In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1811V UNPUBLISHED

CLAUDIA MARQUEZ,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 5, 2022

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination, Onset, and Statutory Six Month Requirement Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Renee J. Gentry, Vaccine Injury Clinic, George Washington Univ. Law School, Washington, DC, for Petitioner.

Parisa Tabbassian, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On November 26, 2019, Claudia Marquez 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 right shoulder/arm pain caused-in-fact by the influenza ("flu") vaccine she received on November 14, 2017, in her right deltoid. Amended Petition at 1, ¶¶ 2, 16, ECF No. 16. 3 Acknowledging that she previously suffered

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact 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).

³ Petitioner filed an amended petition on April 13, 2020, to correct one entry which erroneously listed the date of vaccination as November 24, 2017. *Compare* Petition at 1 *with* Amended Petition at 1.

right shoulder bursitis in 2015, Petitioner maintains that her current pain is distinguishable, began the morning after vaccination, and continued for at least six months. Amended Petition at ¶¶ 3-4, 18.

For the reasons discussed below, I find that the flu vaccine Petitioner received was most likely administered in her right deltoid, and that she suffered right shoulder/arm pain which began the next morning. However, as the record currently stands, there is insufficient evidence to support Petitioner's assertions that her post-vaccination pain was unrelated to the bursitis she previously suffered, or that it continued for more than six months. It is nonetheless my hope that this fact ruling might facilitate a productive settlement discussion.

I. Relevant Procedural History

A few days after filing the Petition, Ms. Marquez filed her vaccine record and some of the medical records required under the Vaccine Act. Exhibits 1-4, ECF No. 5; see Section 11(c). On February 13, 2020, she filed a status report indicating there were no outstanding medical records or additional documentation regarding her site of vaccination. ECF No. 9. Thereafter, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims). ECF No. 10. Approximately one week later, Petitioner filed a better copy and final report of Petitioner's March 12, 2018 orthopedic visit. Exhibit 5, filed Feb. 26, 2020, ECF No. 12.

During a telephonic status conference held on March 16, 2020, the parties discussed the need for Petitioner's affidavit, an amended petition to correct one entry containing an erroneous date of vaccination, the lack of documentation showing the site of vaccination, and the possibility that earlier chiropractic records were still outstanding. ECF No. 15. In April 2020, Petitioner filed her amended petition, detailed affidavit, and additional chiropractic records. Amended Petition, filed Apr. 13, 2020, ECF No. 16; Exhibits 6-7, filed Apr. 16, 2020, ECF Nos. 17-18.

In June 2021, Respondent provided counsel's assessment that potential factual issues exist in this case – specifically regarding site of vaccination and onset of Petitioner's pain. ECF No. 20. In September, Petitioner filed a list of her out-of-pocket medical expenses, and indicated she had forwarded her demand and supporting documentation to Respondent. Status Report, Sept. 25, 2021, ECF No. 22. Exhibit 8, filed Sept. 30, 2021, ECF No. 23.

On June 4, 2021, Respondent filed his Rule 4(c) Report, arguing that I should deny entitlement to compensation in this case. Rule 4(c) Report at 1, ECF No. 26. Specifically,

he maintained that Petitioner has failed to establish that she suffered the residual effects of her shoulder injury for more than six months, a requirement for both Table and non-Table claims. *Id.* at 7; see Section 11(c)(1)(D)(i) (statutory six-month requirement). Additionally, he insisted that Petitioner's injury does not meet the Table definition for shoulder injury related to vaccine administration ("SIRVA") – due to her prior right shoulder pain and failure to establish pain onset within 48 hours of vaccination,⁴ and that Petitioner could not otherwise establish off-Table causation.⁵ Rule 4(c) Report at 4-6; In addition, and although not identified as an issue potentially fatal to Petitioner's claim, Respondent mentioned that the vaccine record did not establish the site of vaccination. *Id.* at 2.

During a second telephonic status conference held on June 29, 2021, the parties were informed of my preliminary view – that an informal settlement for an amount which is proportional to a significant aggravation claim would be appropriate in this case. Order, issued July 2, 2021, at 1, ECF No. 27. Petitioner was instructed to provide a revised demand, if needed, and Respondent was ordered to file a status report indicating whether he was willing to engage in further settlement discussions or wished me to address any of the factual issues in the case. *Id.* at 1-2.

On August 18, 2021, Respondent filed a status report indicating that he "is not interested in settlement negotiations at this time and requests fact-finding regarding the initial onset, site of vaccination, and severity of [P]etitioner's shoulder pain." ECF No. 28. The matter is now ripe for adjudication.

