In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 22-265V

DEBORAH DEFOSSES, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: January 28, 2025

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On March 9, 2022, Deborah Defosses filed a Petition under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"); *see* Section 11(c)(1)(D)(i). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") following her receipt of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine on March 12, 2019. Petition (ECF No. 1); *see also* Amended Petition filed June 9, 2022 (ECF No. 6) (adding citations to the evidence). The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[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).

Based on review of the evidence and briefing, I hereby conclude that Petitioner likely received a covered vaccine in her injured left arm - *prior* to the administrator switching to, and successfully completing the vaccination, in Petitioner's opposing arm). Petitioner has preponderantly established all other requirements for a Table SIRVA claim – making her entitled to compensation.

I. Procedural History

The case was assigned to the SPU in August 2022. In September 2023, Respondent completed his medical review and reported his openness to settlement discussions. ECF No. 25. But after those discussions hit an impasse, the parties briefed the issue of whether Petitioner's Motion for a Ruling on the Record filed Jan. 16, 2024 (ECF No. 31); Respondent's Combined Rule 4(c) Report and Response filed Feb. 29, 2024 (ECF No. 32); Petitioner's Reply filed Mar. 14, 2024 (ECF No. 34) (referencing her newly filed Ex. 8 (ECF No. 33), containing uncertified patient portal messages); Ex. 9 – 11 filed Oct. 28, 2024 (ECF No. 37); Respondent's Supplemental Response filed Dec. 11, 2024). The matter is ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (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 addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying 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;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(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. Evidence

I have reviewed all submitted evidence including all medical records and affidavits, as well as the Petition, the Rule 4(c) Report, and both parties' briefing. I highlight the following:

At the time of the March 12, 2019 vaccination, Petitioner was fifty-five (55) years old, with no history of shoulder pain or dysfunction. Rule 4(c) Report at 2 citing Ex. 1 at 1 – 2, 17 – 18, 94. She is right-hand dominant. Ex. 1 at 193.

The key events in question occurred while Petitioner was seeing her established primary care physician ("PCP") for a complete physical examination, smoking cessation counseling, and evaluation of a sore throat. Ex. 1 at 93 – 99. A registered nurse actually administered the Tdap vaccine, and completed a computerized vaccine administration record's fields including a site of "Right Arm." *Id.* at 102.

Thirteen days later (on March 25, 2019), Petitioner messaged the PCP's office – writing: "I am getting concerned. When I was in the office a couple of weeks ago I had 2 tetanus shots. Something happened to the left side so she had to go get another needle to do the right arm. Ever since then I have horrible pain in my left side. I don't know if it's because she put the needle up so high that maybe it affected muscle. I just know this still hurts so bad. The pain is so terrible. Is anything that can be done?" Ex. 11 at 14. The nurse left Petitioner a voicemail, and then sent a follow-up message, writing: "I am so sorry that you are still having pain in that arm. Can you describe the pain that you are having? Is it a bruised feeling in the upper arm or nerve pain down the arm? Do you still have full range of motion in that arm?" *Id.*

On April 8, 2019, Petitioner responded that her pain had persisted and disrupted her sleep despite taking ibuprofen and applying heat, and her PCP scheduled an evaluation. Ex. 11 at 16. At that appointment three days later, on April 11, 2019, the PCP recorded a history of: "Left arm pain, at site of Tdap injection, given March 12, 2019,

actually injection was not given, nurse changed sides due to resistance… The right arm, where injection *had been given* is not symptomatic." Ex. 1 at 117 (emphasis added). On examination, the left shoulder had pain, but normal range of motion ("ROM"). *Id.* at 120. The PCP expressed uncertainty about what had happened, but prescribed pain medication. *Id.* at 122.

At a May 21, 2019 follow-up, the PCP recorded a similar history, and exam findings of pain, plus a mild decrease in glenohumeral internal rotation and pain. Ex. 1 at 131. The PCP opined that Petitioner previously had injection site pain, plus unrelated "shoulder joint pain." *Id.* The PCP then ordered an x-ray of the left shoulder, which found mild AC joint arthropathy. *Id.* at 143. Over the following week, the PCP then offered referrals to physical therapy and an orthopedist, Ex. 11 at 17 – 19, but no such encounters occurred.

While Petitioner reported "residual" left shoulder pain, her PCP did not document any positive exam findings, assessment, or treatment plan at appointments on September 12, 2019, Ex. 1 at 151 - 56, and August 18, 2020, *id.* at 178 – 84.

