In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-0413V
Filed: September 5, 2018
UNPUBLISHED

TERESA TINLEY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Fact Hearing; Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING[1]

Dorsey, Chief Special Master:

On March 23, 2017, Teresa Tinley ("petitioner") 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 left shoulder injuries caused by an October 30, 2015 influenza ("flu") vaccination. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that the onset of petitioner's left shoulder injuries occurred within 48 hours of her October 30, 2015 influenza vaccination.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). 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, the undersigned agrees that the identified material fits within this definition, the undersigned 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 "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History Prior to Hearing

On March 23, 2017, Ms. Tinley filed her petition (ECF No. 1). On March 28, 2017, she filed medical records marked as Exhibits 1-8 (ECF Nos. 6 and 7). She also filed a Statement of Completion on March 28, 2017 (ECF No. 9). The initial status conference was held on May 2, 2017. (ECF No. 11). Additional medical records were filed as Exhibit 9 on June 7, 2017 (ECF No. 12).

On October 3, 2017, respondent filed a status report requesting additional medical records (ECF No. 18). On November 15, 2017, petitioner filed additional medical records as Exhibits 10 and 11 (ECF No. 21). On December 15, 2017, respondent submitted a status report requesting 45 days to file a Rule 4(c) Report (ECF No. 25). This request was granted.

On January 29, 2018, respondent filed his Rule 4(c) Report (ECF No. 30). Respondent argued that the medical records "fail[ed] to establish by preponderant evidence that the vaccine administration caused petitioner to suffer SIRVA. Petitioner did not complain of shoulder pain to a medical provider until March 22, 2016, approximately five months after vaccination . . . She did not receive any evaluation or treatment of her alleged arm pain until a few weeks later, on April 6, 2016. Therefore, it is not clear that petitioner's pain began within forty-eight hours of vaccination." Respondent's Rule 4(c) Report at 3-4 (ECF No. 30).

In the Rule 4(c) Report, respondent further asserted that a special master "cannot find that a vaccine-related injury occurred based solely upon the claims of petitioner (see 42 U.S.C. § 300aa-13(a)(1)); it must be substantiated by petitioner's medical records, or by a credible expert medical opinion." *Id*. at 4. Respondent argued that in this case "the physicians who evaluated petitioner for her shoulder pain noted the reported temporal association between the flu shot and the shoulder pain, but no physician opined that petitioner's October 30, 2015, flu vaccination was the cause of her alleged injury." *Id*.

Thereafter, following a status conference held by the staff attorney managing this case, the undersigned requested that petitioner inform the court how she wished to proceed in this case. (ECF No. 31). On March 16, 2018, petitioner filed a status report indicating that she wished to proceed with a hearing (ECF No. 32). A fact hearing was scheduled, and petitioner was afforded the opportunity to file additional evidence in the form of an affidavit from her sister (ECF Nos. 33, 34, 36). Petitioner later stated that she would not be submitting an affidavit from her sister. Petitioner's Status Report, filed May 22, 2018 (ECF No. 38).

II. Fact Hearing and Ruling

A fact hearing was held in Washington, D.C., on July 17, 2018. Ms. Tinley was the sole witness and she appeared via video-conferencing from Pennsylvania with her attorney. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue a ruling from the bench. The undersigned stated that her ruling would resolve whether the onset of petitioner's symptoms occurred within 48 hours of vaccination.

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). *See* Vaccine Injury Table: Qualifications and Aids to interpretation. 42 C.F.R. § 100.3(c)(10). Petitioner does not expressly assert a Table SIRVA claim. Nevertheless, the undersigned determines that regardless of whether petitioner's claim is analyzed as a Table claim or a claim asserting that her injuries were caused in fact by her vaccination, the proper course is to evaluate petitioner's claim to determine whether it meets the SIRVA Table requirements, as informed by the Qualifications and Aids to Interpretation for SIRVA criteria. The criteria are as follows:

> 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).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

With these factors in mind, the undersigned made the following preliminary findings of fact:

> After having reviewed all of the exhibits, the medical records, the records of the orthopedist, Dr. Tan, the VAERS report, the affidavit, and heard the testimony here today, I issue the following findings of fact:
>
> The issue requiring this fact hearing held today is whether the onset of Petitioner's symptoms occurred within 48 hours in light of the fact that she did not report the problem to a health care provider for approximately five months after her flu vaccination.
>
> The time period for the first symptoms or manifestation of symptoms for a shoulder injury related to vaccine administration under the Vaccine Injury Table is less than or equal to 48 hours.
>
> There is no issue as to the date of vaccination, which was October 30th, 2015, or the location of vaccination, which was the left arm.

