

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-736V

Filed: November 6, 2019

CAROLYN ORRELL,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Ruling on Entitlement; Table Injury;
Influenza Vaccination; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Michael G. McLaren, Black McLaren, et al., Memphis, TN, for petitioner.

Dhairya Divyakant Jani, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Special Master:

On June 2, 2017, Carolyn Orrell (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”) as a result of a November 7, 2014 influenza (“flu”) vaccination. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

On July 31, 2019, respondent filed a motion to amend the schedule, requesting the opportunity to pursue additional evidence prior to a determination of entitlement.

¹ The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

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

ECF No. 55. Petitioner filed a response, and a counter-motion for a Ruling on the Record. ECF No. 56.

For the reasons set forth below, respondent's motion is denied. Additionally, based on the record as a whole and for the reasons set forth below, the undersigned finds by preponderant evidence that petitioner is entitled to compensation.

I. Procedural History

Following the filing of the June 2, 2017 petition, petitioner submitted medical records, an affidavit, and a statement of completion on June 6, 2017. ECF Nos. 7, 8. Additional outstanding records were filed on August 9, 2017, along with an amended statement of completion. ECF Nos. 10, 11.

Due to numerous subsequent delays and failure to comply with court orders, respondent was ordered to show cause why petitioner was not entitled to compensation by filing a Rule 4(c) Report by Wednesday, February 28, 2018. ECF No. 20.

Respondent filed a Rule 4(c) Report recommending that entitlement be denied in this case on February 1, 2018. ECF No. 23. Respondent's conclusion was based in part on petitioner's delay in reporting left shoulder pain and seeking treatment. *Id.* 8-9. Respondent also argued that there was evidence petitioner's pain and reduced range of motion were not limited to her left shoulder, citing a fall that occurred on August 12, 2015 (10 months after petitioner's vaccination), wherein petitioner injured her right shoulder and ultimately underwent surgery. *Id.* at 8.

On February 21, 2018, petitioner was ordered to submit additional evidence addressing the onset of her injury and the accompanying delay in seeking treatment. ECF No. 24. On February 23, 2018, petitioner submitted three affidavits addressing the onset of her injury. Exs. 6-8.

On April 26, 2018, petitioner filed a joint status report indicating that respondent was willing to engage in settlement negotiations at that time. ECF No. 28.

A status conference was held on October 12, 2018, to discuss the parties' positions. ECF No. 41. At the time, it was noted that causation and entitlement had not been decided and discussed whether a ruling on the record could be useful as opposed to an entitlement or fact hearing. Respondent's counsel indicated that onset of petitioner's injury was the only issue affecting respondent's view of this case as a SIRVA. Petitioner's counsel stated that petitioner may be amendable to a ruling on the record with regard to onset.

On October 15, 2018, petitioner filed a Motion for a Factual Finding as to Onset of SIRVA Within 48 Hours of Vaccination. ECF No. 42. Respondent filed a response on November 30, 2018. ECF No. 43. Respondent stated that a fact hearing would be beneficial to assess the credibility of the witnesses, "particularly given the inconsistencies between the affidavits and the contemporaneous medical records..." *Id.* at 1 n.1. It is unclear what inconsistencies respondent was referencing.

A fact hearing was held on June 4, 2019. At the conclusion of the proceeding, the undersigned issued a ruling from the bench finding that the onset of petitioner's injury was within 48 hours of her November 7, 2014 flu vaccination and that the vaccination was administered in petitioner's left arm. Hearing Transcript ("Tr."), ECF No. 52 at 125-128; Ruling on Facts and Scheduling Order ("Fact Ruling"), ECF No. 54, at 2.

The parties were ordered to file additional evidence regarding entitlement by August 1, 2018. Fact Ruling at 3.

On July 31, 2019, respondent filed a Motion for Additional Record Development, seeking deposition testimony, computer records, and additional medical records. Respondent's Motion for Additional Record Development ("Res. Mot.") ECF No. 55 at 5-8. Petitioner filed a response and a motion for a ruling on the record on August 1, 2019. Petitioner's Response to Respondent's Motion to Amend Schedule for Additional Record Development and Petitioner's Counter-Motion for a Ruling on the Record ("Pet. Mot.") ECF No. 56. No further responses or replies were filed and the matter is now ripe for adjudication.

This case was transferred out of the SPU to the undersigned's non-SPU docket on September 30, 2019.

II. Factual History

A. Petitioner's Medical Records

Petitioner received a flu vaccination on November 7, 2014. Ex. 2 at 337. That same day, petitioner was seen for a follow-up for pneumonia. There is no reference to any shoulder pain at that time. *Id.* at 330.

