

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-0783V

Filed: August 7, 2019

UNPUBLISHED

FAY BLEIER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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

*Jessica Olins, Maglio Christopher & Toale, PA, Washington, DC, for petitioner.
Christine Mary Becer, U.S. Department of Justice, Washington, DC, for respondent.*

FINDINGS OF FACT AND SCHEDULING ORDER¹

Dorsey, Chief Special Master:

On June 4, 2018, 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 as a result of an influenza (“flu”) vaccine administered in her right arm on November 3, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ The undersigned intends 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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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, the undersigned finds the onset of petitioner's right shoulder injury occurred within 48 hours of vaccination and that petitioner's November 3, 2016 flu vaccine was administered into her right arm.

I. Relevant Procedural History

The petition in this case was filed on June 4, 2018 (ECF No. 1). On July 6, 2018, petitioner filed medical records, an affidavit, and a Statement of Completion (ECF Nos. 7-8). On September 13, 2018, petitioner filed a supplemental affidavit and amended Statement of Completion (ECF Nos. 10-11). On October 31, 2018, petitioner filed additional medical records (ECF No. 12).

On April 15, 2019, respondent filed a Rule 4(c) report asserting that compensation was not appropriate in this case (ECF No. 19). Respondent contested entitlement for three reasons. First, respondent asserted that the record did not establish that petitioner suffered a shoulder injury related to vaccine administration ("SIRVA") within 48 hours of vaccination because she did not complain of shoulder pain to a medical provider until November 21, 2016, 18 days after vaccination.

Second, respondent asserted that petitioner's injury was in her right arm but the vaccine administration record reflected that the vaccine was administered in her left arm, and thus she had pain outside of the arm in which the vaccine was given. Third, respondent noted that two of petitioner's physicians suggested that her symptoms stemmed from her cervical spine and that petitioner complained of radicular symptoms that were not limited to her shoulder, i.e., pain running down her arm into her hand and fingers. Thus, respondent argued that because there was "possible cervical spine involvement in her symptomatology," petitioner had not established a Table SIRVA. This ruling addresses only the first and second issues raised by respondent.

On May 28, 2019, the undersigned issued an order allowing the parties to file additional evidence concerning the site of vaccination and onset by June 27, 2019 (ECF No. 21). The undersigned stated that after that date, she intended to issue a fact ruling concerning these issues. The undersigned further stated that if the fact ruling found that the site of vaccination was petitioner's right arm and that onset was within 48 hours of vaccination, petitioner would then be directed to file an expert report.

On June 18, 2019, petitioner filed Petitioner's Exhibit ("Pet. Ex.") 12 (orthopedic records), Pet. Ex. 13 (a VAERS, or Vaccine Adverse Event Reporting System, filing), Pet. Ex. 14 (second supplemental affidavit of petitioner), and Pet. Ex. 15 (affidavit of Gregg Bleier, petitioner's spouse). No other records were filed. The issues of (1) the onset of petitioner's shoulder pain and (2) the site of petitioner's November 3, 2016 flu vaccination are now ripe for resolution.

II. Issue

At issue are (1) 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),³ and (2) the site of petitioner's November 3, 2016 flu vaccination.

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 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).

IV. Finding of Fact

A. Onset

After a complete review of the record to include all medical records, affidavits, respondent's Rule 4 report, and additional evidence filed, the undersigned finds that a preponderance of the evidence demonstrates that the onset of petitioner's shoulder pain occurred within 48 hours of her November 3, 2016 flu vaccination. Specifically, the undersigned bases the finding on the following evidence:

³ Additionally, the Qualifications and aids to interpretation ("QAI") for a Table SIRVA requires that a petitioner's pain occur within this same time frame, 48 hours. 42 C.F.R. § 100.3(c)(10).