II. Issues

At issue is whether the following contentions have preponderant record support:

1) that Petitioner received the vaccination alleged as causal in the injured right deltoid; 2) that she experienced right shoulder/arm pain the morning after vaccination; and 3) that she continued to suffer the residual effects of vaccine-caused pain for more than six months.

⁴ To meet the definition for a Table SIRVA injury, a petitioner must show the lack of prior shoulder pain, inflammation, or dysfunction which would explain her current symptoms and pain onset within 48 hours of vaccination. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(i)-(ii) (additional requirements set forth in the Qualifications and Aids to Interpretation). Acknowledging her prior right shoulder pain, Petitioner has not alleged a Table SIRVA injury in this case.

⁵ To establish causation-in-fact, a petitioner must satisfy the three-pronged test set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Because Petitioner has alleged that the flu vaccine caused her right shoulder/arm pain, she must provide preponderant evidence to satisfy this test.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact: Site and Six-Month Severity

I make findings regarding site of vaccination, onset, and severity after a complete review of the record to include all medical records, affidavits, Respondent's Rule 4(c) Report, and additional evidence. Specifically, I highlight the following:

- Prior to vaccination on November 19, 2015, Petitioner visited her primary care provider ("PCP") complaining of right arm pain which she thought may be due to a pinched nerve. Exhibit 4 at 15-16. Reporting that the pain had started five days earlier, she described it as sharp, "radiat[ing] down the right deltoid and up the right neck, most painful with abduction," and "better with rest." *Id.* at 15. Observing no swelling, the PCP diagnosed Petitioner with bursitis, prescribed a Medrol dose pack, and instructed Petitioner to return if she experienced any swelling or warmth. *Id.* at 15, 17.
- On January 29, 2016, Petitioner visited a chiropractor for neck pain described by Petitioner as a new problem exacerbated by "poor posture while working on her computer for extended periods of time" and rated at a level of five out of ten. Exhibit 7 at 4. Reporting sharpness and tightness in her mid-back and neck, she indicated that the problem improved with rest and stretching. *Id.* Petitioner visited the chiropractor with the same

complaint on nine more occasions during February through November 2016. *Id.* at 5-15.

- Petitioner next visited her PCP for preventive care on June 14, 2016. Exhibit 4 at 8. Petitioner reported that her anxiety was well-controlled by taking sertraline⁶ and that she was currently experiencing no pain. Exhibit 4 at 8, 10. The PCP discussed Petitioner's current medication, diet, and need for a pap smear, colonoscopy, PPD test, and flu vaccine. *Id.* at 11-13. Petitioner declined the flu vaccine and referral for a pap smear, but was administered a PPD test and accepted the referral for a colonoscopy. *Id.* at 12-13.
- By her second to last chiropractic appointment on July 26, 2016, Petitioner reported that her pain was occurring less frequently. Exhibit 7 at 12. She rated its severity as three out of ten. *Id.*
- However, at her last chiropractic appointment on November 28, 2016, Petitioner reported that her neck had become aggravated. Exhibit 7 at 15. She rated her pain at a level of six in her neck and five in her back. *Id.* Upon examination, Petitioner's chiropractor observed that she exhibited moderately tender and taut muscles in her back and neck, a finding indicative of a left muscle strain when turning her head and applying resistance, and some pain and limitations during cervical rotation testing. *Id.* at 13. There are no records of any medical treatment during the year prior to vaccination from late November 2016 appointment until mid-November 2017.
- Petitioner received the flu vaccine at her workplace Medstar Washington Health Center, Occupational Health Department, on November 14, 2017. Exhibit 1 at 4. The vaccine record does not indicate the site or manner of vaccination. *Id.* at 1-4.
- On January 8, 2018 approximately seven to eight weeks after vaccination Petitioner was seen by her PCP for an annual physical. Exhibit 4 at 6-7. Noted to be 51 years old at the time, Petitioner reported receiving the flu vaccine in November, never having had colon cancer screening, and undergoing an eye exam the previous year. *Id.* at 6. Under pain assessment, it was noted that Petitioner was experiencing no pain. *Id.* at 7.

-

⁶ Sertraline hydrochloride "is selective serotonin reuptake inhibitor, used to treat depressive, obsessive-compulsive, and panic disorders." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY at 1699 (32th ed. 2012).

Petitioner underwent a pap smear, but declined colon cancer screening and an ECG. The PCP provided her with a referral for a mammogram, ordered bloodwork, and instructed Petitioner to continue taking sertraline.

