In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1388V
Filed: December 17, 2018
PUBLISHED

MICHAEL RAY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Processing Unit (SPU); Ruling on Entitlement; Causation-In-Fact; Tetanus vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Finding of Fact; Onset

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

Dorsey, Chief Special Master:

On October 24, 2016, petitioner 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 a shoulder injury related to vaccine administration ("SIRVA") as a result of his January 6, 2016 tetanus vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons described below, the undersigned now finds that petitioner is entitled to compensation for his SIRVA.

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

After filing his petition, petitioner filed medical records marked as Exhibits "1" through "6" on November 4, 2016, along with a statement of completion. ECF Nos. 7-8. An initial status conference was held with the staff attorney managing this case on December 12, 2016, and respondent was ordered to indicate how he intended to proceed. ECF No. 9. Respondent indicated that he was amenable to settlement discussions on February 13, 2017, and the parties engaged in damages negotiations until petitioner requested formal proceedings to resolve the case on March 7, 2018.[3] During the course of settlement discussions, additional medical records were filed as Exhibits "7" through "13." ECF Nos. 20, 27, 33, 35.

Respondent filed his Rule 4 Report on April 30, 2018. ECF No. 41. Respondent recommended against compensation in this case, stressing in particular petitioner's three month delay in seeking treatment for his alleged vaccine-related injury. *Id*. at 3-4. Respondent indicated that "[i]n the opinion of medical personnel at the Department of Health and Human Services, Division of Injury Compensation Programs, the significant delay in seeking treatment does not support by preponderant evidence a finding that petitioner's shoulder injury began specifically within forty-eight hours of vaccination." *Id*. at 4.

Subsequently, petitioner filed further medical records marked as Exhibits "14" and "15" and an affidavit marked as Exhibit "16." ECF No. 43. However, respondent maintained the position stated in his Rule 4 Report. ECF No. 46.

Petitioner filed a motion for a ruling on the record on November 1, 2018. ECF No. 47. Petitioner requested that the undersigned find that petitioner's shoulder pain began within 48 hours of receiving his January 6, 2016 tetanus vaccination and that petitioner is entitled to compensation pursuant to the Vaccine Act. *Id*.at 9. Respondent filed a response on November 15, 2018, disputing that there is preponderant evidence that petitioner's shoulder pain began within forty-eight hours of vaccination. ECF No. 48. No reply was filed. Accordingly, this case is now ripe for the undersigned's ruling on entitlement.

II. Factual History

After sustaining a dog bite to his leg on January 6, 2016, petitioner went to urgent care and was administered a tetanus vaccination in his left deltoid.[4] Ex. 1; Ex. 2. Petitioner averred that he thought the injection was "too high" and that he felt pain immediately and thought that it "did not feel like a normal injection." Ex. 16, p. 1.

Petitioner further averred that his pain continued and became more severe. *Id*. He indicated that within 48 hours of vaccination "it was apparent that there was quite a

[3] Settlement discussions were prolonged in part because petitioner underwent shoulder surgery in June of 2017.

[4] Respondent agrees that petitioner's prior medical history "appears non-contributory to his current SIRVA claim." ECF No. 41, p. 1. Accordingly, though the undersigned has reviewed his complete history, it will not be discussed herein.

bit of swelling high on my shoulder." *Id*. He explained that his pain did not abate and that it interfered with his normal activities, including lifting. Ex. 16, p. 1. He indicated that ibuprofen and acetaminophen did not provide relief for the pain, which he characterized as excruciating. *Id*.

Petitioner returned to the urgent care facility on January 14, 2016. Ex. 15. This visit is confirmed by a sign-in sheet; however, no medical record has been produced related to this visit.[5] *Id*. Petitioner averred that the purpose of his visit was to follow up regarding his shoulder pain "to see if something had gone wrong." Ex. 16, p. 1. Petitioner indicated that he reported his symptoms of pain, swelling, and bruising, but that his complaints were, in effect, attributed to normal post-vaccination pain. *Id*. at 2. Petitioner indicated that he was advised to take Ibuprofen and that he did not need treatment. [6] *Id*.

Petitioner indicated that he continued to treat with over the counter medications as recommended for several weeks until he decided to seek a second opinion. Ex. 16, p. 2. On March 29, 2016, petitioner was seen by orthopedist Ricardo Colberg, M.D. Ex. 3, pp. 6-7.

Dr. Colberg recorded a history from petitioner indicating that his "left shoulder pain started on January 6, 2016, when he got a tetanus shot, he had a bruise afterwards. He had severe sharp pain when he was trying to move it. It has subsided to a mild sharp pain when he tries to lift his arm up overhead." Ex. 3, p. 6. Dr. Colberg also noted that "[i]t has failed to go away despite naproxen, ibuprofen, rest, and activity modification." *Id*.

