In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-669V
Filed: August 11, 2023

IVONNE LUTES,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for petitioner.
Nina Ren, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On January 12, 2021, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered a Table Injury of Shoulder Injury Related to Vaccine Administration ("SIRVA") in her left shoulder following an influenza ("flu") vaccination she received on October 16, 2019. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for her alleged Table Injury.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document 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] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination, which is also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. *See* § 300aa-13(a)(1); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a).

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

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Vaccine Program petitioners must establish their claim by a "preponderance of the evidence." § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. *See* § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005); § 300aa-13(a)(1)(B).

II. Procedural History

At the time the petition was filed, petitioner also filed medical records marked as Exhibits 1-5 and an affidavit marked as Exhibit 6. (ECF N. 1.) Further medical records (Exs. 7, 10) were subsequently filed along with two witness statements (Exs. 8-9). Petitioner ultimately filed a Statement of Completion on July 21, 2022. (ECF No. 30.) The case was initially assigned to the Special Processing Unit ("SPU") based on the allegations of the petition. (ECF Nos. 12, 14.)

The parties initially attempted settlement, but advised as of December 14, 2022, that they had reached an impasse. (ECF No. 34.) Respondent filed his Rule 4 Report recommending against compensation on February 13, 2023, and the case was reassigned to the undersigned shortly thereafter on February 23, 2023. (ECF Nos. 36-38.) Respondent's report raised issues with regard to onset of petitioner's shoulder pain as well as whether she suffered adhesive capsulitis caused by her preexisting diabetes. (ECF No. 36, pp. 5-7.)

On February 24, 2023, I instructed the parties to advise as to whether the record was ripe for resolution of the onset issue raised by respondent. (Scheduling Order (Non-PDF), 2/24/2023.) The parties agreed. (ECF No. 39.) Subsequently, petitioner filed a motion for a ruling on the record regarding all aspects of entitlement and requesting that she be found entitled to compensation for a Table Injury of SIRVA. (ECF No. 40.) In his response, respondent confirmed that he "agrees this case is ripe for adjudication." (ECF No. 41, p. 2.) However, respondent argued that the case should be dismissed. (*Id*.) Petitioner filed her reply on May 25, 2023. (ECF No. 42.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that, given the parties' assent, it is appropriate to resolve entitlement on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir.

2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

Petitioner received the flu vaccination at issue in this case on October 16, 2019, at the age of sixty-one. (Ex. 1.) Her prior medical history included chronic pain syndrome, type 2 diabetes, fibromyalgia, carpal tunnel syndrome, and low back pain. (Exs. 2, pp. 17-24; 7, p. 131.) Petitioner was disabled. (*Id*. at 17.)

Petitioner's sister, Catherine Barrios, has provided a signed statement indicating that petitioner contacted her during the third week of October 2019 and complained that her arm "had been very painful" since receiving the flu shot. (Ex. 8.) Thereafter, Ms. Barrios traveled to petitioner's home and stayed for two weeks, during which time she observed petitioner in pain and having reduced range of motion. (*Id.*) Petitioner's niece, Eliza Barrios, states that sometime during the month of October 2019, petitioner told her that she had been suffering pain that was more severe than she experienced with prior vaccinations. (Ex. 9.) She indicates that approximately one week later, petitioner came to her house, where she visualized the injection site and advised petitioner to see a doctor. (*Id.*)

Petitioner first presented for care for her alleged SIRVA on December 26, 2019, which respondent stresses was 71 days post-vaccination. (Ex. 7, p. 15.) At that time, she saw her primary care provider, Dr. Michaels, to review her mammogram results and also complained of pain at her vaccine injection site, which she reported as being severe enough to interfere with her sleep. (*Id*.) Dr. Michaels recorded that she had reduced range of motion in all planes. (*Id*. at 16.) He referred her to physical therapy. (*Id.* at 17.)

