In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-0613V Filed: September 17, 2019 UNPUBLISHED

EMILY JAHN,

Petitioner,

٧.

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)

Shealene Priscilla Mancuso, Muller Brazil, LLP, Dresher, PA, for petitioner. Althea Walker Davis, U.S. Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT¹

Dorsey, Chief Special Master:

On May 1, 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 left shoulder injuries caused in fact by the influenza vaccination she received on December 28, 2016. Petition at 1, ¶¶ 2, 11. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, the undersigned finds the influenza vaccine alleged as causal was administered in petitioner's injured left arm and the onset of

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 Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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).

petitioner's shoulder injury related to vaccine administration ("SIRVA") occurred within 48 hours of vaccination. Specifically, petitioner suffered pain immediately upon vaccination.

I. Relevant Procedural History

Petitioner filed most medical records with her petition on May 1, 2018. See Exhibits 1-9. During the June 22, 2018 initial status conference, the OSM staff attorney managing this SPU case noted that the vaccine record from CVS indicated petitioner received the influenza vaccine alleged as causal in her right, rather than left, arm. Order issued July 6, 2018, at 1 (ECF No. 9). She asked petitioner's counsel to obtain any additional evidence regarding this issue and a corrected vaccine record if available. *Id.* A few days later, petitioner filed a document titled "Corrected Vaccination Record." See Exhibit 10. This document appears to be the second page of a vaccine record from CVS, like the one originally filed, with most of the same information such as the lot number, date of vaccination, and administrator. The only differences are the site of administration, listed as the left deltoid on the corrected form, and the lack of the administrator's signature on the corrected form. *Compare* Exhibit 1 at 3 *with* Exhibit 10.

Two months later, on June 28, 2018, respondent filed a status report noting the lack of signature on the corrected form and the fact that the Vaccine Administration Event Report ("VAERS") form filed with the original vaccine record also lists the right arm as the site of administration. (ECF No. 10). Respondent adds that these issues "will impact respondent's ability to assess petitioner's claim" and asks for clarification now. *Id.* at 3.

In early September 2018, petitioner requested subpoena authority to obtain additional information from CVS regarding the changes made to the vaccine record and identity of the individual who completed and filed the VAERS report. (ECF Nos. 11-12). In response to petitioner's subpoena, petitioner received and filed two emails. See Exhibits 11, 18 (ECF Nos. 16, 19). In the first email, a paralegal at CVS's litigation section indicates the corrected vaccine record was created after petitioner spoke, by telephone, to the Pharmacy Manager Lisa Reilly at the store where she received the vaccination. Exhibit 11 at 1. The email indicated "[t]he date of the call is unknown." *Id.* After a follow-up email from petitioner's counsel, the paralegal confirmed that the VAERS report was completed by Lisa Reilly on November 1, 2018.³ Exhibit 18 at 1.

In late November and December 2018, petitioner filed four witness affidavits from her mother, who was with her when she received the vaccination, and from three friends with whom she discussed her vaccination and left shoulder injury within days of the

2

³ Since the VAERS report was filed in this case on May 1, 2018, the date provided on the report, November 1, 2018, cannot be accurate.

vaccination. Exhibits 14-16 (ECF No. 18); Exhibit 19 (ECF No. 26). She also filed additional medical records. Exhibits 12-13, 17 (ECF No. 18). One of these exhibits is the medical records from visits to Wellsprings Acupuncture on December 29, 2016 and January 9, 2017. Exhibit 17.

II. Issue

There are two factual issues: 1) whether petitioner' received the vaccine alleged as causal 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). 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).

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 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. § 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).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms

that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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." § 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*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Bases for Findings of Fact

The undersigned makes the findings in this ruling after a complete review of the record to include all medical records, affidavits, testimony, expert reports, respondent's Rule 4 report, and additional evidence filed. Specifically, the undersigned bases the findings on the following evidence:

- Despite the dispute regarding the site of administration, the vaccine record initially provided shows petitioner received an influenza vaccination on December 28, 2016. Exhibit 1. This fact does not appear to be disputed by the parties.
- When petitioner first sought medical treatment for her left shoulder pain, at CareWell Urgent Care, on January 13, 2017, she reported aching, dull, and constant left arm pain and decreased range of motion ("ROM") since receiving the influenza vaccination 16 days prior. Exhibit 7 at 3. The nurse practitioner Jeffrey Ayotte who treated petitioner opined that her "shoulder pain seems to be from a vaccine injection to the deltoid that was

to [sic] high up." *Id.* at 4. He instructed petitioner to apply ice or heat and to follow-up with her primary care provider or an orthopedist. *Id.*

