In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-0340V
Filed: December 21, 2017
UNPUBLISHED

HILDA ALMANZAR, 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)

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.
Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.

FACT RULING[1]

Dorsey, Chief Special Master:

On March 16, 2016, Hilda Almanzar ("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 right shoulder injuries caused by an October 9, 2014 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 right shoulder injuries was within 48 hours of her October 9, 2014 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[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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 16, 2016, Ms. Almanzar filed her petition and medical records marked as exhibits 1-4. (ECF No. 1.) She also filed a Statement of Completion. (ECF No. 2.) Subsequently, during the initial status conference held on April 20, 2016, additional outstanding medical records were identified. (ECF No. 8.) Additional records and an amended Statement of Completion were filed on June 20, 2016 and October 5-6, 2016. (ECF Nos. 9-10, 15-16.)

On November 7, 2016, respondent filed a status report stating respondent was interested in pursuing settlement discussions and requested that the deadline for the Rule 4(c) report be suspended. (ECF No. 17). Respondent also requested additional information from petitioner to facilitate settlement discussions. The deadline for respondent to file the Rule 4(c) report was suspended and petitioner was ordered to file a status report in 30 days updating the undersigned on the status of the parties' settlement discussions. (ECF No. 18).

Over the next six months, the parties attempted to informally resolve this matter. On May 8, 2017, petitioner filed a status report stating that the parties had reached an impasse and were requesting a fact hearing. (ECF No. 34). Respondent proposed filing a Rule 4(c) report by June 30, 2017. This request was granted. (ECF No. 35).

On June 30, 2017, respondent filed his Rule 4(c) Report. (ECF No. 36.) Respondent recommended against awarding compensation to petitioner in this case. *Id*. Respondent argued, *inter alia*, that the evidence was insufficient to show a logical sequence of cause and effect or a temporal relationship between vaccination and injury because petitioner did not seek medical attention for her shoulder injury until four months after her vaccination. *Id*. at 7. Respondent argued that the record was unclear regarding the timing of onset of petitioner's injury and as such, petitioner had failed to established causation-in-fact by a preponderance of the evidence. *Id.*

Thereafter, following a status conference held by the staff attorney managing this case, the undersigned concluded that the case was ripe for a fact hearing. (ECF No. 37.) In preparation for the hearing, petitioner filed additional information requested by respondent in her Rule 4(c) report and another Statement of Completion on August 30, 2017. (ECF No. 39-40.)

II. Fact Hearing and Ruling

A fact hearing was held in Washington, D.C., on December 5, 2017. Ms. Almanzar was the sole witness and she appeared via video-conferencing from New Jersey 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 parties consented. 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). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury,

the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. 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 orthopedist, Dr. Mark Schwartz, the affidavits, and hearing testimony today, I issue the following findings of fact.
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> Based on my review of Respondent's Rule 4 report, it appears that the issues requiring this fact hearing today are whether the onset of petitioner's symptoms occurred within 48 hours of the administration of the flu vaccine to Ms. Almanzar in light of the fact that the medical records do not show that she sought treatment until February 11, 2015, approximately four months later. The time period for the first symptom or manifestation of symptoms for a shoulder injury related to vaccine administration under the rules and regulations which govern the Vaccine Program is less than or equal to 48 hours.
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> The second issue is whether petitioner has sustained a shoulder injury related to flu vaccine, or SIRVA, as a result of the flu vaccine administered to her on October 9, 2014. There is no issue as to the date of vaccination or the location where she received the vaccine, which was the right arm. (Pet. Ex. 5.)
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> Shoulder injury related to vaccine administration manifests as shoulder pain and limited range of motion occurring after the administration of vaccine by intramuscular injection 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, etc. A vaccine recipient shall be considered to have suffered SIRVA if she/he manifests all of the following: first, no history of pain, inflammation or dysfunction of the affected shoulder prior to the intramuscular (IM) vaccine administration that would explain the alleged signs, symptoms, examination findings and/or diagnostic studies occurring after vaccine injection. With regard to this criteria, I find that Ms. Almanzar had no history of pain, inflammation or dysfunction of her right shoulder prior to her flu vaccine administration. The records of her primary care physician and orthopedic surgeon do not reveal a history of prior right shoulder problems. Additionally, the testimony here today is consistent with my finding on this point.