Petitioner presented for a physical therapy evaluation on February 6, 2020. (Ex. 2, pp. 24-28.) The reported history indicated that her shoulder pain began "within [a] week of having [the] flu shot." (*Id*.at 26.) A separate notation indicated "[l]eft should[er] pain sincccce [sic] October 2019 after flu shot." (*Id*. at 28.) Confusingly, however, the date of injury is specifically listed as October 6, 2019, which is prior to the date of the subject flu vaccination. (*Id*. at 25.) Petitioner returned to Dr. Michaels on February 19, 2020, continuing to complain of pain and reduced range of motion. (Ex. 7, pp. 10-11.) She was discharged from physical therapy on March 12, 2020, without accomplishing her functional goals. (Ex. 2, p. 309.) The physical therapist recommended that petitioner see an orthopedist. (*Id*. at 309-10.) Petitioner then had a virtual follow up with Dr. Michaels wherein he referred her to orthopedics. (Ex. 7, p. 4, 6-7.)

Petitioner then presented to orthopedist Jennifer Baima, M.D., on June 1, 2020. (Ex. 4, pp. 22, 50.) Dr. Baima recorded the following history:

> She presents today for evaluation of severe chronic left anterolateral shoulder pain. This started after a flu shot. She had a flu shot in October and had onset of anterior lateral shoulder pain immediately after. That was not unusual for her so she thought it would go away. She then had trouble moving her arm. This persisted. The pain radiated into the back of her head. She was sent to physical therapy. Despite compliance with a home exercise program, she has not made any improvement.

(*Id*. at 50.) On physical exam, petitioner had tenderness in the subacromial bursa and abnormal range of motion for active abduction, extension, and external rotation. (*Id.* at 55.) Hawkins and impingement tests were positive. (*Id.*) She was diagnosed with adhesive capsulitis and an MRI of her shoulder was ordered. (*Id*. at 56.)

Petitioner's subsequent MRI of June 8, 2020 was consistent with adhesive capsulitis and also showed a partial rotator cuff tear. (Ex. 4, p. 90-91; Ex. 3, pp. 2-3.) Dr. Baima maintained the adhesive capsulitis diagnosis after review of the MRI and ordered a steroid injection, which petitioner received on June 18, 2020. (Ex. 4, pp. 91, 134.) Petitioner subsequently received several additional steroid injections; however, the remaining medical records are not informative of the issues discussed in this ruling. (Ex. 10, pp. 24-125.)

IV. Discussion

For the reasons discussed below, I conclude that petitioner has met her *prima facie* burden of proof with respect to each of the four QAI criteria for establishing a Table Injury of SIRVA. I further conclude that respondent has not met his burden of proof with respect to whether petitioner's condition was caused by any factor unrelated to vaccination. Accordingly, petitioner is entitled to compensation for a Table SIRVA.

a. Petitioner's *Prima Facie* Showing of a Table SIRVA

i. No history of pain, inflammation or dysfunction of the affected shoulder

The first SIRVA criterion requires "[n]o 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." 42 CFR § 100.3(c)(10)(i). Petitioner notes that she has filed medical records dating back to 2016 and that these records demonstrate she had no prior history of shoulder pain, inflammation, or dysfunction. (ECF No. 40, p. 10.) Respondent has not raised any argument to the contrary. (ECF No. 41.) Based on my review of the medical records, although petitioner had other prior pain complaints, I find petitioner has satisfied this requirement by preponderant evidence.

ii. Pain occurs within 48 hours of vaccination

The second SIRVA criterion requires that the "[p]ain occurs within the specified time-frame," i.e., within 48 hours of vaccination. 42 CFR § 100.3(c)(10)(ii); 42 CFR § 100.3(a). This is the primary issue addressed by the parties. Based on my review of the medical records, I find that, for the reasons discussed below, petitioner has satisfied this requirement by preponderant evidence.

The Vaccine Act instructs that a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 300aa-13(b)(2). However, consistent with petitioner's burden of proof overall, that finding must be supported by preponderant evidence. *Id*.

A special master must consider the medical record as a whole and is not bound by any particular diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he 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 & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Nonetheless, there is no presumption that medical records are complete and accurate. *Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1383 (Fed. Cir. 2021).

