later, Petitioner returned to his medical treater in mid-July, and was now feeling worse, with pain "down through my elbows and was in my wrists and going into my hands," plus growing hand numbness and swelling. Tr. at 22. He also recalled experiencing ongoing shoulder pain and swelling. *Id.* Although Petitioner did not sense that his treater was taking seriously his condition, he was prescribed a steroid and some sleeping medication. *Id.* at 22–23. Petitioner deemed the steroid effective in reducing his swelling/inflammation, although his hand and finger symptoms were making it difficult for him to type at work. *Id.* at 23–24.

Petitioner opted for a different treater (Dr. Masterson) in August, and she continued steroid treatment while also recommending that he see rheumatology and neurology specialists. Tr. at 24–25. He subsequently went to Dr. Hagen, who recommended a different medication from a steroid. *Id.* at 26. By this point, Petitioner was having increased difficulties with arm movement and use of his hands for fine motor actions like buttoning his clothes. *Id.* at 27. But as the record discussed above reveals, Petitioner had been diagnosed with CTS, and he recalled being told by a treater that "severe inflammation and swelling" had caused the nerve blockage resulting in his CTS symptoms. *Id.* at 28. He also testified being told that his shoulder inflammation and problems "had to have been" associated with his CTS, since the problems had "moved right down my arms." *Id.*

Petitioner noted the CTS-related surgeries he had underwent, acknowledging that they improved his hand sensation and use despite the prior nerve damage. Tr. at 29. His shoulders are also improved since the fall of 2018, noting in particular the range of motion improvements, although he does still occasionally experience pain. *Id.* at 29–30. But Petitioner stressed he had never experienced CTS prior to his April 2018 vaccinations. *Id.* at 30. And his post-vaccination symptoms had impacted his ability to work that summer into the fall, as well as his pursuit of a variety of outdoor activities he enjoyed. *Id.* at 30–32. It is Petitioner's belief that the misadministration of the Hep A and B vaccines resulted in the injuries that followed. *Id.* at 32–33.

On cross-examination, Petitioner acknowledged receiving the Hep A and B vaccines in the past without incident. Tr. at 35–36. He clarified that he had reported to Dr. Hagen in August 2018 that his soreness post-vaccination had not become painful until nine days later, but added that he viewed this as a progression in the degree of pain, rather than a difference between soreness and outright pain. *Id.* at 39. Petitioner also noted that he had reported to a treater in the summer of 2018 that he was experiencing morning stiffness that would dissipate as the day went on. *Id.* at 37–38. Today, he has continued treatment with no specialist akin to those he saw that summer, other than a rheumatologist, and continues medication prescribed for rheumatologic conditions. *Id.* at 38.

2. *Dawn Record* – Mrs. Record, the Petitioner's wife, offered brief testimony in support of the claim. Tr. at 67–78. She also received vaccines at the same time as Mr. Record (and at the same location), in advance of their planned international travel. *Id.* at 68. She recalled him informing her the same day that he had received the vaccines at too high a place on his

shoulder, and that he felt immediate soreness and subsequent pain. *Id.* at 69, 70, 77. He also displayed range of motion limits during their travel. *Id.* at 72.

Prior to this incident, Petitioner had been in good health, with no evident issues in his arms. Tr. at 69–70. But Mrs. Record observed Petitioner to continue to experience worsening of symptoms after their trip, and eventually it was recommended that he pursue specialized evaluations. *Id.* at 72–73. She was also present at Petitioner's visit to Dr. Su, who proposed that Petitioner's CTS-hand symptoms could reflect inflammation that had begun in his shoulders. *Id.* at 75. Over the time of his injury, Petitioner found it increasingly difficult to work or engage in pursuits he enjoyed. *Id.* at 75–76. But in the time since Petitioner's hand surgeries and receipt of different medications, he has experienced improvement. *Id.* at 76–77.

B. Petitioner's Expert – Dr. Ava Stanczak

Dr. Stanczak, an osteopathic physician, offered two written reports and testified on behalf of Petitioner. Report, dated Aug. 5, 2022, filed as Ex. 11 (ECF No. 33-1) ("Stanczak First Rep."); Report, dated Feb. 22, 2023, filed as Ex. 12 (ECF No. 43-1) ("Stanczak Supp. Rep."). Dr. Stanczak proposed that Petitioner suffered a shoulder injury bilaterally after receipt of the Hep A and Hep B vaccines. Stanczak First Rep. at 1.

