In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 25, 2021

NANCY RISSLER,	*	No. 18-1208V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Fact Hearing; Onset of Injury; Prevnar-13 Vaccine; Shoulder Injury Related to Vaccine Administration ("SIRVA")
Respondent.	*	

Glen H. Sturtevant, Jr., Rawls Law Group, Richmond, VA, for Petitioner.
Kyle E. Pozza, U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING[1]

On August 14, 2018, Nancy Rissler ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleged that she developed a left shoulder injury related to vaccine administration ("SIRVA"),[3] which was caused-in-fact by the Prevnar-13 vaccine ("pneumococcal conjugate vaccine" or "PCV 13") she received on May 1, 2017. Pet. at 1, ECF No. 1. At this time, I find it is necessary to make a factual determination as to the date of onset of Petitioner's left-sided shoulder pain. After carefully analyzing the information in the record and the testimony provided during the fact hearing, I find that Petitioner has established by a preponderance of the evidence that she experienced left shoulder pain within forty-eight hours of her vaccination. However, as a Table claim is not before me, this factual determination does not reach the issue of whether Petitioner's shoulder injury was caused-in-fact by her PCV 13 vaccination.

[1]This fact ruling shall be posted 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), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted fact ruling. If, upon review, I agree that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act," "the Act," or "the Program"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

[3] At the time of filing of Petitioner's petition, she alleged that she *suffered* from "left shoulder impingement, adhesive capsulitis, tendinopathy, tendinitis, superior labral tearing, and [] debilitating pain, weakness, and restricted range of motion[.]" Pet. at 1.

I. Procedural History

On August 14, 2018, Petitioner filed her petition alleging that she suffered a left-sided SIRVA as a result of the Prevnar-13 vaccine she received on May 1, 2017. Pet. at 1. Three days later, Petitioner filed ten exhibits consisting of her affidavit, medical records, affidavits from Mr. Brett Rissler and Ms. Cami Wilson, and vaccination records. Pet'r's Exs. 1–10, ECF Nos. 5-1–5-10. The same day, Petitioner filed a statement of completion. ECF No. 6.

During a status conference on October 17, 2018, the parties discussed "the obvious issue of the second non-covered vaccination ([s]hingles)[4] administered on June 7, 2017, in the same arm as the vaccination alleged as causal, (Prevnar[-]13, administered May 1, 2017)[.]" Order at 1, ECF No. 8. Petitioner also acknowledged that "the records from [P]etitioner's primary care provider indicated she suffered from neck pain in May 2015[,] and back pain in May 2016[.]" *Id.* at 2. At the conclusion of the status conference, the presiding special master ordered Petitioner to file outstanding medical records, "particularly those from treatment received in May through October 2017[,] which would help identify the onset of [P]etitioner's pain and those from any treatment of [P]etitioner's arthralgia during the three years prior to vaccination[.]" *Id.* at 3.

On January 4, 2019, Petitioner filed four additional medical records exhibits consisting of a pharmacy record and those of treating specialists, including dermatology and gastroenterology. Pet'r's Exs. 11–14, ECF Nos. 9-1–9-4. The same day, Petitioner submitted an amended statement of completion. ECF No. 11. On April 1, 2019, Respondent filed a status report indicating that Petitioner failed to file medical records related to her treatment of bursitis or tendonitis or from "an orthopedist or other specialty [] related to the treatment in May 2015 through May 2017 for neck and back pain and arthralgia." ECF No. 13 at 2. The presiding special master ordered Petitioner to submit the requested outstanding records or an affidavit, if needed. ECF No. 14. In response, Petitioner filed a supplemental affidavit followed by a statement of completion on May 21, 2019. Pet'r's Ex. 15, ECF Nos. 17–18.

Respondent filed his Rule 4(c) report on September 20, 2019. Resp't's Rule 4(c) report, ECF No. 20. In his report, Respondent argued that this case should be dismissed because Petitioner has not shown by a preponderance of the evidence that she suffered a shoulder injury within forty-eight hours of the injection, nor that the injury was limited to the left shoulder as required by the Table. *Id.* at 10–11. Respondent also argued Petitioner could not show her alleged left shoulder injury was unrelated to her prior tendonitis, bursitis, or prior injury, or, alternatively, that her injury was caused-in-fact by the Prevnar-13 vaccine. *Id.* at 11–12.

On October 9, 2019, this case was reassigned to me. ECF Nos. 21–22. On December 4, 2019, I held a status conference with the parties and discussed the evidence filed to date. *See* Min. Entry, docketed Dec. 4, 2019. During the status conference, "Petitioner acknowledged that there is evidence in the medical records that is inconsistent with [Petitioner's] affidavits." Order at 1, ECF No. 23. At the conclusion of the conference, I ordered Petitioner to submit additional evidence corroborating the onset of her symptoms. *Id.*

[4] Zostavax is not a covered vaccine on the Vaccine Injury Table. *See* 42 C.F.R. § 100.3(a)(XIV).

On February 3, 2020, Petitioner filed two additional affidavits from Ms. Cami Wilson and Mr. Brett Rissler. Pet'r's Exs. 16–17, ECF Nos. 24-1–24-2. The same day, Petitioner submitted a status report highlighting the citations in Petitioner's medical records and supplemental affidavits, which corroborate her argument in favor of onset. ECF No. 25.

I held a status conference with the parties on February 11, 2020. *See* Min. Entry, docketed Feb. 12, 2020. Following the status conference, at the parties' request, I scheduled this matter for a fact hearing on May 28, 2020, to determine the date of onset of Petitioner's left shoulder symptoms. Order at 1, ECF No. 26. Due to the COVID-19 pandemic, the fact hearing was not held as scheduled on that date. Non-PDF Order, docketed May 26, 2020. I rescheduled the fact hearing for July 1, 2021, and it was held as scheduled. ECF No. 29. This matter is now ripe for consideration.

II. Summary of Relevant Evidence

a. Medical Records

Petitioner received the Prevnar-13 vaccine at issue on May 1, 2017. Pet'r's Ex. 1 at 1, ECF No. 5-1. Petitioner's immunization record indicates that she received the vaccine in her left deltoid. Pet'r's Ex. 4 at 1, ECF No. 5-4. At the time of vaccination, Petitioner was fifty-two years old, and her prior medical history was significant for neck pain, Crohn's disease,[5] anxiety, insomnia, sinusitis,[6] gastroesophageal reflux disease ("GERD"),[7] eczema,[8] and sciatica.[9] *See* Pet. at 1; Pet'r's Ex. 5 at 1–16, ECF No. 5-5; Pet'r's Ex. 7 at 1, 4–6, ECF No. 5-7. According to her petition, Petitioner had a "past medical history significant for bursitis[10] of her right shoulder (approximately

[5] Crohn's disease is "one of the principal forms of inflammatory bowel disease, a chronic granulomatous disease of the gastrointestinal tract of unknown etiology; it can involve any part of the tract, but most often is found in the terminal ileum. Characteristics include scarring and thickening of the bowel wall that frequently leads to intestinal obstruction, abscesses, and fistula formation. There is a high rate of recurrence after treatment." *Dorland's Illustrated Medical Dictionary* 1263, 531 (32nd ed. 2012) [hereinafter "*Dorland's*"].

