

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-956V

UNPUBLISHED

SALLY IRWIN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: October 18, 2021

Special Processing Unit (SPU);
Findings of Fact; Proof of
Vaccination; Site of Vaccination;
Intramuscular Route of
Administration; Influenza (Flu)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA).

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

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On July 2, 2019, Sally Irwin 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 left shoulder injury related to vaccine administration (“SIRVA”) as result of an influenza (“flu”) vaccine administered on October 6, 2017. Petition at 1. The case was assigned to the Special Processing Unit (“SPU”) of the Office of Special Masters.

¹ Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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 opinion 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 despite the lack of a contemporaneous vaccine administration record, it is more likely than not that a flu vaccine intended for intramuscular administration was given in Petitioner's left upper arm on October 6, 2017.

I. Relevant Procedural History

After initiating her claim, Petitioner promptly served two subpoenas to compel the primary care provider to produce additional medical records of the alleged vaccination. ECF Nos. 8, 34 (yielding, respectively, Exs. 7, 11). Respondent maintained that there was insufficient proof of vaccination, or, moreover, sufficiently severe injury. *see also* ECF Nos. 14, 23-24.

On January 29, 2021, Petitioner filed a motion for a finding of fact that she received the vaccination as alleged. ECF No. 32. On March 4, 2021, Respondent filed an opposing brief, arguing in part that "Petitioner *has not yet* produced any benefits statements, an explanation of benefits for the October 6, 2017, visit, billing records, a vaccine consent form, or other such documentation that could possibly corroborate her assertion regarding her receipt of a flu vaccination at Kaiser [Permanente] on October 6, 2017." ECF No. 33 at n. 5 (emphasis added). Afterwards, Petitioner duly served a third subpoena, this time for the production of any such non-medical record evidence. On October 1, 2021, Petitioner filed her claim benefit summary covering the alleged vaccination date, Ex. 15, followed by a supplemental Statement of Completion. She did not avail herself of the opportunity to file a reply. The matter is now ripe for adjudication.

II. Relevant Factual Evidence

I have reviewed all of the records filed to date. This ruling, however, is limited to determining facts pertaining to Petitioner's alleged vaccination. Accordingly, I will only summarize or discuss evidence that directly pertains to this issue.

- Petitioner was born in 1960. Through enrollment in the Kaiser Permanente managed care consortium, she received regular medical care, primarily at an office in Maui Lani, Hawaii ("the Maui Lani office"). *See generally* Ex. 2.
- Petitioner received seasonal flu vaccines at the Maui Lani office on September 29, 2011; January 16, 2013; and September 26, 2014. Ex. 2 at 59.
- On November 5, 2015, Petitioner presented to the Maui Lani office for a scheduled appointment for rib pain, fatigue, and pelvic pain. Ex. 2 at 59. A physician assessed these complaints and placed an order for quadrivalent flu vaccine. *Id.* at 60. Petitioner completed a screening questionnaire before receiving the vaccine. *Id.* The medical record provides that the vaccine was intended for intramuscular ("IM")

administration, but does not specify the site of administration, manufacturer, brand name, or lot/ batch numbers. *Id.*