On November 21, 2014, petitioner was seen for lower back pain that had occurred since 2010. Ex. 3 at 38. The record does not indicate petitioner complained of shoulder pain.

On December 2, 2014, petitioner was seen by an orthopedist for bilateral hand pain, particularly at the base of her thumbs. Ex. 3 at 35. Petitioner was diagnosed with advanced bilateral thumb carpometacarpal joint disease.

On December 9, 2014, petitioner began physical therapy for lower back pain and radiculopathy in her lower left extremity. Ex. 3 at 52. Petitioner did not indicate she was experiencing shoulder pain at that time. In addition, petitioner's lower extremity pain was indicated as stemming from arthritis. Ex. 4 at 16.

Petitioner first complained of left shoulder pain on January 20, 2015, when she was seen for a physical therapy session regarding her lower back. Ex. 4 at 73. The therapist noted that petitioner reported left shoulder pain that she wanted the therapist

to look at it. The therapist noted “briefly screened L[eft] shoulder: AROM WNL, IR is painful, MMT L scaption and ER 4/5. Issued s/l EF and standing scaption for HEP for the L shoulder but if she continues to have trouble with the shoulder she should contact MD.” *Id.*

On March 5, 2015, petitioner was seen by her primary care physician. At that time, she reported “[p]ain in shoulder after flu shot, still there.” Ex. 2 at 368. The physician also noted that petitioner was seeing a physical therapist for her legs, and has arthritis in her hands, for which she saw an orthopedist. *Id.*

Petitioner saw an orthopedist, Dr. Roy Majors, for left shoulder pain on April 10, 2015. Petitioner stated that she had been experiencing the pain for over five months. Ex. 3 at 32. Dr. Majors noted that petitioner’s shoulder “really started to bother her to move” and that “[a]bout a month ago she got a flu injection,³ and that really seemed to aggravate it.” *Id.* Petitioner reported the pain as dull, aching, and aggravated by reaching and grasping overhead. *Id.* Upon examination, petitioner’s left shoulder was positive for impingement, exhibited pain with abduction across the plane of the chest. *Id.* At that time, petitioner showed “[g]ood strength though painful”. *Id.* Petitioner was assessed with rotator cuff tendinitis in her left shoulder, and possibly a “cuff tear.” *Id.*

On August 12, 2015, petitioner injured her right shoulder in a fall. Ex. 2 at 1089, 1094. A physical exam noted right shoulder tenderness with deformity posterior dislocation, and petitioner was diagnosed with a shoulder dislocation. *Id.* at 1091. There is no indication that the fall injured petitioner’s left shoulder.

On August 21, 2015, petitioner was seen again by Dr. Majors for an evaluation of her recently injured right shoulder. Ex. 3 at 29. Petitioner’s left shoulder was also evaluated at that time. Dr. Majors noted that petitioner had an injection several months previously in her left shoulder that “seems to be wearing off. She is having some soreness on the left.” *Id.* An examination of petitioner’s left shoulder showed full motion with positive impingement, reduced strength, and crepitation with range of motion. *Id.*

Petitioner underwent arthroscopic surgery on her right shoulder on September 10, 2015. Ex. 3 at 45. On September 11, 2015, petitioner was seen for a follow-up of her right shoulder. *Id.* Dr. Majors noted that petitioner “does have some ongoing impingement problems on the left, and she did want an injection.” *Id.* An injection of xylocaine and Kenalog was performed.

Petitioner was next seen on November 11, 2015, for a follow up for her left shoulder. Dr. Majors noted that petitioner’s right shoulder continued to improve, however her left shoulder continued to bother her. Ex. 3 at 16. Upon examination, petitioner’s left shoulder had a full range of motion, however it was positive for impingement and showed reduced strength with discomfort. *Id.*

³ There is no record of a flu vaccination in March of 2015. However, petitioner received a pneumococcal vaccination on March 5, 2015. Ex. 2 at 337.

An MRI of petitioner's left shoulder was performed on November 17, 2015. Ex. 3 at 41. Dr. Majors discussed the MRI with Petitioner on November 20, 2015, and assessed her with a complete tear of her left rotator cuff. Ex. 3 at 14. Petitioner was seen by Dr. Majors again March 14, 2016. Ex. 3 at 1. Dr. Majors assessed petitioner with a small rotator cuff tear on her left shoulder. Petitioner reported that "therapy helped her left shoulder significantly." *Id.*

Petitioner was seen again by her orthopedist for shoulder pain on March 7, 2016. An examination revealed reduced strength in her left shoulder, and she was assessed with a rotator cuff tear. Ex. 2 at 385. On March 14, 2016, during another follow-up with her orthopedist, petitioner reported that physical therapy had significantly helped her left shoulder pain, and she was assessed with minimal impingement and only slightly reduced strength. Ex. 3 at 1.