Respondent notes that petitioner waited 71 days to seek treatment when she first presented for care on December 26, 2019. (ECF No. 41, p. 5 (citing Ex. 7, p. 15).) Moreover, at that time, petitioner described a "months" long injury without specifying whether her pain began within 48 hours of vaccination. (*Id*. at 5-6.) Petitioner stresses, however, that this is not necessarily an unusual length of time to delay treatment of a SIRVA. (ECF No. 40, p. 7 (citing *Hanna v. Sec'y of Health & Human Servs*., No. 18-1455V, 2021 WL 3486248, at *13-14 (Fed. Cl. Spec. Mstr. July 15, 2021); *Lang v. Sec'y of Health & Human Servs*., No. 17-995V, 2020 WL 7873272, at *10 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); *Smallwood v. Sec'y of Health & Human Servs*., No. 18-0291V, 2020 WL 2954958, at *10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020)).) Additionally, petitioner stresses that she specifically associated her symptoms to her vaccination and should not be required to have used any specific verbiage in describing her condition to her physicians. (*Id*. at 7-8.) Upon my own review of the initial treatment record, I conclude that it is best interpreted as being effectively silent as to the particulars of onset of petitioner's condition, though it is *consistent with* petitioner's claim in that it does evidence treatment of a "months" long shoulder condition petitioner attributed to her vaccination. Of note, this record is particularly terse in all respects, which would tend to contribute to the resulting ambiguities. Without more, respondent is unpersuasive in

implying that a two-month delay in seeking treatment is inherently suspicious, as has been observed in the cases cited by petitioner.

Respondent also observes that when petitioner subsequently presented for her first physical therapy appointment, she specifically reported that her pain began "within [a] week of having [the] flu shot." (ECF No. 41, p. 6 (quoting Ex. 3, p. 24).) This notation certainly implies that onset was closer to one week than 48 hours. Petitioner concedes that this notation does not necessarily support her Table claim but argues the record should carry less weight because the records from this particular medical provider are inconsistent and therefore less reliable. (ECF No. 40, p. 8.) Moreover, petitioner stresses that the phrasing "within a week" does not *preclude* onset occurring within 48 hours. (ECF No. 42, p. 3.) Petitioner also counters that another notation from the same encounter record indicates that petitioner was experiencing her symptoms "since October" and "after flu shot." (ECF No. 42, p. 3 (citing Ex. 2, p. 27).) Petitioner is not persuasive in suggesting that this notation of onset "after flu shot" is inconsistent with the notation of onset "within a week" of vaccination. However, upon my review of this record, I agree with petitioner that it is not weighty evidence with regard to onset given its other inconsistent notations. Specifically, while one notation specifies onset occurring "after flu shot," the date of injury is separately specified as "10/06/19," which would be prior to vaccination. (*Compare* Ex. 2, p. 25, *with* Ex. 2, p. 28.) Given the inconsistency, petitioner is persuasive in effectively arguing that the phrasing "within a week" is itself vague and should not be overinterpreted as precluding onset within 48 hours of vaccination when the record otherwise reflects a lack of precision regarding onset.

Petitioner also argues that her subsequent orthopedic records identify an immediate onset. (ECF No. 42, p. 3 (citing ECF No. 41, p. 6).) Specifically, petitioner's June 1, 2020 encounter with Dr. Baima records that "[t]his started after a flu shot. She had a flu shot in October and had onset of anterior lateral shoulder pain immediately after." (Ex. 4, p. 50.) In her reply, petitioner further stresses that, although many of the notations in her medical records are somewhat ambiguous as to onset, not a single medical record contradicts this history by precluding onset occurring within 48 hours of vaccination. (ECF No. 42, p. 3.) Respondent, however, stresses that this history was recorded over seven months post-vaccination. (ECF No. 41, p. 6.) It is not unreasonable for respondent to suggest as a general matter that later-recorded histories should carry less weight. *Accord Anderson v. Sec'y of Health & Human Servs*., No. 20-195V, 2022 WL 17484352, at *10 (Fed. Cl. Spec. Mstr. Nov. 10, 2022) (giving a later-reported history less weight as to injection site where prior records were contradictory). In this case, however, review of the complete records shows Dr. Baima's history to be the most complete and detailed history taken throughout the entire course of petitioner's treatment. This is not necessarily surprising given that it is the first instance in petitioner's treatment history where she had a specialist evaluation. Moreover, even as a somewhat more remote record, it is still entitled to weight as a treatment record generated at a time when proper treatment still hung in the balance. *Cucuras*, 993 F.2d at 1528. Additionally, as petitioner stresses, none of the prior records, though much less precise, explicitly contradict this later-recorded history.