[6] Sinusitis is "inflammation of a sinus, usually a paranasal sinus; it may be purulent or non[-]purulent, acute or chronic. Types are named for the sinus involved." *Dorland's* at 1722.

[7] Gastroesophageal reflux disease ("GERD") is "any condition noted clinically or histopathologically that results from gastroesophageal reflux, ranging in seriousness from mild to life-threatening; principal characteristics are heartburn and regurgitation." *Dorland's* at 533.

[8] Eczema is "any of various pruritic, papulovesicular types of dermatitis occurring as reactions to endogenous or exogenous agents. In acute types there may be erythema, edema, inflammatory infiltrates in the dermis, vesiculation, crusting, and scaling. In chronic types there may be lichenification, skin thickening, signs of excoriation; and areas of hyperpigmentation or hypopigmentation." *Dorland's* at 592.

[9] Sciatica is "a syndrome characterized by pain radiating from the back into the buttock and along the posterior or lateral aspect of the lower limb; it is most often caused by protrusion of a low lumbar intervertebral disk. The term is also used to refer to pain anywhere along the course of the sciatic nerve." *Dorland's* at 1678.

[10] Bursitis is "inflammation of a bursa, occasionally accompanied by a calcific deposit in the underlying tendon; the most common site is the subdeltoid bursa." *Dorland's* at 264.

[twenty-eight] years ago and resolved), [and] tendinitis[11] in both shoulders (approximately [twenty-two] years ago and resolved)." Pet. at 1. Petitioner also reported to medical providers that she suffered a "previous shoulder injury [about twenty] years ago." *See* Pet'r's Ex. 8 at 22, ECF No. 5-8.

On May 3, 2017, two days after receipt of the Prevnar-13 vaccination, Petitioner presented to her gastroenterologist, Dr. Van Dinter, for an "evaluation and second opinion of a new diagnosis of Crohn's disease[.]" Pet'r's Ex. 14 at 329, ECF No. 9-4. During this visit, Dr. Van Dinter noted that Petitioner was taking "daily NSAIDs[12] due to fluctuating oligoasymetric arthritis[13] – shoulders/hips are the most problematic." *Id.* at 330. Dr. Van Dinter opined that Petitioner "likely has [inflammatory bowel disease] ("IBD")[14] associated with arthritis." *Id.* at 332. On May 8 and 10, 2017, Petitioner communicated with Dr. Van Dinter's office via email regarding an MRI to confirm the status of her Crohn's disease. *Id.* at 314. Petitioner did not complain of left shoulder pain during her office visit or email communications with Dr. Van Dinter on these dates. *See id.*

On May 17, 2017, sixteen days after receipt of the Prevnar-13 vaccination, Petitioner presented to her primary care physician ("PCP"), Dr. Bolin, for a two-week history of anxiety. Pet'r's Ex. 5 at 18. Dr. Bolin noted Petitioner's history of GERD and diffuse arthralgia. *Id.* His assessment of Petitioner included "anxiety panic[,] diarrhea[,] GERD[,] allergies[, and] arthralgias[.]" *Id.* Petitioner did not report shoulder pain during this visit. *See id.*

Petitioner communicated with Dr. Van Dinter's office via email on May 23 and June 3, 2017, regarding her MRI testing to confirm the status of her Crohn's disease. Pet'r's Ex. 14 at 293, 308. Dr. Van Dinter indicated that Petitioner's Crohn's disease was "mild." *Id.* at 293. In return, Petitioner wrote that "[s]ymptom wise [she wa]s frustrated." *Id.* Petitioner reported that she was experiencing diarrhea four- to- five- times daily. *Id.* She also reported that "in an effort to reduce stress[,]" she was exercising "more than normal and c[ould not] do any sit ups or ab work without triggering lingering right[-]side pain/twinges." *Id.* Petitioner did not report any complaints of left-sided pain. *See id.*

On June 6, 2017, Petitioner returned to Dr. Van Dinter for a follow-up of her Crohn's disease. *Id.* at 271. Dr. Van Dinter noted that Petitioner had not taken NSAIDs since March 2017, as her arthritis was "better." *Id.* at 275. He also noted that Petitioner had recently received the Prevnar-13 vaccine and she inquired about receiving the Zostavax (shingles) vaccine. *Id.* at 272. Petitioner did not report left shoulder pain during this visit. *See id.* The next day, on June 7, 2017, Petitioner received the Zostavax vaccine in her left arm. Pet'r's Ex. 6 at 1, ECF No. 5-6; Pet. at 2.

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[11] Tendonitis or tendinitis is "inflammation of tendons and of tendon-muscle attachments[.]" *Dorland's* at 1881.

[12] NSAIDs are "nonsteroidal anti-inflammatory drugs. They are any of a large, chemically heterogeneous group of drugs that inhibit cyclooxygenase activity, resulting in decreased synthesis of prostaglandin and thromboxane precursors from arachidonic acid. All NSAIDs have analgesic, antipyretic, and anti[-]inflammatory actions." NSAIDs include ibuprofen, aspirin, and naproxen. *Dorland's* at 1293.

[13] Oligoarthritis or oligoasymetric arthritis is "arthritis of a small number of joints." *Dorland's* at 150.

[14] Inflammatory bowel disease is "a general term for those inflammatory diseases of the intestines that have an unknown etiology[.]" *Dorland's* at 536.

Two days later, on June 9, 2017, Petitioner contacted Dr. Van Dinter via email. Pet'r's Ex. 14 at 256. Petitioner reported that she received a shingles vaccine on June 7, 2017, but did not report any arm pain in the left shoulder or otherwise. *Id.* Petitioner returned to Dr. Van Dinter for a follow-up regarding her Crohn's disease on July 20, 2017. *Id.* at 229. She reported that she was exercising more, and Dr. Van Dinter noted she had "greater exercise capacity/tolerance with less post [] exercise arthralgias." *Id.* at 230. Dr. Van Dinter indicated that Petitioner's Crohn's disease was "improved[.]" *Id.* at 234.

Five months after receiving the Prevnar-13 vaccination, on October 11, 2017, Petitioner presented to her PCP with complaints of "left shoulder discomfort, [and] decrease in mobility[.]" Pet'r's Ex. 5 at 19. Dr. Bolin noted that Petitioner reported the onset of her discomfort after "receiving [the P]revnar vaccine . . . and then shingles vaccine [a] few weeks later[,] uncertain if related[.]" *Id.* Upon examination, Petitioner exhibited full range of motion ("ROM") in her left shoulder. *Id.* Dr. Bolin noted Petitioner had "tenderness to palpation" in the anterior/RC deltoid. *Id.* He assessed Petitioner with left-sided tendonitis. *Id.*

Petitioner presented to orthopedist Dr. Michael Howard on October 17, 2017. Pet'r's Ex. 7 at 1–3. During this visit, Petitioner reported a "history of bursitis ([twenty-five] years ago) and tendonitis ([twenty] years ago), and she previously had injections for both conditions." *Id.* at 1. Petitioner reported that she "started to have pain in her [left] arm after having [two] immunity shots (DOI 06/01/2017). After the shots, her arm became achy, and it has not improved since." *Id.* Dr. Howard noted that "[s]he now has an almost constant achy pain in her volar shoulder around the [acromioclavicular ("AC")] joint,[15] but the pain was originally in her lateral upper arm." *Id.* Upon examination of the left shoulder, Dr. Howard noted that Petitioner exhibited tenderness to palpation, decreased ROM, and positive impingement tests. *Id.* at 2. Dr. Howard diagnosed Petitioner with a "rotator cuff tendinopathy,[16] biceps tendinopathy[,] and [AC] joint tendinitis." *Id.* at 3. He also noted his impression of impingement syndrome,[17] an incomplete rotator cuff tear or rupture, and primary osteoarthritis of the left shoulder. *Id.* at 2. Dr. Howard administered a steroid injection to Petitioner's subacromial joint of the left shoulder and referred her to physical therapy ("PT"). *Id.* at 3.

