In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1340V

TERESA MAZZA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: August 10, 2023

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Ryan D. Pyles, U.S. Department of Justice, Washington, DC, for Respondent.

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

On October 7, 2020, Teresa Mazza 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 alleged that she suffered a shoulder injury related to vaccine administration ("SIRVA") due to an influenza ("flu") vaccine received on October 11, 2018. *See* Petition. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[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, the record does not preponderantly support the conclusion that Petitioner's shoulder pain began within 48 hours post-vaccination – thereby requiring dismissal of her Table claim. This leaves a potential causation-in-fact claim, however – and some final efforts at settlement might be advisable before the case is transferred from SPU.

I. Relevant Procedural History

The petition was accompanied by the affidavit and medical records required by the Vaccine Act. Exs. 1-8, filed October 7, 2020 (ECF No. 1); *see* Section 11(c).[3] In alleging that her symptoms began within forty-eight (48) hours after vaccination, the petition cited to the earliest medical records. Petition at Preamble; ¶¶ 4-5 (citing Ex. 2 at 33-35). Her affidavit does not address onset, however. Ex.8.

Approximately 15 months after the case was activated, Respondent completed his medical review and entered into settlement discussions. Status Report filed November 8, 2021 (ECF No. 24); *see also* Status Report filed May 11, 2021 (ECF No. 18) (indicating Petitioner's earlier conveyance of a demand). Six months later, however, the parties reached an impasse. Status Report filed May 16, 2022 (ECF No. 29).

On June 14, 2022, Respondent filed his report pursuant to Vaccine Rule 4(c), which sets forth his opposition to compensation of the alleged Table SIRVA claim – in part, because Respondent avers, that Petitioner has not established the requisite onset of symptoms within 48 hours after vaccination. Rule 4(c) Report (ECF No. 30).

On September 7, 2022, Petitioner timely filed her Brief in Support of Entitlement ("Brief") (ECF No. 32). She did not avail herself of the opportunity to file any additional evidence, however. On October 19, 2022, Respondent filed his Response (ECF No. 33), which was followed on November 3, 2022, by Petitioner's Reply (ECF No. 34). The matter is now ripe for adjudication.

II. Applicable Legal Standards

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.

[3] *See also* updated medical records filed on November 12, 2020, as Exs. 9-10 (ECF No. 11), and on June 9, 2021, as Ex. 11 (ECF No. 20).

Section 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." *Cucuras v. Sec'y of Health & Hum. 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 & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). 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 & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has 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 & Hum. 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 v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. 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 the medical records, testimony, and 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 & Hum. 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).

Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV) (2017). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation ("QAI") are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Findings of Fact

I make the following findings based on a complete review of the record to include all medical records, affidavits, additional evidence, and arguments by the parties. The following points are particularly relevant:

- Petitioner has received primary care at East Ridge Family Medicine in Rochester, New York, since at least 2014. Ex. 2 at 75-77. Her medical history included depression and anxiety. *Id.* Following a motor vehicle accident in or before 2009, she had chronic pain primarily in her lower back. *See, e.g.*, *id.* at 70-74 (reflecting MRI findings of lumbar spondylosis and degenerative disc disease).

- In January 2018, Petitioner sought care twice for acute neck pain, assessed as either a musculoskeletal injury or nerve impingement and treated with Flexeril and non-steroidal anti-inflammatory drugs ("NSAIDs"). Ex. 2 at 40-45.[4]

- In May 2018, Petitioner complained of a several-week history of right elbow/ forearm pain, which was assessed as lateral epicondylitis, and treated with rest and conservative measures. Ex. 2 at 39-40. This was not addressed at the next encounter on August 24, 2018. *Id.* at 35-37.

- On October 11, 2018, Petitioner received the subject vaccine in her right arm. Ex. 1 at 2.[5]

[4] At the first encounter for this complaint, on January 19, 2018, Petitioner reported "a one-week hx right-sided neck pain." Ex. 2 at 44-45. This is most contemporaneous, specific, and likely to be accurate with regard to the onset of neck pain – notwithstanding the *second* relevant encounter, which provides that it "started on 1/11/**2017**." *Id. at* 42 (emphasis added).

[5] While the primary care provider has supplied a certified immunization summary (and neither the fact of vaccination or its site is in controversy), it is unclear *where* the vaccination actually occurred (i.e. the location of its administration). *See generally* Ex. 2 (not reflecting an encounter for the vaccination date); *id.* at 35 (indicating that the primary care provider recorded the fact of the vaccination afterwards, at her first encounter for right shoulder pain); *but see id.* at 31 (subsequent record with Petitioner's report of receiving vaccination "in this office").