But at the next PCP appointment on February 18, 2021, Petitioner reported "chronic left shoulder pain… in left shoulder laterally from head of humerus to midshaft, still has the pain from attempted vaccination… approximately 2 years ago." Ex. 1 at 197. An exam found grossly symmetrical ROM, but the left shoulder had "a little decreased abduction and full flexion," and "a little weak[ness]." *Id.* at 200. The PCP discussed the differential diagnosis including "labral tear, bursitis, SIRVA." *Id.* at 203.

On her PCP's referral, over the next month, Petitioner underwent an MRI of the left shoulder which showed acromioclavicular joint arthrosis, supraspinatus tendinosis, and a suspected superior labrum anterior to posterior ("SLAP") tear, Ex. 1 at 206, 227 – 28, and she attended three occupational therapy ("OT") sessions, Ex. 3 at 26 – 39.

Then on April 12, 2021, Petitioner established care with an orthopedist, who recorded her same history of chronic left shoulder pain since a tetanus shot two years earlier. Ex. 4 at 12. An exam found atrophy, weakness, tenderness, and difficulty with active abduction and forward flexion – but possible active internal and external rotation, and full passive ROM. *Id.* at 13. The orthopedist commented that the recent MRI did not demonstrate any rotator cuff tearing but did demonstrate tendinopathy and inflammation." *Id.* He obtained an x-ray that was suggestive of calcific tendinitis, assessed impingement syndrome, and recommended additional formal therapy (commenting that "3 sessions is hardly enough for a condition that has been going on for 2 years"). *Id.*

Petitioner never resumed OT, reportedly due to "family issues" and "multiple competing demands and life stressors," and instead performed home exercises. Ex. 4 at 8. At a June 21, 2021, follow-up, the orthopedist documented an ongoing left shoulder injury, and prescribed a prednisone taper. *Id.* at 8 – 9. Nearly two years later, the orthopedist's physician assistant ("PA") documented a still ongoing left shoulder injury and provided a Lidocaine topical patch. Ex. 7 at 4 – 11. It also appears that on the PA's referral, Petitioner began attending formal physical therapy ("PT") in spring 2023, *see id.* at 7, 11, but no corroborating records have been filed.

In a June 2022 affidavit, Petitioner recalls that on March 12, 2019: "As soon as the vaccine needle was inserted into my left arm, I noticed that it was injected far up on the arm. As soon as [the nurse] pressed to administer the contents of the vaccine, I immediately felt a burning sensation. The nurse then informed me that she was unable to get all the vaccine in my arm." Ex. 1 at ¶ 9. Petitioner recalls that the nurse left the room, got another needle, and then administered the rest of the vaccine in her right shoulder. *Id.*

IV. Analysis

In seeking dismissal, Respondent contends that the Vaccine Act does not permit "a claim for an injury arising from a failed attempt to administer a covered vaccine." Combined Rule 4(c) Report and Response at 7 (citing Section 11(c)(1)(a) (requiring a petition to demonstrate that the injured person "received a vaccine" listed in the Vaccine Injury Table)).

The key words – "received a vaccine" – are not defined by the Act or by any precedential ruling. At best, special masters in other cases have evaluated whether a vaccination-like event meets the Act's requirements. *See,* e.g., *Dean v. Sec'y of Health & Hum. Servs.*, No. 16-1245V, 2018 WL 3104388 (Fed. Cl. Spec. Mstr. May 29, 2018) (holding that a percutaneous allergy test did not involve the administration, receipt, or purpose of a vaccine as defined by the Vaccine Act). But I have determined that even an incomplete vaccination at a single situs can give rise to a Vaccine Act claim. *Clark v. Sec'y of Health & Hum. Servs.*, No. 21-421V, 2024 WL 4284924, at *10 (Fed. Cl. Spec. Mstr. Aug. 21, 2024) (concluding that it was "sufficient that [a] vaccination effort resulted in needle penetration and antigen introduction to be deemed to have been 'received,' and the record [in *Clark*] suggests both occurred").

Ms. Defosses's case is strikingly similar to that of the *Clark* petitioner. Ms. Defosses's March 12, 2019 Tdap vaccine administration record lists a right-sided administration, and that record's reliability is not in dispute. But there is also preponderant evidence that the nurse *initially* selected a left-sided site of administration, and that the

vaccine *needle* penetrated the skin and some underlying structures before that initial vaccination effort was deemed "aborted." *See, e.g.*, Ex. 11 at 14 (Petitioner's message and the nurse's response acknowledging the left-sided injury); Ex. 1 at 117 (PCP's note that the "nurse changed sides due to resistance"); *accord* Supplemental Response at 2 (conceding the fact of a left-sided "needle injectio[n]"). Thereafter, a second vaccination attempt was made, and completed on Petitioner's right arm (with no adverse symptoms reported from this).

