In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 16-0670V Filed: August 4, 2017

Unpublished

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CHRISTI JEWELL,	*	
,	*	
Petitioner,	*	Ruling on Entitlement (Non-Table); Fact
V.	*	Hearing; Findings of Fact; Tetanus
	*	Diphtheria acellular Pertussis
SECRETARY OF HEALTH	*	(Tdap) Vaccine; Shoulder Injury
AND HUMAN SERVICES,	*	Related to Vaccine Administration
	*	(SIRVA); Causation-in-Fact;
Respondent.	*	Special Processing Unit (SPU)
·	*	- · · · · · · · · · · · · · · · · · · ·

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for petitioner. Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On June 7, 2016, Christi Jewell ("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 she suffered left shoulder injuries as a result of receiving the tetanus diphtheria acellular pertussis vaccine ("Tdap") on February 19, 2015. Petition at 1-3. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

I. Summary of Procedural History

On July 19, 2016, the staff attorney assigned to manage this case on behalf of the undersigned held the initial telephonic status conference. Paul Brazil appeared for petitioner. Sarah Duncan appeared for respondent. At the conference, respondent's counsel indicated that respondent intended to defend this claim, as respondent believes

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website,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). 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.

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).

the onset of petitioner's shoulder injury symptoms was two weeks subsequent to her vaccination and is therefore not temporally appropriate. Sched. Order, issued July 20, 2016 (ECF No. 8).

Respondent filed his Rule 4(c) Report on September 2, 2016. In respondent's view, petitioner had failed to provide "reliable scientific or medical evidence establishing that the time between her Tdap vaccination and the onset of left shoulder pain two weeks later would be considered 'medically acceptable to infer causation-in-fact." Rule 4(c) Report, filed Sept. 2, 2016 (ECF No 9), at 7 (citing *de Bazan v. HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008)).

Thereafter, the undersigned requested petitioner file an affidavit describing the onset of her injury, as well as updated treatment records. Sched. Order, issued Sept. 8, 2016 (ECF No. 10). After a review of all evidence, including petitioner's updated medical records and affidavit, the undersigned issued an Order urging the parties to informally resolve this claim noting as follows:

while the evidence in regard to the onset of petitioner's shoulder injury is conflicting, the evidence is clear that petitioner's symptoms began shortly after her vaccination and are otherwise consistent with the proposed "Table Injury" of shoulder injury related to vaccination ("SIRVA"). Pet. Ex. 1 at 29 (Pazhaniaandi Tirounilacandin, MD reported petitioner's "pain started about 2 weeks after getting her tetanus shot"); Pet. Ex. 1 at 123 (Mark Verdun, DO reported petitioner "states it [left shoulder pain] began after receiving a tetanus shot in her left shoulder"); Pet. Ex. 2 at 231(petitioner's physical therapy evaluation indicates she received tetanus shot on February 19 and "a few days later she started to notice left shoulder pain"); see, e.g., Pet Ex. 2 at 125, 134, 137, 141) (petitioner's physical therapy notes consistently indicate onset as February 19 "after Tetanus shot").

While the date of onset for petitioner's injury is not clear the evidence suggests that petitioner suffered pain and swelling after her February 19, 2015 Tdap vaccination³ and subsequently had symptoms and diagnoses consistent with SIRVA. These symptoms and diagnoses include: limited abduction and "[a]cute bursitis of left shoulder" (*Id.* at 31), continued pain leading to orthopedic referral (*Id.* at 123), "signs of crossover impingement" (*Id.*), "[a]dhesive capsulitis of left shoulder," "[s]houlder pain, left," and "[r]otator cuff syndrome of left shoulder" (*Id.* at 115).

Sched. Order, issued Nov. 3, 2016 (ECF No. 14).

On December 1, 2016, the staff attorney assigned to manage this case convened a status conference at respondent's request to schedule a fact hearing. The parties

³ Petitioner states [in her affidavit] that it is possible her pain started the day after her vaccination, but that it definitely started within a week of her vaccination. Pet. Ex. 4, ¶3.

agreed that a fact hearing would be the appropriate next step. Sched. Order, issued Dec. 1, 2016 (ECF No. 15).

Based on the parties' input, the undersigned scheduled a fact hearing for April 27, 2017, in Washington, D.C. See Pre-Hearing Order, issued Jan. 11, 2017 (ECF No. 18). Petitioner filed a witness list on April 13, 2017. (ECF No. 22). Respondent did not plan to call any witnesses. Informal Communicated dated April 14, 2017.

The undersigned held the fact hearing as planned, with petitioner and her husband testifying via videoconference.