Dr. Stanczak attended North Texas State University for her undergraduate degree, and Texas College of Osteopathic Medicine for her doctor of osteopathy. *See* Curriculum Vitae, filed Dec. 8, 2022 (ECF No. 40-1) ("Stanczak CV") at 1; Tr. at 41–42. She then completed an internship in Pediatrics, followed by her residency in Pediatrics at Children's Medical Center in Dallas Texas. *Id.* She is currently the Associate Dean of Primary Care at Kansas College of Osteopathic Medicine. *Id.* at 3. Dr. Stanczak is board certified by the American Board of Osteopathic Pediatrics, as well as board certified in Urgent Care Medicine. *Id.* at 1. Dr. Stanczak acknowledged, however, that her focus is not on treatment of vaccine injuries or SIRVAs. Tr. at 62.[9]

Dr. Stanczak began her testimony by stressing how the mechanics of vaccine administration could cause injury. Tr. at 45–46. If not properly administered into the deltoid muscle, a vaccine's antigenic components could enter the bursal space in a joint, producing a significant inflammatory reaction. *Id.* at 46, 49, 50–52 (discussing literature specific to SIRVA). The record in this case suggested to Dr. Stanczak that Petitioner had been given the Hep A and B

[9] There was also some dispute between the parties as to the degree or nature of Dr. Stanczak's expertise as applied to the issues disputed in this action. Tr. at 103–04. As I noted during the trial, however, while I deemed Dr. Stanczak competent to testify in this case generally, I do not accept her as a "SIRVA expert" *specifically*. This only means, however, that opinions she offered about the nature of SIRVA and its purported association with CTS did not gain heft simply due to the fact she supplied them, since she has no demonstrated special knowledge of SIRVA. *Id.* at 104–05. I otherwise have considered carefully her opinion, and took it into account in reaching my decision.

vaccines too high in his shoulder, consistent with a SIRVA injury. *Id.* at 46, 48–49.[10] And Petitioner's pain had likely begun in the timeframe defined by the Table. *Id.* at 50.[11] She thus concluded that the record supported the conclusion that Petitioner experienced a SIRVA. *Id.* at 53.

Dr. Stanczak also endeavored to establish that Petitioner's non-shoulder symptoms and injuries were associated with his purported SIRVA. She sketched out a theory in which vaccination could cause an "acute inflammatory response," leading to cytokine production and downstream symptoms indicative of excessive inflammation, like swelling, pain, and nerve compression. Tr. at 53–54. Nerves in the shoulder branch down into the arm, and could result in CTS due to inflammation and damage beginning in the shoulder. *Id.* at 55, 57–58. Indeed, one such nerve (the median nerve) is connected with CTS. *Id.* at 66–67. Dr. Stanczak derived this opinion in part from record evidence suggesting Petitioner's treaters had proposed such a connection. *Id.* at 56. She also opined that Petitioner's treatment delay had exacerbated his subsequent CTS. *Id.* at 58–59.

On cross, Dr. Stanczak acknowledged that her conclusion that the covered vaccines were misadministered was derived not from a medical record but from Petitioner's testimonial recollection of his vaccinations. Tr. at 63. She further admitted that the opinion offered to establish a mechanistic association between Petitioner's SIRVA and his subsequent CTS was largely not found in her written reports. *Id.* at 64. The only independent evidence she could offer for this alleged association was in an article specific to SIRVA. *See* S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Ex. 12.1 (ECF No. 43-2) ("Atanasoff").

Dr. Stanczak was also recalled for Petitioner's rebuttal case. *See generally* Tr. at 105–06. She maintained that she had referenced some independent literature involving CTS and its association with SIRVA. *Id.* at 105; *see* M. Bodor & E. Montalvo, *Vaccine-Related Shoulder Dysfunction*, 25 Vaccine 585 (2009), filed as Ex. 12.3 (ECF No. 43-4) ("Bodor & Montalvo"). She also reiterated her view that the record supported Petitioner's SIRVA claim allegations, and that she properly took into account the Petitioner's personal contentions (along with other fact witnesses like Mrs. Record) in reaching the opinions she espoused. Tr. at 105–06.