Petitioner next reported shoulder pain on September 12, 2017. Ex. 9 at 9. Petitioner stated that she was experiencing bilateral shoulder pain, and that she has a large rotator cuff tear in her left shoulder documented on an MRI in November of 2015. *Id.* At that time, petitioner stated that her left arm caused her more pain than her right. Petitioner was next seen on October 9, 2017 for left shoulder pain. Ex. 5 at 5-6. She was assessed with a "cuff tear on the left" that was "unlikely to respond well to repair as she has inferior osteophytosis and early rotator cuff arthropathy." *Id.* at 6.

On May 2, 2018, petitioner was evaluated for a follow-up of left shoulder pain by Dr. Majors. Ex. 9 at 5. Dr. Majors noted that "[o]n [petitioner's] left shoulder, the workup has revealed a small to medium sized rotator cuff tear on the left. However, the MRI was from 2015. The patient has not had any real improvement in her left shoulder symptoms." *Id.*

Petitioner was next seen on May 16, 2018, for shoulder pain in her left shoulder. Ex. 9 at 1. A physical examination revealed "she has crepitation with range of motion. Strength is 4 to 4-/5. The patient has positive impingement sign and positive Hawkins sign. She is tender in the bicipital groove." Ex. 9 at 1. At that time, a repeat MRI was also performed. Ex. 9 at 9-10. The MRI showed a large full-thickness tear of petitioner's left rotator cuff, degenerative changes to the glenohumeral joint, and a dislocated long head of the biceps into the glenohumeral joint. Ex. 9 at 10.

B. Affidavits

In support of her petition, petitioner submitted four affidavits: Petitioner's Affidavit (Ex. 1), Affidavit of Helen Sublette (Ex. 6), Affidavit of Susan Orrell (Ex. 7), and Affidavit of James Orrell (Ex. 8).

In her own affidavit, petitioner stated that at the time of vaccination, she noticed that the vaccine was administered unusually high on her shoulder. Ex. 1 at 2. Further, petitioner stated that "[i]mmediately after receiving the influenza vaccination, within 48 hours, I began experienced pain in my left shoulder. The pain lingered and worsened as time progressed." *Id.*

Helen Sublette, petitioner's sister, also submitted an affidavit. Ex. 6. Ms. Sublette stated that she recalled petitioner "complained that her arm and shoulder were still unusually sore for a while after she received the shot" and that petitioner "mentioned to me that it was given high up on her arm and that she thought perhaps the nurse might have hit the bone or bruised the muscle." Ex. 6 at 1. Ms. Sublette did not indicate when petitioner first experienced pain, or when petitioner first commented on any soreness associated with a vaccination.

Susan Orrell, petitioner's daughter, also submitted an affidavit. Ex. 7. Ms. Orrell stated that "when my mom first got the shot" she "complained about how much it had hurt." Ex. 7 at 1. Ms. Orrell also stated that petitioner's pain was particularly difficult over the holidays when she was trying to cook and prepare holiday meals. *Id.*

James Orrell, petitioner's husband, also submitted an affidavit. Ex. 8. Mr. Orrell stated that petitioner complained about the flu shot "she received November 7, 2014 immediately when she came home that day." Ex. 8 at 1. Further, petitioner "continued to talk about how much her shoulder hurt ever since the day she received the shot" and that "she thought it would gradually get better." *Id.* at 2.

C. Hearing Testimony

The undersigned held a fact hearing on June 4, 2019, with petitioner and three other lay witnesses testifying.

During the hearing, petitioner testified that she graduated from Wake Forest College with a degree in English and worked at a family owned insurance company. Tr. 7-8. Petitioner was articulate, precise, and credible in her answers. Further, the undersigned found petitioner's answers were consistent, and had no questions or concerns regarding the veracity of her testimony.

Petitioner testified that her flu vaccine was administered on November 7, 2014 in her left arm. Tr. 12-14, 20. Petitioner also described the administration in detail, stating that she was sitting down, that the nurse administering it was standing, and that the shot was administered "on top of my shoulder." Tr. 16. Petitioner further noted it was an odd place to receive a shot and thought at the time that the nurse "hit the bone." *Id.*

Additionally, petitioner testified that her shoulder began hurting within 30 minutes of receiving the flu vaccination, and it "kept hurting and it never went away." Tr. 19-20. Petitioner further recalled telling her husband of the pain, stating that she mentioned it "right away when I got home" the same day she received the vaccination. Tr. 20, 21.