Petitioner reported to PT at Plano Therapy Center on October 18, 2017. Pet'r's Ex. 8 at 20–25. During this visit, Petitioner reported that her left shoulder pain began on May 1, 2017, with a "gradual onset." *Id.* at 21. She "denied any specific traumatic onset of symptoms." *Id.* at 22. She reported pain when reaching behind, overhead, or in "weird positions." *Id.* Upon examination, Petitioner had "mild ROM deficits, especially extension . . . local weakness, and decreased posterior and inferior glenohumeral joint mobility contributing to aberrant movement patterns and pain." *Id.* at 23. The reporting physical therapist recommended treatment with PT two- to- three

[15] The acromioclavicular ("AC") joint is "the synovial joint between the acromion of the scapula and the acromial extremity of the clavicle[.]" *Dorland's* at 971.

[16] Tendinopathy is "any pathologic condition of a tendon; also called tendinitis." *Dorland's* at 1881.

[17] Impingement syndrome is "a type of overuse injury with progressive pathologic changes resulting from mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff; changes may include reversible edema and hemorrhage, fibrosis, tendinitis, pain, bone spur formation, and tendon rupture." *Dorland's* at 1834.

times per week for eight weeks. *Id.* at 24. Petitioner attended only one additional PT appointment at Plano Therapy Center on October 25, 2017. *Id.* at 30–31.

On October 19, 2017, Petitioner followed up with Dr. Van Dinter regarding her Crohn's disease. Pet'r's Ex. 14 at 192. During this visit, Dr. Van Dinter noted that Petitioner had a history of "[l]eft shoulder pain[.]" *Id.* at 193. Dr. Van Dinter indicated that Petitioner's "[a]rthritis [wa]s better and [she] continue[d] to note improved exercise tolerance – running 2–3 times per week and doing hot yoga[.]" *Id.* He also noted that her Crohn's disease was "[i]mproved." *Id.* at 196.

Petitioner followed up with Dr. Howard on January 16, 2018. Pet'r's Ex. 7 at 4–6. Petitioner reported that following her left subacromial injection, she experienced "a few weeks of relief, but her pain ha[d] returned and [wa]s progressively getting worse." *Id.* at 4. Dr. Howard noted that Petitioner was "unable to reach behind her back or reach over her head." *Id.* Upon examination, Dr. Howard noted Petitioner had a decreased ROM, mild AC tenderness, and positive impingement signs. *Id.* at 5. Dr. Howard's impression was "[a]dhesive capsulitis[,][18] impingement/rotator cuff tendinopathy[, b]iceps tendinitis and superior labral tear[, and AC] arthritis[.]" *Id.* He opined that "[h]er symptoms represent a constellation of mild aggravation and likely adhesive capsulitis." *Id.* Dr. Howard administered another steroid injection and referred Petitioner back to PT. *Id.* at 6.

Petitioner presented to PT at Clair Physical Therapy on January 17, 2018. Pet'r's Ex. 9 at 7. Petitioner reported that she "started having difficulty at her [left] shoulder [with] pain and flexibility in May 2017 after receiving a pneumonia injection in her shoulder." *Id.* Petitioner continued that "her pain got gradually worse over the next few months, [especially] in October [2017.]" *Id.* Petitioner described her pain as a "constant dull, aching pain at her [left] ant[erior]/lat[eral shoulder] that can become sharp/shooting at times." *Id.* at 8. Petitioner also reported intermittent numbness and tingling, that radiated from her left forearm into her left first through third digits. *Id.* The reporting physical therapist recommended continued PT. *Id.* at 9.

Petitioner had an MRI of her left shoulder on January 22, 2018. Pet'r's Ex. 7 at 12–13. Petitioner's clinical history taken during this visit noted that she had been experiencing "left shoulder pain for [six] months." *Id.* at 12. Dr. Ramandeep Singh noted that the findings of the MRI showed Petitioner had "small glenohumeral joint effusion, mild supraspinatus and infraspinatus tendinopathy, mild tendinopathy of the biceps tendon[,] and no tears of the rotator cuff." *Id.* at 13.

On February 13, 2018, Petitioner followed up with Dr. Howard. *Id.* at 7. During this visit, Petitioner reported her "shoulder has improved since the last visit[]" in January 2018. *Id.* She also reported an increased active ROM and strength. *Id.* Upon examination, Dr. Howard noted "mild [AC] tenderness [and n]egative impingement signs." *Id.* at 8. Dr. Howard reviewed Petitioner's January 22, 2018 MRI with her and noted it revealed "mild inflammation in the inferior capsule, thickening of the superior and middle glenohumeral ligaments[,] which can be seen with adhesive

[18] Adhesive capsulitis is "adhesive inflammation between the joint capsule and the peripheral articular cartilage of the shoulder with obliteration of the subdeltoid bursa, characterized by shoulder pain of gradual onset, with increasing pain, stiffness, and limitation of motion. Called also adhesive bursitis and frozen shoulder." *Dorland's* at 286.

capsulitis[.]" *Id.* He assessed Petitioner with "improving" adhesive capsulitis, biceps tendinitis, impingement, and AC arthritis and recommended additional PT. *Id.*

Petitioner reported to physical therapist Mark McBride on February 15, 2018. Pet'r's Ex. 9 at 29. Petitioner indicated that she had attended ten PT appointments so far. *Id.* She reported that her left shoulder "ha[d] been doing much better overall . . . but [she] still ha[d] tightness [with external and internal rotation]." *Id.* at 30. However, Petitioner reported that she felt her ROM was improving. *Id.*

Petitioner followed up with Dr. Howard on March 22, 2018. Pet'r's Ex. 7 at 10. Petitioner reported that she had been attending PT once per week to work on her ROM. *Id.* However, she indicated that she had "pain during and after [PT.]" *Id.* Petitioner acknowledged that her ROM had improved, but not in the last couple of weeks. *Id.* She also reported difficulties getting dressed. *Id.*

Petitioner returned to PT on April 2, 2018. Pet'r's Ex. 9 at 49. Petitioner indicated she had attended nineteen appointments since evaluation. *Id.* During this visit, Petitioner reported her "[left] shoulder [wa]s getting better . . . [and] she only ha[d] pain [with] reaching in certain directions, such as behind her back to clasp her bra, but it [wa]s getting better[,] as was performing her regular daily activities." *Id.* at 50. However, Petitioner exhibited "deficits in strength and ROM[.]" *Id.* at 51. Petitioner did not return to PT after this visit, and she was discharged from PT on May 8, 2018. *Id.* at 5.

