

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1179V

Filed: February 16, 2022

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MAUREEN C. CLAVIO,

* PUBLISHED

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Petitioner,

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v.

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Dismissal; Untimely Filed; Onset;

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Lookback Provision; Causation; Tetanus,

SECRETARY OF HEALTH

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Diphtheria, acellular Pertussis (Tdap)

AND HUMAN SERVICES,

*

Vaccine; Shoulder Injury Related to

Respondent.

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Vaccine Administration (SIRVA)

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Leah Durant, Esq., Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Debra Begley, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Roth, Special Master:

On August 31, 2017, Maureen Clavio (“Ms. Clavio”) filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program.² The petition alleges that Ms. Clavio suffered a left shoulder injury caused in fact by the tetanus, diphtheria, acellular pertussis (“Tdap”) vaccine she received on February 2, 2012. Petition at ¶¶ 1, 10, ECF No. 1. Following my factual finding that the onset of her left shoulder pain occurred approximately two months post-

¹ This Decision has been formally designated “published” and will be posted on the Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** However, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

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).

vaccination,³ Ms. Clavio requested that I decide whether she is entitled to compensation and issue a decision on the existing record. ECF Nos. 41, 43-44.

Having considered the entire record in this case, including the arguments made by the parties, I find that dismissal is appropriate. As discussed in more detail below, because the claim does not meet the Table requirements for a SIRVA claim, I find the Vaccine Act's extended filing period following a revision to the Vaccine Injury Table, commonly termed the "lookback" provision,⁴ does not apply. Thus, petitioner's petition is untimely. Even if timely filed, dismissal would still be appropriate because petitioner has not provided preponderant evidence of causation.

I. Relevant Procedural History⁵

Petitioner originally filed her petition *pro se* on August 31, 2017. ECF No. 1. She was encouraged to seek counsel but remained *pro se* until Leah Durant was substituted as counsel one year later. *See* Consented Motion to Substitute Leah V. Durant as Counsel, filed Aug. 30, 2018, ECF No. 25; Order issued Sept. 5, 2017, ECF No. 5 (providing a list of attorneys commonly appearing in the Vaccine Program).

Approximately one week after filing her petition, Ms. Clavio filed medical records from her orthopedist, chiropractor, primary care provider, neurologist, and dentist, a letter from her primary care provider meant to supplement the information contained in his medical records, and her affidavit. Pet. Ex. 1-8, filed Sept. 8, 2017, ECF No. 7. In the primary care provider's letter dated May 18, 2017, the provider indicated that he "d[id] not currently have access to [petitioner's] past records to check the accuracy of dates referenced." Pet. Ex. 7 at 1.

A recorded status conference was held on November 1, 2017. Emphasizing the greater weight given to contemporaneously created medical records, I discussed the weaknesses in petitioner's case. Scheduling Order at 1-2, ECF No. 10. Specifically, I noted that the medical records revealed that the onset of petitioner's symptoms occurred in April 2012, two months post-vaccination; that petitioner did not seek treatment of her left shoulder pain until June 2012; and that petitioner did not return for treatment thereafter until February 2013. *Id.* at 2. I encouraged petitioner to file any additional medical records or affidavits to support her claim. *Id.*

On November 7, 2017, petitioner filed letters from two co-workers at Carl Sandberg High School: David Kreis, the school's athletic trainer, and Nancy Cassidy, the school nurse. Pet. Ex. 8-9, ECF No. 11.⁶ Both letters were signed but not notarized, and Ms. Cassidy's letter was dated

³ *Clavio v. Sec'y of Health & Hum. Servs.*, No. 17-1179V, 2020 WL 1672956 (Fed. Cl. Spec. Mstr. Mar. 11, 2020). I will refer to this Ruling as my "Ruling on Onset" throughout this Decision.

⁴ *E.g., Randolph v. Sec'y of Health & Hum. Servs.*, No. 18-1231V, 2020 WL 542735 (Fed. Cl. Spec. Mstr. Jan. 2, 2020).

⁵ A detailed procedural history from the petition filing date through early March 2020 can be found in my Ruling on Onset issued on March 11, 2020. *Clavio*, 2020 WL 1672956, at *1-3.

