

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0538V

G. MATTHEW KOSMA,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 28, 2023

Nancy Routh Meyers, Turning Point Litigation, Greensboro, NC, for Petitioner.

Madelyn Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On January 11, 2021, G. Matthew Kosma 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 he suffered a left-sided shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, which was causally related to his receipt of an influenza (“flu”) vaccine on February 15, 2020. For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner’s left arm, as alleged.

¹ Because this 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 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).

I. Relevant Procedural History

The Petition averred that the vaccine administration record “incorrectly notes that the influenza vaccine was given in the right deltoid, when it was in fact given in the left deltoid.” Petition (ECF No. 1) at ¶ 2. Five months later, Mr. Kosma filed the statutorily-required medical records and affidavits (which had been cited in the Petition). Exs. 1-9, at ECF No. 6. Exhibit 7 is an affidavit from his wife, who recalled witnessing the subject vaccine’s administration into Petitioner’s left arm. Ex. 7 at ¶ 3. On December 2, 2021, the case was activated and assigned to OSM’s Special Processing Unit (“SPU”), which is intended to resolve likely-to-settle claims. ECF No. 10.

On March 16, 2022, Respondent requested that Petitioner submit “any and all available evidence to support his allegation that the vaccine was administered in his left arm.” ECF No. 14. On April 29, 2022, Petitioner filed the complaint report he submitted to the North Carolina Board of Pharmacy on March 5, 2020. Ex. 11, at ECF No. 17. He also filed orthopedics records. Ex. 10, at ECF No. 16.

In May 2022, the parties were informed that I was willing to receive any briefing and then formally resolve the site issue (a factual issue capable of resolution while the case awaited Respondent’s medical review). Respondent objected, asserting that his still-pending medical review might point instead towards an alternative diagnosis of brachial neuritis (also known as Parsonage-Turner syndrome) which would render the site issue moot, since brachial neuritis can occur in the non-vaccinated arm.³ But on July 20, 2022, I advised that the vaccine administration record was likely not fatal to the site issue (and hence more broadly to the SIRVA claim), and therefore directed Petitioner to convey a demand to Respondent. See ECF No. 19; see *a/so* ECF No. 20 (reporting conveyance of a demand on September 19, 2022).

On February 6, 2023, Respondent informally advised that he had completed a medical review of the case, and he requested a fact ruling determining the site of vaccine administration. The parties subsequently agreed upon a briefing schedule. See Informal Communication and Scheduling Order dated February 8, 2023 (Non-PDF). Petitioner filed his Motion on March 30, 2023, ECF No. 23 (“Motion”). Respondent filed a Response on May 31, 2023, ECF No. 25 (“Response”). Petitioner filed a Reply on June 20, 2023, ECF No. 27 (“Reply”). The site issue is now ripe for adjudication.

³ See, e.g., 42 C.F.R. §§ 100.3(a)(1), (c)(6) (supporting this proposition – albeit in the context of the Table listing for brachial neuritis following tetanus toxoid vaccines, which are not at issue in this case).

II. Issue

At issue is whether (a) Petitioner received the subject vaccine in his injured left arm. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10).

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. Findings of Fact

I have reviewed all of the evidence filed to date. This ruling, however, is limited to resolving only a single fact issue: the site of vaccine administration. Accordingly, I will only summarize or discuss evidence that directly pertains to this issue, as informed by both parties’ respective citations to the record and their arguments. Specifically:

- On February 15, 2020, Petitioner presented to a CVS pharmacy, where he handwrote answers to certain screening questions and signed his consent to receiving the subject flu vaccine. Ex. 1 at 1-2. The same record contains printed information regarding the patient, indicates “**Site: Right Deltoid**”, and indicates the vaccine administrator “Small Inurinh, RPh”. *Id.* The administrator’s handwritten signature is illegible. *Id.* at 2.
- Sixteen (16) days after vaccination, on March 2, 2020, Petitioner presented to his established primary care provider, Jennifer Day, M.D., for a chief complaint of **left shoulder pain**. Ex. 2 at 63. Petitioner reported that the pain had “started

immediately after a flu shot given at a local CVS... the shot was given in the upper part of the arm... the person who administered it was standing and pointed the needle at an angle.” *Id.* Petitioner reported that the pain had persisted and worsened over time. *Id.* A physical exam of the left shoulder revealed pain and limited range of motion but no redness, warmth, or swelling. *Id.* at 64. Dr. Day’s assessment was acute pain of the left shoulder, for which she prescribed tramadol. *Id.* Dr. Day also would “try to obtain records from CVS for his flu shot administration.” *Id.* After an x-ray was unrevealing, she referred to an orthopedist (identified below) for further evaluation. *Id.* at 72.

- At a March 4, 2020, initial consult with orthopedist Zachary Sandbulte, M.D., Petitioner reported a **left shoulder injury** with onset of February 15, 2020. Ex. 3 at 5. He reported that “A flu vaccine precipitated his symptoms... The vaccine was ‘higher on his shoulder than normal,’ located directly inferior to the lateral aspect of the acromion... He has had significant pain or weakness in his shoulder since that time... He ha[d] not injured the shoulder in the past.” *Id.* After undertaking a physical exam, Dr. Sandbulte assessed a left rotator cuff injury, for which he prescribed diclofenac. *Id.* at 5-8. Dr. Sandbulte reevaluated Petitioner on several occasions throughout 2020 – but the records do not contain any different or additional information pertaining to the site of vaccine administration. See *generally* Ex. 3.
- On March 5, 2020, Petitioner submitted a complaint to the North Carolina Board of Pharmacy, concerning a “**left rotator cuff injury due to improperly placed injection.**” Ex. 11 at 2. He reported:

“My wife and I went to CVS... for flu vaccines. The pharmacist [Small Anurinh, named elsewhere in the complaint] prepared the paperwork and sent us to a room next to the pharmacy counter. Then a pharmacy technician came in. Her name is Kinsey Richardson. The pharmacist did not come in to supervise. My wife got her injection first as I watched. I noticed that Ms. Richardson placed the shot very high on the shoulder directly into the shoulder joint at a downward angle. I thought that was odd, but assumed she knew what she was doing. Then she did the same thing to me... Within hours, I was in quite a bit of pain...”