On July 16, 2018, Petitioner followed up with gastroenterologist Dr. Van Dinter. Pet'r's Ex. 14 at 5. Dr. Van Dinter noted that Petitioner was taking Celebrex for her left shoulder pain starting in December 2017, but stopped in February 2018. *Id.* He noted that Petitioner felt her use of Celebrex could have affected her Crohn's disease. *Id.* Petitioner has not filed any additional medical records after this date.

b. Affidavits

i. Petitioner's Affidavits

Petitioner has filed two affidavits in support of her claim and testified at the fact hearing. Pet'r's Exs. 1, 15, ECF Nos. 5-1, 17-1; Tr. 9–147. Petitioner attested that she did not have arm or shoulder pain prior to the Prevnar-13 vaccine she received on May 1, 2017. Pet'r's Ex. 1 at 1, 3. In her supplemental affidavit, Petitioner clarified that in May 2015, she reported to her PCP, Dr. Bolin, for neck pain which resolved with medications. Pet'r's Ex. 15 at 1. She noted that in May 2016, she returned to Dr. Bolin for low back pain, which was again resolved with medications, including a Toradol[19] injection. *Id.*

Petitioner wrote that she received the Prevnar-13 vaccine during her annual physical examination on May 1, 2017. Pet'r's Ex. 1 at 1. Petitioner attested that she received the vaccine in

[19] Toradol is "the trademark for preparations of ketorolac tromethamine." *Dorland's* at 1940. Ketorolac tromethamine is "a nonsteroidal anti[-]inflammatory drug [NSAID] administered intramuscularly, intravenously, or orally for short-term management of pain; also applied topically to the conjunctiva in the treatment of allergic conjunctivitis and of ocular inflammation following cataract surgery." *Id.* at 984.

her upper left arm and that "[i]t seemed to be injected with an unusual amount of force and it hurt more than prior vaccinations [she] had received." *Id.* Petitioner wrote that, following the vaccine, her left upper arm was then "sore" and that she "developed a large red welt that was warm to the touch[.]" *Id.* She noted that during the same appointment, she inquired about also receiving the shingles vaccination but was told that her PCP's office "no longer offered it[.]" *Id.*

Petitioner posited that "[a] month later," her "left upper arm/shoulder was still sore to the touch and sometimes it hurt when [she] moved it." *Id.* She explained that she "thought about going to the doctor at this time," but due to her recent Crohn's disease diagnosis, she refrained. *Id.* She wrote, instead, she used "heat and ice on [her] left arm and shoulder and [was] taking Tylenol for the pain[.]" *Id.*

Notably, Petitioner acknowledged that she had an appointment with Dr. Bolin on May 17, 2017, sixteen days following her Prevnar-13 vaccine, for the purpose of discussing her increased anxiety associated with her recent Crohn's disease diagnosis. Pet'r's Ex. 15 at 1. Petitioner agreed that during this visit, Dr. Bolin wrote that she had arthralgias, but she opined "he was referring to [her] hip pain . . . because that is what [she] told the GI doctor as part of [her] Crohn's disease treatment." *Id.* Petitioner wrote that she was experiencing "left arm pain from the vaccination during this time but [] didn't mention it because . . . [she] assumed that it still was the temporary pain associated with vaccinations and that it would resolve itself and [that] it wasn't related to the Crohn's or the anxiety [she] was having." *Id.*

Petitioner wrote that she received the shingles vaccine on June 7, 2017, in her lower left arm, the same arm in which she received her PCV 13 vaccination. Pet'r's Ex. 1 at 1. She attested that she did not receive the injection in her right arm out of concern that she "might end up with two painful arms." *Id.* Petitioner wrote that she experienced "mild soreness in the area of the injection" but that this soreness "was gone in a few days." *Id.*

Petitioner further wrote that throughout the summer of 2017, she noticed "stiffness in [her] left shoulder in the mornings on waking, and [she] had difficulty with certain movements with [her] left arm." *Id.* at 2. She explained that the pain and stiffness in her left shoulder increased in frequency and was "fairly constant" by October 2017. *Id.* She also noted her difficulties with "tasks such as putting on or taking off a jacket[]" and sleeping during this time. *Id.*

Petitioner wrote that she first sought treatment on October 11, 2017, for her left-sided shoulder pain that she "had been having [] since the Prevnar-13 vaccination." *Id.* She indicated that Dr. Bolin prescribed her a Medrol Dosepak,[20] but that it did not relieve her symptoms. *Id.* Petitioner wrote that she then made an appointment with orthopedic surgeon, Dr. Howard, on October 17, 2017. *Id.* Petitioner further wrote that when asked how she injured her shoulder, she reported that "the problems had started with the Prevnar-13 vaccination on May 1, 2017." *Id.* She also noted that she received the shingles vaccine a month later, "but that it was given in a different location in [her] arm and had not hurt like the Prevnar-13 vaccination." *Id.*

[20] A Medrol Dosepak is a prescription of Medrol. Medrol is the "trademark for preparation of methylprednisolone." *Dorland's* at 1120. Methylprednisolone is "a synthetic glucocorticoid [steroid] derived from progesterone, used in replacement therapy for adrenocortical insufficiency and as an anti[-]inflammatory and immunosuppressant in a wide variety of disorders[.]" *Id.* at 1154.

Petitioner continued that, by Thanksgiving 2017, she could not take her coat off, reach behind her to hook her bra, or do certain yoga poses that required her to lift her left arm or extend her left shoulder without "severe pain." *Id.* Petitioner wrote that for insurance purposes, she chose to forego having an MRI until January 2018. *Id.* She noted that Dr. Howard diagnosed her with impingement syndrome, bicipital tendinitis, and adhesive capsulitis of the left shoulder on January 16, 2018. *Id.* Petitioner explained that Dr. Howard recommended treatment with PT, but "[t]he sessions were very painful and each time [she] dreaded having to go." *Id.* at 2–3. Despite this pain, Petitioner admitted her ROM was improving by February 13, 2018, and she "no longer ha[d] pain[]" as of April 2, 2018. *Id.* at 3.

ii. Mr. Brett Rissler's Affidavits

Mr. Brett Rissler submitted two affidavits in support of Petitioner's claim and testified at the fact hearing. Pet'r's Exs. 2, 17, ECF Nos. 5-2, 24-2; Tr. 147–170. Mr. Rissler is married to Petitioner. Pet'r's Ex. 2 at 1. He wrote that Petitioner "came home from work the day of the [Prevnar-13] vaccination [on May 1, 2017,] complaining of pain in her left arm[, and s]he had a large red welt where the shot had been given." *Id.* Mr. Rissler further wrote that Petitioner had pain and discomfort and "was clearly having a hard time sleeping on her left side[]" over the next couple of weeks following the Prevnar-13 vaccine. *Id.*

He continued that "[a]bout a month later," Petitioner received the shingles vaccine in the same arm as the Prevnar-13 vaccine, which "was still bothering her [] from the month before[.]" Pet'r's Ex. 17 at 1. Mr. Rissler attested that Petitioner told him that she received the shingles vaccine "down lower and toward the back of her [left] arm." *Id.* He wrote that Petitioner "didn't complain about pain from the shingles shot like she did with the Prevnar-13 vaccine . . . [and] she didn't form a red welt[.]" *Id.*