Petitioner also explained why she delayed in seeking treatment and did not mention her pain during multiple medical appointments. Petitioner originally thought her shoulder pain "was just because it was a bruise similar to a sprain or something where you just – you know, just have to wait it out and time will take care of it." Tr. 19-20. Further, the intervening appointments were for ailments unrelated to her shoulder, and with medical specialists that did not treat shoulder injuries. Tr. 23-27, 61-67. Petitioner

also reiterated that she assumed her shoulder would “get better with time.” Tr. 27, 31. Petitioner finally mentioned her shoulder pain on December 30, 2014 at a physical therapy visit for leg and back pain. According to petitioner, she mentioned her shoulder at that time because it was “getting into something like five or six weeks or some period where I thought this isn’t going away and it should be going away and what can I do about it and make it better.” Tr. 28, 31.

James E. Orrell, petitioner’s husband, also provided testimony. Mr. Orrell testified that petitioner “came home and was complaining that her shoulder hurt” after she received a vaccination and complained that the vaccination hurt “when it was given.” Tr. 84, 85.

Petitioner’s daughter, Susan Elizabeth Orrell, testified as well. Ms. Orrell testified that petitioner recalled the flu vaccination was administered in her left shoulder, and that it “really hurt [] more than it usually did.” Tr. 99-100. Ms. Orrell also noted that petitioner was frustrated and in pain and that she “had all this stuff to try and prepare for Christmas.” Tr. 100.

Helen Sublette, petitioner’s sister, provided additional testimony. Ms. Sublette testified that she spoke to petitioner shortly after she received her flu vaccine. Further, she stated that petitioner reported the vaccination was “unusually painful and she’d never had one before that was that painful.” Tr. 115. Ms. Sublette also stated that petitioner was having difficulty with daily tasks the weekend after her vaccination. Tr. 116.

After the testimony concluded, the undersigned ruled that the onset of petitioner’s injury was within 48 hours of her vaccination. Tr. 126. With regard to the cite of vaccination, the undersigned found that the vaccination was administered in petitioner’s left arm. Tr. 126. These findings were based on the evidence submitted in this case, including the exhibits, medical records, affidavits, and testimony. Tr. 126. Respondent did not object to proceeding with the fact hearing, or the issuing a ruling from the bench. See Tr. 128-129. Respondent did not file his motion for additional record development until July 31, 2019, on the eve of the deadline to file any additional evidence. At that point this case had been pending for over two years.

III. Respondent’s Motion for Additional Record Development

Respondent’s motion seeks additional record development prior to a determination of entitlement. Respondent states that the Chief Special Master’s ruling from the bench at the fact hearing was premature and problematic, as it denied respondent a full and fair opportunity to make arguments at the conclusion of the hearing that could counter the onset allegations made by petitioner and her family. Res. Mot. at 4, 5.⁴ Respondent asserts that material evidence regarding onset remains outstanding, without which the undersigned cannot make an onset determination in this

⁴ Respondent also notes that the previously-filed request for post-hearing briefing at the conclusion of the fact hearing was not addressed. *Id.* at 3-4.

case. *Id.* at 4-5.⁵ Respondent seeks authorization to depose individuals, the production of certain documents or affidavits explaining the absence of certain documents, and submission of additional allegedly still-outstanding updated medical records.

A. Discovery in the Vaccine Program

In general, there is no discovery as a matter of right in Vaccine Act cases. Vaccine Rule 7. The Vaccine Act contains provisions that address discovery and provides that a special master may require such evidence, or the testimony of any person and the production of any documents, as may be reasonable and necessary. §12(d)(3)(B).⁶

To determine whether requested material is “necessary” in vaccine proceedings, the standard is whether, based on the overall context of the factual issues to be decided, the special master could not make a fair and well-informed ruling on those factual issues without the requested material. *In re Omnibus Autism Proceeding (“OAP”)*, 2007 WL 1983780, at *7 (Fed. Cl. Spec. Mstr. May 25, 2007); *Mostovoy v. HHS*, No. 02-10V, 2013 WL 3368236 at *11 (Fed. Cl. Spec. Mstr. June 12, 2013). If production of the requested material is found to be necessary, the special master must also consider whether it is reasonable under the circumstances. *Mostovoy*, 2013 WL 3368236, at *11. The reasonableness inquiry requires the special master to consider the burden to be placed on the party or person who would bear responsibility for producing the information. *OAP*, 2007 WL 1983780, at *7. The importance of the requested material to the special master’s ruling must be balanced against the burden imposed on the producing party or person. *Id.*

