

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1849V

UNPUBLISHED

KATHRYN VASHRO,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 5, 2023

Maximillian J. Muller, Muller Brazil, Drescher, LLP, PA, for Petitioner.

Ronaldo Elnetta Kosh, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On December 14, 2020, Kathryn Vashro filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleged that she suffered a right shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, or in the alternative a caused-in-fact injury, after receiving an influenza (“flu”) vaccine on October 24, 2019. Petition at 1, ¶¶ 1, 11.

However, the record in this case establishes that the pain Petitioner suffered post-vaccination is more likely a continuation of prior right shoulder pain. Therefore, she has failed to satisfy two of the requirements of a Table SIRVA injury (a lack of prior shoulder

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² 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 (2018).

pain, and onset within 48 hours of vaccination). See 42 C.F.R. § 100.3(a)XIV(B) & (c)(10)(i)-(ii) (2017). Additionally, and despite due opportunity, Petitioner has not provided the preponderant evidence needed to overcome these deficiencies and succeed under a causation-in-fact claim. See *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (three-pronged test for actual causation). I therefore DENY entitlement in this case.

I. Relevant Procedural History

Along with the Petition, Ms. Vashro filed a declaration³ and most of the medical records required under the Vaccine Act. Exhibits 1-8; Section 11(c). The case was assigned to SPU on February 2, 2021. ECF No. 8. On August 31, 2021, Respondent identified additional medical records which needed to be provided, specifically a more legible copy of the vaccine record, results from any MRI, and updated medical records. ECF No. 13. During the subsequent two months, Petitioner provided the requested medical records. Exhibits 9-12, ECF Nos. 14-15.

On April 29, 2022, Respondent filed his Rule 4(c) Report challenging compensation because (among other things) Petitioner had failed to demonstrate onset within 48 hours. Rule 4(c) Report at 9-10, ECF No. 20. Respondent also submitted that Petitioner appears to have experienced arm pain (in the relevant arm) prior to vaccination. *Id.* at 9. Additionally, Respondent maintained Petitioner had not provided sufficient evidence to support a causation-in-fact claim. *Id.* at 10-11.

Following the Rule 4(c) Report, Petitioner filed a supplemental declaration⁴ insisting that her reports of right arm pain prior to vaccination were related to a bee sting. Exhibit 13 at ¶ 3, ECF No. 21. Petitioner also stated that the October 2019 vaccination was painful at administration and continued thereafter. *Id.* at ¶ 4.

On January 20, 2023, I issued an Order to Show Cause, allowing Petitioner a final chance to obtain and to file the evidence needed to support her allegations. ECF No. 24. I informed Petitioner that she needed to provide a logical rationale for her varied reports of onset and an explanation regarding any pre-existing and/or co-existing issues and alternative cause(s). *Id.* at 5. In response, Petitioner filed a status report indicating she had no other evidence to offer in support of her claim. ECF No. 26.

³ Although characterized as an affidavit, the declaration was not notarized or signed under penalty of perjury as required by 28 U.S.C.A. § 1746. See Exhibit 2.

⁴ Like the previously filed declaration, this document was not notarized or signed under penalty of perjury as required by 28 U.S.C.A. § 1746. See Exhibit 13.

The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has “sustained, or endured the significant aggravation of any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). According to the most recent version of the Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA 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) (additional requirements set forth in the *Qualifications and Aids to Interpretations* (“QAI”)). If a petitioner establishes that the vaccinee has suffered a “Table Injury,” causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. 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 her claim by preponderant evidence. Section 13(a)(1)(A). This standard is “one of . . . simple preponderance, or ‘more probable than not’ causation.” *Althen*, 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec’y of Health & Hum. 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 & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. See 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner’s medical issues.

Cucuras v. Sec’y of Health & Hum. Servs., 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

III. Analysis

In this case, Petitioner has failed to provide sufficient evidence to satisfy QAI criteria one and two. Her varied reports of onset and evidence of pre-existing shoulder pain undercut her assertions of no prior right shoulder pain, and also do not establish pain onset within 48 hours of vaccination. Despite already having reported arm pain in October and November of 2019, Petitioner made no mention of the subject vaccination until December 17, 2019. Exhibit 3 at 20. Then it was not until February 25, 2020 (four months post-vaccination) that Petitioner reported onset occurred “within one week of the influenza injection.” ECF No. 20 at 10; Exhibit 6 at 4. Later, on March 5, 2020, Petitioner reported that her shoulder pain “all started on October 24 of 2019 when she received a flu shot.” Exhibit 5 at 31.