Mr. Rissler corroborated Petitioner's difficulties with "certain movements causing her pain and discomfort," including getting dressed, hooking her bra or swimsuit top, or reaching behind her back in the course of her usual activities throughout the summer of 2017. Pet'r's Ex. 2 at 1. He wrote that Petitioner dealt with the pain in her left arm "[f]or months" prior to receiving treatment with Dr. Bolin in October 2017. *Id.*

iii. Ms. Cami Wilson's Affidavits

Ms. Cami Wilson submitted two affidavits in support of Petitioner's claim and testified at the fact hearing. Pet'r's Exs. 3, 16, ECF Nos. 5-3, 24-1; Tr. 172–191. Ms. Wilson is Petitioner's colleague as a clinical dietician. Pet'r's Ex. 3 at 1. Ms. Wilson attested that Petitioner first reported pain and decreased mobility in her upper left arm and shoulder following her receipt of the Prevnar-13 vaccine on May 1, 2017. *Id.* Specifically, Ms. Wilson wrote that she "remembere[d] the day [Petitioner] got the Prevnar shot because she was complaining to [her], saying it was the worst shot [Petitioner had] ever had due to the pain and soreness associated with it." Pet'r's Ex. 16 at 1.

Ms. Wilson wrote that Petitioner's "mobility complaints progressed over the course of about a year . . . [and b]y the summer time, . . . [Petitioner] found it difficult to put her jacket on[.]" Pet'r's Ex. 3 at 1. She also noted that Petitioner's arm and shoulder "started out as sore/tender, and

[she] would often see [Petitioner] rubbing/massaging her left shoulder." *Id.* Ms. Wilson corroborated that Petitioner had increased pain in the fall of 2017. *Id.*; *see also* Pet'r's Ex. 16 at 1.

Regarding Petitioner's shingles vaccination she received on June 7, 2017, Ms. Wilson noted that Petitioner explained that she received the shingles vaccine also "in the left arm[]" because "the [left] arm already hurt[,] and she didn't want both arms hurting[]" during that time. Pet'r's Ex. 16 at 1. Ms. Wilson wrote that Petitioner received a flu vaccine in October 2017, but chose to get it in her right arm because the pain associated with her Prevnar-13 vaccine had not subsided on her left side. *Id.*

c. Testimony

i. Petitioner

Petitioner began her testimony by explaining her prior history of shoulder, back and neck pain. She described pain decades prior from working as a waitress and carrying her daughter when she was a small child. Tr. 15–16. That pain, she testified, resolved years prior to the start of her post-vaccination pain. Tr. 17:11–19. Petitioner then discussed her treatment for neck pain and back pain in May of 2015 and 2016, respectively. Tr. 18:17–25, 19:1–12, 18–23. She testified that "it wasn't to do with my shoulders at all." Tr. 19:20–21. The pain was "on [her] back, like on either side of [her] neck, that muscle that sits there right on the top." Tr. 19:18–19. The doctor "called it the trapezius muscle that was spasming." Tr. 19:22–23.

At the time that Petitioner got her PCV 13 vaccine, she was dealing with her recent Crohn's disease diagnosis. She testified that the diagnosis "caused me anxiety. It made me question, you know, my health in general." Tr. 23:14–15. Petitioner remembered very specific details about her vaccination. Petitioner testified that through the course of her care at her PCP's office, she recognized the nurse that administered the vaccine and described her as "a little hyper nurse" that is always "high energy." Tr. 27:24. Petitioner noted that for this vaccination she was sitting on the examination table, but with "all the immunizations [she's] gotten, [she] rarely ever g[o]t on immunization in the doctor's office." Tr. 26:24–25, 27:1. She described the color of the needle and said that she thought that it was "big shot." Tr. 28:6–15. Petitioner said she tried to relax and didn't "want to tense up when the needle [wa]s coming close." Tr. 29:5. Petitioner explained that she looked away, but she remembered grabbing the table with her right hand because she "felt the force." Tr. 29:7–8. Petitioner stated that the needle went into her skin at an angle pointing up. Tr. 29:13–14. She testified that "[i]t hurt like a shot has never hurt." Tr. 29:15–16. Petitioner did not have a specific recollection of discussing her pain the day of vaccination, but testified that "I can't believe I wouldn't have mentioned to [Ms.Wilson] how bad that shot hurt. And then I definitely remember talking to her when I got the shingles shot because I was just kind of relieved how easy that shot went" when compared to the Prevnar-13 shot. Tr. 10–14.

Petitioner testified that she "couldn't sleep on that arm," the night of her Prevnar-13 vaccine. Tr. 31:15. The next day, she noticed a welt and "definitely a lot of pain, more pain than normal." Tr. 31:24–25. In the following days, Petitioner stated that she noticed that her left arm hurt, but she decided to minimize use of it because she is right-hand dominant. Tr. 33:20–24. She did not go to the hospital and considered,"[w]as [the pain] a seven or eight? No, because I was

able to isolate it and not really use that arm." Tr. 34:18–19. The pain was not hindering Petitioner's ability to do her everyday things, and she self-medicated. Tr. 49–50.

When asked why she did not bring up her shoulder pain at her doctor's visit two days post vaccination on May 3, 2017, Petitioner noted that Dr. Van Dinter is a gastroenterologist that was treating her Crohn's disease. Tr. 36:7–8. According to Petitioner, it did not make sense to her to talk to Dr. Van Dinter about her shoulder pain, because it was unrelated to her Crohn's and outside of his area of expertise. Tr. 36:8–10. Petitioner also explained that she "didn't even entertain going to a doctor [for her shoulder pain] because it's not like they can take the shot away," and due to her autoimmune disease, she is unable to take commonly prescribed pain medications. Tr. 38:12–14. She did not want to be perceived as a "pain seeker." Tr. 38:15–16. Despite this assertion, Dr. Van Dinter noted in the visit notes that Petitioner was taking NSAIDs for shoulder/hip pain due to her fluctuating oligoasymetric arthritis during this time. Pet'r's Ex. 14 at 330. Petitioner described talking to Dr. Van Dinter and clarified that if she felt aches and pain in her hips, she "would mindlessly pop a Motrin and just chalk it up to getting older." Tr. 40:13–24. She did not "recall at this visit talking about [her] shoulders because that pain was more like — you know, it was kind of achy hip kind of pain." Tr. 40:15–18. She testified that she "ha[d] no idea why he put [a note about her shoulder] in there." Tr. 42:16–17. Petitioner said although she was experiencing shoulder pain at this time, it was not related to the arthritis pain she was experiencing in her hips, which Dr. Van Dinter proposed could also be an inflammatory result of her Crohn's disease. Tr. 39:25–42:17. She noted that prior to her Prevnar 13 vaccination, and even leading up to this appointment with Dr. Van Dinter, she was not "having any shoulder achiness or [symptoms that she] would consider arthritic . . . just [] achiness in [her] hips[.]" Tr. 42:18–24.

