

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1316V

Filed: December 20, 2019

UNPUBLISHED

MINDY PUCKETT,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Findings of Fact; Onset and Site of
Vaccination; Influenza (Flu) Vaccine;
Shoulder Injury Related to Vaccine
Administration (SIRVA)

Isaiah Kalinowski, Maglio Christopher and Toale, PA, Washington, DC, for Petitioner.

Lara Englund, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

Oler, Special Master:

On September 25, 2017, 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 a Shoulder Injury Related to Vaccine Administration (“SIRVA”) as a result of an influenza (“flu”) vaccine administered on October 26, 2015. Petition at 1.

¹ I intend to post this ruling on the United States Court of Federal Claims' website. **This means the ruling 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. Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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).

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).

For the reasons discussed below, I find that Petitioner was administered a flu vaccine on October 26, 2015 in her left arm and that the onset of her shoulder pain occurred within 48 hours of vaccination.

I. Relevant Procedural History

On September 25, 2017, Petitioner filed a petition alleging that she suffered from SIRVA as a result of a flu vaccine administered on October 26, 2015. Pet. at 1. Petitioner filed medical records on October 3, 2017, January 3, 2018, and October 22, 2018. ECF Nos. 7, 12, 24. Petitioner filed her initial affidavit on November 27, 2017. Ex. 2.

On July 30, 2018, Respondent filed a Rule 4(c) Report (“Resp’t’s Rep.”). ECF No. 19. Respondent stated that Petitioner had not established a Table injury because she had not adequately documented onset of shoulder pain within 48 hours of vaccination, and because Petitioner had not demonstrated that she received her vaccination in her left shoulder. Resp’t’s Rep. at 7. Respondent further stated that Petitioner had not provided evidence that satisfies her burden of proof under *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005), and thus has not established causation in fact. *Id.* at 8-9.

Petitioner filed a second affidavit on August 9, 2018, noting, among other things, that her vaccination form was incorrect when it noted that she received the flu vaccine in her right arm. Ex. 9. In support of this assertion, on August 28, 2019, Petitioner filed an affidavit from the owner of M-D Pharmacy, Mr. Michael Glessing. Ex. 10.

Petitioner filed a Supplemental Affidavit on January 9, 2019. Ex. 12. In that document, Petitioner stated that she did not sign the vaccination form on the date of vaccination. *Id.* at 2. She further indicated that based on her conversations with representatives from the pharmacy, they do not keep contemporaneous records detailing vaccination. *Id.*

I held a status conference with the parties on March 1, 2019 where we discussed the posture of the case. I told the parties that I found Mr. Glessing’s affidavit to be somewhat unclear and asked that he answer some specific questions from me. *See* ECF No. 29.

On June 7, 2019, Petitioner submitted a second affidavit from Mr. Glessing which answered my questions. Ex. 13. In this document, Mr. Glessing stated that the original vaccination record had been lost, and the document submitted was recreated after the fact. *Id.* at 3. I ordered Respondent to file a status report indicating how he would like to proceed. *See* Non-PDF dated 6/17/2019.

On July 30, 2019, Respondent filed a status report stating their position had not changed. *See* ECF No. 33. Respondent indicated that the vaccination form is not reliable and “thus, there is no contemporaneous evidence of the site of petitioner’s vaccination.” *Id.* at 2. Respondent further stated that Petitioner has either “created the false impression that the consent form was a contemporaneous medical record” or “was involved in creating a falsified document.” *Id.* at 2-3.

I issued an order on October 2, 2019, scheduling a fact hearing in this case. ECF No. 36. I conducted the hearing on November 21, 2019 in Washington, D.C. *See* Minute Entry of November 21, 2019. This matter is now ripe for a determination on facts.

II. Issues

There are two issues in this case: (1) whether Petitioner was administered a flu vaccine on October 26, 2015 in her injured left arm, and (2) whether Petitioner's first symptom or manifestation of onset after vaccine administration was within 48 hours as set forth in the Vaccine Injury Table. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination). The Qualifications and aids to interpretation ("QAI") for a Table SIRVA also require that a Petitioner's pain occurs within 48 hours. 42 C.F.R. § 100.3(c)(10).

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Vaccine Act § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

A special master must consider, but is not bound by, any 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. Vaccine Act § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The 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." *Curcuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Additionally, when determining the impact of the evidence presented, the special master should consider factors such as the reliability and consistency of the evidence. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 416 (Fed. Cir. 1993). "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent. If a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 74931, at *4 (Fed. Cl. Spec. Mstr. Apr.

25, 1991), *mot. for rev. denied*, 23 Cl. Ct. 726 (1991), *aff'd per curium*, 968 F.2d 1226 (Fed. Cir. 1992).

IV. Findings of Fact

a. Site of Vaccination

I find that the record in this case establishes by a preponderance of the evidence that Petitioner was administered a flu vaccine in her left arm on October 26, 2015. I make the aforementioned finding after a complete review of the record, including all medical records, Petitioner's affidavits, other documentary evidence, and Respondent's Rule 4(c) Report.