⁶ Both petitioner's statement and Mr. Kreis's statement were filed as Pet. Ex. 8. In his Rule 4(c) Report,

April 27, 2017. *Id.* In December 2017, petitioner filed signed and notarized letters from her mother, Florine Martin; husband, Wayne Clavio; a former co-worker, Yolanda Kolliniatis; and a friend, Jeannie Murawski. Pet. Ex. 10-11, filed Dec. 12, 2017, ECF No. 12; Pet. Ex. 12-13, filed Dec. 29, 2017, ECF No. 13. These later filed letters were dated in November and December 2017. *Id.*

On April 9, 2018, respondent filed a status report, stating that he would continue to defend this case, proposing a 45-day deadline for his Rule 4(c) Report, and requesting petitioner file all records from her primary care provider for the two years prior to vaccination. ECF No. 17. In response, Petitioner filed additional primary care provider records on June 6, 2018. Pet. Ex. 14, ECF No. 21.

Respondent filed his Rule 4(c) Report on June 28, 2018. ECF No. 22. He submitted that petitioner's alleged injury did not fit the criteria for SIRVA because petitioner did not provide evidence that her pain began within 48 hours of vaccination and that her pain and reduced range of motion were limited to her left shoulder. *Id.* at 12-14 (citing the second and third Qualifications and Aids to Interpretation ("QAI") listed at 42 C.F.R. § 100.3(c)(10)(ii)-(iii)). Respondent maintained that the later provided letters and affidavits were not sufficient to counter entries in the contemporaneously created medical records, describing a later onset for petitioner's left shoulder pain. *Id.* at 13-14. Additionally, he noted that multiple medical records indicate that petitioner reported pain in her temple and neck and retained full range of motion of her shoulder throughout her alleged injury. *Id.* at 14.

Respondent further submitted that petitioner "ha[d] failed to present a prima facie case of actual causation." Rule 4(c) Report at 14-15. Specifically, he maintained that petitioner had failed to provide evidence of an appropriate temporal relationship between vaccination and the onset of her left shoulder pain or showing "that the February 2, 2012 Tdap vaccination caused her [to] develop SIRVA, or any other injury." *Id.* at 15.

During a second recorded status conference, held on July 31, 2018, petitioner advised that she had not hired an attorney but was receiving filing and strategy assistance from a vaccine attorney. Order at 1, issued Aug. 1, 2018, ECF No. 24. I once again discussed the weight given contemporaneously created medical records, the lack of evidence therein supporting petitioner's claim of left shoulder pain within 48 hours of vaccination, and the atypical symptoms she suffered. *Id.* at 1-2. Petitioner was further advised of various ways to exit the Vaccine Program. *Id.* at 2.

On August 30, 2018, Leah Durant entered her appearance as petitioner's counsel, and petitioner filed a status report advising that she intended to file a Motion for a Ruling on the Record ("Motion for a Ruling on Onset"), addressing the factual onset issue. ECF No. 27. Petitioner filed her Motion for a Ruling on Onset on December 3, 2018, and the parties completed all briefing by June 13, 2019. ECF Nos. 31, 34, 38. On March 11, 2020, I issued my Ruling on Onset, determining that petitioner's left shoulder pain began in April 2012. ECF No. 39.

respondent referenced petitioner's statement as Pet. Ex. 8 and Mr. Kreis's statement as Pet. Ex. 8.2 to avoid confusion. *See* Rule 4(c) Report at 9, n.11. Petitioner adopted these citations for her motion. *See* Motion for a Ruling on Onset at 5, n.1. For continuity purposes, I will adopt these citations as well.

One month later, on April 13, 2020, petitioner filed a status report requesting additional time to supplement the record and proposing that I issue a decision thereafter. ECF No. 41. She filed medical literature on April 30, 2020. Pet. Ex. 15-19, ECF No. 42. Petitioner reiterated her request for a decision on the record as it currently stood in a status report filed on June 1, 2020. ECF 43. Pursuant to my instruction, she filed a Second Motion for a Ruling on the Record (“Motion”) on August 31, 2020, providing her specific arguments regarding entitlement. ECF No. 44. Petitioner asserts that she has provided sufficient evidence to establish causation. Motion at 9.

Approximately one month later, respondent filed a Response to Petitioner’s Motion (“Response”), maintaining that petitioner was not entitled to compensation. ECF No. 46. Specifically, he submits that, given my finding regarding onset, petitioner cannot satisfy the requirements for a Table SIRVA injury and her non-Table claim is barred by the statute of limitations. Response at 14. He further submits that, even if I find the Vaccine Act’s “lookback provision” applies and the claim is not untimely filed, petitioner has failed to establish sufficient evidence of causation. *Id.*

This matter is now ripe for determination.