Petitioner described her appointment with PCP, Dr. Bolin, and discussed the anxiety she felt about upcoming testing related to another possible autoimmune disease, rheumatoid arthritis ("RA").[21] Tr. 46:12–14. She did not discuss the shoulder pain during that appointment because she was wholly focused on the anxiety related to her Crohn's and test results for RA. Tr. 47:1–16. Petitioner "wouldn't say [the shoulder pain] was resolved, but it wasn't to the point of pain like after the first couple weeks of the shot either." Tr. 11–13. During the month of May and into June, Petitioner testified that she self-medicated with Tylenol, heat, and ice. Tr. 49:16–20. Specifically, Petitioner remembered using Tylenol "four or five times out of the week." Tr. 51:1–2.

Leading up to her shingles vaccination, Petitioner stated that she did not want to risk having arm pain in both arms. Tr. 52:4–6. She testified that she decided to get the shingles vaccine in the left arm because it was already hurting, and unlike the inter-muscular PCV 13 vaccination, the shingles vaccination was subcutaneous.[22] Tr. 52:9–13; *see also* Pet'r's Ex. 6 at 1 (noting that

[21] Rheumatoid arthritis is "a chronic systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction of the bones. In late stages, deformity and ankylosis develop. The cause is unknown, but autoimmune mechanisms and virus infection have been postulated." *Dorland's* at 157.

[22] It is well-established in the Program that a SIRVA is limited to injuries following intramuscular injections only, not subcutaneous injections. *See* 42 C.F.R. § 100.3(c)(10) (indicating that "SIRVA manifests as shoulder pain and limited [ROM] occurring after the administration of a vaccine intended for intramuscular administration in the upper arm."); *see also Small v. Sec'y of Health & Hum. Servs.*, No. 15-478V, 2019 WL 6463985, at *11 (Fed. Cl. Spec. Mstr. Nov. 1, 2019) (finding that the petitioner's "influenza vaccination

Petitioner's shingles vaccine was subcutaneous). Petitioner explained that she understood the difference between an inter-muscular injection, such as the PCV 13 shot or her Humira shots, and subcutaneous injections. Tr. 51:11–17. She noted that "[t]he shingle [sic] shot was a sub-Q. So[,] it means it just goes underneath the skin; it doesn't need to go into a muscle." Tr. 51:16–18. Petitioner clarified that she didn't know that the shingles vaccination was different than the PCV 13 vaccine before her appointment, but the person who administered the vaccine, told her that she could get the shingles injection on the lower, fatty part of her arm. Tr. 53:9–15. Unlike her PCV 13 vaccine, Petitioner testified that there was no pain following the shingles vaccination, and she did not develop any redness or swelling in the area. Tr. 55:23–25.

Throughout June and July 2017, Petitioner continued to experience shoulder pain, but she did not have any regularly scheduled appointments with her PCP and did not feel it necessary to schedule an appointment for her shoulder pain alone. Petitioner testified, "it was achy, and it — I want to say, the pain at this point had kind of evolved." Tr. 61:8–9. She continued that her "arm didn't hurt that bad anymore to touch where the area of the shot went into, but the achiness, it kind of just — it kind of just drifted up into the shoulder and it was just kind of a — like a dull ache." Tr. 61:10–13. Petitioner was unable to say why she did not approach her doctor about a cortisone shot similar to the one she received for her pain in previous decades. She stated, "I didn't even think along those lines." Tr. 63:14–15.

Petitioner described "a lightbulb moment" in September 2017, that finally convinced her to go see her PCP. Tr. 66:16–19. She explained that she was in the car with her husband, and she tried to reach behind the front seat to grab a water from the cooler in the back. Tr. 9–12. Petitioner stated that "[i]t was just too painful" for her to reach, and she had to unbuckle her seatbelt to get the water for him while he was driving. Tr. 66:20–21. Petitioner explained that when she did go see Dr. Bolin in October, she related her pain back to the PCV 13 shot "because the shot was so painful" at the time of vaccination and thereafter. Tr. 68:23–25.

Petitioner testified that she told Dr. Howard her pain began in May 2017 because that was the month of the PCV 13 vaccination. She testified that she "[doesn't] know why he put 6/1/2017, because that's not the date of either one of those shots." Tr. 71:3–5. Petitioner noted that at that time of vaccination, she "didn't even know about the shot court." Tr. 71:12. She said, "okay, [the pain is caused by] one of these shots, you know, like something's — you know, of course, the first one, this was the one that made sense because it hurt so bad and it was hurting for a full month before I got the second shot, the shingles shot. So yeah, I just kind of jointly talked about the two shots together." Tr. 71:14–19.

Petitioner testified that the cortisone shot that she received in October 2017 helped her with the pain, "but not as dramatic as it had in the past." Tr. 74:20. She explained that the shot lessened the pain but did not alleviate it completely. Tr. 74:5–19. She described the pain "like [] a headache in my shoulder." Tr. 75:15. That pain turned into a "sharp, shooting pain" towards Christmas time

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was intramuscularly administered[,] and her shingles vaccine subcutaneously administered. Therefore, to the extent petitioner suffered any vaccine-related [shoulder] injury, her flu vaccine would have been more likely than her shingles vaccine to have caused her injury."). I find the same is true here. To the extent that Petitioner suffered a SIRVA, her intermuscular flu vaccine is more likely than her subcutaneous shingles vaccine to have caused her shoulder injury.

and "it felt like somebody was pulling [her] arm out of [her] socket like the pain that just takes your breath away." Tr. 75:16, 19–21. Specifically, Petitioner discussed "making Christmas cookies" and stated, "I reached up . . . just without even thinking." Tr. 82:15–17. She said the pain "knock[ed] the wind out of me," and she then believed she needed to schedule the MRI that her doctor previously referred her for. Tr. 82:21–24.

Petitioner was asked about her experience with physical therapy. She testified that she described the pain at the beginning of her physical therapy as stabbing, burning, and achy. Tr. 86:14–15. She explained that the experience was "degrading and it hurt like hell." Tr. 90:22. Petitioner felt like she could do the exercises at home. Tr. 90:25. Now, Petitioner says it "feel[s] like I have really good range of motion" and no pain. Tr. 93:4–6.

On cross-examination, Petitioner was asked why she did not bring up her injury from the Prevnar-13 vaccination during her receipt of the shingles vaccination. She said she was "not going to complain about a shot to a doctor. I just didn't want to seem whiney." Tr. 118:16–17. Petitioner also clarified the tingling and numbness that she felt following the PCV 13 vaccine. She described it as a tingling sensation she would feel occasionally at night. Tr. 130:23–24. Petitioner also described tingling when "reaching up above" accompanied by "a quick, sharp pain." Tr. 131:13–14. This type of pain first began, according to Petitioner, in the summer of 2017. Tr. 132:3–4. During the summer, the tingling occurred at night, but "as October, November's rolling around, December, that's when [she was] like going, okay, when [she] made a movement with that arm, [she would] feel some tingling." Tr. 133:6–8.