B. Deposition Testimony from Petitioner’s Grandson’s Healthcare Providers is Neither Necessary nor Reasonable

Petitioner testified at the Fact Hearing that her grandson (who has special medical needs) lives with her and has nursing care 16 hours a day provided by the nursing service J & D Healthcare, and in particular by a nurse Ola. Tr. 7-10, 45. Petitioner also testified that, during the time period of her shoulder pain, she interacted on a daily basis with her husband, her daughters, her son, her grandson, and the nurses that cares for him. Tr. 44. Respondent seeks the testimony of any and all J&D Healthcare home health nurses that may have cared for petitioner’s grandson because they “may have independent information regarding [petitioner’s] condition after her vaccination.” *Id.* at 5. Deposition testimony from various health care providers treating

⁵ Respondent did not object to proceeding with the fact hearing, or the undersigned issuing a ruling from the bench. See Tr. 128-129. Respondent did not file his motion for additional record development until July 31, 2019, on the eve of the deadline to file any additional evidence. At that point this case had been pending for over two years.

⁶ Discovery in Vaccine Act cases is in contrast to discovery in other federal litigation where parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense. RCFC 26(b)(1); Fed. R. Civ. P. 26(b)(1).

petitioner's grandson is unnecessary for the undersigned to provide a fair and well-informed decision with regard to onset, for the reasons set forth below.

First, respondent has not established that the additional testimony is likely to disclose relevant facts. Respondent asserts that the health care providers, including nurse Ola, would be in the best independent position to testify as to the timeline of petitioner's post-vaccination symptoms. However, the identity of the nurse who was present on the date of petitioner's vaccination is unclear. See Tr. 44 (petitioner stating a nurse named Ola was "probably the one there, but I don't know that"). Further, there is no evidence that petitioner discussed her shoulder pain with the at-home health care providers that care for her grandson, which respondent concedes in his motion. Res. Mot. at 5 (respondent asserted that "Mrs. Orrell testified that she may have gone home immediately after her administered vaccination" and the home health nurses "may have independent information regarding Mrs. Orrell's condition after her vaccination") (emphasis added). The mere possibility of evidence does not satisfy the "reasonable and necessary" standard. *Phillips-DeLoatch v. HHS*, No. 09-171V, 2015 WL 1950107, at *6 (Fed. Cl. Spec. Mstr. Apr. 9, 2015).

Second, respondent has failed to show the need for the requested deposition testimony. Respondent emphasizes the necessity for independent witnesses,⁷ however, he did not question the credibility of the evidence and witnesses provided by petitioner at the hearing and does not do so in his motion. The undersigned found no reason to question the veracity of petitioner's testimony. To the contrary, petitioner was cogent and her testimony was credible. See Tr. 127 (the undersigned stating that she found petitioner's testimony to be consistent, articulate, and credible). Therefore, respondent does not establish why additional testimony from third parties who may or may not have relevant information is necessary.

Third, there is ample evidence already available elsewhere regarding the onset of petitioner's injury. As stated in further detail below, the undersigned found the onset of petitioner's injury was within 48 hours of her vaccination based on previously-filed medical records, affidavits, and testimony provided at the hearing. See sec. IV.a.ii. *infra*. The existence of this evidence, without respondent challenging its credibility, strongly supports the conclusion that additional deposition testimony of petitioner's grandson's health care providers is not necessary.

For the sake of completeness, the undersigned considers whether respondent's discovery request is reasonable. The reasonable inquiry requires the special master to consider the burden to be placed on the party or person who would bear responsibility for producing the information. *OAP*, 2007 WL 1983780, at *7. Here, respondent seeks authorization to subpoena any home health nurses from the nursing company that

⁷ See Respondent's Pre-Hearing Status Report, ECF No. 48 ("While the undersigned counsel recognizes that the Chief Special Master ultimately has wide discretion to assess the testimony of the witnesses proffered by petitioner at the onset hearing...respondent nonetheless believes that *independent* corroborating witness testimony provided on behalf of petitioner would be the most credible form of testimony in resolving the factual issue of onset.") (emphasis in original); Res. Mot. at 5 (stating "Ola would be in the *best independent position* to testify as to the timeline of petitioner's post vaccination symptoms in this case.") (emphasis in original).

provides care for petitioner's grandson, J & D Healthcare. The burden for producing the information would fall on the nursing company, J&D Healthcare. Further, respondent has not limited the time period or individuals he seeks to depose, instead seeking disposition testimony from "Ola,' and any other home health nurses from J&D Healthcare that were present at petitioner's home during the immediate post-vaccination time period." Res. Mot. at 5. This may result in J&D Healthcare being responsible for preparing and producing any and all home health nurses that may have cared for petitioner's grandson during an undefined time period. This burden is not only excessive, but unreasonable given that the requested discovery is unnecessary.