On physical exam, Dr. Colberg found no atrophy or tenderness to palpation, but did report decreased range of motion and a positive empty can test. *Id*. X-ray and ultrasound imaging was performed and the diagnostic impression was "[l[eft shoulder pain with mild AC joint osteoarthritis and supraspinatus strain with residual tendinitis after a tetanus shot on January 6, 2016." *Id*. at 7. Conservative treatment, including physical therapy, was recommended. *Id*.

The next day, on March 30, 2016, petitioner had an initial physical therapy evaluation. Ex. 4, p. 21. Petitioner again reported that his pain began with his tetanus vaccination. The physical therapist noted that petitioner presented "with pain in his left shoulder since given a tetanus shot in his left arm in January. Pt. reports the pain has continued since then." *Id*. Additionally, on his physical therapy intake form, petitioner explicitly listed "1/6/16" as the "Date of Injury/Onset." *Id*. at 28. Petitioner was recommended four weeks of twice-weekly physical therapy. *Id*. at 23.

[5] Petitioner indicated in his affidavit that he subsequently learned that his visit on January 14, 2016 had been considered "informal" and that no record was generated. Ex. 16, p. 2. In that regard, he confirmed that he did not pay any co-pay for the visit. *Id*. The sign in sheet itself indicates that petitioner was "not seen." Ex. 15, p. 4.

[6] Petitioner indicated that "I felt the nurse didn't take my pain seriously" and that the encounter left him embarrassed. Ex. 16, p. 2.

Petitioner returned to Dr. Colberg on April 28, 2016. Ex. 3, pp. 4-5. His symptoms were reported to be worsening. *Id*. at 4. Dr. Colberg indicated that petitioner "describes moderate-to-severe sharp, aching pain in the lateral aspect of his shoulder, worse with overhead activities, better at rest with associated weakness." *Id*. On physical exam, reduced range of motion was again noted as was a positive empty can test. *Id*. Petitioner also demonstrated positive signs of impingement. *Id*. At this time, petitioner received a cortisone injection into his bursa. *Id*. at 5. Petitioner's diagnosis changed to "left shoulder pain secondary to subacromial bursitis" following "interval development of subacromial bursitis"; however, Dr. Colberg still relied on January 6, 2016 as the date of onset. *Id*. at 4-5.

Petitioner again returned to Dr. Colberg on May 17, 2016. Ex. 3, pp. 2-3. At that time, due to petitioner's lack of improvement, Dr. Colberg became concerned petitioner may have a rotator cuff tear. Ex. 3, p. 2. He recommended a left shoulder MRI before determining further treatment. *Id*. The MRI was performed on May 18, 2016. Ex. 3, p. 15. It showed minimal AC joint hypertrophy and mild supraspinatus tendinosis, but "no MR evidence for rotator cuff tear, or other internal derangement of the left shoulder joint." *Id*. Petitioner returned to Dr. Colberg on June 20, 2016, for a plasma rich platelet injection. Ex. 3, p. 1. At that time his diagnosis was "left shoulder pain due to chronic rotator cuff tendinosis." *Id*.

About a year later, petitioner returned to Dr. Colberg and had a repeat MRI. Ex. 8, pp. 1-5. The MRI findings included a tear of the superior, posterior, and inferior labrum and "mild chondrosis in the glenohumeral joint with minimal humeral head marginal osteophyte formation." Ex. 8, p. 4. Petitioner's orthopedist additionally noted petitioner's subacromial bursitis and mild impingement. Ex. 8, p. 8.

Petitioner underwent arthroscopic surgery on June 30, 2017. Ex. 10, p. 3. His post-surgical diagnosis included a labral tear (type 1) as well as biceps tendinosis and shoulder impingement. *Id*.

Initially, petitioner was recovering well following his surgery; however, during recovery he tripped and fell on his arm, rupturing his bicep tendon and requiring a further surgery. Ex. 8, p. 6; Ex. 10, pp. 1-2. The remainder of petitioner's medical records focus on his recovery from his bicep rupture.

III. Ruling on Entitlement

a. Legal Standard

In this case, because petitioner's claim predates the inclusion of SIRVA on the Vaccine Injury Table, petitioner must prove his claim by showing that his injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the

"preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279.

The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Under the leading *Althen* test, petitioner must satisfy three elements. The *Althen* court explained this "causation-in-fact" standard, as follows:

> Concisely stated, *Althen's* burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

b. Analysis

The undersigned finds that petitioner satisfies the three prongs of *Althen* as follows:

i. *Althen* Prong 1

Under *Althen* Prong One, there must be preponderant evidence of a medical theory causally connecting petitioner's vaccination to his injury. In satisfaction of *Althen* Prong One, the undersigned takes notice of the fact that respondent has added SIRVA to the Vaccine Injury Table for tetanus-containing vaccines intended for intramuscular administration in the upper arm. *See* 42 C.F.R. § 100.3; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052); *see also Doe 21 v. HHS*, 88 Fed. Cl. 178 (July 30, 2009), *rev'd on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013)(holding that recognition of

a link between vaccine and injury on the Vaccine Injury Table supports petitioner's burden under *Althen* Prong One.)

