

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 23-0371V

JOYA WOTILA,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: October 25, 2024

Jonathan Joseph Svitak, Shannon Law Group, P.C., Woodridge, IL, for Petitioner.

Nathaniel Trager, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE¹

On March 14, 2023, Joya Wotila 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 alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table Injury, after receiving a tetanus-containing³ vaccine on February 8, 2021. Petition at 1, ¶¶ 2, 15-16.

However, the record in this case contains insufficient evidence to establish the pain onset within the timeframe required for a Table SIRVA, or even to support any causal link

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).

³ The vaccine record in this case reveals Petitioner specifically received a tetanus, diphtheria, acellular pertussis (“Tdap”) vaccine. Ex. 2 at 1.

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

I. Relevant Procedural History

Within three months of filing the Petition, Ms. Wotila filed sworn declarations from her daughter and herself⁴ and the medical records required by the Vaccine Act. Exs. 1-9; see Section 11(c). On October 17, 2023, the case was activated and assigned to SPU. ECF No. 15.

On July 1, 2024, Respondent filed his Rule 4(c) Report opposing compensation. ECF No. 21. He maintains that Petitioner cannot establish pain onset within 48 hours of vaccination. *Id.* at 8 (citing 42 C.F.R. § 100.3(c)(10)(ii) (second QAI criterion). Although less clear, Respondent presents arguments related to severity and a potential non-Table claim as well. *Id.* at 7-10.

On August 23, 2024, I issued an Order to Show Cause, allowing Petitioner a final chance to obtain and file the evidence needed to support her allegations. ECF No. 23. After receiving two extensions of time until October 18, 2024 (ECF Nos. 25-26), Petitioner has failed to provide any additional evidence. 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

⁴ These declarations comport with the requirements of 28 U.S.C.A. § 1746; they were signed under penalty of perjury. Exs. 1, 9.

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 Federal Circuit 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 adds 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

The medical records show that despite several visits for primary care and chiropractic treatment post-vaccination,⁵ Petitioner never complained of left shoulder pain

⁵ For example, during chiropractic visits, Petitioner sought treatment for back and neck pain which appears to have been a continuation of symptoms she first reported in during the year prior to vaccination. On October 4 and 11, 2020, Petitioner suffered mid to lower back pain and muscle spasms, thought to be caused by physical labor – moving boxes in her new house. Ex. 3 at 13-18. Post-vaccination, she returned to the chiropractor on April 22, 2021, and October 12, 2021, complaining of pain and tightness in her back and neck. *Id.* at 19-27.

until December 1, 2021 - almost *ten months* after receiving the Tdap vaccine. Ex. 5 at 6; see also Ex. 2 at 1 (vaccine record). Because she requested *additional* microcurrent treatment, it appears that this pain was also present in November 2021, when Petitioner was seen for “chronic pain and myalgia,” which she thought may be due to her recent COVID illness. Ex. 5 at 7 (noting Petitioner agreed to microcurrent treatment).

In addition, when Petitioner did seek treatment for left shoulder pain in December 2021, she did not attribute that pain to the Tdap vaccine she had received ten months earlier. Ex. 5 at 6. And at a chiropractic appointment on January 6, 2022, she wondered about the source of her left shoulder pain, “stat[ing] she is not sure what happened, but her left shoulder has been hurting to the point she is not able to function or lift anything above her head.” Ex. 3 at 28. Furthermore, when seen by an orthopedic surgeon on February 22, 2022 (now more than one-year post-vaccination), Petitioner reported “a six-month history of left shoulder pain *without specific injury*.” Ex. 7 at 15 (emphasis added). This history equates to a pain onset consistent with the diffuse pain Petitioner was experiencing beginning in the fall of 2021, but more than six-months post-vaccination.

Thus, the medical records in this case do not support the conclusion that Petitioner’s shoulder pain began within 48 hours of vaccination. Instead, they establish that Petitioner suffered back and neck pain, likely due to physical activity, prior to and after vaccination. Petitioner also appears to have experienced diffuse pain and myalgia throughout her body beginning in the fall of 2021, which she theorized might be connected to her COVID illness. Pain in her left shoulder intensified in December 2021, and she continued to seek treatment for this condition with no mention of the Tdap vaccine in 2022.

It appears that Petitioner did not attribute her left shoulder pain to the Tdap vaccine she received until filing the Petition in this case, more than two years post-vaccination. Although she has provided sworn declarations from her daughter and herself to support onset and other disputed factual issues, these documents were not signed (and thus, likely not created) until shortly before their filing – more than four months after the initiation of this claim. See Exs. 1, 9. As they provide the only evidence supporting an appropriate temporal relationship, and given their non-contemporaneous quality when compared to the filed medical records, I do not give them significant weight. Petitioner cannot prevail pursuant to either a Table or non-Table claim.

Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support her allegation of a left shoulder injury that meets the definition for a Table SIRVA or was caused by the Tdap vaccine she received on February

8, 2021. 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. The Clerk of Court shall enter judgment accordingly.⁶

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁶ 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.