[10] Although Petitioner received a non-covered vaccine (yellow fever) at the time he also received the Hep A and B vaccines, Dr. Stanczak proposed it unlikely the yellow fever vaccine had been mis-administered, since the record showed it was a vaccine administered subcutaneously, with no risk it might have been introduced into the wrong place on the arm. Tr. at 47.

[11] Dr. Stancak was also asked some conclusory questions about Petitioner's success in meeting other SIRVA elements (Tr. at 50, 52–53, 60–61), but I do not summarize those responses since such vouching is not persuasive, or the proper role of an expert.

C. Respondent's Expert – Dr. Geoffrey D. Abrams

Dr. Abrams, a board-certified orthopedic surgeon, offered one written report and testified on behalf of Respondent. Report, dated Nov. 6, 2022, filed as Ex. A (ECF No. 38-1) ("Abrams Rep."). He opined that Petitioner's shoulder symptoms following receipt of the relevant vaccines are not consistent with that of a SIRVA injury, and were not otherwise vaccine-caused (including Petitioner' CTS). *Id.* at 6.

Dr. Abrams attended Stanford University for his undergraduate degree, and the University of California, San Diego for his medical degree. *See* Curriculum Vitae, filed as Ex. B (ECF No. 38-9) ("Abrams CV") at 1. He then completed a surgical internship followed by his residency at Stanford University Hospital and Clinics. *Id.* Thereafter, Dr. Abrams completed a fellowship in Orthopedic Sports Medicine at Rush University Medical Center. *Id.* He is currently an Associate Professor of Orthopedic Surgery at Stanford University School of Medicine, as well as the Director of the Lacob Family Sports Medicine Center at Stanford University. *Id.*; Abrams Rep. at 1. Dr. Abrams also serves as Team Physician for numerous professional and collegiate sports teams in the San Francisco Bay Area. Abrams CV at 32–33; Abrams Rep. at 1. He has a surgical practice that focuses on orthopedic conditions of the shoulder, and he has also published extensively on shoulder and other musculoskeletal pathology. Abrams Rep. at 1.

Dr. Abrams started his testimony with an explanation for how SIRVA injuries are theorized to occur (consistent with Dr. Stanczak's opinion). Tr. at 81–82. He characterized SIRVA as featuring not only the elements relevant to the Table claim (such as immediate pain and range of motion limits) but also "bone bruising, swelling in the subacromial bursa space, as well as occasional rotator cuff problems," with bursitis, tendinitis, and capsulitis as common diagnoses connected to a SIRVA. *Id.* at 82, 83. But SIRVA is often comorbid with preexisting but benign deficits that only manifest after the initial SIRVA pain, like tears or arthritic conditions. *Id.* at 82–84. It also is characterized by shoulder-specific inflammation that does not migrate down the arm or elsewhere. *Id.* at 88–89.

Petitioner's description of his injury course, Dr. Abrams contended, was not consistent with the acute nature of a SIRVA. Dr. Abrams understood Petitioner to have experienced a gradual onset of pain over time, with some intermittent improvement, and he deemed that "atypical" of a SIRVA. Tr. at 85. He also maintained that range of motion issues would be immediately associated with initial vaccine administration—such that Petitioner's lack of reported range of motion limits in mid-June 2018 (as opposed to pain *with* motion) was also not SIRVA-like. *Id.* at 86–87. Moreover, Petitioner reported the most treatment success with methotrexate—an immunosuppressant drug not commonly used in the treatment of SIRVA injuries (although it is used for inflammation associated with rheumatic conditions). *Id.* at 87–88, 101–02. (On cross-examination, however, Dr. Abrams allowed that Petitioner had testified to experiencing more traditional SIRVA-associated symptoms, even if Dr. Abrams interpreted the record as inconsistent with the injury. Tr. at 100).

