In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-0952V

UNPUBLISHED

DONNA BELL, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: July 12, 2023 Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

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Catherine Elizabeth Stolar, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On July 1, 2019, Donna Bell 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") from an influenza ("flu") vaccine she received on October 18, 2016. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact 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.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section 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 although there is preponderant evidence that Petitioner's flu vaccine was likely administered to her left arm, Petitioner's Table SIRVA claim must be dismissed because the evidentiary record does not support the conclusion that the requisite onset of her pain occurred within 48 hours following administration of the flu vaccine. This leaves a possible causation-in-fact claim to be adjudicated, however, so the matter will be transferred out of SPU for further proceedings in that regard.

I. Relevant Procedural History

On October 5, 2020, about 15 months after the case was initiated, Respondent filed a status report stating that he wished to engage in settlement discussions regarding Petitioner's vaccine claim. ECF No. 16. The parties continued to engage in negotiations until August 25, 2022, when Petitioner filed (at my instruction) a Motion for Ruling on the Record Regarding Entitlement ("Mot."). ECF No. 37. On October 26, 2022, Respondent filed a response to the motion ("Resp."). ECF No. 38. The issues of site of vaccination and onset are ripe for a fact ruling.

II. Issue

The following issues are contested: (1) whether Petitioner received the vaccination alleged as causal in her right or left arm; and (2) whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(c)(10)(ii)-(iii) (required onset for pain listed in the QAI; pain and reduced range of motion limited to the shoulder in which the intramuscular vaccine was administered).[3]

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove by a preponderance of the evidence the matters required in the petition by Vaccine Act Section 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. Section 13(b)(1). The Federal Circuit has said that

[3] Respondent also argues that Petitioner's shoulder symptoms are likely due to underlying lymphatic issues and that Petitioner has not preponderantly established a causation-in-fact claim. *See* Resp. at 16-17. However, because Petitioner's claim is to be transferred out of SPU, these issues are not decided herein.

> 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.

Cucuras 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. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

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).

Thus, 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." Section 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 not only the medical records, testimony, but also all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 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). And although later oral testimony that conflicts with medical records is less reliable as a general matter, it is appropriate for a special master to credit a petitioner's lay testimony where is does not conflict with the contemporaneous records. *Kirby*, 997 F.3d at 1382-84.

IV. Finding of Fact

A. Site of Vaccination

Based on a review of the entire record, including all medical records and affidavits, the arguments in Petitioner's Motion and the arguments in Respondent's opposition brief, I find that the flu vaccine Petitioner received in October 2016 was likely administered in her left arm, as she contends. The following points are particularly relevant to that finding:

- Petitioner's pre-vaccination medical records reveal no injuries, inflammation, or dysfunction in her left shoulder or arm. Petitioner had a history of right shoulder pain and back surgery for radicular pain to her lower extremities. Ex. 2 at 63; Ex. 5 at 10-11.

- Petitioner received the flu vaccine at her employer, South Country Hospital, in Wakefield, RI, on October 18, 2016. Ex.1 at 188. The vaccine administration record does not indicate into which arm the vaccine was administered. *Id.*

- Petitioner has stated that she received the vaccination in her left upper arm. Ex. 7 at ¶1. Leah Arsenault, R.N. stated that she administered Petitioner's vaccination on October 18, 2016. Ex. 6 at ¶2. Nurse Arsenault also stated that the vaccine was administered to Petitioner's left arm. *Id*.

- At her first visit to her doctor for her shoulder pain, on November 10, 2016, Petitioner reported that she had a swollen arm after a flu shot four weeks prior. Ex. 2 at 4. On exam, Petitioner's *left* arm was swollen and tender. *Id*.