In addition to the medical records, petitioner argues that the witness statements from her sister, Catherine Barrios, and her niece, Eliza Barrios, are consistent with her alleged onset, having observed petitioner's condition during the period after her vaccination. (ECF No. 40, pp. 9-10 (citing Exs. 8-9).) Respondent counters, however, that the specific observations contained in the statements do not actually confirm onset of shoulder pain within 48 hours of vaccination. (ECF No. 41, pp. 6-7.) While these witness statements certainly do not harm petitioner's claim, I agree with respondent that they lack the kind of detail that could provide meaningful support for a finding that onset of shoulder pain occurred specifically within 48 hours of vaccination.

This is a close question; however, I conclude that, in balancing all of the above, there is preponderant evidence that petitioner's shoulder pain began within 48 hours of her vaccination. While petitioner's treatment records do not explicitly confirm the appropriate onset until well into her treatment history, onset within 48 hours of vaccination is confirmed by medical treatment records. Though none of the other record evidence is sufficient to confirm onset occurring within 48 hours of vaccination, it can be read in harmony with the more specific orthopedic record.

iii. Pain and reduced range of motion are limited to the affected shoulder

The third SIRVA criterion requires that the "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 CFR § 100.3(c)(10)(iii). Petitioner asserts that there is no evidence that petitioner had complaints beyond her affected shoulder. (ECF No. 40, p. 10.) Respondent has not raised any argument to the contrary. (ECF No. 41.) Petitioner acknowledges a prior history of bilateral hand numbness, but asserts that this is explained by her diabetic neuropathy and predates her vaccination. (ECF No. 40, p. 10.) I also note that petitioner did complain to Dr. Baima of head and neck pain occurring subsequent to onset of her shoulder pain (Ex. 4, p. 50); however, there is no evidence that Dr. Baima found any significance in these symptoms. Petitioner's cervical neck exam was normal. (*Id*. at 54.) Based on my review of the medical records, I find petitioner has satisfied this requirement by preponderant evidence.

iv. No other condition or abnormality is present that would explain the patient's symptoms

Finally, the fourth SIRVA criterion requires that "[n]o other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 CFR § 100.3(c)(10)(iv). With regard to this requirement, respondent argues that "[p]etitioner indisputably suffers from preexisting and disabling [diabetes mellitus] 2, which is a more likely cause of her adhesive capsulitis." (ECF No. 41, p. 7.) However, respondent's argument misconstrues the fourth SIRVA criterion. Based on my review of the medical records, I find petitioner has satisfied this requirement by preponderant evidence.

Importantly, respondent is arguing that diabetes can cause adhesive capsulitis, not that adhesive capsulitis is a feature or symptom of the diabetes itself. Therefore, it is not the case that diabetes is a condition the presence of which explains petitioner's SIRVA symptoms. However, because petitioner's adhesive capsulitis *is her SIRVA*, it cannot also be some *other condition* that would separately explain her symptoms.[3] Thus, respondent is not identifying another condition that explains petitioner's shoulder symptoms under SIRVA criterion four. He is asserting that the injury petitioner alleges to be a SIRVA (adhesive capsulitis) was itself caused by a factor unrelated to vaccination (diabetes). That argument is more properly addressed as part of respondent's shifted burden of proof, discussed separately below, rather than as evidence weighing against petitioner's *prima facie* showing of a Table Injury.[4]