As set forth above, the deposition testimony from health care providers caring for petitioner's grandson is neither necessary nor reasonable. Therefore, respondent's request to file a motion for authorization to subpoena any J&D Healthcare home health nurses is denied.

C. Deposition Testimony from the Vaccine Administrator is Neither Necessary nor Reasonable

Respondent also seeks the deposition testimony of the vaccine administrator, Tammy Armstrong, stating that since respondent was not given the opportunity to solicit testimony from the administrator at the fact hearing, he "must be given an opportunity to take deposition testimony ... to appropriately develop the record in this case." Res. Mot. at 7. Respondent further asserts that the standard of care provided by the vaccine administrator has been called into question, and she "deserves the opportunity to respond to the allegations." *Id.* In fact, the Vaccine Act does not require that standard of care, or the liability of the vaccine administrator, be addressed or adjudicated. Thus, the conduct of the vaccine administrator is not at issue in this case, rendering it irrelevant. See § 13 (setting forth matters to be considered when determining eligibility and compensation).

Deposition testimony from the vaccine administrator is otherwise unnecessary to provide a fair and well-informed decision regarding the onset of petitioner's injury or any other elements of petitioner's claim. As stated in further detail below, the undersigned found the onset of petitioner's injury was within 48 hours of her vaccination, based on medical records, affidavits, and testimony provided at the hearing. See sec. IV.a.ii, *infra*. Further, respondent fails to establish how the testimony from the vaccine administrator is relevant to the determination of the onset of petitioner's injury.⁸

As explained above, there is no discovery as a matter of right in Vaccine Act cases. Vaccine Rule 7. Further, respondent fails to establish how deposition testimony from the vaccine administrator is either necessary or reasonable in this case. Therefore, respondent's request to file a motion for authorization to subpoena Tammy Armstrong is denied.

⁸ Instead, respondent states that "respondent must be given an opportunity to take deposition testimony of Nurse Armstrong to appropriately develop the record in this case" and that the vaccine administrator "deserves the opportunity to respond to the allegations" that her standard of care provided was called into question. Res. Mot. at 7.

D. Copies of Emails Seeking Information About the Vaccine Program are Neither Necessary Nor Reasonable

Petitioner testified that she learned about the Vaccine Program “almost two years later” from a TV news report, and that she e-mailed the television reporter for more information. Tr. 47-48. Petitioner further stated that the reporter replied but knew nothing further than what was on the news report. Unfortunately, petitioner also testified that she lost many emails when her computer “crashed about two or three months ago”. *Id.* Respondent asserts that these emails are “material and probative contemporaneous records as to petitioner’s onset allegations....” Res. Mot. at 7. Respondent “requests that those emails be submitted” or, “[i]f [petitioner’s] work computer was in fact wiped clean, respondent requests objective evidence to corroborate her testimony, such as affidavits from the computer repair company she used to resolve her computer issues.” Res. Mot. at 8.

Communications from petitioner to a reporter sent several years after petitioner’s alleged injury are neither necessary nor reasonable. First, respondent has not established that the discovery is relevant. Respondent asserts that the emails are probative contemporaneous records regarding petitioner’s onset allegations. However as petitioner testified, the communication occurred approximately two years after her injury, and thus are not truly contemporaneous. Further, there is no indication that the emails included any additional information relating to the onset of petitioner’s injury.

Second, respondent has failed to show the need for the requested discovery. As stated above, respondent did not question the credibility of the evidence and witnesses provided by petitioner at the hearing relating to onset. Respondent also fails to provide any reasoning as to why additional evidence is needed, particularly evidence of such limited probative value as email communications several years after petitioner’s alleged injury.

Third, there is ample evidence from the existing record regarding the onset of petitioner’s injury. As stated in further detail below, the undersigned found the onset of petitioner’s injury was within 48 hours of her vaccination, based on medical records, affidavits, and testimony provided at the hearing. See sec. IV.a.ii, *infra*. The existence of this evidence, without respondent challenging its credibility, strongly supports the conclusion that additional discovery is not necessary.

The undersigned also considers whether respondent’s discovery request is reasonable. The reasonable inquiry requires the special master to consider the burden to be placed on the party or person who would bear responsibility for producing the information. *OAP*, 2007 WL 1983780, at *7. Here, respondent seeks email communications from petitioner, or affidavits from a computer repair company. The burden for producing the information would fall on petitioner to either produce the emails or procure affidavit evidence attesting to the emails being unavailable. Given that the discovery is of extremely limited probative value, the burden is not only excessive, but unnecessary.