- The record from petitioner's follow-up visit to an orthopedist on January 27, 2017 indicates petitioner "describes 1 month of left shoulder discomfort, which she relates to having flu shot." Exhibit 4 at 7. The orthopedist, Dr. Thomas Gross, at UMass Memorial Medical Center, assessed petitioner as suffering from "an impingement problem, possibly related to her flu injection." Id.
- When petitioner returned to UMass Memorial Medical Center on April 28, 2017, she reported immediate pain after receiving "a flu shot in her left shoulder about 4 months ago." *Id.* at 4. This record indicates petitioner is right handed. *Id.*
- At her first physical therapy session, on February 22, 2017, petitioner reported that she "noticed left shoulder pain following a flu shot." Exhibit 5 at 2.
- When petitioner visited her acupuncturist on January 9, 2017, for treatment of her back spasms and pain, she reported that her left arm was still painful after receiving a "flu shot 10 days ago." Exhibit 17 at 8.
- Petitioner has provided affidavits from four other individuals, one of whom, her mother, accompanied her to the store when she received the vaccination alleged as causal. All affiants recall that petitioner discussed, in person or by telephone or text, the left shoulder pain she experienced vaccination. According to the affiants, these communications occurred the same day (exhibit 14 at 2), the next day (exhibit 19 at 3), four to five days after vaccination (exhibit 15 at 3), and a few days after Christmas (exhibit 16 at 3).

V. Site of Vaccination

The above medical entries show that petitioner consistently connected her left shoulder injury to the influenza vaccination she had received. Throughout these medical records, petitioner indicates she received the influenza vaccination in her left arm.

The only documentation which indicates the vaccination was administered in petitioner's right, rather than left arm, is the vaccine record which was created on December 28, 2016, and the VAERS report which was appears to have been created by the Pharmacy Manager at the store where the vaccination was administered. Although the date that the VAERS report was created is not known, it is likely that the site of vaccination noted in the VAERS report was based on that listed in the original vaccine record. At some point, the vaccine record was amended to indicate the

vaccination was administered in petitioner's left, rather than right, arm in response to a telephone call from petitioner.

The validity of both documents which list the site of vaccination as petitioner's right arm is questionable. However, this evidence is outweighed by the evidence indicating the vaccination was received in petitioner's injured left arm. Although much of this evidence can be found in medical histories provided by petitioner, most were provided less than a month after vaccination for the purpose of obtaining medical care. All were provided within four months of vaccination. Moreover, petitioner has provided affidavits from four other individuals indicating that petitioner discussed her vaccination and left shoulder pain with them several days to several weeks after vaccination.

As such, the undersigned finds preponderant evidence that petitioner received the influenza vaccine alleged as causal in her injured left arm.

VI. Onset of Petitioner's Pain

In the same five medical histories provided close in time to vaccination, petitioner relates the onset of her left arm pain to the influenza vaccination she received on December 28, 2016. When visiting her acupuncturist, for back spasms and pain, on January 9, 2017, petitioner reported that her back pain was much better but that her "arm [was] still painful" after receiving the "flu shot 10 days ago." Exhibit 17 at 8. When she sought treatment for her left arm pain four days later, petitioner reported decreased ROM and stiffness since her influenza vaccination. Exhibit 7 at 3. She described her pain as aching, dull, and constant. *Id.* When seen by an orthopedist 31 days after vaccination, she "describe[d] 1 month of left shoulder discomfort." Exhibit 4 at 7. At her first PT appointment, petitioner again identified the influenza vaccination as the start of her pain. She indicated "she noticed left shoulder pain following a flu shot." Exhibit 5 at 2. At her second orthopedic appointment, petitioner indicated that "she noticed immediate shoulder pain after the injection." Exhibit 4 at 4.

Thus, the undersigned finds that the evidence in the medical records establish that the onset was immediate. There is no entry which indicates onset occurred later.

As such, the undersigned finds preponderant evidence that petitioner's manifestation of onset after vaccine administration immediately, occurred within 48 hours.

VII. Scheduling Order

Given the undersigned's findings of fact regarding the site of vaccination and the onset of petitioner's pain, respondent should evaluate and provide his current position regarding the merits of petitioner's case.

Respondent shall file a status report indicating how he intends to proceed in this case by no later than <u>Monday</u>, <u>October 21, 2019</u>. At a minimum, the status report shall indicate whether he is willing to engage in tentative discussions regarding settlement or proffer, is opposed to negotiating at this time, or that the Secretary has not

yet determined his position. In the event respondent wishes to file a Rule 4(c) report, he may propose a date for filing it, but shall indicate his position on entering into negotiations regardless of whether he wishes to file a Rule 4(c) report.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey Chief Special Master