- On March 12, 2018, Petitioner visited an orthopedist, complaining of constant right shoulder pain for three months. Exhibit 2 at 8. She indicated that her symptoms started after receiving the flu vaccine three months earlier. Acknowledging that she had a history of shoulder bursitis, Petitioner described her current pain as constant. An examination revealed Petitioner exhibited impingement but normal range of motion ("ROM"). The orthopedist diagnosed Petitioner with tendinosis of the rotator cuff and prescribed physical therapy ("PT") and a cortisone injection. *Id.* Petitioner declined the PT but agreed to a cortisone injection which was administered at that appointment. *Id.* at 6, 8, 13-14.
- On June 4, 2018, Petitioner visited a different chiropractor than seen in 2016,⁷ complaining of bilateral neck pain mostly on the right side of her neck and upper trapezius. Exhibit 3 at 2-8. On the intake form, the area between Petitioner's neck and shoulder, over her trapezius, is marked as the location of her pain. *Id.* at 7. Petitioner now identified December 1, 2018⁸ as the date of onset but also indicated (inconsistently) that her pain began the day after she received the flu shot. *Id.* at 2. Describing her pain as constant, dull, and aching, Petitioner added that it was now radiating, occurred "mostly with movement like moving the computer mouse," increased when lifting or laying upon her arm, decreased with stretching, and interrupted her sleep. *Id.* at 2, 7. She indicated that she was currently working 40 hours per week. *Id.* at 2. Responding to a query about past treatment of her condition, Petitioner indicated she had tried massage and that her "last chiropractic treatment was one year ago." *Id.*
- At her next chiropractic appointment on June 12, 2018, Petitioner again described dull and aching neck pain mostly on the right side. Exhibit 3 at 12. Rating the level of her pain as four to five out of ten, Petitioner reported that her discomfort "occur[ed] approximately 30% of the time," "increase[d] with sitting for too long," and "[wa]s better since the last visit." Id. The treatment provided is described as palpitation of trigger points in the

⁷ Petitioner indicated her previous chiropractor, last seen in 2016, had retired. Exhibit 6 at ¶ 11.

⁸ Given that the visit occurred on June 14, 2018, the year provided by Petitioner is clearly a mistake. It can be reasonably concluded that she meant December 1, 2017.

muscles from the base of the neck down along the spine and of the cervical joints. *Id.*

- These same descriptive paragraphs of Petitioner's complaint and treatment are repeated during seven additional visits to the chiropractor from late June 2018 through April 2019. Exhibit 3 at 13-19. By her sixth visit on December 12, 2018, Petitioner "was able to lateral[ly] bend her neck to the right side without pain and at a full range." *Id.* at 17.
- In her affidavit, executed on March 27, 2020, Petitioner indicated that her right shoulder pain began the day after vaccination. Exhibit 6 at ¶ 3. Stressing that the pain she experienced post-vaccination was excruciating, radiated into her shoulder and arm, was not relieved by stretching, and affected every aspect of her life, Petitioner distinguished it from the pain she experienced in 2015. *Id.* at ¶ 6. She maintained that her 2015 pain, due to mouse overuse at her full-time job, had resolved before fall 2017. *Id.* at ¶¶ 1, 6.
- Petitioner asserted that she did not mention the right shoulder pain which began in November 2017 at her physical several months later, characterized by Petitioner as a well-women visit, "because it wasn't the purpose/focus of the visit . . . [and she] was also still considering whether this pain might have been related to [her] previous diagnosis." *Id.* at ¶ 7. After purchasing a correction device in late February 2018 (*id.* at ¶ 8), Petitioner "recognized that this pain was different," and wondered if she was "suffering a pinched nerve or an issue with [her] clavicle" issues she had not experienced with her 2015 pain. *Id.* at ¶ 9.
- Petitioner also maintained that her pain did not dissipate after the cortisone injection she received in March 2018. Exhibit 6 at ¶ 10. Reporting that her prior chiropractor had retired, Petitioner indicated that the chiropractic treatment she pursued beginning in June 2018 was for her vaccine-related injury and pain. *Id.* at ¶ 11. Describing the exacerbation of her shoulder pain when moving and lifting boxes in 2019, Petitioner insisted that she continued to suffer from her injury in late 2020, when her affidavit was executed. *Id.* at ¶¶ 12, 14.