Shoulder injury related to vaccine administration 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 the vaccine 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, to tendons, ligaments, bursa, et cetera. A vaccine recipient shall be considered to have suffered from SIRVA if the recipient manifests all of the following: First, no history of pain, inflammation or dysfunction of the affected shoulder prior to IM vaccine administration that would explain the alleged signs, symptoms, examination, findings and/or diagnostic studies occurring after the vaccine injection. With regard to this criteria, I find that Ms. Tinley had no history of pain, inflammation or dysfunction of her left shoulder prior to her flu vaccine administration. Specifically, the Petitioner's health history questionnaire completed on April 6th, 2016, noted no past medical problems and no previous surgery other than her tubal ligation in 1983, see Exhibit 3 at page 4; also, the history and the review of symptoms documented by her eye doctor, Dr. David Grosswald, on April 14th, 2015, at Exhibit 5, page 1, and on April 24th, 2015, found at Exhibit 5, page 6. That is also consistent with her testimony here today.

The next criteria for SIRVA is that the pain occur within the specified time frame of less than or equal to 48 hours. As to onset, I find that based on the Petitioner's affidavit and her testimony today, as well as numerous entries in the medical records, including the onset documented in the VAERS report dated March 22nd, 2016, which lists the adverse event onset of October 31st, 2015, see Exhibit 6 at page 1; the patient questionnaire completed by the Petitioner on April 6th, 2016, which states that the date of injury or first symptoms was October 30th, 2015, and that she had pain immediately which progressively worsened, see Exhibit 3 at page 3; the note by Karen Richard Reynolds, family nurse practitioner, on May 25th, 2016, which states that when the flu shot was given, it felt like something tore in her arm, Exhibit 2 at page 1; the note by Miranda Stone, physician assistant on June 9th, 2016, which states that when Ms. Tinley got the flu vaccine on October 30th, 2015, and since that time, her arm has been in pain, see Exhibit 2 at page 4; and all of the physical therapy records beginning with the initial evaluation by Stevi Wheeler on -- in June 2016, which all document date of onset to be October 30th, 2015, see Exhibit 4 at pages 7, 10, 13 and 15.

Based on all of these medical records and the testimony and affidavit, I find that onset of pain was immediately when the flu vaccine was administered and that this was in the specified time frame of 48 hours.

The next criteria is that the pain and reduced range of motion be limited to the shoulder in which the IM injection was administered. I find that based on the Petitioner's testimony here today and the medical records that Petitioner's pain

and reduced range of motion are limited to her left shoulder in which the vaccine was administered. I also base this finding on the demonstration by the Petitioner here during the hearing.

The next criteria is that there be no other condition or abnormality that would explain the patient's symptoms. I find that there is no other condition or abnormality identified by Dr. Tan or revealed in the medical records or the testimony here today which would explain her symptoms.

With regard to causation and the Althen prongs, I have covered the mechanism of injury as set forth in the Vaccine Injury Table. With regard to the logical sequence of a cause and effect, I find that the totality of the facts and circumstances set forth in the exhibits and given here today, that there is preponderant evidence of causation, specifically that the Petitioner presented to Dr. Tan on April 6th, 2016, and her records show the signs and symptoms of a diagnosis of reduced range of motion, pain and diagnosis of left rotator cuff syndrome and tendinitis. I find that these are casually related to her flu vaccine and that there is preponderant evidence sufficient to fulfill her obligation with regard to the presumption established by the Vaccine Injury Table.

That is the end of my ruling.

Transcript of July 17, 2018 Hearing, ECF No. 42, at 42-47.

III. Closing of the Record Regarding Entitlement

Following the hearing, the undersigned took judicial notice of two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II (ECF No. 45). The parties have been provided until October 5, 2018 to provide any evidence concerning entitlement or any response to the court exhibits. *Id*.

IV. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records, credible witness testimony, and findings of fact, the undersigned finds that the onset of petitioner's right shoulder injuries was within 48 hours of her October 30, 2015 influenza vaccination.

A scheduling order has been issued granting parties until October 5, 2018 to submit any additional evidence on entitlement. (ECF No. 45). After the record closes, the undersigned intends to issue a decision on entitlement based on all the evidence submitted into the record, and consistent with the findings set forth in this ruling.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master