Respondent contends that even if record evidence supports the conclusion that a failed initial effort at vaccination in Petitioner's left shoulder is established, it has not been shown that any Tdap vaccine *antigen* was injected during the left-sided failed attempt. Supplemental Response at 7 - 8. Certainly the fact that vaccine administration on the left side was not completed somewhat supports this conclusion. And it is fair for Respondent to question whether this is an aspect of "vaccine administration" that must be proven – especially in the context of injuries that are less about an antigenic reaction than some other vaccine-related negligence (although such cases have resulted in compensation – albeit where there was no question that the vaccine's contents were "administered"). *See,* e.g., *Silver v. Sec'y of Health & Hum. Servs.*, No. 20-1V, 2024 WL 2799285, at *10 (Fed. Cl. Spec. Mstr. Apr. 25, 2024) (Vaccine Program broadly permits "claims involving the 'cleanliness' of vaccine needles/ syringes, or even the circumstances of administration more broadly, to be actionable 'vaccine-related' injuries").

However, the record is ambiguous but ultimately close on this disputed point. *See generally* Ex. 1 at 117. This particular record, created just two weeks post-vaccination, contains Petitioner's account that the nurse switched sides after encountering "resistance" on the left. Ex. 1 at 117. While this note does not specify whether the "resistance" was to the needle or to attempted injection of the vaccine antigen, the fact of the effort is established, along with its incompletion – *not* that the introduction of vaccine antigen did not occur *at all. Compare Dean*, 2018 WL 3104388 at *7 – 8 (concluding that an individual did not "receive a vaccine" upon being "exposed to only a minute amount of [influenza antigen] upon the outermost layer of her skin," during an allergy test). And it is reasonable to expect that the fast process of vaccination might include coterminous piercing of a patient's skin by the vaccine needle with introduction of antigen as well; it is not the usual experience of vaccination for the needle to be *first* pushed down entirely.

The Program counsels special masters to resolve close questions in favor of Petitioners. *See, e.g.*, *Prude v. Sec'y of Health & Hum. Servs.*, No. 19-1537V, 2021 WL 3913930, at *6 (Fed. Cl. Spec. Mstr. July 29, 2021) ("[t]he facts of this case present a very close call… Program law does counsel to decide such matters in favor of the petitioner"); *Al-Uffi v. Sec'y of Health & Hum. Servs.*, No. 13-956V, 2017 WL 1713113, at *17, 19 (Fed.

Cl. Spec. Mstr. Feb. 22, 2017) (resolving intertwined onset and causation questions in favor of the petitioner) (citing *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

Although another case might involve better evidence that no antigenic introduction occurred,[4] this one allows for the inference it did – and given the overall context, the record permits the finding that the first vaccination effort here involved *some* antigenic introduction, sufficient to constitute "vaccine administration." There is, therefore, preponderant evidence to conclude that Ms. Defosses received a covered Tdap vaccine in her left upper arm or shoulder.

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement, *see generally* Combined Rule 4(c) Report and Response. He was obligated to have done so pursuant to Vaccine Rule 4(c) (stating that the Rule 4(c) Report "must… contain Respondent's medical analysis of Petitioner's claims and must present *any* legal arguments that Respondent may have in opposition to the petition") (emphasis added).

Based on my independent review, I find that Petitioner has preponderantly established all requirements for a Table SIRVA claim. 42 C.F.R. §§ 100.3(a), (c)(10). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a SIRVA following a March 12, 2019, left-sided receipt of a covered Tdap vaccine.** Therefore, the case is now formally in the damages phase.

[4] My hypothetical from *Silver* illustrates such a circumstance. *Silver*, 2024 WL 2799285 at n. 11. If a vaccine syringe filled with the vaccine was hurled, dart-like, at a person and the needle caused harm, but no antigen was delivered, I would not find any vaccine has been administered, even if after this event the claimant received a second vaccination to account for the failed first.

By no later than Friday, March 14, 2025, Petitioner shall file a Status Report updating on the parties' efforts towards informally resolving damages.[5]

IT IS SO ORDERED.

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

[5] Previously in June 2023, Petitioner conveyed a demand, which included satisfaction of a Medicaid lien, for Respondent's consideration. *See* Status Report filed Oct. 13, 2023 (ECF No. 27). Petitioner's (unsolicited) damages briefing, at ECF No. 31, only discusses past pain and suffering, and does not address the lien. I am deferring any substantive review of the appropriate award of damages in hopes that the parties will reach an informal resolution on that topic. However, if the parties again hit an impasse, I expect to promptly receive Respondent's briefing on the appropriate award of damages, followed by any Reply from Petitioner.