I asked Petitioner to help me establish a chronology for her NSAID use leading up to and around the time of her Prevnar-13 vaccination. She testified that she was "one of these people if [she] had an ache, [she] would pop a pill. Pop an NSAID." Tr. 125:25, 126:1. Petitioner asserted that she stopped taking NSAIDs in March 2017, pre vaccination, because her doctor told her they "were causing [her gastrointestinal] issues[]" related to her Crohn's disease. Tr. 126:7.

ii. Mr. Brett Rissler

Testifying on behalf of his wife, Mr. Rissler reiterated the account he provided in his affidavits. He explained that on May 1, 2017, Petitioner's left shoulder was "definitely sore to the touch [and s]he [] had some stiffness[.]" Tr. 151:8–9. He specifically focused on his wife's inability to sleep due to the pain. Tr. 153:8–14. Mr. Rissler said, "she definitely had pain, discomfort, limitations. It was affecting her sleep as well. She wouldn't be able to lay on her side and she was typically a side sleeper." Tr. 153:13–14. He added that in the weeks immediately following her vaccination, he would see Petitioner "sitting watching TV and [he] would look over and [he] would see her rubbing [her arm] and working it too, as well." Tr. 153:21–23. Mr. Rissler said his wife is "not a complainer" and noted "we didn't really talk about it much that way and her focus was really kind of dealing with the Crohn's diagnosis and everything around that." Tr. 153:24–25, 154:1.

Generally, Mr. Rissler testified that his wife's pain "was intermittent so it wasn't, you know, a constant daily complaint or anything." Tr. 157:12–13. He continued, that "it seemed to

oddly progress[,] and it would be — it would wax and wane a little bit where some days or weeks it would be less noticeable but always there." Tr. 157:14–17.

Mr. Rissler also remembered when Petitioner received the shingles vaccination. He described their conversation about her getting that vaccine in the same arm as the PCV 13 vaccine. He explained that Petitioner wanted the shot in the "[s]ame shoulder, so if there was [sic] problems and discomfort, it would be just one shoulder. She's very dominant right-handed so she didn't want to risk anything going on that way for work or anything else." Tr. 155:8–12. Mr. Rissler testified that eventually, he told his wife that she needed to make an appointment with her doctor, and in "late September, early October" she went to see Dr. Bolin. Tr. 158:23. Mr. Rissler described Petitioner's response to the physical therapy prescribed by Dr. Bolin and noted that the physical therapy "was very difficult for her, not only the pain, but just the emotional side of it, the frustration with even having to deal with it as well." Tr. 159:23–25.

After her Prevnar-13 vaccine, Mr. Rissler and his wife shifted from "an equal partnership when it came to taking care of the house," to Mr. Rissler taking on more responsibilities, particularly when it came to yardwork and other things outside. Tr. 161:13–17. Mr. Rissler corroborated that in the summer of 2017, he began needing to help his wife "with her shirt or a couple times just even getting her bra on [because s]he couldn't reach back to her back very consistently that way." Tr. 162:4–6.

iii. Ms. Cami Wilson

Ms. Wilson testified consistent with her affidavits. She provided a timeline for Petitioner's pain progression. She stated that she noticed "initially, [Petitioner complained to her about] just soreness . . . [which she thought Petitioner] kind of babied [] a little bit." Tr. 176:1–4. Ms. Wilson explained that the day after Petitioner's Prevnar-13 vaccine, Petitioner told her that "there was this sharp pain. Any time [Petitioner] touched it, it was very, very painful to touch." Tr. 175:15–17. Ms. Wilson was not sure if this conversation took place on the day Petitioner received the vaccine, or the next day. Tr. 175:4–6. She stated that she did not see the red welt on Petitioner's arm because they "often wear[] long sleeves at work[,]" but that Petitioner "just talked [to her] about it." Tr. 175:20–23. But then by summer, Ms. Wilson observed that Petitioner "started losing some mobility," and she could not reach behind her back to put on a coat when it was cold in their office. Tr. 176:7–14.

Ms. Wilson noted that, at one point, Petitioner "was losing sleep with her coming in late." Tr. 182:23–24. Petitioner told Ms. Wilson that she would "wake up [with] this sharp pain and it would kind of take her a while to like fall back asleep." Tr. 183:2. Ms. Wilson said Petitioner was running on low sleep and she was taking Ambien, but it did not help. Tr. 182:24–25. Ms. Wilson testified that "towards the fall, definitely into the winter, she was having a hard time — she was like 'I had to go and buy new bras' because she was having a hard time reaching back behind her." Tr. 183:9–12. Ms. Wilson explained that Petitioner "was just altering her work schedule, coming in later, staying later in the day and then also just kind of changing her habits of — due to mobility problems towards the fall." Tr. 183:14–17.

I asked Ms. Wilson to tell me how she remembered the year of Petitioner's vaccination. She testified that "the affidavit helped, but I would have said it was — we— I can remember the time frame of where we were in the office." Tr. 189:22–24. She continued that "[s]he and I have moved into four different offices in the seven years that I have been there, so we — I'm able to remember around what time frame that happened based on the office that we were in." Tr. 189:24–15, 190:1–2.

Ms. Wilson was also asked if she spoke to Petitioner about her testimony and she responded, "at the end of the day, I would always tell her, like, it's — what happened to you[.] I don't know what happened to you because I'm not her. I can only speak on the things that I saw and that I — I saw her [do] or she told me." Tr. 186:3–7.

III. Applicable Legal Standard

To receive compensation under the Vaccine Act, Petitioner must demonstrate either that: (1) she suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that she suffered an "off-Table injury," one not listed on the Table as a result of her receipt of a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006).

The Vaccine Injury Table considers a SIRVA a presumptive injury for the Prevnar-13 vaccine if the first symptom or manifestation of onset of the illness occurs within forty-eight hours of an intramuscular vaccine administration. *See* 42 C.F.R. § 100.3(a)(XIV). The Qualifications and Aids to Interpretation ("QAI") further specify:

> A vaccine recipient shall be considered to have suffered a 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). If, Petitioner is unable to succeed on a Table claim, Petitioner may, alternatively, prove that her injury was caused-in-fact by a Table vaccine. In order to succeed on a theory of causation-in-fact, Petitioner would have to show:

> by preponderant evidence that the vaccination brought about [the] 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.

See Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. § 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993). Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole, 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. § 13(b)(1).

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). This is because "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.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Hum. Servs.*, 933 F.2d 1525, 1528 (Fed. Cir. 1993). Indeed, contemporaneous medical records are ordinarily to be given significant weight due to the fact that "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." *Id.* However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition.). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

Judges of the Court of Federal Claims have reaffirmed the finding in *Cucuras* that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. *See*, *e.g.*, *Doe/70 v. Sec'y of Health & Hum. Servs.,* 95 Fed. Cl. 598, 608 (Fed. Cl. 2010) (stating "[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y*

of Health & Hum. Servs., 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion)*; Doe/17 v. Sec'y of Health & Hum. Servs.*, 84 Fed. Cl. 691, 711 (2008); *Ryman v. Sec'y of Health & Hum. Servs.*, 65 Fed. Cl. 35, 41-42 (2005); *Snyder v. Sec'y of Health & Hum. Servs.*, 36 Fed. Cl. 461, 465 (1996) (stating "[t]he special master apparently reasoned that, if Petitioner suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Petitioner during his life to date. Finding Petitioner's medical history silent on his loss of developmental milestones, the special master questioned Petitioner's memory of the events, not her sincerity."), *aff'd*, 117 F.3d 545, 547–48 (Fed. Cir. 1997).

For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete. To overcome the weight of medical records, testimony is required to be "consistent, clear, cogent, and compelling." *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998).