In any event, although respondent discussed petitioner's burden to establish a medical theory, he has not disputed that the tetanus vaccine can cause SIRVA. In that regard, it is worth noting that there is a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program. *See, e.g. Loeding v. HHS*, No. 15-740V, 2015 WL 7253760 (Fed. Cl. Spec. Mstr. Oct. 15, 2015)(noting that "respondent 'has concluded that petitioner's injury is consistent with SIRVA; that a preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner's SIRVA were identified."); *see also Johnson v. HHS*, No. 16-165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. April 13, 2016)(awarding compensation for a SIRVA caused-in-fact by the influenza vaccine); *Koenig v. HHS*, No. 16-1496V, 2017 WL6206391 (Fed. Cl. Spec. Mstr. April 13, 2017)(same); *Telonidis v. HHS*, No. 15-450V, 2015 WL 5724746 (Fed. Cl. Spec. Mstr. Sept. 2, 2015); *Salas v. HHS*, No. 16-739V, 2016 WL 8459834 (Fed. Cl. Spec. Mstr. Nov. 7, 2016).

ii. *Althen* Prong 2

Under *Althen* Prong Two, petitioner must demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury. Although petitioner's claim does not constitute a Table Injury, the undersigned finds the Qualifications and Aids to Interpretation ("QAI") criteria for SIRVA to be persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect.[7] The criteria under the QAI are as follows:

> 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) (Qualifications and Aids to Interpretation for SIRVA).

[7] Of note, although respondent does not explicitly endorse the use of the QAI to guide a determination as to causation-in-fact, he does cite the 48 hour requirement from the Vaccine Injury Table as a necessary showing by petitioner. (ECF Nos. 41, pp. 3-4; 48, p. 2.)

In light of the factual history above, the undersigned finds that all four of the criteria listed in the QAI for SIRVA are satisfied by preponderant evidence. With regard to three of these criteria, there is little controversy.

As noted above, respondent concedes that there is no history of any medical condition contributing to petitioner's alleged SIRVA. The undersigned agrees. That is, the undersigned finds that there is no history of pain, inflammation or dysfunction of petitioner's left shoulder prior to his January 6, 2016 vaccination. Additionally, the undersigned finds that petitioner's pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered and that no other condition or abnormality is present that would explain petitioner's symptoms. Respondent did not raise any argument suggesting a contrary finding.

The only SIRVA criteria meaningfully disputed in this case is whether petitioner's shoulder pain began within the specified timeframe (*i.e.* forty-eight hours). On that point, respondent argues that this case is based on petitioner's claim alone, unsubstantiated by independent evidence. ECF No. 48, pp. 1-2. The undersigned disagrees.

Petitioner's contemporaneous treatment records repeatedly and consistently record the fact that petitioner's shoulder pain began on January 6, 2016. *See, e.g.* Ex. 3, pp. 6-7; Ex. 4, p. 21, 28. Indeed, the medical records include petitioner's own hand-written intake form on which he explicitly indicated that the date of onset for his shoulder condition was January 6, 2016. Ex. 4, p. 28. None of petitioner's medical records indicate any other time of onset.

Nonetheless, respondent argues that "these records are also based on the representations of petitioner alone as reported histories. There is no independent evidence to support petitioner's assertions." ECF No. 48, p. 2. This argument is unavailing. Medical records generally "warrant consideration as trustworthy evidence." *Cucuras v.HHS,* 993 F.2d 1525, 1528 (Fed.Cir.1993). Greater weight is typically given to contemporaneous records. *Vergara v. HHS*, 08-882V, 2014 WL 2795491,*4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.")

Respondent cites *Lett v. HHS*, 39 Fed. Cl. 259, 260 (1997), for the proposition that "[u]ltimately, the petitioner must substantiate the occurrence of a compensable, vaccine-related injury with independent evidence." ECF No. 48, p. 2. However, nothing in *Lett* suggests that a contemporaneously recorded patient history contained in petitioner's medical records is insufficient to corroborate a vaccine injury claim.[8] In *Lett*, petitioner's expert sought to rely on a history of seizures based on petitioner's claim of such a history even though no medical record filed in the case contained any reference

[8] Such a holding would be a dramatic departure from how cases in this program have been adjudicated for decades and inconsistent with prior Federal Circuit guidance. *See Cucuras, supra*.

of any kind to such a symptom. *Lett* is simply not relevant to the circumstances in this case.