II. Legal Standards for Entitlement

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). § 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.* In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement, 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. § 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. § 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a Tdap vaccine. 42 C.F.R. § 100.3(a)(I-II) and satisfies the additional criteria in the accompanying QAI.⁷

⁷ 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:

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a “non-Table or [an] off-Table” claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). The Federal Circuit has held that to establish an off-Table injury, petitioner must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

In order to prove causation, the Federal Circuit has indicated that a petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

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 a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Even if all other requirements for compensation have been met, “no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date

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- (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).

of the occurrence of the first symptom or manifestation of onset.” § 16(a)(2). “[I]f a death occurred as a result of the administration of such vaccine,” no petition may be filed more than 24 months after death and 48 months after the first symptom or manifestation of onset. § 16(a)(3).

An exception to the usual statute of limitations, commonly known as the lookback provision, is allowed following a revision to the Vaccine Injury Table. § 16(b); *see, e.g., Randolph*, 2020 WL 542735. For two years thereafter, a petition for a vaccine-related injury or death occurring not more than eight years prior to the Table revision is permitted *if* the additional criteria set forth in § 16(b) is satisfied. The lookback provision permits the filing of a petition for an injury otherwise barred by the statute of limitations within a specified amount of time if “the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation.” § 16(b).

III. Analysis

Because I have determined that her left shoulder pain began in April 2012, approximately two months post-vaccination, petitioner is unable to satisfy the requirements for a Table SIRVA injury. Specifically, she cannot establish that her pain began within 48 hours of vaccination as required by the second QAI criterion. 42 C.F.R. § 100.3(c)(10)(ii). Thus, she is entitled to compensation only if I find that her petition which alleges a non-Table claim was timely filed *and* that she has provided preponderant evidence of causation.

A. Timeliness of Petitioner’s Non-Table claim

In her Motion, petitioner did not address the timeliness of her petition and respondent previously accepted that petitioner’s petition was timely filed due to the addition of SIRVA to the Vaccine Injury Table effective March 21, 2017.⁸ Rule 4(c) Report at 1 n.1 (citing the eight-year lookback provision found at § 16(b)).

However, now arguing that petitioner’s petition should be dismissed, respondent maintains that, given petitioner’s inability to establish that she suffered a SIRVA Table injury, the Vaccine Act’s lookback provision does not apply. Response at 6; *see* § 16(b) (requirements for this extended filing period). He asserts that petitioner’s petition, filed more than five years after the onset of her left shoulder pain, is therefore time barred. *Id.*; *see* § 16(a)(2) (usual statute of limitations for cases not involving death).

Respondent provides two bases for the inapplicability of this extended filing period to petitions alleging non-Table claims. Discussing previous holdings in *Gorski* and *Randolph*,⁹ he

⁸ Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the 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).

⁹ Response at 6-8 (citing *Gorski v. Sec’y of Health & Hum. Servs.*, No. 97-0156V, 1997 WL 739497 (Fed.

maintains that “petitioner could have filed her claim prior to the Table revision and within the three-year statute of limitations following the onset of her injury.” Response at 8. To support this argument, respondent cites to data and specific cases from 2012-2015 involving compensated shoulder injury cases. *Id.* at 9. Additionally, respondent maintains that petitioner has not shown that her “symptoms were associated with a shoulder condition,” and thus, the addition of SIRVA to the Table would have no effect on the likelihood of compensation in her case. *Id.*

At issue is the meaning of the Vaccine Act’s language indicating that the lookback provision is triggered when “the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation.” § 16(b). Although clearly applicable to injuries meeting the definition for a newly added Table injury,¹⁰ several of my colleagues have determined that the lookback provision did not apply in non-Table cases alleging the same injury.

When first addressed in the 1997 *Gorski* decision, the special master determined that “the benefit of the extended limitations period would be available only if [the] petitioner could show that her injury fits within the new ‘Table Injury’ category.” *Gorski*, 1997 WL 739497, at *6. Rejecting the proposition that the additional weight afforded a general theory of causation when an injury is added to the Table would similarly affect the question of actual causation, the special master stressed that evidence of actual causation “must be evaluated on its own scientific merit” in every case. *Id.* at *5. He also noted that the *Gorski* petitioner could have filed her causation-in-fact claim prior to the Table revision. *Id.* Thus, he determined the addition of a Table injury “would not in a practical sense affect” the *Gorski* petitioner’s causation-in-fact claim. *Id.* (emphasis in original). Less than one year later, this special master reiterated this holding in *Muchnick v. Sec’y of Health & Hum. Servs.*, No. 97-0089V, 1998 WL 1012801 (Fed. Cl. Spec. Mstr. July 15, 1998).