b. Factor Unrelated

Once petitioner has satisfied her own *prima facie* burden, the burden of proof shifts to respondent to demonstrate that her injury was caused by factors unrelated to vaccination. § 300aa-13(a)(1)(B); *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In order to meet his burden, respondent must demonstrate by preponderant evidence "that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. Aug. 28, 2008) (emphasis omitted). As with petitioner's burden under *Althen*, respondent must show a logical sequence of cause and effect linking the injury to the proposed factor unrelated to vaccination. *Deribeaux ex rel. Deribeaux*, 717 F.3d at 1368-69. It need not be scientifically certain but must be legally probable. *Id*. Conditions or other factors that are "idiopathic, unexplained, unknown, hypothetical, or undocumentable" cannot defeat a petitioner's claim. § 300aa-13(a)(2); *Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994).

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[3] *Accord Lang*, 2020 WL 787372, at *13 n. 9 (observing that, in presenting a *prima facie* Table SIRVA claim, "petitioner does not bear any burden of proving causation generally or to show that her shoulder pathology can be directly related to her vaccination as causal. It would be incompatible with the very idea of the Vaccine Injury Table to hold petitioner to a burden of proving causation to establish a Table Injury.") Per the QAI definition, SIRVA is an unspecified "injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.)." 42 CFR § 100.3(c)(10). Moreover, the QAI definition of SIRVA was specifically drafted to encompass adhesive capsulitis among the various conditions falling under the SIRVA umbrella. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132-01, 45136 (July 29, 2015), 2015 WL 4538923; *see also Gurney v. Sec'y of Health & Human Servs.*, No.17-481V, 2019 WL 2865490, at *7 (Fed. Cl. Spec. Mstr. Apr. 24, 2019) (finding that "the timing and course of petitioner's adhesive capsulitis remains consistent with a post-vaccination sequela to her SIRVA as described in the [Atanasoff study] and as envisioned by the rulemaking which created SIRVA as a Table Injury.").

[4] In the interest of completeness, I note that on this record the distinction is immaterial. Even if I considered respondent's proffered evidence regarding diabetes and adhesive capsulitis under QAI criterion four, I would still find the argument unpersuasive for largely the same substantive reasons as discussed below.

In this case, respondent argues that petitioner's preexisting diabetes is a more likely cause of petitioner's adhesive capsulitis. (ECF No. 41, p. 7.) However, there is no medical opinion on this record supporting that conclusion. Petitioner's treating physicians never attributed her shoulder condition to her diabetes and respondent has not presented any expert medical opinion to support his contention. Instead, respondent cites a single meta-analysis regarding the prevalence of diabetes among adhesive capsulitis patients and vice versa. Zreik et al., *Adhesive capsulitis of the shoulder and diabetes: a meta-analysis of prevalence*, MUSCLES LIGAMENTS TENDONS J. 6(1):26-34 (Jan-Mar 2016).[5] The study suggests that diabetes sufferers are five times more likely to develop adhesive capsulitis compared to non-diabetic controls. However, without more, demonstration of an increased prevalence of adhesive capsulitis among diabetics does not establish a direct causal relationship or demonstrate that, among patients with both conditions, the diabetes was the sole cause of the adhesive capsulitis. Even if petitioner's diabetes was a predisposing factor to development of adhesive capsulitis, that would not preclude the vaccine from being an additional cause precisely in the manner posited by respondent's regulatory rulemaking with respect to SIRVA. 42 CFR § 100.3(c)(10) (explaining that SIRVA is 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"). The study cited by respondent showed that, even with a higher prevalence, only a small minority (13.4%) of diabetics developed adhesive capsulitis.

V. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA resulting from her October 16, 2019 flu vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[5] Respondent did not file the article, but provided a link, last accessed February 13, 2023. (ECF No. 41, n. 2.) That link is https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915459, last accessed by the undersigned on August 10, 2023.