

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1001V

Filed: December 20, 2021

MERILYNNE DELIO,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Findings of Fact; Onset; SIRVA
(Not to be Published)

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner
Adriana R. Teitel, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ONSET¹

Oler, Special Master:

On July 12, 2018, Merilynne Delio (“Ms. Delio” or “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” or “Program”). The petition alleges that the Petitioner developed a shoulder injury related to vaccine administration (“SIRVA”) as a result of the flu vaccine she received on November 9, 2016. Pet. at 1.

¹ Because this unpublished Ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims’ website, in accordance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). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id.*

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).

After carefully considering the evidence presented in this case, to include the medical records, and affidavits, I find that Petitioner's right shoulder pain began sometime between December 14, 2016 and January of 2017.

I. Procedural History

Petitioner filed her petition on July 12, 2018. Pet., ECF No. 1. Ms. Delio also filed supporting medical records and an affidavit with the petition. Exs. 1-6. Petitioner filed a supplemental affidavit on August 7, 2018 (Ex. 7) and additional medical records on November 26, 2018 (Ex. 11) and March 5, 2019 (Ex. 12).

Respondent filed his Rule 4(c) Report on June 17, 2019. Resp't's Rep.; ECF No. 21. Respondent argued that this case is not appropriate for compensation because the medical records do not reflect that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination. Resp't's Rep. at 7.

This case was assigned to my docket on July 23, 2019. ECF No. 25.

I held a status conference on September 25, 2019 where I indicated that I "viewed onset of shoulder pain to be around December 2016, after the December 14, 2016 medical visit at which Petitioner denied any shoulder pain." Scheduling Order dated Sept. 26, 2019, ECF No. 29. Petitioner indicated that she wanted to seek the opinion of an expert. *Id.* I granted her request informing counsel that "any expert opinion should consider my views regarding onset". *Id.* Furthermore, I "directed counsel to share this Order with experts willing to opine in this matter." *Id.*

On November 25, 2019, Petitioner filed an expert report from Naveed Natanzi, DO as well as supporting medical literature. Exs. 13, 14A-14M. In Petitioner's expert report, Dr. Natanzi began his analysis stating that Petitioner "presented with right shoulder pain that began immediately after an influenza vaccination in her right arm on 11/9/16." ECF No. 28. Because this statement was inconsistent with my preliminary views regarding onset expressed during the September 25, 2019 status conference, I issued an order on November 26, 2019, requesting that Petitioner's expert respond to the following question: "Assuming shoulder pain began sometime in December 2016 (after December 14, 2016), do you believe Petitioner's flu shot caused her pain? Please explain your answer." See Scheduling Order dated Nov. 26, 2019, ECF No. 29.

Petitioner filed a supplemental expert report on January 28, 2020. Ex. 15. In this report, Dr. Natanzi stated that "If I were to assume that Ms. Delio's right shoulder pain began sometime after 12/14/16 it would make a SIRVA injury much less likely." Ex. 15 at 1. Dr. Natanzi went on to reiterate his position that Petitioner's shoulder pain likely did start immediately after her vaccination. *Id.* His reasons for this were 1) she recounted immediate pain post-vaccination in her affidavit; 2) in her affidavit, she explained why she did not discuss her symptoms with Dr. Hansen on November 14, 2016 or December 14, 2016; and 3) there is no alternate explanation for her shoulder pain. *Id.*

Petitioner filed updated medical records on April 22, 2020 (Ex. 16) and June 25, 2020 (Ex. 17).

On October 2, 2020, Respondent filed an expert report from Dr. Geoffrey Abrams and supporting medical literature. Exs. A, B, A-1-A-9. On October 27, 2020, Petitioner filed a second supplemental expert report from Dr. Natanzi.³ Ex. 18.

I held a status conference on April 1, 2021 where I discussed the possibility that I rule on the record concerning the issue of onset. *See* Scheduling Order dated April 1, 2021, ECF No. 44. Respondent's counsel indicated that a ruling on onset would likely help to move the case forward. *Id.* Ms. Senerth stated she had to confer with her client regarding whether she was amenable to an onset determination. I ordered Petitioner to file a status report in 10 days outlining her position. *Id.*

On April 12, 2021, Petitioner filed several affidavits. Exs. 19-21. She filed a status report on April 13, 2021 indicating that she was amenable to an onset determination on the existing record. ECF No. 46.