Subsequent to the hearing, the undersigned convened a status conference with the parties' counsel on May 2, 2017. Sched. Order, issued May 5, 2017 (ECF No. 24). With the agreement of the parties, the undersigned provided her preliminary findings in this claim, and indicated her intent to file the medical journal article, S. Atanasoff et al., Shoulder injury related to vaccine administration (SIRVA), 28 Vaccine 8049 (2010), as Court's Exhibit 1 (hereinafter "Atanasoff"). *Id.* The undersigned further indicated her intent to issue a written ruling in regard to onset and entitlement, finding petitioner entitled to compensation, subsequent to the filing of the hearing transcript. *Id.* The parties were ordered to file any additional evidence within thirty days subsequent to the filing of the transcript of the April 27, 2017 Hearing. *Id.* at 2. The April 27, 2017 Hearing transcript was filed on May 16, 2017. Hearing Transcript ("Tr."), filed May 16, 2017 (ECF No. 26). No additional evidence was filed by either party.

On June 14, 2017, respondent filed a status report indicating that "[i]n light of the Chief Special Master's preliminary findings and conclusions in the May 5, 2017 Scheduling Order, respondent reports that he is interested in pursuing settlement negotiations." Status Report, filed June 14, 2017. (ECF No. 27). Since that time the parties have been engaged in discussions to resolve this claim. Notwithstanding respondent's June 14, 2017 Status Report the undersigned issued an Order on July 26, 2017, reiterating her intent to issue a Ruling on Onset and Entitlement in this claim consistent with her May 5, 2017 Scheduling Order. Order, issued July 26, 2017 (ECF No. 31).

Accordingly, this claim is ripe for a ruling. The undersigned notes that there are two issues to be resolved: (1) the onset of petitioner's symptoms, and (2) whether petitioner sustained a shoulder injury related to vaccine administration ("SIRVA") caused-in-fact by her Tdap vaccination. The undersigned's ruling below is based upon the record as whole, including the filed medical records, the testimony of Mr. and Mrs. Jewell on April 27, 2017, a review of the April 27, 2017 Hearing transcript, and Atanasoff, *supra*.

II. Onset

With regard to the onset of symptoms, the undersigned finds that petitioner experienced pain within 72 hours subsequent to her February 19, 2015 Tdap vaccination. In making this determination the undersigned relied heavily on petitioner's physical therapy records. In the undersigned's experience physical therapists perform

thorough initial evaluations, and follow-up examinations, generally keeping accurate records. In this case, petitioner's physical therapy records note that "she had a tetanus shot on Feb[uary] 19th. After that shot a few days later she started to notice left shoulder pain." Pet Ex. 2 at 231.⁴ In addition the undersigned found petitioner to be a highly credible, candid and intelligent witness whose testimony, after a review of her own medical records, placed the onset of her shoulder injury either the day of, or day after, her vaccination. Tr. at 10-12, 16, 37-38, 48-51. The undersigned further finds petitioner credibly explained why records from her primary care provider and orthopedist might indicate a longer onset. Tr. at 25-32, 40-43.⁵

III. Causation

With regard to whether petitioner suffered a SIRVA, the undersigned finds that petitioner fulfilled all of the criteria for a Table SIRVA injury except for establishing onset of her injury within 48 hours.⁶ Petitioner has 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; petitioner experienced pain and reduced range of motion limited to the shoulder in which her intramuscular influenza vaccine was administered; and no other condition or abnormality is present that would explain her symptoms.

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).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA); see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff).

⁴ Petitioner testified that to her "a few means two to three days." Tr. at 45.

⁵ Petitioner testified that she began reviewing her medical records because she felt that she could not rely on Dr. Verdun's notes based on an error she found in his records, and referral. Tr. at 31-32, 40-43. In support of her testimony petitioner filed a corrected record from Dr. Verdun demonstrating Dr. Verdun initially incorrectly identified petitioner's injury as pertaining to her right, instead of her left, shoulder. Pet. Ex. 6 at 2.

⁶ Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294, Jan. 19, 2017; National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321, Feb. 22, 2017 (delaying the effective date of the final rule until March 21, 2017). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings are informed by the criteria used to evaluate such claims. The criteria are as follows:

Further, although the undersigned cannot find that petitioner experienced the onset of her shoulder injury within 48 hours as required by the current Table, the undersigned finds that petitioner experienced the onset of her shoulder injury within 72 hours. This is a medically appropriate temporal relationship to her vaccination as evidenced by Atanasoff. Atanasoff found that one of thirteen patients (8 percent) experienced the onset of a shoulder injury related to vaccination at 4 days. Court's Ex. 1 at Table 1 (ECF No. 24-1).

Accordingly, based on all of the above the undersigned then found that petitioner had met her burden of proving causation-in-fact under *Althen v. HHS*, 418 F.3d 1274 (Fed. Cir. 2005).

IV. Conclusion

In view of the submitted evidence, including the medical records, credible witness testimony, findings of fact, and the medical literature, the undersigned finds petitioner entitled to Vaccine Act compensation.

IT IS SO ORDERED.

s/Nora Beth DorseyNora Beth DorseyChief Special Master