- The record does not address whether Petitioner received or declined a flu vaccine during the 2016 – 2017 season.
- There is no evidence in the record that Petitioner had an adverse reaction to any vaccinations or developed a fear of needles.
- On May 1, 2017, Petitioner presented to the Maui Lani office for a pre-scheduled annual adult health examination. Ex. 2 at 131. The appointment did not address any complaints at or around the shoulder, or recommended future vaccines. *Id.* at 114-31.
- In addition to the original batch of primary care records (at Ex. 2), Petitioner has filed a separate record from the Maui Lani office dated October 6, 2017, which suggests that she obtained treatment on this date. The record does not set forth any current complaints, a physical examination, or any indication that she was seen by a physician. Ex. 7 at 1-4. However, it does indicate that the reason for visit was “Immunization.” *Id.* at 1. Physician’s assistant (“PA”) Jayne O’Gorman entered orders to test Petitioner’s immunity against measles (rubeola), mumps, and rubella. *Id.* at 3. But those tests were never conducted. Ex. 2 at 322 (“no result”).
- Twenty-six (26) days later, on November 1, 2017, Petitioner scheduled a same-day appointment at the Maui Lani medical office, to address right-sided breast tenderness. Ex. 2 at 140-41. That same day at approximately 9:00 a.m., Petitioner met first with a nurse, then with Dr. Drosie Rosaro, who assessed mastodynia and ordered an ultrasound. The encounter notes do not address Petitioner’s left shoulder. *Id.* at 134-39.
- Later that same day, at 10:40 a.m., nurse practitioner (“NP”) Malia Kelly³ updated Petitioner’s immunization history to add her receipt of “INF (Influenza) unspecified formulation”) on October 6, 2017, Ex. 1 at 7. This record also states: “External: PT RPT,” but does not specify the site of administration, manufacturer, brand name, or lot/ batch numbers. *Id.*
- On November 9, 2017, Petitioner scheduled a same-day appointment at the Maui Lani medical office to address “[p]ain in left shoulder since the flu vaccination about 3 weeks ago that is getting worse.” Ex. 2 at 153. She denied seeing any provider outside of Kaiser Permanente. *Id.* at 144. This record’s immunization history lists a flu vaccine on October 6, 2017. *Id.* Dr. Megha Chandoke observed that Petitioner’s left shoulder had no swelling or bruising, normal strength and sensation, full range of motion, but “minimal” tenderness over the lateral aspect

³ There is no evidence in the record that NP Kelly either saw Petitioner on October 6, 2017, or participated in the appointment on November 1, 2017.

and pain with internal rotation. *Id.* at 146. An x-ray was unremarkable. *Id.* Dr. Chandoke recommended conservative measures to manage the pain and following up within two weeks. *Id.* at 147.

- On November 14, 2017, Petitioner emailed Dr. Rosaro regarding shoulder pain “since getting a flu shot October 8th.” Ex. 3 at 1. She described that for about a month, the pain was generally located at the injection site; then, on about November 4th, it moved to the top of her shoulder and got worse. *Id.* Petitioner described that this was “[a]pparently... a somewhat common injury from injections done to[o] high on the shoulder and into the bursa.” *Id.* She requested that “the nurse” who administered the vaccine receive corrective training, she and asked whether acupuncture would help with the pain. *Id.* Dr. Rosaro responded that she was sorry about Petitioner’s shoulder, she would advise the nurse, and acupuncture and physical therapy could both be helpful. *Id.* at 2.
- Nearly four months later, on March 5, 2018, Petitioner presented for physical therapy (“PT”), reporting that after getting a flu shot she developed pain in the left deltoid region, which then shifted to the superior shoulder. Ex. 2 at 171. The pain was worse upon dressing, sleeping on her left side, bearing weight, abducting the arm, and the empty can maneuver (resisting downward pressure on the arm). *Id.* at 172. She was given a theraband and instructions for home exercises. *Id.* at 173. She would also attend PT once a week for four to six weeks, or if needed. *Id.*
- At the second PT session on March 12, 2018, Petitioner reported that she had been doing the prescribed home exercise program and her shoulder was “a little better.” Ex. 2 at 178-80.
- At the third and final PT session on April 3, 2018, Petitioner reported that she had slightly more pain, particularly on external rotation (“ER,” in the record) as she progressed with exercises. She had backed off and was “back to baseline” with persistent pain upon elevating and bearing weight through the left arm. Ex. 2 at 185-87. The therapist assessed that Petitioner would discontinue external rotation and gradually progress load with full can again.” *Id.* at 186.⁴
- Eleven (11) months after the alleged vaccination at issue, on September 7, 2018, Petitioner returned to the Maui Lani office. A physician evaluated her chief complaint of skin itching. Petitioner then completed a questionnaire, and a registered nurse administered a quadrivalent flu vaccine which was intended for intramuscular administration (brand name Flulaval, manufactured by GlaxoSmithKline). Ex. 2 at 242, 253-54.

⁴The subsequent medical records do not address whether Petitioner’s left shoulder injury resolved or persisted. Those records are focused on other complaints that are primarily gynecological in nature. Petitioner also reported increased stress due to her husband undergoing a triple bypass surgery in the summer of 2018. See, e.g., Ex. 2 at 193, 268.