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (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 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

When weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than oral testimony. *Cucuras*, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993). However, compelling oral testimony may be more persuasive than written records. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.") (citation omitted), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992).

IV. Discussion

a. Date of Initial Complaint of Injury

Although Petitioner has not alleged a Table claim, the accompanying QAIs for a SIRVA Table claim are nonetheless informative and help frame the analysis of the facts currently in dispute, namely the onset of pain. Despite the lack of contemporaneously created medical records immediately following Petitioner's PCV 13 vaccine, I find she has provided preponderant evidence that she experienced pain consistent with SIRVA within forty-eight hours of injection. It is true that Petitioner does not have medical records that document a complaint of shoulder pain consistent with SIRVA to a medical provider for more than five months post vaccination. However, when Petitioner did initially complain about the relevant shoulder pain in October 2017 and thereafter, she consistently related it back to her PCV 13 vaccination. Petitioner credibly explained that she did not seek treatment immediately because she has received vaccines in the past and expected some degree of soreness and pain. She also testified that she was more concerned about her recently diagnosed autoimmune disease and did not want to seem as though she was complaining about a routine vaccine to a specialist. Although contemporaneous medical records often contain evidence that is contradictory to a petitioner's claim, the lack of medical records or treatment is not *per se* evidence that a petitioner was not suffering from an injury. *See* 42 U.S.C. § 300aa-13(b)(2); *see also Kirby*, 997 F.3d at 1383. Indeed, it is not uncommon in the Program for individuals not to seek treatment immediately for shoulder pain post vaccination. *See*, *e.g.*, *Lang v. Sec'y of Health & Hum. Servs.*, No. 17-995V, 2020 WL 7873272, at *11 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (citing *Forman-Franco v. Sec'y of Health & Hum. Servs.*, No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec'y of Health & Hum. Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); *Gurney v. Sec'y of Health & Hum. Servs.*, No. 17-481V, 2019 WL 2298790 (Fed. Cl. Spec. Mstr. Mar. 19, 2019)). In fact, it is not at all unusual for people not to seek immediate medical care for an injury consistent with SIRVA. *See*, *e.g.*, *Hanna v. Sec'y of Health & Hum. Servs.*, No. 18-1455V, 2021 WL 3486248 (Fed. Cl. Spec. Mstr. July 15, 2021) (citing *Lang*, 2020 WL 7873272, at *10 (noting that "[R]espondent's expert has conceded that there is no such thing as an 'appropriate' time to seek treatment" for SIRVA); *Smallwood v. Sec'y of Health & Hum. Servs.*, No. 18-291V, 2020 WL 2954958, at *10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (finding that it is "common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own.")). It is also reasonable that an individual seeing a gastroenterologist for treatment of Crohn's disease may decide not to discuss a recent joint injury. Petitioner has therefore presented a logical explanation for her delay in seeking medical treatment.

Petitioner gave a very detailed, credible account of her vaccination, which trumps the lack of contemporaneous medical records post vaccination. *See Blutstein,* 1998 WL 408611, at *5. She described the nurse who administered the shot, her location in the room, and the color and size of the syringe and needle. She described her behavior in the moments leading up to the vaccination and the way the needle felt as it entered her arm. Petitioner also described the subsequent lingering pain in her arm and the red welt that formed at the injection site. Petitioner provided contextual details throughout her testimony, including during her discussions of her Crohn's disease and interactions with family and coworkers, that bolstered her credibility.

Her fact witnesses also presented credible evidence to support Petitioner's assertion that she complained of pain within a day of her vaccination. *See id.* Mr. Rissler corroborated Petitioner's account in a filed affidavit and during his consistent and credible hearing testimony, as did Petitioner's co-worker, Ms. Wilson. Ms. Wilson's testimony was also credible in its context. Ms. Wilson testified that while she did not see the welt, she remembered Petitioner describing the pain and redness she experienced immediately after her vaccination. Ms. Wilson testified that she could not remember if the conversation she had with Petitioner was the same day as the vaccine, or the day after, but was confident that it was one of those days. She did remember the year and the time of year however, because she and Petitioner had changed offices several times during that period. Ms. Wilson explained that she could remember when the conversation occurred based on the location of her office space. Ms. Wilson's ability to relate her conversation with Petitioner back to a specific time of year and place, even though it occurred several years ago, is reasonable and persuasive. Therefore, I find that Petitioner has established it more likely than not that she experienced shoulder pain within forty-eight hours of vaccination.

b. Table Claim

The majority of SIRVA injuries seen in the Program are presented as Table claims. However, in this case, a Table claim is not before me, because Petitioner does not state a claim based on a Table injury. Instead, she asserts in her petition that her "left shoulder impingement, adhesive capsulitis, tendinopathy, tendinitis, superior labral tearing, and the debilitating pain, weakness, and restricted range of motion associated with these conditions [] were caused-in-fact by the vaccination." Pet. at 1. Although Petitioner has presented preponderant evidence of shoulder pain within forty-eight hours of vaccination, this Ruling does not reach whether Petitioner's pain was caused-in-fact by her Prevnar-13 vaccination.

For her claim to be successful, Petitioner must still establish by preponderant evidence that her shoulder pain resulted from her vaccination rather than from any of her pre-vaccination conditions. Petitioner's medical records include several related conditions and ailments that preceded her vaccination, including a history of neck and low back pain, and arthralgias associated with Crohn's disease. Furthermore, Dr. Van Dinter noted two days post vaccination that Petitioner had fluctuating arthritis in her shoulders and hips. Pet'r's Ex. 14 at 330. This record was contradicted by later evidence[23] that showed she stopped self-medicating with NSAIDs for arthritis-related pain in March 2017, and any arthritis pain at that time was limited to her hips. However, the inconsistencies in the record with regard to Petitioner's pre-vaccination history of

[23] Petitioner's medical records indicate that she had been diagnosed with, and was self-medicating with NSAIDs for, asymmetric oligoarthritis in her shoulders and hips prior to vaccination. Petitioner testified that the arthritis pain she was experiencing at the time of her May 3, 2017 appointment with Dr. Van Dinter was only in her hips. Tr. 40:15–18. She was unsure why Dr. Van Dinter noted she was taking NSAIDs for arthritic shoulder pain at that time. Tr. 42:16–17. Petitioner also clarified that she took Motrin as needed for general aches and pain, but discontinued her NSAID use in March of 2017, two months prior to her PCV 13 vaccination due to concerns related to her Crohn's disease. Petitioner's medical records are less helpful on this point because a record from her evaluation with Dr. Van Dinter two days post vaccination documents continued daily NSAID use, Pet'r's Ex. 14 at 330, while a subsequent record from the same provider from a June 2017 visit, notes that Petitioner ceased all NSAID use in March 2017. *Id.* at 275.

shoulder problems must be fleshed out and reconciled in order for her vaccine-caused shoulder injury claim to be successful.

V. Conclusion

Based on the above reasoning, I find that the evidence submitted by Petitioner establishes by a preponderant standard that she experienced an onset of left-sided shoulder pain within forty-eight hours following her PCV 13 vaccination. Without expert testimony, I am unable to reach a decision regarding the cause of said injury. Accordingly, Petitioner has fourteen (14) days from the filing of this Ruling to file a status report indicating how she wishes to proceed.

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master