- Petitioner returned to her doctor on November 30, 2016, with continued complaints of left upper arm pain. Ex. 2 at 4. The doctor recorded that Petitioner's "pain all began after receiving a flu shot 6-8 weeks ago." *Id*. On exam, Petitioner had swelling in her left upper arm, severe pain with rotation, and tenderness in her triceps. *Id.*

- On December 1, 2016, Petitioner had x-rays of her left shoulder and humerus, and a venous doppler study of her left arm to rule out a deep vein thrombosis. Ex. 1 at 21, 23.

- On December 9, 2016, Petitioner began a course of physical therapy. Ex. 4 at 185. She reported that she "received a flu shot on 10/18 with resulting left [upper extremity] redness and swelling." *Id.*

- On January 6, 2017, Petitioner presented to an orthopedist, Dr. Burns, complaining of pain in her left arm. Ex. 3 at 8. She reported that "after she received the flu shot, she had significant pain and swelling in her upper arm." *Id*. Dr. Burns examined Petitioner's left arm and found edema and a "fluid wave." *Id*. The following day, Petitioner had an MRI of her left humerus. Ex. 1 at 14.

The entirety of the record preponderantly supports the conclusion that Petitioner more likely than not received the October 18, 2016 flu vaccine in her left arm.

I note the degree to which Petitioner was consistent when attributing her shoulder pain to her vaccination when seeking treatment. At her first visit to her primary care physician on November 10, 2016, Petitioner reported swelling and pain after her flu shot. Ex. 2 at 4. At that visit, Petitioner's left arm was examined and found to be swollen and tender. *Id.* When she returned three weeks later, Petitioner continued to complain of left upper arm pain that "all began after receiving a flu shot." *Id*. Again, Petitioner's left arm was examined and found to be swollen and painful with movement. *Id.* Petitioner made similar statements at her initial physical therapy evaluation and to her orthopedist. *See* Ex. 4 at 185; Ex. 3 at 8. Petitioner never complained of right shoulder pain.

Admittedly, Petitioner's initial vaccine administration record is silent as to the site of administration. Ex. 1 at 188. Petitioner's affidavit and the affidavit of Leah Arsenault, R.N., however, provide additional details about the administration that provide support for her claim that she received the vaccination in her left arm. Petitioner explained that she

received the flu vaccine in her left arm. Ex. 7 at ¶1. Nurse Arsenault stated that she administered the vaccine into Petitioner's left arm and noted that she documented the administration on the vaccine administration record.[4] Ex. 6 at 2; Ex. 1 at 188. She also recalled Petitioner telling her after the vaccination that she had pain, swelling, and redness in her left upper arm. *Id*. at 3.

Given that the initial vaccine administration record is silent on the issue of situs, this is not a case where a testimonial assertion on the disputed fact seeks to *vary* or negate a record's content. Thus, though it is well-settled that "oral testimony *in conflict with* contemporaneous documentary evidence deserves little weight," such testimony can be credited where it provides detail that the record omits. *Kirby*, 997 F.3d at 1383 (emphasis added). Here, Petitioner's statements about the vaccination do not conflict with the vaccine administration record, but provide detail that was not recorded at the time of the vaccine or for which other documentary evidence cannot be obtained. And otherwise there is no evidence in the record that Petitioner received the vaccine in her *right* arm.

There are other reasons to conclude as I do on this question. Petitioner's medical records show that she had no history of any pain, inflammation, or dysfunction in her left shoulder or arm before her flu vaccination. And she received treatment only to her left shoulder, including physical examinations, x-rays, an MRI, a doppler venous study, physical therapy, and surgery. Ex. 1 at 14, 21, 23; Ex. 2 at 4; Ex. 3 at 8; Ex. 4 at 185.

Overall, Petitioner's own assertions are sufficiently corroborated by the medical record to accept her contention of vaccine situs. I therefore find it more likely than not that the vaccine alleged as causal in this case was administered to Petitioner in the left shoulder on October 18, 2016.