A. Nature of Petitioner's Injury

The medical records show that Petitioner complained of neck, shoulder, and/or arm pain on the following occasions (some of which predated vaccination):

- 1) sharp right shoulder pain to her PCP in November 2015,
- 2) neck and mid-back pain and tightness to her chiropractor from late-January 2016 through November 2016,
- 3) constant right shoulder pain to an orthopedist since her vaccination in November 2017 through March 2018, and
- 4) dull and aching neck pain mostly on the right side of her neck and shoulder to her current chiropractor in June 2018 through April 2019.

Due to similarities related to the descriptions contained throughout the medical records, it is difficult to characterize the symptoms Petitioner experienced throughout 2015 to 2019 as originating from unrelated injuries or conditions. Indeed, Petitioner treated at least the last three instances of right shoulder, arm, and neck pain as a continuation of the same condition when completing the chiropractic intake form in early June 2018. Exhibit 3 at 2. And Petitioner's later attempts to distinguish the pain she experienced post-vaccination from that suffered previously, and to connect all later pain to the same, vaccine-related injury, are not supported by the information contained in the contemporaneously created medical records.

In her affidavit, Petitioner maintained that the symptoms she suffered postvaccination were distinguishable from those she suffered in November 2015, because the later symptoms included pain that radiated in her right shoulder and arm. Exhibit 6 at ¶ 6. She insisted that the earlier, bursitis-related pain, by contrast, "was easily relieved with some stretching, weight exercises, and over the counter medication . . . [and] neither radiated nor prevented [her] from lifting her arm." Id. However, this description of Petitioner's 2015 pain (provided in 2020) more closely resembles the more contemporaneously provided information regarding the symptoms suffered in 2016 and treated by her chiropractor. See, e.g., Exhibit 7 at 4 (describing 2016 pain). The medical records regarding Petitioner's complaint in November 2015 clearly show that she described pain which "hurts with motion . . . [and] radiated down the right deltoid and up the right neck" and required oral steroids. Exhibit 4 at 15, 17-18. Additionally, Petitioner proposed the same possible pinched nerve injury for both the pain she felt in 2015 and post-vaccination in 2017. Compare Exhibit 4 at 16 with Exhibit 6 at ¶ 9. These similarities undercut Petitioner's attempts to distinguish her post-vaccination pain from the bursitis she suffered in 2015.

Additionally, Petitioner has insisted that the neck and shoulder pain she experienced in June 2018 and later was a continuation of the pain she reported in March 2018. Exhibit 11-12, 14. And there is some evidence to support this assertion – when completing the intake form on June 4, 2018, Petitioner linked her June 2018 pain to the

flu vaccine she received. Exhibit 3 at 2. However, on that same the intake form, Petitioner indicated her pain was last treated by a chiropractor a year ago. *Id.* And the medical records reveal that this later pain more closely resembles the pain Petitioner suffered in 2016. *Compare* Exhibit 7 *with* Exhibit 3. Both instances of pain were attributed to extended computer and mouse use and described as improving with stretching and rest. *E.g.,* Exhibit 3 at 2; Exhibit 7 at 4. In that respect, even the pain Petitioner experienced in 2015, which was also attributed to computer and mouse overuse, is more closely connected to this later 2018 neck and shoulder pain. See Exhibit 6 at ¶ 6 (describing the 2015 bursitis-related pain as due to long hours at the computer). By June 2018, Petitioner again reporting working full-time – 40 hours per week. Exhibit 7 at 2.

Considering all medical records and other evidence, the pain Petitioner experienced in June 2018 and later appears to be a continuation of the condition(s) which caused her earlier pain, especially that experienced in 2016 – and thus her claim is best understood as one alleging significant aggravation of a pre-vaccination condition. As such, Petitioner would be able to satisfy the statutory six-month requirement and would not be required to distinguish her post-vaccination pain from her earlier bursitis. However, to prevail, Petitioner would be required to satisfy the six-pronged *Loving* test – constituting of the three-prongs of *Althen* with additional requirements establishing the significant aggravation of a petitioner's prior condition. *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009).

Because Petitioner has alleged only a causation-in-fact claim, I will address the issues of site, onset, and six-month severity in that context. However, I make no definitive findings regarding the associations between the above instances of pain. And my onset finding applies only to the pain for which Petitioner first sought treatment in March 2018.

B. Site and Onset

Despite the above discussion and other instances of pain, it is evident from the record that the constant right shoulder/arm pain Petitioner reported in March 2018 likely began the day after vaccination. When she first sought treatment, Petitioner described the duration of her pain as only having existed for three months. Exhibit 2 at 8. Although this description would effectively place onset a month after the November 2017 vaccination, Petitioner repeated this same erroneous timing when discussing the date of vaccination as well. She reported this information – incorrect timing for both her pain onset and vaccination when seeking chiropractic treatment in June 2018. Exhibit 3 at 2. Thus, the repeated error regarding the timing of Petitioner's vaccination and pain onset reflects Petitioner's lack of precision when describing these events. It does not diminish the impact of her statements tying the onset of her pain to the flu vaccine she received.