As explained above, there is no discovery as a matter of right in Vaccine Act cases. Vaccine Rule 7. Further, respondent fails to establish how the production of emails several years after petitioner's alleged injury is either necessary or reasonable in this case. Therefore, respondent's request for emails or objective evidence corroborating her testimony is denied.

E. Recent Medical Records are Neither Necessary Nor Reasonable for Determining Entitlement

Recent medical records from petitioner's orthopedic medical provider are unnecessary to provide a fair and well-informed decision regarding entitlement in this case. Petitioner testified that she discussed the possibility of rotator cuff surgery "within the past six months" with Dr. Majors, but that it had degenerated and thus a shoulder replacement was needed. Tr. 39, 77.⁹ Respondent asserts that updated medical records would be potentially relevant as to onset and "may reveal that petitioner's degeneration of her left shoulder ... is a pre-existing 'dysfunction' ... which, in turn, could potentially reflect that she cannot meet the requirements of a Table SIRVA injury in this case." Res. Mot. at 8. However, there is ample evidence regarding the condition of petitioner's left shoulder. Prior to petitioner's November 7, 2014 flu vaccine there is no indication that any pre-existing dysfunction. See Ex. 2 at 338 (listing of petitioner's medical history). Further, there is ample evidence elsewhere regarding the condition of petitioner's shoulder prior to her vaccination. See sec. IV.a.i, *infra*. However, so that the medical records will be complete for the damages phase of this case, the undersigned will order petitioner to produce these records.

IV. Ruling on Entitlement

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if she has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that she has suffered a "Table Injury," causation is presumed.

Section 11(c)(1) also contains requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A), (B), (D) and (E). With regard to duration, a petitioner must that establish she suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine. § 11(c)(1)(D).

⁹ Petitioner's testimony places the date of her visit to Dr. Majors in late 2018 or early 2019, four to five years after the vaccination at issue.

A. Analysis

Petitioner alleges that she developed a SIRVA following a November 7, 2014 flu vaccination. Pet. at 1. Further, petitioner alleges that her injury meets the definition of a SIRVA as set forth in the Vaccine Injury Table. *Id.*

Respondent opposes compensation in this case, arguing that petitioner has not provided evidence to show the onset of her alleged injury occurred in a timeframe within which vaccine causation could be ascribed. Rule 4(c) Report at 8. Respondent also argues that petitioner's reduced range of motion was not limited to her left shoulder. *Id.*

Effective for petitions filed beginning on March 21, 2017, a SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). The Qualifications and Aids to Interpretation for a SIRVA are used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.

For the reasons set forth below, the undersigned finds petitioner has provided evidence sufficient to establish that she is entitled to compensation. Specifically, petitioner has established that she suffered a SIRVA as set forth in the Vaccine Injury Table.

i. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

Prior to petitioner's November 7, 2014 flu vaccination, there is no record of a history of pain, inflammation, or dysfunction of her left shoulder. See, e.g., Ex. 2 at 330. Respondent contends, for the first time, in his motion for additional record development that certain potentially outstanding records "may reveal that petitioner's degeneration of her left shoulder ... is a pre-existing 'dysfunction'". Res. Mot. at 8 (citing to Tr. 38-39). However, there is no evidence in the medical record, affidavit evidence, or hearing

testimony that petitioner had any prior abnormality or dysfunction. See Ex. 2 at 338 (petitioner's pre-vaccination medical history listing prior conditions as tobacco abuse, osteopenia, hyperlipidemia, hypertension, pre-diabetes mellitus, hypothyroidism, GERD, and spinal stenosis). Further, when petitioner received an MRI on November 17, 2015, degeneration was not evident. See Ex. 3 at 41.

When viewed in the entirety, the records, affidavit, and testimony provided in this case are sufficient to establish, by preponderant evidence, that petitioner did not have a history of any left shoulder dysfunction prior to the November 7, 2014 flu vaccination.

ii. Onset occurred within the specified time frame.

The interval of onset set forth in the Table for a SIRVA claim is within 48 hours after vaccination. 42 C.F.R. § 100.3. The undersigned held a fact hearing on June 4, 2019, at the conclusion of which a ruling from the bench regarding the onset of petitioner's symptoms was provided. Tr. 125-127. The undersigned found, based on the medical records, affidavit evidence, and oral testimony, that petitioner experienced symptoms within 48 hours of the November 7, 2014 flu vaccination. Tr. 126. Respondent contends that material evidence regarding onset remains outstanding, and that an appropriate onset determination in this case cannot be made without it. Res. Mot. at 4-5. However, there is ample evidence in the record to establish petitioner experienced onset of a SIRVA within 48 hours of her vaccination.