B. Onset

Based on a review of the entire record, including all medical records and affidavits, the arguments in Petitioner's Motion, and the arguments in Respondent's response thereto, I find the following facts to be particularly relevant:

- Petitioner's pre-vaccination medical records reveal no injuries, inflammation, or dysfunction in her left shoulder or arm. Petitioner had a history of right shoulder pain and back surgery for radicular pain to her lower extremities. Ex. 2 at 63; Ex. 5 at 10-11.

- Petitioner received the flu vaccine at her employer, South Country Hospital, in Wakefield, RI, on October 18, 2016. Ex.1 at 188.

[4] Nurse Arsenault's signature appears on the vaccine administration record. Ex. 1 at 188.

- Petitioner stated that she received the vaccination in her left upper arm and that she "experienced and reported pain immediately upon administration" of the vaccine, and then later developed redness, edema, weakness, and stiffness. Ex. 7 at ¶1-2. She thought her symptoms "would pass with time." *Id*. at ¶3.

- Leah Arsenault, R.N. stated that she administered Petitioner's flu vaccination on October 18, 2016. Ex. 6 at ¶2. She recalled that she saw Petitioner at work "a day or two following" the vaccination, and that Petitioner told her about her left shoulder pain, swelling, and redness.[5] *Id.* at 3. Both Petitioner and Nurse Arsenault remembered Nurse Arsenault advising Petitioner to see her primary care physician if her symptoms did not resolve or worsened. Ex. 6 at ¶3; Ex. 7 at ¶3.

- On October 19, 2016, the day after her vaccination, Petitioner presented to her physical therapist for treatment on her lower back. Ex. 4 at 180. She returned to her physical therapist on October 24, 2016, six days after her vaccination, when she was discharged. *Id*. at 182-184. Neither record contains any reference to left shoulder symptoms.

- On October 21, 2016, three days after her vaccination, Petitioner visited her primary care physician for an annual physical. Ex. 2 at 4. That record does not contain any references to left shoulder symptoms.

- On November 10, 2016, Petitioner reported to her primary care physician that she had a swollen arm after a flu shot four weeks prior. Ex. 2 at 4. The doctor recorded that Petitioner "had flu shot 4 weeks ago, had swollen arm and applied ice, then heat, has taken Advil/Aleve with little relief." *Id.* On exam, Petitioner's left arm was swollen and tender. *Id*. She was diagnosed with an adverse reaction to vaccination and prescribed prednisone. *Id.* This record does not specify when the swelling first manifested.

- Petitioner returned to her doctor on November 30, 2016, with continued complaints of left upper arm pain. Ex. 2 at 4. The doctor recorded that Petitioner's "pain all began after receiving a flu shot 6-8 weeks ago." *Id*. On exam, Petitioner had swelling in her left upper arm, severe pain with rotation, and tenderness in her triceps. *Id.*

[5] Petitioner recalled the same interaction with Nurse Arsenault, placing it 24-48 hours after her vaccination. Ex. 7 at ¶3.

- On December 1, 2016, Petitioner had x-rays of her left shoulder and humerus, and a venous doppler study of her left arm to rule out a deep vein thrombosis. Ex. 1 at 21, 23.

- On December 9, 2016, Petitioner began a course of physical therapy. Ex. 4 at 185. She reported that she "received a flu shot on 10/18 with resulting left [upper extremity] redness and swelling." *Id.* Petitioner reported that "3-4 weeks ago she began to experience L shoulder pain and progressive loss of mobility." *Id*. A month from this date would be early November – not mid to late October, when the vaccine was administered.

- On January 6, 2017, Petitioner presented to an orthopedist, to whom she reported that "after she received the flu shot, she had significant pain and swelling in her upper arm." Ex. 3 at 8. She now reported (with specificity, for the first time in the records) that "the onset was sudden with injury which occurred on 10/11/2016[sic]." *Id*. Dr. Burns examined Petitioner's left arm and found edema and a "fluid wave." *Id*. The following day, Petitioner had an MRI of her left humerus. Ex. 1 at 14.