- In addition to the medical records themselves, I have also reviewed Petitioner's discovery requests, including on June 1, 2018, for: "detailed immunization records and reports, including any vaccine administration forms in your possession relating to" the alleged vaccination. Ex. 1 at 3. A records custodian provided the record from November 1, 2017, in which NP Kelly recorded that Petitioner had received a flu vaccine, according to "External: PT REPT." *Id.* at 7. The records custodian then stated: "Immunization not given @ Kaiser." *Id.* at 5-6. But two weeks later, an unspecified individual at the Maui Lani office responded that: "[Petitioner] was scheduled and checked in for an appointment on October 6, 2017, at 11:00 a.m. The appointment notes state: 'Flu shot + MMR?.'" *Id.* at 1.
- In response to two separate subpoenas, the Maui Lani office provided the October 6, 2017, record of an encounter for an unspecified immunization and/or MMR immunity testing. *Compare* Exs. 7 and 11.
- Petitioner also served a subpoena onto Kaiser Permanente, whose health information management personnel could not locate any further records of the alleged vaccination at any of their health care facilities in Hawaii. Ex. 11 at 1.
- Petitioner has filed what looks to be a screenshot from her Kaiser Permanente electronic patient portal, which reflects an October 6, 2017, encounter for an unspecified "injection" with the Maui Lani office's nursing department, with Nurse Kelly listed as the "care team." Ex. 14.
- At my direction, Petitioner obtained her Kaiser Permanente insurance benefit statement from October 6, 2017, to the present. However, the statement does not reflect charges for any medical encounter, immunization, or lab work from that date. Ex. 15 at 5; *compare id.* at 7 (charge for the following year's flu vaccine).
- In her affidavits, Petitioner recalls receiving the flu vaccine in her left shoulder at the Maui Lani office on October 6, 2017. Ex. 5 at ¶ 2. She does not recall whether the administration was different from that of any other vaccines, but recalls that she developed "immediat[e]" and persistent pain. *Id.* at ¶ 3; Ex. 9 at ¶ 2.
- Petitioner's husband recalls that in early October 2017, Petitioner described getting a flu vaccine that day and she was experiencing much more pain than usual. Ex. 10 at ¶ 3. The following day, she reported that she had not slept well on account of the pain. *Id.*
- Carol Aldred is employed as a registered nurse. Ex. 6 at ¶ 4. After becoming friends in approximately 2005, she and Petitioner had regular conversations about health topics. Ex. 6 at ¶ 2. They also bonded over their mutual interest in exercise and attended yoga regularly, about three to four times per week. *Id.* at ¶¶ 2-3, 6. She recalled that Petitioner first complained of left arm pain and soreness around the site of a flu vaccination she had received about 2-3 weeks earlier. *Id.* at ¶ 4. Ms. Aldred recommended that Petitioner should "go back to her doctor about it." *Id.*

III. Authority

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 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. § 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 & 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.

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).

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*, 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). 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 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 § 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).

IV. Findings of Fact

Despite repeated efforts, Petitioner was unable to obtain a complete, authoritative vaccination record. *See, e.g.*, First Subpoena Motion (ECF No. 13). In her brief, however, she avers that even if the total record is somewhat “incomplete,” the available medical records, supported by testimony, preponderantly establish that (i) she received a flu vaccine on October 6, 2017; (ii) the vaccine was given in her left upper arm; and (iii) the vaccine was intended for intramuscular administration. Respondent, by contrast, argues that there is insufficient evidence of all three facts.

As to the first question, it is relevant that Petitioner received seasonal flu vaccines from 2012 – 2015, as well as in 2018. At each of these encounters, a physician evaluated unrelated complaints, then entered the order for flu vaccine. In contrast, the October 6, 2017 record does not reflect any complaints or a physical examination. There is no indication that a physician met with her or entered the orders that appear in the record. But the record from that date *does* indicate a reason for the encounter: “immunization.” Admittedly, the PA’s order for MMR immunity testing might suggest a contrary reason for the encounter. However, those orders were automatically cancelled 180 days later due to a lack of results, and Petitioner was never billed for either that testing or any immunization. Moreover, an employee later reported that the appointment was for “flu shot + MMR?” Ex. 1 at 1. Thus, although this record is vague, it is not wholly inconsistent with Petitioner’s allegations.