Petitioner filed a motion for a ruling on the record concerning onset on June 15, 2021.⁴ ECF No. 48. Respondent filed a response on November 1, 2021. ECF No. 54. This case is now ripe for a fact ruling.

II. Petitioner's Medical Records that Pertain to the Issue of Onset

On October 21, 2016, Petitioner visited Dr. Thomas Hansen complaining of "right elbow pain that began around January 2016". Ex. 4 at 1. Dr. Hansen assessed her with right lateral epicondylitis and carpal tunnel syndrome; he recommended a right lateral epicondyle debridement and carpal tunnel release. *Id.* at 2. Petitioner had these procedures performed on November 1, 2016. *Id.* at 31-32.

³ In his second supplemental expert report, Dr. Natanzi provided additional reasoning to support onset of Petitioner's shoulder pain immediately after vaccination. He stated that the nurse who administered Petitioner's vaccine told her that her post-vaccination pain was likely related to her recent surgery. Ex. 18 at 1. He further noted that "When the elbow surgery pain improved but her shoulder symptoms did not, she thought – as anyone would – that there must be something else going on." *Id.* I have considered each of the points raised by Dr. Natanzi in all three of his expert reports in arriving at my factual determination in this case.

⁴ Although the parties discussed a ruling on onset during the April 1, 2021 status conference, and Petitioner indicated that she was "amenable to an onset determination based on the record" in her status report filed on April 13, 2021 (ECF No. 46), Petitioner filed a brief requesting that I issue an entitlement ruling. (*See* Pet'r's Mot. at 7-8, stating, "Therefore, Petitioner respectfully requests that this Court find that Petitioner has demonstrated by a preponderance of the evidence that [s]he suffered a left shoulder (SIRVA) "Table" injury, and thus is entitled to a presumption of causation. Alternatively, should this Court find that Petitioner does not meet the criteria to establish a Table claim, Petitioner respectfully requests that this Court find that the evidence in this case demonstrates that Petitioner suffered a right shoulder injury caused-in-fact by the flu shot administered on November 9, 2016."). I have elected to rule on the factual issue of onset, as originally discussed on April 1, 2021. *See* Scheduling Order, dated April 1, 2021, ECF No. 44.

Petitioner received her flu vaccine in her right deltoid on November 9, 2016. Ex. 1 at 1.

On November 14, 2016, Petitioner visited Dr. Hansen for a follow-up appointment after her surgery. Ex. 4 at 3. She reported some slightly limited range of motion, but denied having “numbness, swelling, or trouble sleeping secondary to pain.” *Id.* Petitioner denied experiencing shoulder pain. *Id.* Her sutures were removed during this visit. *Id.* at 4.

Petitioner visited Dr. Hansen on December 14, 2016 for a six week post-op visit. Ex. 4 at 5. She indicated that her pain had increased lately. *Id.* She described pain in her right hand that was “‘burning’, ‘sensitive’, and an intermittent feeling of an electric current throughout her hand.” *Id.* She also described her right elbow pain as squeezing. *Id.* Petitioner indicated she had trouble sleeping secondary to pain. *Id.* She denied numbness, swelling, or limited range of motion. *Id.* Petitioner again affirmatively denied having shoulder pain. *Id.*

On January 10, 2017, Petitioner presented to Avondale Family Care for fever and body aches. Ex. 2 at 29. She tested positive for the flu and was given Tamiflu. *Id.* Petitioner denied experiencing muscle aches, painful joints, swollen joints, weakness, and loss of strength. *Id.* at 30-31.

Petitioner returned to Avondale Family Care on February 8, 2017 for a diabetes follow-up appointment. Ex. 2 at 25. Petitioner reported she was “having R shoulder pain now” and that she was “still healing from elbow.” *Id.* Petitioner received a cortisone injection in her right shoulder. *Id.* at 27.

On April 8, 2017, Petitioner had an MRI of her right shoulder. Ex. 4 at 36. The history indicates: “Pain for 4 months. Throbbing pain. Keeps her up at night. No known trauma. Previous rotator cuff surgery of the right shoulder.” *Id.*

On May 10, 2017, Petitioner presented to Dr. Hansen with complaints of right shoulder pain. Ex. 4 at 7. The HPI notes “the patient complains of right shoulder pain has been present since January of 2017 and is not the result of any accident, injury, or trauma.” *Id.* Petitioner described her pain as “dull, with intermittent sharpness, burning, stabbing, throbbing pain.” *Id.* Dr. Hansen assessed Petitioner with bursitis. *Id.* at 8.