Petitioner received a flu vaccination on November 14, 2014. Ex. 2 at 1. Petitioner first reported shoulder pain on January 20, 2015. Ex. 4 at 73. Further, petitioner next reported shoulder pain on March 5, 2015, stating to her primary care physician that she had "[p]ain in shoulder after flu shot, still there." Ex. 2 at 368. Petitioner reported shoulder pain again on April 10, 2015, stating that she had been experiencing the pain for over five months. Ex. 3 at 32.

Petitioner also submitted affidavit evidence in support of her claim, including affidavits from herself, Ms. Orrell (petitioner's daughter), and Mr. Orrell (petitioner's husband). In her affidavit, petitioner stated that "[i]mmediately after receiving the influenza vaccination, within 48 hours, I began experienced pain in my left shoulder. The pain lingered and worsened as time progressed." Ex. 1 at 2. Ms. Orrell and Mr. Orrell's affidavits also state that petitioner complained of pain when she received the vaccination. Ex. 7 at 1 (Ms. Orrell stated that she recalled that "when my mom first got the shot" she "complained about how much it had hurt"); and Ex. 8 at 1 (Mr. Orrell stated that petitioner complained about the flu shot "she received November 7, 2014 immediately when she came home that day).

Further, testimony was provided at the hearing held on June 4, 2019, that onset of petitioner's pain was within 48 hours. Petitioner testified that her shoulder began hurting within 30 minutes of receiving the November 7, 2014 flu vaccination, and it "kept hurting and it never went away." Tr. 12-14, 19-20; see also Tr. 85 (Mr. Orrell testifying that petitioner reported the vaccination hurt "when it was given").

Respondent notes that petitioner attended several medical appointments with orthopedists and physical therapists in the weeks following the vaccination without any complaints of shoulder pain. Rule 4(c) Report at 8; see *also* Ex. 3 at 35, 53; Ex. 4 at 16, 75.¹⁰ Petitioner explained at the hearing that the intervening appointments were for ailments unrelated to her shoulder, and with medical specialists that did not treat shoulder injuries. Tr. 23-27, 61-67. Petitioner also explained why she delayed in seeking treatment, stating at several points that she assumed her shoulder would “get better with time.” Tr. 19-20, 27, 31.

When viewed in the entirety, the records, affidavit, and testimony provided in this case are sufficient to establish, by preponderant evidence, that she experienced pain within 48 hours of receiving a flu vaccination.

iii. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

The undersigned finds that petitioner’s pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered. See, e.g., Ex. 4 at 73 (petitioner reported left shoulder pain following her flu vaccination).

At the conclusion of the fact hearing, the undersigned found that the vaccination was administered in petitioner’s left arm. Tr. 126.¹¹ Further, the reduced range of motion and pain attributed to the flu shot was limited to her left shoulder. See Ex. 4 at 73; Ex. 2 at 368; Ex. 3 at 32, 41.

Respondent argued in his Rule 4 report that petitioner’s pain and reduced range of motion were not limited to her left shoulder. Rule 4(c) Report at 8. Respondent contends that petitioner suffered a serious fall and sustained an injury to her right shoulder for which she underwent surgery. *Id.* Petitioner did suffer a fall on August 12, 2015, resulting in her dislocating her right shoulder. Ex. 2 at 1089. However, this event occurred after petitioner’s November 7, 2014 flu vaccination and the onset of her left shoulder pain. Further, at no point does petitioner contend that her left shoulder pain or reduced range of motion is in any way related to, or impacted by, her right-shoulder dislocation or subsequent treatment.

When viewed in the entirety, the medical records establish, by preponderant evidence, that petitioner’s pain and reduced range of motion were limited to her left shoulder, the location of her flu vaccination.

iv. No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical

¹⁰ The appointments included treatment for bilateral hand pain on December 2, 2014 (Ex. 3 at 35) and physical therapy for lower back pain and radiculopathy in her lower left extremity (Ex. 3 at 52).

¹¹ Respondent does not dispute that petitioner received an intramuscular flu vaccine in her left shoulder, however the undersigned notes that the vaccine record does not specify the site of administration. See Ex. 2 at 337.

evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Petitioner's medical records contain no evidence of any condition or abnormality that would explain her symptoms. Further, respondent does not contend that any other condition or abnormality would explain petitioner's symptoms.

V. Conclusion

In light of the above, and in view of the submitted evidence, the undersigned GRANTS petitioner's motion and finds that petitioner is entitled to Vaccine Act compensation.

IT IS SO ORDERED.

/s/Nora Beth Dorsey

Nora Beth Dorsey
Special Master