Subsequent treatment records corroborate Petitioner’s assertions. Starting less than one month later, Petitioner consistently reported that she had received a flu vaccine on October 7, 2017. Respondent makes much of Nurse Kelly’s November 1, 2017, notation of “External PT RPT,” as well as the custodian’s June 1, 2018 statement that “immunization not given @ Kaiser,” Ex. 1 at 5-7. At the same time, a different employee recorded that the purpose of Petitioner’s October 6, 2017 appointment was to receive a

flu vaccine. Ex. 1 at 1. More important are the November 14, 2017 emails in which Petitioner and Dr. Rosario discussed that a nurse *at the Maui Lani office* had potentially mis-administered her vaccine and should be told about the potential for injury. Ex. 3 at 1-2.⁵ Based upon all of the above, the contemporaneous medical record, supplemented by the later medical records and the affidavits, preponderantly establish that Petitioner likely received a flu vaccine on October 6, 2017, at the Maui Lani office.⁶

On the second question, Petitioner consistently reported left shoulder pain ever since the vaccination, and she first registered such complaints within a month of the purported vaccination. Ex. 2 at 142, 170-74, 178-80, 185-87; Ex. 3 at 1. Witness testimony also supports this contention. Petitioner's husband recalls her complaints of left arm pain shortly after vaccination. Ex. 10 at ¶ 3. Her friend recalls that Petitioner's left arm was "very sore right around where the shot was given" in late October 2017. Ex. 6 at ¶ 4. Moreover, vaccination in the left arm would be consistent with Petitioner being right-handed, see Ex. 2 at 145; Ex. 9 ¶ at 6. Finally, Petitioner accurately observes that nothing in the record contradicts her position as to the situs of vaccine administration. Brief at 9 (emphasis added) (analogizing to *Baker v. Sec'y of Health & Human Servs.*, No. 19-1771V, 2020 WL 6580192 (Fed. Cl. Spec. Mstr. Oct. 9, 2020) (in which the record did not specify the site of administration, but later medical records and testimony were probative). Based on this reasoning and the lack of evidence to the contrary, I find it more likely than not that the site was Petitioner's *left* arm, as alleged.

Third, to establish a presumptive Table SIRVA, Petitioner must show that the vaccine was intended for intramuscular administration – e.g., injected into a muscle. See 42 C.F.R. § 100.3(c)(10). Respondent contends that Petitioner has not affirmatively showed this fact. Response at 8. Respondent bases this argument on his assertion that during the 2017 – 2018 flu season, one vaccine manufacturer (Sanofi-Pasteur) offered "the first" intradermal method of administration, which used a "90 percent smaller, 1.5 mm microneedle" for its Fluzone quadrivalent seasonal flu vaccine.⁷

⁵ In her email, Petitioner stated that the vaccine was given on October 8th rather than October 1st, 2015. Regardless of this discrepancy, Petitioner recalled that the vaccine was given by an employee of the Maui Lani office, and a doctor acknowledged her concern.

⁶ Respondent correctly distinguishes a prior case, in which the petitioner produced her handwritten consent to receive the vaccine. Response at 8-9 (citing *Dorris v. Sec'y of Health & Human Servs.*, No. 18-1265V, 2019 WL 7212165, at *1 (Fed. Cl. Spec. Mstr. Nov. 13, 2019)). But in every case, the evidence on supporting the parties' positions is weighed on its own merits. The present case contains evidence of a different nature supporting the fact of vaccination.

⁷ Sanofi-Pasteur – News, *Sanofi-Pasteur Ships First of its U.S. Influenza Vaccine Doses for 2017 – 2018 Season* (July 17, 2017), available at <https://www.news.sanofi.us/2017-07-17-Sanofi-Pasteur-Ships-First-of-its-U-S-Influenza-Vaccine-Doses-for-2017-2018-Season>) (last accessed October 1, 2021), cited at Response at 12-13.