Petitioner returned to Dr. Hansen on December 27, 2017. Ex. 4 at 9. She complained of pain in her right shoulder and requested a cortisone injection. *Id.* She told Dr. Hansen that her pain had been present since “approximately November of 2016.” *Id.* Petitioner told Dr. Hansen that her pain was not the result of any accident, injury, or trauma. *Id.* She also described left elbow and left forearm pain present since May of 2017. *Id.* Petitioner had positive impingement signs, full range of motion, and some tenderness over the AC joint. *Id.* at 10. Dr. Hansen assessed Petitioner with bursitis. *Id.* He administered a cortisone injection. *Id.*

On January 18, 2018, Petitioner had a PT evaluation for right shoulder pain and left medial elbow pain. Ex. 4 at 54. During this visit, Petitioner stated that “she rec’d a flu shot in her right arm on November 8, 2016 that caused her increased shoulder pain. . . . Since flu shot, her pain has gotten worse. She waited to see if her pain would improve but it did not.” *Id.* On February 5, 2018,

Petitioner was discharged from PT because she did not return for her scheduled appointments. *Id.* at 52. No other records pertinent to the issue of onset have been filed.

III. Affidavits that Address the Issue of Onset

A. Petitioner's First Affidavit

Petitioner signed her first affidavit on June 5, 2018. She averred that she received a flu vaccine on November 9, 2016. Ex. 6 at 1. Petitioner stated that she had undergone rotator cuff repair in 2004, but that at the time of vaccination, she had no shoulder pain. *Id.* She further averred that she experienced pain in her right shoulder “immediately after vaccination.” *Id.*

B. Petitioner's Second Affidavit

Petitioner signed her second affidavit on July 24, 2018. In this document, she stated that on November 1, 2016, she underwent right carpal tunnel release and right lateral epicondyle release. Ex. 7 at 1. She stated that she specifically recalled the day of her vaccination “because of the severe pain that the shot gave me right away.” *Id.* Petitioner described it as “[t]he kind of pain you don’t forget.” *Id.* Petitioner described that she was sitting in a chair while the nurse stood and administered the vaccine. *Id.* at 2. Petitioner described that immediately following vaccination, she had pain in her right shoulder. *Id.* She averred that she told the nurse how much pain she was experiencing. *Id.* “The nurse’s response was that it could be due to the surgery I had.” *Id.* Petitioner drove herself home and used ice on her shoulder for the rest of the day. *Id.*

Petitioner averred that she continued to experience pain from the shot as she recovered from her surgery. Ex. 7 at 2. She hoped the pain would go away, but it did not. *Id.* Petitioner explained why she did not mention her shoulder pain to Dr. Hansen on November 14, 2016 or December 14, 2016. She stated: “I thought my shoulder pain could have originated from my underlying surgery because that is what the nurse who administered the vaccine told me.” *Id.* She stated that after she recovered from her November 1 surgery and her right shoulder pain continued, she decided to tell her PCP she had been experiencing right shoulder pain since the flu vaccine. *Id.*

C. Petitioner's Third Affidavit

Petitioner signed her third affidavit on December 23, 2019. In this document, Petitioner stated that she reviewed Dr. Hansen’s notes from her May 10, 2017 medical appointment. Ex. 21 at 1. She opined that these notes indicate that her right shoulder pain began in January because “I told Dr. Hansen that my pain had increased and that I was having arm and shoulder pain.” Petitioner further stated that “I thought this pain was part of the healing process because the nurse that gave me the flu shot told me that the pain I felt with the injection was because of my surgery.” *Id.*

D. Affidavit of Jennifer Guerrero

Jennifer Guerrero signed her affidavit on December 23, 2019. She is Petitioner’s daughter. Ex. 19 at 1. Ms. Guerrero stated that although she was not with her mother when she received the

flu vaccine, she saw her that evening. *Id.* Ms. Guerrero stated that Petitioner remarked about how much pain she was in from the flu vaccine. *Id.* She also recalls her mother telling her that the nurse who administered the vaccine attributed Petitioner's pain to her surgery. *Id.* at 2.