- Pet. Ex. 4 at 56, a record of petitioner’s November 21, 2016 appointment with nurse practitioner Mary Smith, 18 days after vaccination, noting that petitioner presented with a complaint of a sore arm and indicated that “she did receive a flu shot in that arm and had a significant reaction after.” The record further indicates the reason for the appointment was “*rt. [right] arm pain deltoid/bicipt since the flu shot 11/3/16.*” *Id.* (emphasis added).
- Pet. Ex. 4 at 58, a record of petitioner’s December 7, 2016 appointment with nurse practitioner Nicole Drake, noting that petitioner “[p]resents to be seen for right arm pain, *has had pain since her flu shot over a month ago*” (emphasis added).
- Pet. Ex. 3 at 3, a record of petitioner’s January 16, 2017 appointment with Dr. Mohaned Al-Humadi, noting “The patient is a 64 year old female who on 11/03/2016 did have a flu shot done in her right upper arm. *Since then she has noticed significant pain*” (emphasis added).
- Pet. Ex. 2 at 1, a record of petitioner’s February 6, 2017 appointment with orthopedist Dr. Lisa Daye, stating that petitioner presented for evaluation of right shoulder pain that began in early November and that petitioner stated “she got a flu shot and *it has bothered her since then.* She states it hurt at the time of the shot and was throbbing for the rest of the day” (emphasis added).
- Pet. Ex. 6 at 5, a record of petitioner’s February 14, 2018 appointment with Dr. Donald Deforno, noting that petitioner had been experiencing right shoulder pain “for about a year and a half after receiving the flu shot in right arm.”
- Pet. Ex. 13 at 3, a VAERS report submitted by petitioner on February 21, 2017, reporting that “[w]ithin 15 minute of injection developed severe pain in area of injection. Next day (11/4/16) arm from neck to fingers was in pain.”
- Pet. Ex. 8 at ¶ 2, petitioner’s September 13, 2018 supplemental affidavit, stating that her right shoulder “began to hurt *the day I was given the shot*” (emphasis added).
- Pet. Ex. 14 at ¶¶ 5-7, petitioner’s June 12, 2019 second supplemental affidavit, stating that on the way home from the doctor’s office on November 3, 2016 “my right arm was still hurting . . . my arm was in so much pain and throbbing It continued to worsen throughout the day. By evening, I couldn’t lift my right arm. My whole right arm was throbbing

from my ear to my fingertips. It felt like an awful toothache all the way down my arm.”

- Pet. Ex. 15 at ¶¶ 3-5, the June 17, 2019 affidavit of Gregg Bleier, petitioner’s husband, stating that when petitioner came home from her appointment she called him “complaining of very bad pain in her right arm. She told me *she had received a flu shot and it hurt immediately when the shot was administered and got much worse on her drive home*” (emphasis added). Mr. Bleier’s affidavit further indicates that he suggested taking Tylenol or Motrin for pain relief and that when he came home the evening of the vaccination petitioner “again complained about how severe the pain was and said she had taken Motrin but it hadn’t helped.” *Id.* at ¶¶ 4-5.

The above evidence shows that petitioner suffered pain immediately following the vaccination that continued while driving home from the appointment and persisted the evening of the vaccination even after taking pain relief medication. As such, the undersigned finds that a preponderance of the evidence demonstrates that the onset of petitioner’s pain occurred within 48 hours after vaccine administration.

B. Site of Vaccination

On November 3, 2016, petitioner reported to Foothills Medical Group, Salamanca Health Center, for a flu vaccine. Pet. Ex. 4 at 55, Pet. Ex. 1 at 1. The record of the visit that day indicates that the flu vaccine was administered in petitioner’s left arm by LPN Judith Hoag. *Id.* In addition, petitioner’s vaccine administration record in the records of Foothills Medical Group summarizing her vaccines from 2012-2016 also indicates that the November 3, 2016 flu vaccine was administered in petitioner’s left arm. Pet. Ex. 3 at 71.

