In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0756V

UNPUBLISHED

STEVEN LAPIDUS, M.D., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 30, 2022 Special Processing Unit (SPU); Findings of Fact; Site of Vaccination;Onset; Tetanus, Diphtheria, acellular Pertussis (Tdap) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Bruce William Slane, Law Office of Bruce W. Slane, P.C., White Plains, NY, for Petitioner.

Terrence Kevin Mangan, Jr., U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On January 15, 2021, Steven Lapidus, M.D., 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 he suffered "injuries including right radial neuropathy of the right shoulder/arm, paresthesia of the right shoulder/arm, and

[1] Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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). **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).

dysesthesias[3] of the right shoulder/arm, dysesthesia within the superficial cutaneous nerve to the forearm and wrist, that were caused-in-fact by the adverse effects of an Tdap vaccin[e] . . . received on May 26, 2020." Petition at 1.

For the reasons discussed below, I find the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine in question was most likely administered in Petitioner's right shoulder, as alleged, and that onset of Petitioner's pain occurred immediately upon vaccination.

I. Relevant Procedural History

During the three months after his petition was filed, Dr. Lapidus filed the affidavit and medical records required under the Vaccine Act. Exhibits 1-11, ECF Nos. 6, 9; *see* Section 11(c). On August 19, 2021, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims (the "SPU")). ECF No. 13.

Observing that the vaccine record indicated the influenza vaccine was administered intramuscularly in Petitioner's *left* shoulder, rather than *right* shoulder as alleged, I instructed Petitioner to file any additional evidence regarding site of vaccination while awaiting Respondent's review of the claim. Order, issued Jan. 24, 2022, at 1, ECF No. 17. Although I recognized that his injury is not a typical shoulder injury (like a "SIRVA," or "shoulder injury related to vaccine administration"), being neurologic in nature, I still instructed Petitioner to finalize a demand which he could convey, along with supporting documentation, to Respondent at any time. *Id.*

After completing his review, Respondent indicated that he believed the case was not appropriate for compensation. ECF No. 18. In his Rule 4(c) Report, dated April 22, 2022, Respondent stresses that the vaccine record indicates the opposing site of vaccination; insists that Petitioner has not provided an expert report or medical records evidence, other than the results of an EMG/NCS to support his claim; and argues that the onset description provided by Petitioner is vague. Rule 4(c) Report at 4-5, ECF No. 19.

After reviewing the record as it currently stands, I have determined that factual findings regarding the site of vaccination and onset are currently needed in this case.

[3] Dysesthesias is a "distortion of any sense, especially of that of touch" or "an unpleasant abnormal sensation produced by normal stimuli." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 577 (32th ed. 2012).

II. Issue

At issue is (a) whether Petitioner received the vaccination alleged as causal in his injured right arm, and (b) the timing of the onset of his pain began.

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). "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).

IV. Finding of Fact

I make the following findings regarding site of vaccination and onset after a complete review of the record, including medical records, affidavits, and other additional evidence filed showing:

- Age 79 years old at the time of vaccination, Petitioner is a plastic surgeon who earned his medical degree in 1967. Exhibit 1 (birth certificate); Exhibit 3, Tab 1 (curriculum vitae).

- Petitioner's prior medical records show he was a former smoker, who suffered from high blood pressure and cholesterol, cardiomyopathy, coronary heart disease, peripheral vascular disease, renal insufficiency,

GERD, Lyme disease, lumbosacral radiculopathy, and metatarsalgia[4] of the left foot. *See* Exhibits 10-11. Chest x-rays - taken on October 3, 2019, show stenting, and an epicardial pacemaker from a prior open-heart surgery. Exhibit 10 at 19.

- The vaccine record indicates Petitioner received a Tdap vaccine on November 8, 2019, at a Rite Aid Pharmacy. Exhibit 9 at 6. The vaccine record specifies the vaccine was administered in Petitioner's "Left Upper Arm." *Id.*

- In his affidavit, Petitioner stated that "[i]mmediately after the vaccination, [he] experienced soreness and discomfort in [his] right shoulder at the injection site." Exhibit 3 at ¶ 6. Averring that he "noticed that the vaccine was administered too low, and the needle went in too deep," Petitioner identified the injection site as located "where the radial bundle of nerves [wa]s located along the groove of the humerus." *Id.*

- Petitioner further claims that he "came to realize that [he] sustained nerve damage to [his] right shoulder" when he "began to experience paresthesia and dysesthesias that radiated down [his] right shoulder to [his] forearm." Exhibit 3 at ¶ 7. He stated that he did not seek treatment earlier because, as a surgeon, he knew "it would be extremely difficult to find/get to the injured radial nerve fibers, . . . was only a partial injury to the radial nerve, . . . [and] would ha[ve] made no sense from a surgical standpoint to undergo any treatment." Exhibit 3 at ¶ 10.

- In his affidavit, Petitioner maintained that he reported his injury to Rite Aid Pharmacy in July or August 2020. Exhibit 3 at ¶ 12. At the same time, he spoke to two colleagues, Loren Rosenthal, M.D. and Mark Bodack, M.D., about his condition – who agreed with his assessment and conclusion that there was no available treatment for his condition. *Id.*

- After receiving a letter from the Rite Aid Pharmacy, dated September 8, 2020, regarding his complaint of an adverse vaccine reaction and the existence of and contact information for the National Vaccine Injury Compensation Program, Petitioner stated that he called the telephone number provided, and was told that he could not report his injury until six

[4] Metatarsalgia "is a condition in which the ball of your foot becomes painful and inflamed." https://www.mayoclinic.org/diseases-conditions/metatarsalgia/symptoms-causes/syc-20354790 (last visited on June 27, 2022).

months had passed. Exhibit 3 at ¶ 13. He provided a copy of the letter he received. Exhibit 4.