The next criteria for a SIRVA injury is that onset of the pain occur within the specified timeframe of less than or equal to 48 hours. As to onset, based on petitioner's affidavit, her testimony today, the history documented by Dr. Zenon Switenko on February 11, 2015, that petitioner had pain which began 4 months prior, Pet. Ex. 2 at 2, the history by Dr. Schwartz, when he documented that petitioner 'attributed shoulder pain to flu' shot, (Pet. Ex. 3-1), and the evaluation by physical therapist, Gary Harris, on December 28, 2015, when he documented 'onset following flu vaccine to right shoulder' on October 9, 2014, and 'onset speed – Sudden,' (Pet. Ex. 8 at 1), I find that petitioner's pain began within 48 hours of the vaccine. (See also Novacare Rehab records, Pet. Ex. 14 at 1 (dated 3/25/2015) 'Mechanism of Injury…patient reports onset of mid aspect of right humerus after receiving flu injection on October 9, 2014').

There is one conflicting piece of evidence, a note by physical therapist, Todd Updike, on June 17, 2015, stating that petitioner had an 'insidious onset of pain.' (Pet. Ex. 4 at 1). The use of the word 'insidious' implies that the problem developed gradually. However, this entry can be explained by petitioner's affidavit, paragraph three, where she states, 'Immediately after the vaccination, I felt some pain in my right shoulder. Over the next two weeks, I developed more significant discomfort, pain and range of motion issues in the shoulder.' Thus, the onset was immediate, and sudden, as documented by Mr. Harris, and the problem became gradually worse, and was insidious as documented by Mr. Updike. I find that the onset of pain occurred immediately after the flu vaccine was administered and that this was within the specified time frame of 48 hours.

As for petitioner's delay in seeking treatment until February, 2015, I find the reasons for the delay set forth in her affidavit and her testimony today to be credible and reasonable. Specifically, petitioner described that she tried to schedule an earlier appointment with her PCP, Dr. Sapna Jain, but she had no available appointments until January, 2015. An appointment was made for January 6, 2015, which was cancelled due to a snowstorm. A subsequent appointment set for January 26, 2015 was also cancelled due to a snowstorm. For these reasons, she was unable to see a doctor until February 11, 2015. Again, I find this delay in seeking treatment to be reasonable given the facts and circumstances.

The next criteria is that the pain and reduced range of motion are limited to the shoulder in which the vaccine was administered. This finding is based upon the petitioner's testimony and the medical records that petitioner's pain and reduced range of motion are limited to the right shoulder, in which the vaccine was administered. (Pet. Ex. 3 at 4 – 'pain in limitation of motion…right shoulder appears to have restriction of motion…' dated 04/16/2015).

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. Schwartz, or revealed in the testimony today which would explain petitioner's symptoms.

With regard to causation and the *Althen*[3] prongs, I have covered the mechanism of injury as set forth in the rules and regulations. With regard to the logical sequence of cause and effect, I find that the totality of the facts and circumstances set forth in the medical records, other exhibits, and testimony today, that there is preponderant evidence of causation establishing that petitioner has proven a clinical course consistent with a SIRVA claim. Specifically petitioner presented to Dr. Switenko on February 11, 2015, and the records show that the signs and symptoms and a diagnosis of pain aggravated by daily activity (Pet. Ex. 2 at 2), reduced range of motion, impingement of the right shoulder (Pet. Ex. 2 at 4), with diagnosis of right shoulder tendonitis (Pet. Ex. 2 at 1). Subsequently, she underwent an MRI on February 18, 2015, which showed mild to moderate supraspinatus and infraspinatus tendinosis, and subdeltoid bursitis (Pet. Ex. 2 at 9). On March 19, 2015, Ms. Almanzar saw orthopedist, Dr. Schwartz, who diagnosed her with tendinitis of the right shoulder, and he administered a steroid injection. (Pet. Ex. 3 at 3-4). In April 2015, she continued to complain of right shoulder pain and she had limited range of motion (ROM). On May 5, 2015, her diagnosis was adhesive capsulitis, impingement syndrome, and rotator cuff tendinitis. She underwent surgery, manipulation of her right shoulder, arthroscopy and lysis of adhesions, and rotator cuff repair. (Pet. Ex. 3 at 12). She went on to attend physical therapy from June 2015 thought December 2015, or longer. On April 7, 2016, eleven months post-op, she saw Dr. Schwartz and reported that in the last several months, she had noted an increase in her pain. A repeat steroid injection was administered. (Pet. Ex. 9 at 3).

Petitioner described today that she has improved, but she still experiences pain and continues to take over-the-counter medication, particularly at night. Also, as demonstrated today, she still has some limitations with her range of motion, although again, she is much improved. In summary, Ms. Almanzar's clinical course is consistent with a SIRVA injury. This is the end of my ruling.

[3] *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

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. 42.) The parties have been provided 30 days to provide any additional evidence regarding 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 9, 2014 influenza vaccination.

A scheduling order has been issued granting parties until January 19, 2018, to submit any additional evidence on entitlement. (ECF No. 42). 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