My current colleagues, however, have reached differing results regarding this issue.¹¹ In *Simpson*, a case involving a claim of Guillain-Barré Syndrome (“GBS”) which narrowly missed the onset required under the Table, the special master determined the lookback provision applied and thus, the petition was timely filed. 2019 WL 11815360, at *7. In reaching that result, the special master stressed Congressional intent when forming the Vaccine Program and the lack of specific language in the lookback provision excluding causation-in-fact claims. *Id.* at *5-6 (citing legislative history at H.R. REP. NO. 99-908, at 3 *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344).

Cl. Spec. Mstr. Nov. 13, 1997) and *Randolph*, 2020 WL 542735).

¹⁰ See, e.g., *Hill v. Sec’y of Health & Hum. Servs.*, No. 19-0384V, 2020 WL 7231990 (Fed. Cl. Spec. Mstr. Nov. 13, 2020); *Castaneda v. Sec’y of Health & Hum. Servs.*, No. 18-1958V, 2021 WL 2547911 (Fed. Cl. Spec. Mstr. June 1, 2021) (finding the Table definition met and the petition timely filed under the Vaccine Act’s lookback provision).

¹¹ Compare *Randolph*, 2020 WL 542735 (following the holding in *Gorski*) with *Simpson v. Sec’y of Health & Hum. Servs.*, No. 17-0944V, 2019 WL 11815360 (Fed. Cl. Spec. Mstr. Aug. 7, 2019) (finding the lookback provision applied to a non-Table claim). This difference in outcome is permitted. See *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998), *aff’d*, 191 F.3d 1344 (Fed. Cir. 1999) (noting that “[s]pecial masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand”).

Disagreeing with the *Gorski* special master, she determined that the addition of a Table GBS injury significantly increased the *Simpson* petitioner's likelihood for compensation. *Simpson*, 2019 WL 11815360, at *6-7.

In contrast, the current chief special master has adopted the *Gorski* holding in numerous decisions.¹² When first addressing this issue in *Randolph*, a case involving a GBS onset more than 30 days past the time allowed for a Table GBS, he determined that the provision would not save a non-Table version of an injury recently added to the Vaccine Injury Table. *Randolph*, 2020 WL 542735, at *8. Finding the reasoning in *Gorski* to be more persuasive, he emphasized the ability of a petitioner to file a successful GBS claim both prior to and after the Table revision and the well-established proposition that petitioners may not utilize their ability to satisfy at least some Table requirements to prove their causation-in-fact claims. *Id.* at *10 (citing *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-0631, 2019 WL 4072110, at *16 n.18 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (emphasizing the need for actual evidence of causation as opposed to arguments stressing similarities or differences to Table injury requirements)).

I agree with the reasoning and more-narrow reading of the § 16(b) language regarding the applicability of the extended filing period expressed in *Gorski* and *Randolph*. The lookback provision was not meant to save untimely filed non-Table claims which could have been filed prior to the Table revision. And the mere addition of the alleged injury to the Vaccine Injury Table does not provide a significant increase in the likelihood that compensation will be awarded in non-Table cases.

Petitioner was fully able to file her claim, pled as a causation-in-fact case, within the three years following onset of her left shoulder pain. There is nothing to show that the addition of SIRVA to the Vaccine Injury Table significantly increased her likelihood of obtaining compensation.¹³ In fact, the record contains substantial evidence showing petitioner's injury is not properly characterized as a shoulder injury. *See infra* discussion in Section III.B.3. Thus, petitioner's causation-in-fact claim may not benefit from the extended filing period set forth in § 16(b). Rather, it is subject to the usual Vaccine Act's statute of limitations.

¹² *See Christensen v. Sec'y of Health & Hum. Servs.*, No. 18-1477V, 2021 WL 2419720 (Fed. Cl. Spec. Mstr. May 12, 2021); *Anderson v. Sec'y of Health & Hum. Servs.*, No. 19-0403V, 2021 WL 836898 (Fed. Cl. Spec. Mstr. Jan. 27, 2021); *Etheridge v. Sec'y of Health & Hum. Servs.*, No. 18-0411V, 2020 WL 7054411 (Fed. Cl. Spec. Mstr. Oct. 30, 2020); *Randolph*, 2020 WL 542735.