In addition, Dr. Abrams noted the extent to which a large number of Petitioner's post-vaccination complaints were not shoulder-specific. For example, Petitioner had noted he had sleep difficulties due to forearm pain, which was not characteristic of SIRVA. Tr. at 89. Dr. Abrams also disputed that wrist pain could ever *be* a SIRVA symptom. *Id.* at 90. The same, he maintained, was true of CTS itself, not something thought to have any relationship with SIRVA. *Id.*

Dr. Abrams particularly disputed Dr. Stanczak's argument that CTS could be the downstream result of shoulder inflammation, noting that authority offered by the Petitioner for this contention did not address CTS. Tr. at 91; *See generally* Atanasoff, Bodor & Montalvo. He similarly denied that the inflammation associated with a SIRVA could ever become severe enough to cause median nerve compression at that situs that would then result in downstream wrist harm. Tr. at 92. Anatomically, he maintained, inflammation in the bursa would not be expected to spread down the arm in the manner proposed in Dr. Stanczak's theory. Tr. at 92–94. To illustrate the point, Dr. Abrams used a visual aid of nerves in the shoulder and bursal region. *Id.* at 95–96. In fact, Dr. Abrams argued, if inflammation in the median nerve starting at the shoulder *could* spread down the arm, one would expect inflammation all the way down throughout the arm—but Petitioner's EMG/NCS test results did not confirm the presence of that universal degree of nerve-related dysfunction. *Id.* at 96–98.

III. Procedural History

After the case's initiation, the matter was assigned to a different special master before being reassigned to me in August 2021. Respondent filed his Rule 4(c) Report contesting Petitioner's right to compensation on February 28, 2022 (ECF No. 29). On August 26, 2022, Petitioner filed an amended petition asserting a SIRVA Table claim. *See* Amended Petition, dated Aug. 26, 2022 (ECF No. 35). The process of obtaining expert reports began, with the final report from Dr. Stanczak filed in April 2023. The parties submitted pre-hearing submissions, and then a one-day Entitlement Hearing occurred on March 13, 2024. The matter is now fully ripe for resolution.

IV. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*,

440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] Petitioner asserts a Table SIRVA claim, in addition to a non-Table claim based on the same facts.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface*, 165 F.3d at 1352–53); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & 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 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen*

[12] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary

evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical

records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the

accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to

determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. Petitioner Cannot Preponderantly Establish a Table SIRVA Claim

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 pain from the vaccine administration manifests within 48 hours.

42 C.F. R. § 100.3(a)(XIV)(B). Additional relevant criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("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 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).

Here, Petitioner can substantiate some elements of a Table SIRVA. For example, the record establishes his onset of pain as occurring within 48 hours of vaccination—based on a combination of record proof and witness contentions. In addition, Mr. Record reported range of motion limits, even if not consistently. And he had no demonstrated prior history of *shoulder* pain (as opposed to CTS).

However, other aspects of the record are inconsistent with a Table SIRVA. The largest deficiency with the claim is the fact that Petitioner eventually reported pain and other symptoms *not* characteristic of SIRVA, affecting his hands and wrists in particular. Indeed, these issues eventually predominated his treatment. Thus, by the late summer/early fall of 2018, Petitioner was predominantly receiving rheumatologic care for his complaints, and medications more specific to such treatment. The CTS-oriented surgical procedures he underwent are also wholly uncharacteristic of SIRVA. Thus, the record overall does not establish that Petitioner's complaints

were shoulder-specific, even if *initially* they appeared to be. And an alternative explanation—reactive arthritis—was proposed by several treaters, and never ruled out, nor was SIRVA itself embraced as the most likely diagnostic explanation for what Petitioner experienced.

My conclusion remains even if I ignored all the CTS-oriented treatment the Petitioner received, and focused only on SIRVA-specific elements. This is because a Table claim is subject to the same requirement of proof of six months severity that any Program claim must meet. *Song v. Sec'y of Health & Hum. Servs.*, 31 Fed. Cl. 61, 65 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 1994) (unpublished); *Crabbe v. Sec'y of Health & Hum. Servs.*, No. 10-762V, 2011 WL 4436724, at *1 (Fed. Cl. Spec. Mstr. Aug. 26, 2011). And the evidence in this case does not preponderate in favor of a finding of severity.