- Petitioner also submitted a letter, dated December 9, 2020, from neurologist Dr. Rosenthal, stating that Petitioner "had a tetanus injection in his right shoulder on 5/26/2020 [and] [s]ince that time, he has had paresthesia in the right radial distribution in his arm." Exhibit 6 at 2. She further represented that she had discussed Petitioner's condition with him on October 1, 2020, and recommended that he see Dr. Bodack, a physiatrist, for evaluation. She noted Petitioner was scheduled for an EMG and NCV. *Id.*

- On December 24, 2020, Petitioner underwent an EMG and was seen by Dr. Bodack thereafter. In the patient history of the EMG report, it is noted that Petitioner presented with right upper pain and dysesthesias after receiving a painful injection to his right upper arm on May 26, 2020. Exhibit 7 at 5. According to this history, Petitioner noticed his pain immediately after the injection. *Id.*

- The results of the EMG revealed right radial neuropathy, right median sensorimotor neuropathy at the wrist, and no evidence of additional focal neuropathy or cervical radiculopathy. Exhibit 7 at 6. Dr. Bodack diagnosed Petitioner with "[n]europathy of [the] right radial nerve" and dysesthesia. *Id.* at 7.

- It appears that Dr. Rosenthal examined Petitioner six days later. Exhibit 6 at 3. She provided a letter, dated December 30, 2020, discussing the results of the EMG and noting that her "examination [wa]s consistent with needle penetration of the radial nerve at the lower subdeltoid level of the right arm." *Id.* In this record, it was again reported that Petitioner received the injection on May 26, 2020, in "his right posterolateral upper arm . . . [and] subsequently felt pain and dysesthesia in the arm which is exacerbated by activity." *Id.*

- Petitioner also provided a copy of an email from the Vaccine Adverse Events Reporting System ("VAERS"), confirming a report was completed on December 3, 2020, and a temporary identification number assigned. Exhibit 5.

The quantity of medical records in this case is limited – a reasonable situation considering Petitioner is a plastic surgeon who undoubtedly self-treated on numerous

occasions. However, those records preponderate in favor of Petitioner's situs contentions. In every medical record which exists, Petitioner *consistently* described a right shoulder Tdap injection which cause immediate pain upon administration. Without fail, he attributed his injury to the Tdap vaccine he received on May 26, 2020. Petitioner provided extremely consistent and detailed accounts of his injury and the onset of his pain – exhibiting a significant understanding of the circumstances and extent of his injury. While these entries were based upon information provided by Petitioner, they still should be afforded weight, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care.

The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

Additionally, the descriptions provided by Petitioner of his injury were clearly accepted by the neurologist and physiatrist who he saw - Dr. Rosenthal and Dr. Bodack, respectively. Both agreed with Petitioner's assessment of his condition and injury, and that it impacted his right arm rather than left (although obviously subsequent treaters could not confirm or rebut the situs contentions at issue).

The only evidence which points to administration in Petitioner's *left*, rather than *right* arm, is the vaccine record itself. Exhibit 9 at 6. But this document, besides being cursory in nature, is not corroborated by any other item of evidence. Thus, there are many more items of evidence reasonably entitled to some weight that are consistent with Petitioner's contentions.

Moreover, based upon my experience resolving SPU SIRVA cases (approximately 1,300 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled in chambers it is not unusual for the information regarding site of vaccination in computerized systems to be incorrect. Many of these systems use a "dropdown" menu which may not be updated each time a separate vaccine is administered to a different individual. *See, e.g., Mezzacapo v. Sec'y of Health & Hum. Servs.,* No. 18-1977V, 2021 WL 1940435, at *6 (Fed. Cl. Spec. Mstr. Apr. 19, 2021)[5];

[5] In this ruling by one of my special master colleagues, the pharmacist who had administered the relevant vaccination testified that she inputs "left deltoid" into the computer system as a matter of course, without confirming the actual site of vaccination, because most vaccinees are right-handed. *Mezzacapo*, 2021 WL 1940435, at *6. The pharmacist's testimony was deemed credible, and the site of vaccination found to be as the petitioner alleged, rather than what was indicated in the vaccine record.

Desai v. Sec'y of Health & Hum. Servs., No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); *Stoliker v. Sec'y of Health & Hum Servs.*, No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018). Even though such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply *because* they come first – and in fact the nature of their creation provides some basis for not accepting them at face value.

Given the character of the vaccine record in this case - which appears to be the printed results of computer search query, and the fact that the record indicates the vaccine was administered in Petitioner's left deltoid – the default option often chosen (*see supra* note 5), I find it is not sufficient by itself to counter Petitioner's consistent reports of administration in his right deltoid contained in the contemporaneously created medical records. Nor does it automatically receive evidentiary weight because it temporally came "first." Additionally, Petitioner's similar reports of pain upon vaccination are sufficient to establish an immediate pain onset.

V. Scheduling Order

In light of my finding regarding the site of vaccination and onset, Respondent should consider his position in this case. **Respondent shall file a status report indicating how he intends to proceed following my ruling by no later than Friday, August 12, 2022**.

IT IS SO ORDERED.

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