¹³ Data collected from cases resolved within the Special Processing Unit ("SPU"), which was created on July 1, 2014, reveals that respondent conceded entitlement in more than 500 SPU cases involving a shoulder injury which were filed prior to the effective date of the revised Vaccine Injury Table containing SIRVA. *See, e.g., Cothorn v. Sec'y of Health & Hum. Servs.*, No. 14-0574V, 2014 WL 6609687 (Fed. Cl. Spec. Mstr. Oct. 15, 2014) (the first such SPU case). Additionally, prior to the creation of the SPU, respondent has conceded entitlement in cases alleging a shoulder injury from an improperly injected vaccine. *See, e.g., Gainey v. Sec'y of Health & Hum. Servs.*, No. 09-0597V, 2010 WL 2483748 (Fed. Cl. Spec. Mstr. May 12, 2010).

Based upon my determination that the onset of Petitioner's left shoulder pain began in April 2012, petitioner was required to file her petition within three years of onset, in April 2015. Because Ms. Clavio filed her petition in late August 2017, it was untimely filed and must be dismissed.

B. Causation-in-Fact

Even if I had determined petitioner's case was timely filed, she still must prove causation by satisfying the three-pronged test set forth in *Althen* by the preponderance of evidence standard required in the Vaccine Act. 418 F.3d at 1278. Petitioner maintains she "has satisfied all three *Althen* prongs, has established causation in fact, and is entitled to vaccine compensation." Motion at 8 (*Althen* altered from underlining to italics). In response, Respondent insists that "petitioner has not established any of the *Althen* criteria." Response at 14. As a threshold matter, he further insists petitioner has not established that she suffered a shoulder injury as alleged. *Id.* at 10 (citing *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) and *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011)).

The record in this case contains evidence suggesting that petitioner's condition is not properly characterized as a shoulder injury. *See infra* Section III.B.3. Assuming, however, that it is, petitioner has clearly failed to satisfy the requirements of the three-pronged *Althen* test.

1. Requirements of Three-Pronged *Althen* Test

Although the first and second prongs of *Althen* appear to be similar, these analyses involve different inquiries. *See Doe 93 v. Sec'y of Health & Hum. Servs.*, 98 Fed. Cl. 553, 566-67 (2011). The first prong focuses on general causation, whether the administered vaccine can cause the particular injury suffered by the petitioner, and the second prong focuses on specific causation, whether the administered vaccine did cause the injury. *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). This distinction "has been described as the 'can cause' vs. 'did cause' distinction." *Stapleton v. Sec'y of Health & Hum. Servs.*, No. 03-0234V, 2009 WL 1456441, at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994).

To satisfy the second prong of the *Althen* test, a petitioner must establish a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect need only be "logical and legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49; *accord. Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

In establishing that a vaccine did cause the injury in question, the opinions and views of treating physicians are entitled to some weight. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1376 (Fed. Cir. 2009); *Capizzano*, 440 F.3d at 1326 ("treating physicians are likely to be in

the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). However, the opinions of treating physician opinions are not sacrosanct. *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009).

The third *Althen* prong requiring an appropriate temporal relationship contains two parts. First, a petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec’y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff’d without op.*, 503 F. App’x 952 (Fed. Cir. 2013). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury utilized to satisfy the first prong. *Shapiro*, 101 Fed. Cl. at 542; *Koehn v. Sec’y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

2. Althen Prongs One and Three

Because of the interrelationship between the first and third *Althen* prongs and given the specific circumstances in this case, it is best to discuss these requirements together. To support her assertion that she has satisfied the first *Althen* prong, petitioner relies upon medical literature filed as exhibits 15-19 and the addition of SIRVA to the Table. Motion at 5. Regarding the third prong, she references the inclusion of two patients who complained of pain within two months of vaccination, along with the clear majority who experienced pain within 24 hours of vaccination, as proof that her 59-day onset was medically appropriate. *Id.* at 8 (citing Arias, et al., *Risk of bursitis and their injuries and dysfunctions of the shoulder following vaccinations*, VACCINE 35: 4870-4876 (2017) (filed as Pet. Ex. 16) (hereinafter “Arias”).