E. Affidavit of Patrick Delio

Patrick Delio signed his affidavit on December 24, 2019. He is Petitioner's husband. Ex. 20 at 1. Mr. Delio stated that he was at work when Petitioner received her flu shot. *Id.* He further stated that Petitioner called him from the parking lot in tears after she received her vaccination. *Id.* According to Mr. Delio, "[s]he told me how painful the shot was and that the pain was not letting up." *Id.* When he got home, Petitioner was still in pain. *Id.* She told him that her surgery was not giving her any issues, but that she had pain in her shoulder going down her arm. *Id.*

IV. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). 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 & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

In order to make a determination concerning factual issues, such as the timing of onset of petitioner's alleged injury, the special master should first look to the medical records. "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." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2006 WL 3734216, at *8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete. *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010).

Contemporaneous medical records generally merit greater evidentiary weight than oral testimony; this is particularly true where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight")).

However, there are situations in which compelling oral testimony may be more persuasive than written records--for instance in cases where records are found to be incomplete or inaccurate. *Campbell*, 69 Fed. Cl. at 779 ("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*, 2005 WL 6117475, at *19 ("Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed 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 & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). A special master making a determination whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at a hearing must have evidence suggesting the decision was a rational determination. *Burns by Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

V. Findings of Fact

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

The question to be resolved is when Petitioner’s initial right shoulder pain began. Petitioner contends that it began on November 9, 2016 the day of vaccination. Pet’r’s Mot. at 1. Respondent asserts Petitioner’s right shoulder pain began in the December 2016-January 2017 timeframe. Resp’t’s Resp. at 11. After reviewing the medical records and affidavits presented in this case, and after my careful examination of the record as a whole, I find there is preponderant evidence that the onset of Petitioner’s symptoms of right shoulder pain began sometime between December 14, 2016 and January of 2017.

Petitioner had two medical appointments that took place close-in-time to her November 9, 2016 vaccination: her medical appointment on November 14, 2016, and her appointment on December 14, 2016. Petitioner saw Dr. Hansen at both visits. Dr. Hansen specifically asked whether she was experiencing shoulder pain at both of these appointments, and both times Petitioner indicated that she was not. Ex. 4 at 4, 5.

In her affidavit, Petitioner explains this she thought her shoulder pain that she experienced during this timeframe could have resulted from her November 1 surgery, as that is what the nurse who administered her flu shot told her. Ex. 7 at 2. Although this account might have been a logical one in a situation where Petitioner simply did not mention shoulder pain to Dr. Hansen, it does not provide a reasonable explanation as to why she specifically denied this pain when directly asked. As the court noted in *Lowrie*, “it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” *Lowrie*, 2006 WL, at *7.

Further, at an appointment on April 8, 2017, when she did mention experiencing right shoulder pain, Petitioner indicated she had been experiencing pain for four months, and that there was “No known trauma.” Ex. 4 at 36.⁵ Four months before April 8, 2017 was December 8, 2016. Additionally, on May 10, 2017, Petitioner presented to Dr. Hansen with complaints of right shoulder pain. Ex. 4 at 7. The HPI notes “the patient complains of right shoulder pain has been present since January of 2017 and is not the result of any accident, injury, or trauma.” *Id.* When considered in conjunction with the records from November 14 and December 14, these additional records further support the fact that Petitioner was not experiencing shoulder pain within 48 hours of her vaccination, and instead, that this pain developed in the timeframe between December 14, 2016 and January 2017.

Petitioner first indicated that her pain began in November of 2016 at a medical appointment with Dr. Hansen on December 27, 2017, more than one year after her vaccination. Ex. 4 at 9. Petitioner specifically stated that her right shoulder pain began after her flu vaccine at her initial PT consultation on January 18, 2018. Ex. 4 at 54. I have also considered Petitioner’s affidavits as well as those submitted on her behalf. In making these factual determinations, I have ultimately concluded that the medical records and medical histories, provided close-in-time to Petitioner’s injury, are more persuasive than the medical records and affidavits presented by Petitioner and her family members between one and three years after the fact. “Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.” *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

VI. Conclusion

I find that Petitioner’s contemporaneous medical records preponderantly establish that she began to experience right shoulder pain sometime between December 14, 2016 and January of 2017.

The following is therefore ORDERED:

By no later than **January 20, 2022**, Petitioner shall file a status report indicating how she would like to proceed based on the facts articulated in this ruling.

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler
Special Master

⁵ Although Petitioner had a medical appointment on February 8, 2017 where she mentioned right shoulder pain, there is no indication in the medical record regarding when this pain began. See Ex. 2 at 25. I note this record does indicate that Petitioner was “having R shoulder pain now” which tends to suggest that the onset of pain was more recent. See *id.*