Assuming that Petitioner's pain onset began the day of, or even one day after the April 30, 2018 vaccinations, the record does not show that his shoulder-specific concerns continued through the end of October 2018. On the contrary—by that time, his entire focus was on CTS, for which he was seeing a rheumatologist, Dr. Hagen. And his treatments were all aimed at remedying those symptoms. Thus, this case does not present circumstances common to SIRVAs, where a person either (in the worst case) undergoes arthroscopic surgery, obtains steroid shots to minimize pain, or otherwise engages in extensive physical therapy. This record does not establish that any initial pain Petitioner might have experienced due to vaccine misadministration was severe enough to meet the Act's foundational severity requirement. *Wagner v. Sec'y of Health & Hum. Servs.*, No. 17-1388V, 2019 WL 3297509, at *5 (Fed. Cl. Spec. Mstr. May 8, 2019) (finding that "[w]hile even mild symptoms that do not require medical care may satisfy the severity requirement, ongoing medical treatment for conditions *unrelated* to the alleged vaccine injury do not") (emphasis in original).

In so determining, I find unpersuasive Petitioner's strained effort to connect his documented CTS issues with any SIRVA-like symptoms he experienced post-vaccination—and thus the ongoing nature of his CTS diagnosis and treatment is not a SIRVA-related sequelae that could meet the severity requirement, even after his shoulder complaints had ceased. SIRVA and CTS are simply *unrelated* conditions. And as Dr. Abrams established, it is *highly* unlikely that SIRVA-associated inflammation would both "spread" down the arm and also be capable of causing the symptoms associated with, or leading to, CTS. By contrast, Dr. Stanczak was unpersuasive on this issue, and lacked a sufficient personal background in treating or studying *either* condition (let alone their relationship) to offer a reliable opinion on the topic. In addition, no other independent evidence was referenced suggesting CTS and SIRVA could be related as alleged herein. And it is undisputed that Petitioner had experienced CTS prior to vaccination in any event.

II. Petitioner Cannot Establish a Causation-in-Fact Claim

The same facts and findings set forth above lead me to conclude that no causation-in-fact claim would be viable. Because Petitioner cannot establish that his SIRVA persisted for more than six months, any causation claim would involve a finding that the Hep A and B vaccines caused him to experience CTS. But the record does not support this determination, in several regards.

As noted, Dr. Stanczak did not credibly establish that a SIRVA could morph into CTS, or worsen[13] a preexisting case of it. In addition, the *Althen* prongs were not at all met on a theory that the Hep A and/or B vaccines can cause CTS in the first place. Dr. Stanczak also did not offer a reliable theory that these vaccines (or even any covered vaccine) could worsen CTS. Rather, the entirety of her theory relied on connecting the SIRVA to CTS, but she did not persuasively establish this (for the reasons previously discussed).

The record similarly does not support the conclusion that these vaccines likely "did cause" Petitioner's CTS. While some treaters, like Dr. Masterson (in reaction to Petitioner's reports to them) allowed for a possibility of a vaccine reaction, that conclusion was not later accepted or deemed likely. Petitioner's history at most suggests an initial SIRVA-like reaction that later waned, with his preexisting CTS flaring up independently and concurrently—but *coincidental* to vaccination. Nor has Petitioner established his CTS began, or worsened, in a medically acceptable timeframe measured from the date of vaccination. The record suggests Petitioner first complained of wrist or hand-associated issues in mid-July 2018, or two and one-half months after vaccination at the end of April. At best, based on his own testimony, he first felt post-vaccination hand symptoms like swelling at the end of June—two months after the vaccinations. But no reliable

[13] Petitioner has not formally alleged a significant aggravation claim based on the six-prong test set in *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). The *Loving* test's elements require establishing:

> (1) The person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

In *Sharpe v. Sec'y of Health & Hum. Servs.*, 964 F.3d 1072 (Fed. Cir. 2020), the Federal Circuit further elaborated on the *Loving* framework. Under Prong (3) of the *Loving* test, the Petitioner need not demonstrate an *expected* outcome, but merely that her current-post vaccination condition was worse than pre-vaccination. *Sharpe*, 964 F.3d at 1081. And a claimant may make out a prima facie case of significant aggravation overall without eliminating a preexisting condition as the potential cause of her significantly aggravated injury (although the Circuit's recasting of the significant aggravation standard sill permits Respondent to attempt to establish alternative cause, where a petitioner's showing is enough to make out a prima facie case and thereby shift the burden of proof to Respondent). *Id.* at 1083.

evidence has been offered in this case supporting a timeframe of two or more months after vaccination as medically acceptable.

CONCLUSION

Petitioner has not carried his burden of proof, and therefore the claim is dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision. [14]

IT IS SO ORDERED.

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

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