Emphasizing the lack of medical expert opinion, respondent submits the theory offered, characterized as simply counsel’s summary of the contents of the medical literature provided, is insufficient. Response at 11. Additionally, he maintains that “none of the articles appear to support petitioner’s claim” (*id.*) and petitioner should not be allowed to rely upon the theory behind a Table injury, the requirements of which the petitioner is unable to satisfy (*id.* at 11-13).

Because the timing of her left shoulder pain is clearly outside that required for a Table SIRVA – approximately two months post-vaccination, unlike a petitioner with a pain onset just past the maximum of 48 hours, petitioner may not simply rely upon the medical theory which forms the basis for a Table SIRVA. As reflected in the QAI criteria for a Table SIRVA, as well as the medical literature provided by petitioner, this theory relies heavily upon a pain onset within 48 hours of vaccination. Instead, to satisfy the *Althen* prong one requirement, petitioner must provide a medical theory which explains how a vaccination could cause a shoulder injury with a delayed onset of pain, such as the one exhibited in petitioner’s case.

Even if I were to accept the theory and supporting literature which provided the foundation for adding SIRVA to the Vaccine Injury Table as sufficient to satisfy the first *Althen* prong in this

case,¹⁴ petitioner would still run afoul of the requirements of the third *Althen* prong. To support her assertion that she has provided evidence of an appropriate timeframe, petitioner quotes language from *one* of her cited articles indicating that for the eight patients included from the Spanish Pharmacovigilance System database, known as FEDRA, “6 in 8 FEDRA patients complained of increasing severity pain starting within the first 24 h[ours] or few days (4-7) post-vaccination, **and 2 reported pain within 2 months.**” Motion at 8 n.1 (quoting Pet. Ex. 16 at 3 (Arias 4872); emphasis added in the Motion). However, no further details regarding the pain onset for these 2 FEDRA patients were provided, and the meaning of this sentence is not clear. Furthermore, the next sentence in the Arias article describes a shorter pain onset for all 37 cases included from medical literature: within 24 hours of vaccination for 81.8% of the cases and within four days of vaccination for the remaining 18.9% cases. Petitioner’s reliance upon the inclusion of this small minority of only two FEDRA patients with a possible pain onset like the one petitioner alleges, without further explanation regarding the basis for their inclusion, is not sufficient to show petitioner’s injury occurred within a medically appropriate timeframe. Petitioner has provided no expert report or literature that would support a finding of causation under the theory forming the basis for the Table SIRVA injury for a shoulder injury associated with the receipt of a vaccine with onset 59 days post-vaccination.

Petitioner has failed to provide the preponderant evidence needed to satisfy either of these *Althen* prongs. At a minimum, evidence showing “a proximate temporal relationship between vaccination and injury” is clearly lacking. *Althen*, 418 F.3d at 1278.

3. Althen Prong Two

Most problematic for petitioner is the requirement enumerated in the second *Althen* prong. Petitioner insists that her “medical records support the logical sequence of cause and effect” required to satisfy the second *Althen* prong but cites only one record, from a chiropractic visit more than a year post-vaccination. Motion at 6. Petitioner presents information contained in this April

¹⁴ In non-Table cases, “a link to a Table injury can support a petitioner's ability to fulfill *Althen's* first prong.” *C.C. v. Sec’y of Health & Hum. Servs.*, No. 17-0708V, 2021 WL 2182817, at *21 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (citing *Doe 21 v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 178, 199 (2009), *rev’d on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013)). Special masters have taken judicial notice of the addition of SIRVA to the Vaccine Injury Table when addressing the requirements of the first *Althen* prong in numerous causation-in-fact cases alleging shoulder injuries. *L.J. v. Sec’y of Health & Hum. Servs.*, No. 17-0059V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Wolford v. Sec’y of Health & Hum. Servs.*, No. 17-0451V, 2021 WL 3357987, at *12 (Fed. Cl. Spec. Mstr. July 9, 2021); *C.C.*, 2021 WL 2182817, at *21; *Shafer v. Sec’y of Health & Hum. Servs.*, No. 16-0593V, 2021 WL 650127, at *7 (Fed. Cl. Spec. Mstr. Jan. 25, 2021); *Bishop v. Sec’y of Health & Hum. Servs.*, No. 18-0027V, 2020 WL 7978258, at *11, 11 n.6 (Fed. Cl. Spec. Mstr. Nov. 20, 2020); *Goldman v. Sec’y of Health & Hum. Servs.*, No. 16-1523V, 2020 WL 6882186, at *16 (Fed. Cl. Spec. Mstr. Nov. 2, 2020); *Taylor v. Sec’y of Health & Hum. Servs.*, No. 16-1403V, 2020 WL 6706078, at *13 (Fed. Cl. Spec. Mstr. Oct. 20, 2020); *Desai v. Sec’y of Health & Hum. Servs.*, No. 18-0411V, 2020 WL 4919777, at *15 (Fed. Cl. Spec. Mstr. July 30, 2020); *Leshner v. Sec’y of Health & Hum. Servs.*, No. 17-1076V, 2020 WL 4522381, at *11 (Fed. Cl. Spec. Mstr. July 2, 2020) (stating “[s]uch recognition of the causal link between vaccine and injury has been held to support the establishment of the theory require by the first *Althen* prong, since it suggests the existence of reliable medical or scientific evidence supporting the ‘can cause’ prong”).