- The next medical record is signed by Marc Lavender, M.D., after an in-person encounter on Monday, October 22, 2018. Ex. 2 at 33-34.

    - It provides: "***Writer*** spoke to patient over weekend for symptoms suspicious for neuropathic pain into right arm and hand following flu shot a week prior (see note below)." *Id.* at 33 (emphasis added).

    - The "note below" reads: "10/20/18 Telephone call note: ***3 days after flu shot was given on 10/11/18*** in her dominant right arm (usually has in left arm), developed pain at injection site with intermittent radiation to her wrist. Has dropped things due to sharp pains. Office recommended Tylenol and heat – no help. No shortness of breath, no rash." Ex. 2 at 33.

    - On October 22, 2018, Dr. Lavender recorded that Petitioner's pain was no longer going to the right hand, only to the right elbow. Ex. 2 at 33. On exam, the right arm had normal range of motion, but "notable reproducible right lateral upper arm pain" and right deltoid tenderness. *Id.* at 34. Dr. Lavender assessed that the pain was "likely related to localized inflammation triggered by the immunization, with possible stimulation of adjacent nervous system structures resulting in pain." *Id.* Petitioner refused gabapentin (for fear of addiction), ibuprofen (for fear of stomach irritation), and Tylenol (as ineffective); she would start with conservative measures. *Id.*

- Next, on October 30, 2018, Erin Lineman, M.D., recorded Petitioner's report that after the October 11th vaccination, "***her right arm felt fine, but the next morning she woke up and it was very sore. The following day, she felt like she 'could not move' her right arm at all***." Ex. 2 at 31. Petitioner was "quite stressed" about the pain and potential that the vaccine was "given wrong." *Id.* Dr. Lineman provided home exercises, recommended continuation of ibuprofen, and prescribed gabapentin for additional pain relief. Ex. 2 at 31.[6]

- On October 31, 2018, Petitioner presented to the University of Rochester-Strong Memorial Hospital emergency room. She reported "right extremity pain since flu vaccine 21 days ago," upon undergoing an ultrasound, which was unrevealing. Ex. 3 at 17. An x-ray revealed calcific tendinopathy. *Id.* at 19.

[6] Petitioner returned repeatedly to the primary care practice, meeting specifically with Dr. Lineman, for her persistent right shoulder pain. The medical records reflect Petitioner's continued concern that the injury was caused by the subject flu vaccine – but no additional notations about the specific onset of the injury. *See, e.g.*, Ex. 2 at 7-8. 18-19, 26-28, 29-30.

- Dr. Lineman referred Petitioner for a course of physical therapy ("PT"). Ex. 2 at 29-30. The December 12, 2018, PT initial assessment lists the mechanism of injury as "***Flu shot – 2 days later could not move her arm***." Ex. 4 at 20 (emphasis added). However, the PT record also lists the injury onset as ***10/20/18***. *Id.* (emphasis added).[7]

- After Petitioner's pain persisted for over a year (despite the aforementioned PT, and two steroid injections), Dr. Lineman entered a referral to orthopedics. Ex. 2 at 7-8. At the December 12, 2019, orthopedics initial consultation, a physician assistant ("PA") recorded Petitioner's history of "***pain since a flu shot… in October 2018. She had immediate reaction with increased swelling, redness, and the inability to use her arm.***" Ex. 5 at 33.[8]

- Petitioner has not submitted any additional contemporaneous evidence, or any later recollections, pertaining to onset. Her affidavit, required under the Vaccine Act, does not address the question. Ex. 8.

I acknowledge that the standard applied to resolving onset for an alleged SIRVA is liberal and will often permit a determination in a petitioner's favor, especially in the *absence* of fairly contemporaneous and direct statements to the contrary within the contemporaneous medical records. However, not every case can be so preponderantly established. Ultimately, the resolution of onset involves weighing different pieces of evidence found within the specific case record (supplemented by witness statements and other independent items).

Here, Petitioner suggests that the first notation of onset as "3 days after flu shot" (Ex. 2 at 33) may have been recorded sometime after that telephone call, even two days later (in conjunction with the first office visit). Brief at 7. She emphasizes that the telephone encounter note provides that "[the primary care] office recommended Tylenol and heat – no help." This may have been a suggestion of common conservative treatments, which Petitioner had in fact tried independently, prior to the call. Respondent argues that the telephone encounter note was most likely recorded contemporaneously, then copied into the office visit record. Response at 2-3.