While variations in onset reports are common, the evidence preponderates against Table onset here. In particular, the report of onset one-week post-vaccination precludes establishing onset consistent with the SIRVA Table claim requirement. Furthermore, Petitioner did not report a specific onset until after she had “followed up with a group that may help provide support for folks that have had symptoms from the flu shot.” ECF No. 20 at 9; Exhibit 3 at 16. Similarly, when Petitioner reported onset on February 25, 2020, she reported having “researched whether she is having a problem that (sic) SIRVA fund would support feeling that there is a connection between her flu shot and shoulder pain.” Exhibit 6 at 4. There are thus good grounds for giving less weight to the specific cites of onset consistent with the Table, versus the longer onset reported before those other references.

More problematic is the issue of pre-existing and/or co-existing pain. Petitioner’s medical records prior to administration of the subject flu vaccine undeniably indicate right arm pain. Exhibit 3 at 23-26; Exhibit 6 at 13-17. Thus, on July 26, 2019, Petitioner reported arm pain in both triceps for more than six months, which she believed was due to overuse. Exhibit 6 at 13. On October 24, 2019, the day of vaccination, Petitioner also reported that her right arm pain radiated to her fingers—she “[felt] it was muscular,” plus radiating pain while putting on her jacket. *Id.* Petitioner’s physician recommended a chiropractor or massage therapist for her right arm pain. *Id.* at 26. Later that same day she received the subject flu vaccine in her right arm. Exhibit 1 at 3.

Petitioner attempted to minimize this evidence by suggesting that her complaints have had to do with a bee sting - "I remember telling the doctor on that day [October 24, 2019] about the swelling of my finger on my right hand from a bee sting . . . I may have reacted to the bee sting by having pain in my hand and forearm." Exhibit 13 at ¶ 3. However, Petitioner's physician addressed the bee sting and arm pain separately, noting different symptoms and recommendations for each. See Exhibit 3 at 24, 26. Furthermore, Petitioner's explanation does not address and contradicts her own reporting of tingling, pain, and difficulty of a muscular nature. See Exhibit 3 at 24.

Moreover, Petitioner's right arm symptoms post-vaccination are similar to what she previously reported, thus appearing to be a mere continuation of her earlier pain. When Petitioner attended a physical therapy evaluation on November 12, 2019, for right arm pain, Petitioner reported similar issues as what she reported to her physician on October 24, 2019, prior to vaccination: "reaching behind hurt...tingling in digit 4 and 5...dull pain in arm most of time." Exhibit 4 at 23. The physical therapist also noted "lots of tingling with arm motions." *Id.* The record is absent of any mention of vaccination or pain associated with vaccination, and cervicalgia and right arm pain were the diagnoses. See Exhibit 4 at 22-23. Examination revealed impingement, some external rotation weakness, and pain when reaching. *Id.* at 23. At Petitioner's appointment on December 17, 2019, Petitioner reported having followed-up with physical therapy for her right arm pain, which was initially reported at her October 24, 2019 appointment. Exhibit 3 at 20.

While Petitioner later identified her vaccination as the onset of her pain, and Dr. Karen Boseli "question[ed] as to whether the flu vaccination may have initiated some sort of inflammatory response," Petitioner has not adequately addressed her pre-existing and/or co-existing issues. Moreover, Petitioner's right arm pain was addressed as "multifactorial in origin" (Petitioner's July 2020 MRI showed possible signs of adhesive capsulitis, osteoarthopathy, tendinosis) and presented similar to Petitioner's chronic left shoulder pain which was diagnosed as cervical radiculopathy. ECF No. 20 at 10; Exhibit 4 at 4, 22-26; Exhibit 5 at 13-16, 26-33; Exhibit 6 at 4-7. Petitioner has failed to address the history of pain in her right arm or distinguish her alleged Table SIRVA from pre-existing and/or co-existing issues.

Petitioner was allowed ample opportunity to provide additional evidence and argument regarding these evidentiary shortcomings - but declined to do so. Accordingly, I cannot find on the record as it stands that *either* a Table SIRVA claim, or non-Table claim, could be sustained.

Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support her allegation of a right shoulder injury that meets the definition for a Table SIRVA or was caused by the flu vaccine she received on October 24, 2019. Petitioner was informed that failure to provide preponderant evidence to support her claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for the claim. Accordingly, this case is DISMISSED for failure to prosecute and insufficient evidence. The Clerk of Court shall enter judgment accordingly.⁵

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁵ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.