21, 2013 medical record as evidence of medical provider opinion. *Id.* at 6 (citing Pet. Ex. 3 at 1-2). However, there are several significant inaccuracies related to petitioner's argument and the information contained in the record which affect its probative value.

To support her actual causation argument, petitioner references an entry regarding the lack of any specific triggering event other than the Tdap vaccine petitioner received the previous day, attributing the statement to her chiropractor. Motion at 6 (quoting Pet. Ex. 3 at 2). However, a review of the medical record reveals that this language reflects petitioner's opinion, not the opinion of the chiropractor. Pet. Ex. 3 at 2. When including this information in the case summary, the chiropractor clearly indicated that the information originated with Petitioner and expressed no opinion regarding its accuracy. *Id.*

The second entry cited by petitioner shows that her chiropractor considered whether the Tdap vaccination could be a precipitating event for petitioner's pain, along with a second option of a more gradual rotator cuff disease. Pet. Ex. 3 at 1. Notably, this entry: "TDAP injection in April 2012?" (*id.*) shows that, when considering a possible causal relationship, the chiropractor believed petitioner received the Tdap vaccine in April 2012 - one day before the onset of her pain, as she reported. Exhibit 3 at 2. No doubt the inaccurate date of vaccination formed the primary basis for his hypothesis. Thus, the persuasive value of the information contained in the record is greatly diminished. *See Ryman v. Sec'y of Health & Hum. Servs.*, 65 Fed. Cl. 35, 41-42 (2005) (indicating that the chief special master was not arbitrary in declining to rely upon a treater who obtained an inaccurate history).

Petitioner directs the remainder of her argument to respondent's earlier contention – that the temple and neck pain she experienced prevented her from satisfying the third QAI SIRVA criterion. Motion at 6-7; *see* Rule 4(c) Report at 14 (respondent's earlier argument). In response, respondent maintains the requirements for a Table SIRVA are not relevant to petitioner's causation argument because non-Table petitioners do not get to utilize the existence and details of the Table requirements to prove actual causation. Response at 13-14 (quoting *Randolph*, 2020 WL 542735, at *10 (citing *Gorski*, 1997 WL 739497, at *5)).

While recognizing there is an existing dispute regarding the scope and meaning of the third QAI Table SIRVA criterion,¹⁵ I agree that any discussion of this issue or determination as to

¹⁵ This third criterion requires that a petitioner's "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii). Respondent has argued that pain in other locations, such as a petitioner's lower arm, hand, neck, or back will prevent a petitioner from satisfying this criterion. *See Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *7 (Fed. Cl. Spec. Mstr. July 27, 2020); *Rodgers v. Sec'y of Health & Hum. Servs.*, No. 18-0559V, 2021 WL 4772097, at *6 (Fed. Cl. Spec. Mstr. Sept. 9, 2021). As in this case, petitioners have countered that pain which can be characterized as compensatory and clearly attributable to a petitioner's shoulder condition does not prevent a petitioner from satisfying the third QAI criterion. *See* Motion at 6-7 (citing a response provided by respondent to public comment, 82 Fed. Reg. 6294 (Jan. 19, 2017)); *Werning*, 2020 WL 5051154, at *10 (finding that a few initial complaints of pain radiating to her fingers, did not prevent the petitioner from satisfying the third QAI criterion as she "was diagnosed and treated solely for pain and limited range of motion to her right shoulder"). Other petitioners have argued that this criterion applies only to the initial symptoms suffered by a petitioner and not to those symptoms clearly attributable to simultaneous and unrelated conditions. *See Rodgers*, 2021 WL 4772097, at *8-9

whether petitioner's injury would satisfy the criterion is not relevant to my determination in this case. As the Federal Circuit has stated "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation." *Grant*, 956 F.2d at 1148.