In addition, besides providing important, contemporaneous information regarding the onset of Petitioner's right shoulder/arm pain, these statements provide evidence that Petitioner received the vaccine in her right deltoid as alleged. It would be illogical for Petitioner to attribute her pain to the flu vaccine she received if the vaccine had been administered in her opposing, left deltoid. And other than the silence of the vaccine record on the situs issue, there is no other record proof suggesting a *different* administration situs.

To further counter Petitioner's assertions regarding onset, Respondent has argued that Petitioner's failure to mention her pain at the physical she attended in January 2018, undercuts her claims of an immediate onset. Rule 4(c) Report at 4-5. However, Petitioner made a similar omission during her June 2016 physical, despite being treated for neck and upper back pain throughout 2016. Exhibit 4 at 10-14; see Exhibit 7 at 7-10 (chiropractic records from visits on April 20, June 23, and June 30, 2016). This earlier omission is evidence which supports Petitioner's claim that she was experiencing right shoulder/arm pain in January 2018, but did not mention it during her January 2018 physical because she believed it outside the focus of the PCP visit. See Exhibit 6 at ¶ 7.

Although a close call, Petitioner's descriptions of immediate pain the day after vaccination provided to the orthopedist in March 2018 and to the chiropractor in June 2018 constitutes sufficient evidence to establish that Petitioner received the flu vaccine in her right deltoid, and suffered pain beginning the next day, as alleged.

C. Six-Month Severity

More problematic is the question of severity. To establish that she suffered the residual effects of her injury for more than six months, Petitioner must show that her symptoms continued beyond mid-May 2018. She must link the symptoms she experienced in June 2018 and later to the shoulder injury she alleges.

In her affidavit, Petitioner insisted that the pain she reported during the orthopedic appointment on March 12, 2018, did not dissipate after the cortisone injection she received at that visit and was the reason she sought chiropractic care in June 2018. Exhibit 6 at ¶ 10. However, the June 2018 pain was located in her neck and right trapezius, and appears to be similar to the muscle strain she experienced in 2016. Like in 2016, the pain Petitioner reported in June 2018, and later, worsened with overuse and improved with stretching. Exhibit 3 at 2, 7. It does not appear to be related to pain she reported in March 2018, and described more fully in her affidavit, which may or may not be vaccine caused.

V. Conclusion and Scheduling Order

I have determined that the record contains the preponderant evidence needed to establish that Petitioner received the flu vaccine alleged as causal in her right, injured arm, and that she experienced pain which began the day after vaccination which *may* constitute a new injury or aggravation of a pre-vaccination injury. However, for Petitioner's currently alleged causation-in-fact claim, there is insufficient evidence to satisfy the Vaccine Act's six-month severity requirement.

For Petitioner's causation-in-fact claim to succeed, she must provide preponderant evidence establishing that the pain she experienced in March 2018 was caused by the flu vaccine she received on November 14, 2017. She also must provide preponderant evidence establishing that symptoms related to her shoulder injury continued beyond mid-May 2018 – that the later pain she experienced in June 2018 was related to her vaccine injury. If Petitioner chooses to proceed under a significant aggravation claim, she must establish that the vaccine significantly aggravated her prior condition. As it currently stands, Petitioner is unable to satisfy these requirements.

As I previously stated, I believe this case is appropriate for informal settlement based upon an amount lower than that which would be awarded if entitlement to compensation was established. I encourage the parties to engage in informal settlement discussions to determine if an agreement can be reached. Otherwise, Petitioner will be required to provide an expert report and any additional evidence needed to prove causation and six months of sequelae or significant aggravation, and the case will likely need to be transferred out of SPU. Having reviewed the medical records and current evidence in this case, I am not convinced that Petitioner's claim can succeed. However, a final attempt at a litigative risk settlement is warranted.

The parties shall file a joint status report indicating whether they have engaged in additional settlement discussions, and believe the case can be informally resolved within SPU sometime before the end of the summer, by no later than <u>Tuesday</u>, <u>May 10</u>, <u>2022</u>. If the parties believe an informal resolution can be reached, they should provide an estimate of the amount of time needed. Otherwise, the matter will be transferred out of SPU.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master