Specifically, I base this finding on the following evidence:

- On October 26, 2015, Petitioner visited M-D Pharmacy and received her flu shot. *See* Ex. 1 at 1-4. This record (hereinafter "screening questionnaire") indicates that the administration site was "RA" or right arm. *Id.* at 4. What purports to be Petitioner's signature appears on this screening questionnaire. *Id.*
- Mr. Michael Glessing, the owner of M-D Pharmacy, signed two affidavits in this case. Notably, Mr. Glessing stated that the original vaccination record had been lost, and the screening questionnaire was recreated after the fact. Ex. 13 at 1. According to Mr. Glessing, the duplicate screening questionnaire was signed by him and by Petitioner. *Id.* at 2. He repeatedly stated that this form should not be trusted because it was not a contemporaneously-created document. *Id.*
- Petitioner agrees that the screening questionnaire was not created at the time of vaccination. She disputes that she signed the screening questionnaire, and states that the only signature she provided relating to her flu shot was when she signed a screen indicating receipt of her medication and flu vaccine. Tr. at 34, 79. *See* Ex. 1 at 2.
- Petitioner testified that on April 6, 2017, Mr. Glessing asked her to come into the pharmacy to sign a HIPAA form so that her medical documents from M-D Pharmacy could be released to her attorney. Ex. 12 at 2. Tr. at 22-23. She signed the form on that date. *See* Ex. 12 at 7.
- Petitioner testified that she never signed the duplicate screening questionnaire and that her signature was forged. Tr. at 16. Petitioner believes that Mr. Glessing used her signature from the HIPAA form to forge her signature on the duplicate screening questionnaire. *Id.* at 80.
- Because of these documented irregularities, I find that the screening questionnaire is not a reliable document.
- Petitioner's medical records clarify that she received her flu shot in her left arm.
- On November 11, 2015, Petitioner visited her primary care provider. During this visit, she complained of a sore left shoulder. Ex. 2 at 17.
- On January 14, 2016 Petitioner saw Dr. Ostlie and stated that she had been having left shoulder discomfort since October 2015. Ex. 2 at 7.

- On June 9, 2016, Petitioner had an MRI of her left shoulder. Ex. 3 at 1-2.
- On July 14, 2016, Petitioner attributed her left shoulder pain to her flu shot. Ex. 5 at 1648.
- On September 14, 2016, Petitioner reported that she had been experiencing left shoulder pain for one year. Ex. 5 at 1700.
- On November 7, 2016, Petitioner had left shoulder surgery due to a left shoulder rotator cuff tear. Ex. 5 at 1820.
- In her affidavits, Petitioner stated that she received her flu shot in her left arm. Ex. 9 at 1; Ex. 12 at 1.
- During the fact hearing, Petitioner testified that she received her flu shot in her left arm. Tr. at 69.

b. Onset

Based upon the record as a whole, and specifically the evidence cited below, I find by a preponderance of the evidence that the onset of Petitioner's left shoulder pain occurred within 48 hours after the administration of the October 26, 2015 flu vaccine.

- As established above, Petitioner received a flu vaccine in her left arm on October 26, 2015.
- On November 11, 2015, 16 days after vaccination, Petitioner presented to Dr. Topley, her primary care doctor. Ex. 2 at 17. Petitioner told Dr. Topley that she had a sore left shoulder. Although the record reflects Dr. Topley's observation that Petitioner had been carrying a heavy purse, the record does not indicate that Petitioner attributed her pain to any specific event. During the hearing, Petitioner specifically testified that she did not believe the large purse contributed to her shoulder pain. Tr. at 40.
- Petitioner sent an email to Dr. Topley on January 8, 2016. In this email she wrote, "I went through my schedule and realized that I had my flu shot at my pharmacy the same day that my shoulder started bothering me. Is it possible that this is related?" Ex. 7 at 1.
- On January 14, 2016, Petitioner saw Dr. Ostlie and stated that she had been having left shoulder discomfort since October 2015. Ex. 2 at 7.
- Petitioner completed a VAERS form on May 26, 2016. In it she stated "After supper on 10/26/15 I noticed my arm was sore and hurt when I moved it. This pain and restricted movement has not changed since then." Ex. 15 at 1.
- On July 14, 2016, Petitioner visited Dr. Sehgal and attributed her left shoulder pain to her flu shot. Ex. 5 at 1646.
- In her affidavit dated August 9, 2018, Petitioner stated that she developed pain and stiffness in her left shoulder on the same day she received the flu shot. Ex. 9 at 2.
- During the fact hearing, Petitioner testified that she experienced pain the same day that she received the flu vaccine. Tr. at 35-38, 70-71.

I find that the affidavits submitted by and on behalf of Petitioner, the testimony, the medical records, and other documentary evidence work in concert to provide preponderant evidence that Petitioner's left shoulder pain began within 48 hours of her vaccination.

V. Conclusion

In light of all of the above and in view of the record as a whole, I find that (1) Petitioner was administered an influenza vaccine in her left arm on October 26, 2015, and (2) the onset of Petitioner's left shoulder symptoms, including pain, occurred within 48 hours of vaccination.

The parties are encouraged to consider an informal resolution of this claim. Petitioner shall file a joint status report by no later than Tuesday, February 18, 2020, updating the court on the status of the parties' settlement discussions.

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler
Special Master