To the extent respondent would argue that the medical records in this case are not credible because they are not contemporaneous to the onset of petitioner's injury, the undersigned is not persuaded. Indeed, the undersigned has previously rejected this exact argument, noting that a delay of several months before seeking treatment does not necessarily defeat a SIRVA claim. *See, e.g. Cooper v HHS*, 16-1387V, 2018 WL 1835179, *6 (Fed. Cl. Spec. Mstr. Jan. 18, 2018) (holding that "the undersigned does not find a delay in treatment of several months to be dispositive in and of itself regarding the question of onset in a SIRVA case such as this.")

The medical records at issue (beginning March 29, 2016) represent the first time petitioner was formally evaluated by a medical professional for his injury and his injury was still ongoing at that time with active treatment continuing for several months after. They are therefore contemporaneous *treatment* records and are entitled to significant weight as they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528. As the Federal Circuit has previously noted, treatment records are considered trustworthy at least in part because "[w]ith proper treatment hanging in the balance, accuracy has an extra premium." *Id*. This remains true regardless of whether there is some delay in seeking treatment.[9]

Moreover, respondent is incorrect that petitioner's medical records are limited to petitioner's own representations. On multiple occasions, petitioner's orthopedist discussed his findings upon physical examination. Moreover, his diagnostic impression included interpretation of objective imaging results on X-ray, ultrasound, and MRI. Ex. 3, pp. 2-3, 7; Ex. 8, p. 4. Upon consideration of these findings as well as petitioner's history, Dr. Colberg opined that petitioner's shoulder injury was related to his January 6, 2016 tetanus vaccination.[10] Ex. 3, p. 4-5, 7. Thus, contrary to respondent's contention,

[9] There is also some dispute between the parties regarding the weight to be afforded the urgent care sign in sheet filed by petitioner as Exhibit 15. Although the affidavit and sign in sheet provide some evidence supporting petitioner's claim, these documents do not factor heavily into the undersigned's conclusion. The undersigned notes that there would be preponderant evidence supporting *Althen* Prong 2 even in the complete absence of either piece of evidence. Petitioner's account of the first three months of his injury is corroborated, albeit incompletely, by the urgent care sign in sheet filed as Exhibit 15. Respondent stresses that "the urgent care ledger contains no medical information and notes that petitioner was not seen" (ECF No. 48, p. 1); however, the sign in sheet does corroborate petitioner's affidavit testimony that he returned to the facility on that date and nothing in the record contradicts any aspect of petitioner's sworn account. This lends credibility to petitioner's account even if it does not provide complete corroboration. Most significantly, however, nothing in petitioner's affidavit nor in the urgent care sign in sheet is contrary to the above-discussed treatment records.

[10] Although later records do not continue to specifically attribute petitioner's condition to his prior vaccination, nothing in petitioner's medical records retracts or contradicts Dr. Colberg's initial attribution of petitioner's condition to his tetanus vaccination. Dr. Colberg indicated in May of 2016 that he suspected a rotator cuff tear, but that suspicion was not confirmed by the subsequent MRI and Dr. Coberg's post-MRI diagnostic impression was rotator cuff tendinosis. And although petitioner's second MRI study and post-

petitioner's claim is substantiated by medical records and by medical opinion in satisfaction of § 13(a)(1) of the Vaccine Act.

For all these reasons the undersigned finds that there is preponderant evidence that petitioner's shoulder pain began within forty eight hours of receiving his tetanus vaccination. Therefore, the undersigned finds that petitioner has presented preponderant evidence pursuant to *Althen* Prong Two of a logical sequence of cause and effect supported by medical opinion showing that his injury was vaccine-caused.

iii. *Althen* Prong 3

Under *Althen* Prong Three, there must be a proximate temporal relationship between vaccination and injury. In this case, respondent agrees that the relevant, medically accepted, timeframe for onset of a SIRVA injury is within 48 hours of vaccination. ECF Nos. 41, pp. 3-4; 48, p. 2. Thus, in light of the above finding that petitioner's shoulder pain began on January 6, 2016 (*i.e*. within forty-eight hours of vaccination), petitioner has necessarily satisfied *Althen* Prong Three.

iv. Factors Unrelated to Vaccination

Respondent has not asserted, nor would the undersigned find, that there is any evidence in the record to support respondent's burden of establishing an alternative cause for petitioner's injury unrelated to vaccination.

IV. Conclusion

Thus, in light of all of the above, the undersigned GRANTS petitioner's motion and finds that petitioner is entitled to compensation for a SIRVA.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

operative diagnosis later revealed an additional labral tear, the records also indicate ongoing impingement, bursitis and tendinosis.