Although I do not find petitioner's arguments persuasive, in order to provide a thorough actual causation analysis, further discussion of the evidence is warranted. The Ruling on Onset in this matter provides an in depth and detailed medical history in this matter. However, some examples are added here to show petitioner's inability to support her argument under the second *Althen* Prong, though the referenced entries are by no means exhaustive.

The medical records show that petitioner did not seek treatment for her pain until June 2012, more than four months post-vaccination. During this four-month period, from early February through mid-June 2012, petitioner visited her primary care provider for a complaint of sinusitis, faxed him the results of bloodwork testing performed by her employer, and visited her dentist for a complaint of temporomandibular joint pain, commonly known as TMJ. Pet. Ex. 4 at 13, 72; Pet. Ex. 6 at 1. There is no mention of left shoulder pain in the medical records from these visits. Pet. Ex. 4 at 13-15, 72-74; Pet. Ex. 6 at 1.

When she did seek treatment for her pain, from mid-June 2012 through late June 2013, petitioner consistently described pain in her left temple, neck, and shoulder which began in April 2012. She failed to identify as causal, or even mention, the Tdap vaccine she received on February 2, 2012.

For example, when she first complained of pain to her primary care provider on June 13, 2012, petitioner described her pain as beginning two months earlier in her temple then noticing it in her arm. Pet. Ex. 4 at 9. Exhibiting normal strength and full range of motion with pain at the extremes, she denied experiencing any injury. *Id.* at 9, 12. When treated by an orthopedist five days later, petitioner exhibited full range of motion and no shoulder tenderness. Pet. Ex. 2 at 3. During a visit to a neurologist on June 29, 2012, petitioner again described pain which began around Easter and was located initially in her temple, and then in her neck and shoulder. Pet. Ex. 5 at 10. She again reported "[t]here was no injury involved." *Id.*

Additionally, none of petitioner's treating physicians opined that petitioner's temple, neck, and left shoulder pain was caused by the Tdap vaccine she received in February 2012. The primary care provider who first treated petitioner believed her pain was due to "shoulder tendinitis leading to compensatory neck muscle pain." Pet. Ex. 4 at 12. The orthopedist disagreed, indicating he did not believe her condition "correlate[d] well with a shoulder problem." Pet. Ex. 2 at 3. Mentioning petitioner's earlier TMJ, the orthopedist referred her to a neurologist. *Id.* The neurologist believed petitioner's "pain [wa]s mainly muscular in etiology . . . involv[ing] the trapezius muscle as well as the temporalis." Pet. Ex. 5 at 12.

(Although the chief special master rejected the *Rodgers* petitioner's timing argument, he determined that the third QAI criterion "does not prevent a petitioner with simultaneous areas of pain due to unrelated conditions from also meeting the Table SIRVA definition.").

To satisfy the second *Althen* prong, petitioner must show that the Tdap vaccine she received caused her alleged shoulder injury. The record in this case shows petitioner did not relate her pain to the Tdap vaccine until more than fourteen months post-vaccination, that her presentation was not typical of that normally seen in SIRVA cases, and that none of the three treating physicians she first saw attributed her pain to the vaccination she received. The only medical provider who considered a causal link, her chiropractor, did so after being erroneously informed by petitioner that she received the vaccination in April 2012, one day before her pain began.

Petitioner must provide preponderant evidence of a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. An examination of the record in this case reveals a dearth of evidence supporting any causal connection. Petitioner has failed to prove actual causation as required under the second *Althen* prong.

IV. Conclusion

To date, and despite ample opportunity, Petitioner has failed to file preponderant evidence to establish her Table claim, rendering the petition untimely filed. She also has not provided preponderant evidence of causation. Accordingly, this case is DISMISSED as untimely filed and for failure to satisfy the requirements of *Althen* for a causation-in-fact claim. The clerk shall enter judgment accordingly.¹⁶

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master

¹⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties’ joint filing of notice renouncing the right to seek review.