I acknowledge that the standard applied to resolving onset for an alleged Table SIRVA is liberal, and will often permit a determination in a petitioner's favor, especially in the *absence* of fairly contemporaneous and direct statements within the petitioner's medical records to the contrary. However, not every case can be so preponderantly established. Ultimately, the resolution of such fact issues involves weighing different items of evidence against the overall record.

Here, Petitioner's claims of immediate onset are offset against a record created very near-in-time to vaccination, in which Petitioner did not mention any left shoulder symptoms at *three consecutive* medical appointments. Although Petitioner and Nurse Arsenault have submitted affidavits supporting onset of shoulder pain within the required 48-hour period, the first three post-vaccination records (from the October 19, 2016, and October 24, 2016, visits with physical therapy and the October 21, 2016, annual physical) specifically *refute* such contention. Ex. 2 at 4; Ex. 4 at 180-184.

Petitioner first linked her left shoulder pain to her flu shot at the time of her appointment with her primary care physician on November 10, 2016 (23 days after her vaccination) – but that record does not specifically place onset within 48 hours of vaccination. Ex. 2 at 4. The doctor recorded that Petitioner "had flu shot 4 weeks ago, had swollen arm and applied ice, then heat, has taken Advil/Aleve with little relief." *Id.* Three weeks later when she followed-up, Petitioner reported that her "pain all began after receiving a flu shot 6-8 weeks ago," still not providing any specific information about the

onset of her pain. *Id*. Then, when Petitioner presented for a physical therapy evaluation on December 6, 2016, she reported that her shoulder pain began "3-4 weeks ago" – or roughly early November – which coincides with when she first sought treatment from her primary care physician (November 10, 2016). *See* Ex. 4 at 185. These records, all created within the first two months after vaccination, suggest that the onset of Petitioner's shoulder pain occurred outside of the 48 hours required to establish a Table SIRVA. (Swelling followed by shoulder pain later would not save the claim, even if the swelling occurred in 48 hours of vaccination).

Further, the affidavit testimony provided directly contradicts the facts recorded in the contemporaneous medical records. Petitioner stated that she "experienced and reported pain immediately upon administration," and mentioned her continuing pain to Nurse Arsenault within 24-48 hours after her vaccination. Ex. 7 at ¶2. However, Petitioner did not mention her shoulder pain to her medical providers, including her primary care physician, during the same time period. There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). But not every SIRVA claim can be so preponderantly established, and certainly not where the sequential and contemporaneous record does not lend support to the Petitioner's allegations.

Finally, Petitioner has not provided any credible explanation as to why she did not report her left shoulder symptoms to her physical therapist or to her primary care physician during her visits in the six days after her vaccination. Even if Petitioner believed her symptoms would resolve with time, she reported visible redness and swelling in her left upper arm within 24-48 hours of her vaccination, which worsened over time. Ex. 7 at ¶2-3. Both Petitioner and Nurse Arsenault recalled that Nurse Arsenault advised Petitioner to see her primary care physician without symptoms. Ex. 6 at ¶3; Ex. 7 at ¶3. Without any alternative explanation from Petitioner, it is reasonable to believe that if Petitioner had the symptoms she reports in her affidavit within a day or so after her vaccination, she would have reported them to her primary care physician at an annual physical on October 21, 2016. There is no evidence that she did so.

Accordingly, I find Petitioner has not preponderantly established that onset of her pain occurred within 48 hours of vaccination – meaning that she cannot proceed in this action with a Table SIRVA claim. Petitioner has, however, a potential causation-in-fact injury claim, so the matter will be transferred out of SPU in order to evaluate such an alternative version of the claim.

Conclusion

Because Petitioner has not preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination, she cannot proceed in this action with a Table SIRVA claim. Petitioner's Table SIRVA claim is therefore dismissed, for the reasons set forth above and the case will be reassigned to a Special Master outside of SPU.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master