On November 21, 2016, 18 days after vaccination, petitioner was seen at Foothills Medical Group complaining of a sore arm. The medical record indicates that the reason for the appointment was, “C/o [complains of] rt. [right] arm pain deltoid/bicipit since the flu shot 11/3/16.” Pet. Ex. 4 at 56. The history indicates that petitioner “states that she did received a flu shot in that arm and had a significant reaction after. She had pain all the way to her fingertips. She states it has improved somewhat but is still very uncomfortable and she points to her biceps tendon.” *Id.* On examination, she was found to have “marked tenderness to palpation over her right biceps tendon.” Pet. Ex. 4 at 57.

On December 7, 2016, she was seen at Foothills “for right arm pain, has had pain since her flu shot over a month ago.” Pet. Ex. 4 at 58. Similarly, at her January 16, 2017 appointment with the same medical group, she reported that “on 11/03/2016 [she had] a flu shot done in her right upper arm.” Pet. Ex. 3 at 3.

On February 6, 2017, petitioner was seen by Dr. Lisa Daye or Excelsior Orthopaedics, LLP, and reported right shoulder pain that she related to her flu shot in early November. Pet. Ex. 2 at 1.

On February 14, 2018, petitioner was seen by Dr. Donald Deforno and reported that she had been experiencing “right shoulder pain for about a year and a half after receiving the flu shot in right arm.” Pet. Ex. 6 at 5.

In Exhibit 8, petitioner’s supplemental affidavit, petitioner states, “[t]he vaccine I received on November 3, 2016 was given to me in my right shoulder.” Pet. Ex. 8 at ¶ 1. Petitioner states that she remembers “the specific shoulder being my right shoulder because that shoulder began to hurt the day I was given the shot as I told my primary care physician on November 21, 2016.” *Id.* at ¶ 2. Petitioner further confirms that she “did not otherwise injure [her] right arm or shoulder between when I received the vaccine and when I went to my primary care physician and told them about it.” *Id.* at ¶ 3. In Exhibit 14, petitioner’s second supplemental affidavit, petitioner explains that she is “right hand dominant and following the right shoulder injury, [she] was almost completely unable to use [her] right arm at all.”

In Exhibit 15, petitioner’s husband avers that petitioner called him “complaining of very bad pain in her right arm. She told me she had received a flu shot and it hurt immediately when the shot was administered and got much worse on her drive home.” Pet. Ex. 15 at ¶ 3.

Based on the evidence of record, the undersigned finds that the preponderance of the evidence demonstrates that petitioner’s November 3, 2016 flu vaccine was administered in her right arm. Although the vaccine administration record indicates that the vaccine was administered in her left arm, numerous other medical records consistently documented that petitioner’s vaccine was administered in her right arm.

In particular, the undersigned notes that petitioner’s appointments on November 21, 2016, December 7, 2016, and January 16, 2017 were with the same medical practice, Foothills Medical Group, where petitioner’s November 3, 2016 vaccine was administered. Thus, the health care providers who evaluated petitioner on these dates presumably had access to her vaccine administration record but recorded in their medical records that the flu vaccine was administered in her right arm and did not question the vaccination site. This supports the medical record and affidavit evidence documenting that the vaccine was administered in her right arm.

V. Conclusion

In light of all of the above and after a review of the record as a whole, the undersigned finds (1) that the onset of petitioner’s shoulder pain occurred within 48 hours of her November 3, 2016 flu vaccination, and (2) that the November 3, 2016 flu vaccine was administered into petitioner’s right arm.

VI. Scheduling Order

In the May 28, 2019 scheduling order, the undersigned indicated that if a finding was made that onset was within 48 hours of vaccination and that the vaccine was administered into petitioner's right arm, the undersigned would direct petitioner to file an expert report.

Accordingly, IT IS ORDERED THAT:

- **Petitioner shall file, by Monday, October 07, 2019, an expert report addressing the issues raised in respondent's Rule 4(c) Report, which of petitioner's symptoms are attributable to cervical spine issues and what symptoms are related to the vaccination, and whether petitioner's injury was caused in fact by her vaccination**, which requires providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master