[7] After six formal PT sessions, Petitioner was discharged to a home exercise program on February 22, 2019. The PT records do not contain additional information relevant to my onset determination. Ex. 4 at 13-147.

[8] Petitioner subsequently underwent an MRI of the right shoulder with findings including tendinopathy and bursal tearing; followed up with an orthopedic surgeon; and underwent arthroscopic surgery and post-operative PT. *See* Ex. 6 at 35; Ex. 5 at 55; Ex. 7 at 59; Ex. 9 at 200-392.

But even crediting Petitioner's argument, the available evidence supports that both the telephone call and the office visit were with the same primary care physician, Dr. Lavender. *See* Ex. 2 at 33 (reflecting that "writer spoke to patient over weekend…"). This is also the most contemporaneous evidence – from *less than two weeks post-vaccination*. Dr. Lavender's "telephone encounter" note of onset "3 days after flu vaccine" does not contradict his office note of onset "following flu shot a week prior," or even necessarily his assessment that the flu vaccine had caused an inflammatory reaction. This evidence thus warrants significant weight.

I recognize that just nineteen (19) days later, a different primary care physician recorded onset as having occurred 48 hours after vaccination. Ex. 2 at 31. Respondent argues that it would be an absurd result for "typical" acute injection site soreness to represent the onset of a Table SIRVA, *see* Response at 2. However, Respondent does not grapple with the detail that Petitioner maintains that she "could not move her right arm at all" during that timeframe. This would suggest post-vaccination pain that was unusually severe. *Standing alone*, such a notation would likely support a favorable Table SIRVA onset determination. However, this record is in direct tension with the earlier notation that the pain began "3 days after flu shot" – which I find to be more probative.

The remaining medical records were created later in time, and state more generally that the shoulder injury occurred "since" or "following" the vaccination. They do not demonstrate that onset was specifically within 48 hours. Petitioner has also declined to provide any contemporaneous non-medical evidence or later recollections that may have shed additional light on the circumstances (although those of course, would have had to be particularly compelling to outweigh the very detailed contemporaneous medical records). The evidence before me thus supports the determination that onset occurred most likely after 48 hours, but not less than 72 hours after vaccination – too long for a successful Table claim.

Conclusion and Scheduling Order

The above factual finding dictates **DISMISSAL** of Petitioner's Table SIRVA claim.

I note, however, that Petitioner has a potential causation-in-fact claim, which has some support within the existing medical record. *See, e.g.*, Ex. 2 at 33 (Dr. Lavender's endorsement that the vaccination triggered inflammation and/or nervous system stimulation, notwithstanding his understanding of a three-day onset). Respondent's Rule 4(c) Report does not analyze the viability of a non-Table claim.

A non-Table claim could *potentially* include symptoms not limited to the shoulder, if adequately explained. *See* Rule 4(c) at 6, Response at 2-3 (averring that Petitioner's complaints of pain radiating down the arm were incompatible with a *Table* claim, citing 42 C.F.R. § 100.3(c)(10)(iii)). However, a non-Table claim would likely require expert support[9] – which I am not inclined to authorize while the case remains in SPU.

Before transferring the case out of SPU for further proceedings, I will allow the parties a brief opportunity to revisit their settlement discussions.

The parties are hereby ORDERED to file a joint status report indicating whether they believe an informal resolution can be reached and providing their preferred next step(s) in the case within 60 days, by no later than Tuesday, October 10, 2023.

IT IS SO ORDERED.

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

[9] *See, e.g.*:

- *Morris v. Sec'y of Health & Human Servs.*, 19-1570V, 2023 WL 5092691 (Fed. Cl. Spec. Mstr. July 11, 2023) (concluding in a non-SPU case, upon consideration of the petitioner's unrebutted medical expert opinions, that she had established causation-in-fact for persistent shoulder pain beginning beyond 48 hours, but within 72 hours after vaccination).

- *Lee v. Sec'y of Health & Hum. Servs.*, No. 18-0486V, 2023 WL 4444843 (Fed. Cl. Spec. Mstr. June 16, 2023) (concluding in a non-SPU case, that the petitioner had not established causation-in-fact for persistent shoulder pain beginning approximately 4 days post-vaccination, and noting alternative explanation of cervical radiculopathy).