Thus, it is *plausible* that Petitioner's vaccine was not the intramuscular-administered kind. This is especially so in the absence of record evidence of the manufacturer, brand name, or lot/batch number for the vaccine Petitioner alleges she received.⁸ Petitioner herself cannot shed light on this dispute, since she cannot recollect specific facts about the vaccination that would suggest which form of administration she received. Response at 10; see also Ex. 9 at ¶ 2.

Respondent's argument, however, is ultimately speculative – and other record evidence does support the conclusion that the version in question was intramuscularly administered. Petitioner received flu vaccines intended for *intramuscular* administration both before and afterwards. Ex. 2 at 60, 242. There is no evidence that Petitioner developed a fear of needles or experienced some other adverse event which would have motivated her to request an alternate means of administration in 2017. Moreover, there is no evidence that the Maui Lani office took up the intradermal method in 2017. It is also true that vaccination records seen in the Program often neglect to specify the administration method (allowing the inference that in situations where an intradermal vaccine was administered, the record will more likely than not so specify).⁹ I therefore do not find that this question has sufficient evidentiary support to find the vaccine was likely administered intradermally.

V. Conclusion

Based on the entire record, I find that there is preponderant evidence that on October 6, 2017, at the Maui Lani office, Petitioner received a flu vaccine in her left arm that was intended for intramuscular administration.

⁸ Respondent also questions Petitioner's recollection five months afterwards that the vaccine was given in her left deltoid. Response at 10 (citing Ex. 2 at 179). This detail, however, would not resolve the question of intramuscular or intradermal administration, as both methods are administered at the area of the deltoid. Sanofi-Pasteur, *Package Insert – FluZone Intradermal Quadrivalent*, available at <http://www.fda.gov/media/106170/download> (last accessed October 1, 2021) at 2, cited at Response at 12-13; see also *Fitzgerald v. Sec'y of Health & Human Servs.*, No. 19-282V, 2020 WL 7078325, at *1 (Fed. Cl. Spec. Mstr. Nov. 3, 2020).

⁹ In addition, it is my experience in the Program that the vast majority of flu vaccines at issue in Vaccine Act cases are intended for intramuscular administration. Indeed, after the 2017 – 2018 flu season, Sanofi-Pasteur discontinued production of the intradermal form, and no other manufacturer has offered the intradermal administration method for use in the United States since then. See, e.g., Centers for Disease Control and Prevention ("CDC"), *Frequently Asked Questions 2018 – 2019 Flu Season*, available at <https://www.cdc.gov/flu/about/season/flu-season-2018-2019.htm> (last accessed October 14, 2021) ("No intradermal flu vaccine will be available"); CDC, *Seasonal Flu Vaccines*, available at <https://www.cdc.gov/flu/prevent/flushot.htm> (last accessed October 14, 2021) (not listing intradermal method). While this does not conclusively establish the form of administration *in this case*, it does suggest that an intradermal administration herein was unlikely – especially in the absence of evidence to the contrary.

While not briefed by the parties, I am also inclined (based on the record) to find that Petitioner's left shoulder injury persisted for over six months, see Ex. 2 at 185-87 (final physical therapy record from 5 months and 27 days post-vaccination, providing that Petitioner had ongoing pain on abduction and bearing weight, and that she would continue with a home exercise program). The current record does not, however, establish significant pain or disruptions to Petitioner's life beyond six months, despite her affidavits, and I would not look favorably if Petitioner were to file updated records describing ongoing residuals. I also overall note that the record does not suggest Petitioner's SIRVA was particularly severe, especially given the treatment gaps and the lack of evidence of intrusive medical interventions. Accordingly, Petitioner would be well-advised to seek a prompt resolution of what was by all accounts a mild injury, and which therefore should not entail more than a modest damages award.

Petitioner shall file a status report confirming that she has conveyed a demand to Respondent by **Wednesday, November 17, 2021**. Respondent shall file a status report indicating how he intends to proceed in this case, including whether he is willing to engage in tentative discussions regarding settlement or proffer, **within 30 days thereafter**.

IT IS SO ORDERED.

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