Ex. 11 at 1. Petitioner also reported that CVS had not yet fulfilled his doctor’s records request. *Id.* Petitioner expressed hope that the pharmacy board would take his complaint “very seriously,” and stated concern for “more victims.” *Id.*

A header message confirms that Petitioner had “successfully submitted [his] complaint” and that the board “would review [his] complaint and take appropriate action as necessary...” including possibly “contact[ing] [Petitioner] or any other involved parties [he] entered for additional details.” *Id.* at 1. No further information about the complaint has been filed.

- An EMG/NCS report reflects a patient history of “**left shoulder pain** after a flu shot.” Ex. 4 at 23.
- At a November 13, 2020, initial consult with neurologist Lucie Lauve, M.D., Petitioner recounted that on February 15th, at his local CVS, a flu vaccine was “delivered into his shoulder joint” and “almost immediately he had severe pain and weakness” in his **left shoulder**. Ex. 4 at 48-50.
- At a March 17, 2021, follow-up, Dr. Lauve wrote that Petitioner “developed severe arm pain and weakness immediately following a flu vaccination at CVS that was delivered directly into his **left shoulder joint** on 02/15/2020.” Ex. 5 at 8.
- At a May 18, 2021, initial consult, orthopedic surgeon Mark Schweppe, M.D. recorded that “[Petitioner] had experienced shoulder symptoms since receiving a flu vaccination on 2/14/2020. After the injection, he noted significant discomfort localized to the shoulder with associated weakness...” Ex. 10 at 17; *see also id.* at 8-9 (follow-up encounter).
- In their May 27, 2021, affidavits, Petitioner and his wife briefly recount going to CVS together and both observing the subject vaccine’s administration in Petitioner’s left arm. *See generally* Exs. 7-8.

As recognized above (and in numerous prior opinions), “[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. But based upon my experience resolving SPU SIRVA cases (over 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 to enter information, and the relevant fields are often not 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); *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). Later provided and more detailed documentation, such as a consent form on which the site is handwritten or circled, tends to be more reliable.

Here, the CVS record contains printed information regarding the patient, the vaccine, and the administrator of the vaccine. Ex. 1 at 1-2. But just nineteen (19) days later, in his complaint to the pharmacy board, Petitioner recalled that the pharmacist pre-printed the CVS record *before* a technician actually administered the vaccine, outside of the pharmacist’s supervision. Ex. 11 at 1. This complaint is roughly contemporaneous to the events described. While not a medical record, the complaint was supplied to a medical licensing board in the interests of documenting Petitioner’s own injury as well as preventing similar injuries to other individuals. The complaint therefore carries some indicia of reliability, and it is specific reason to doubt the CVS record’s accuracy about the facts surrounding the vaccine’s administration.

Respondent avers that the complaint “does not specify whether he received the flu vaccination in his right or left arm, but only states that he developed left arm pain after receiving the flu vaccination.” Response at 7. But Petitioner correctly notes in response that this argument “ignores the overall content and context of the document.” Reply at 6. Respondent also suggests that any *responses* from CVS and/or the individuals involved “could shed further light on Petitioner’s claim.” Response at n. 1. However, Petitioner filed *his copy* of his complaint over a year ago, in April 2022, and Respondent has had ample opportunity to request any additional information. It is not apparent that Petitioner would have access to any additional proceedings conducted by the state pharmacy board – or that those would be particularly probative in this case.

The overall tenor of the medical records support Petitioner’s situs argument. Starting just sixteen (16) days after vaccination, Petitioner consistently complained of left-shoulder pain, and described a vaccine administration occurring higher than normal. The earliest medical records do not expressly state that the administration was on the same side as his pain – but that is a logical reading of the records, and at least the first two encounters, Petitioner and his medical providers were not aware of the CVS record that indicated a differing site. Later medical records are even more explicit. See, e.g., Ex. 5 at 8 (“flu vaccination... was delivered directly into his left shoulder joint”). These medical records warrant consideration even when they simply memorialize Petitioner’s own report, which was given in the interest of accurate diagnosis and treatment.

For the foregoing reasons, I find that Petitioner has provided preponderant evidence supporting a left arm site of vaccine administration. **Thus, Petitioner's Motion (ECF No. 23) is GRANTED.**

V. Scheduling Order

In the February 2023 informal communications which prompted this fact ruling, Respondent indicated that he had completed a medical review of this case.

Accordingly, by Friday, August 11, 2023, Respondent shall file a status report indicating his tentative position. If Respondent wishes to discuss either settlement or damages, the status report shall reflect the date by which Respondent responded, or intends to respond, to Petitioner's previously-submitted demand. If Respondent wishes to file his report pursuant to Vaccine Rule 4(c), the status report shall propose a deadline for doing so.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran

Chief Special Master