# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 17-0280V**
**Filed: February 1, 2019**
PUBLISHED

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| CHERYL GILL,<br><br>Petitioner,<br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA) |

*Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for petitioner.*
*Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for respondent.*

## FACT RULING AND SCHEDULING ORDER – SPECIAL PROCESSING UNIT[1]

**Dorsey**, Chief Special Master:

On February 28, 2017, Cheryl Gill ("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"). Ms. Gill alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her left arm on September 26, 2014. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed below, the undersigned finds that the onset of petitioner's left shoulder injury was within 48 hours of her September 26, 2014 influenza vaccination.

[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 published 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).

## I. Procedural History

On February 28, 2017, Ms. Gill filed her petition for compensation and five medical record exhibits. (ECF No. 1). She filed five additional exhibits and a Statement of Completion on April 7, 2017. (ECF Nos. 7, 9-10). On April 7, 2017, the initial status conference was held and a deadline was set for respondent to file his status report indicating how he intended to proceed with the case. (ECF No. 8).

On August 14, 2017, respondent filed a status report stating that he was not amenable to settlement discussions and requested a deadline of September 28, 2017 to file the Rule 4(c) report. (ECF No. 17). This request was granted.

In respondent's Rule 4(c) report filed on September 27, 2017, respondent recommended that compensation be denied in this case, arguing that petitioner's claim would not meet the Table criteria for SIRVA because the contemporaneous medical records did not support petitioner's claim that the onset of her shoulder pain was within 48 hours of vaccination, that on examination petitioner's left arm showed no redness, swelling, tenderness and her range of motion was normal. Respondent also noted that one physician stated that petitioner's subjective symptoms were not consistent with the physical examination and doubted any relationship to the flu vaccine. Respondent's Report at 6-7.

A status conference was held on April 3, 2018, with the staff attorney managing this case. The parties requested a fact hearing determination to resolve the issue of onset. A scheduling order was issued the same day ordering petitioner to file any additional witness affidavits to help establish the onset of her shoulder injury. (ECF No. 19). Petitioner filed a supplemental affidavit on April 5, 2018 (ECF No. 26) and an affidavit from one other fact witness, Bernadette Abraham (ECF No. 30).

A fact hearing was held on Tuesday, November 13, 2018. Ms. Gill and Ms. Abraham testified by video-conferencing. (ECF No. 37, Hearing Transcript ("Tr.")). The undersigned now issues this fact ruling.

## II. Factual History

Ms. Gill was 57 years-old at the time she received the flu vaccination at issue in this case. Petition at 1, ¶1; Petitioner's Exhibit ("Pet. Ex.") 2 at 1. Her medical history is significant for insomnia. *See* Pet. Ex. 3 at 10. She was diagnosed with stage one breast cancer in April 2015. Pet. Ex. 3 at 9. Otherwise, Ms. Gill's medical history does not appear to be contributory to her claim in this case.

On September 26, 2014, Ms. Gill presented to her primary care physician, Dr. Usha Kandasamy, at Einstein Medical Center, for her annual wellness exam as well as for complaints of nasal itching and a runny nose. Pet. Ex. 3 at 28. Ms. Gill described her general state of health as good. *Id*. During this visit, she received a flu vaccine in her left deltoid.[3] Pet. Ex. 1 at 1; Pet. Ex. 5 at 8. At the time, Ms. Gill was working as a

[3] Dr. Kandasamy also wrote an order for Ms. Gill to receive a Tdap vaccine on the same day. The record is unclear whether Ms. Gill received the Tdap vaccination on this date. Pet. Ex. 1 at 2. Ms. Gill has not alleged that the Tdap vaccine caused any injury to her left shoulder.

classroom assistant in a school located in Philadelphia, Pennsylvania. Pet. Ex. 1 at 1. She was also employed by a private agency called Epic Services as a home healthcare aide. Tr. 6-7.

Ms. Gill complained that immediately after the vaccine was administered, she felt pain in her left shoulder (her dominant arm). Pet. Ex. 14 at 1; Tr. 7. The pain continued into the evening as a radiating, achy, throbbing pain "running up and down my left arm, from my shoulder down to my lower arm." Tr. 9. Ms. Gill stated that there was redness and swelling at the injection site. Tr. 10. However, she believed the pain would lessen in a day or two as it did with all her previous injections. *Id*.

Ms. Gill averred that she called Dr. Kandasamy's office on September 29, 2014 to report her left shoulder pain. Pet. Ex. 15 at 1. She stated that spoke to a receptionist about her shoulder pain and was told that a physician would return her call. *Id*. Ms. Gill stated that when she did not receive a return call, she again called Einstein Family Medicine on September 30, 2014. *Id*. She received the same response from the receptionist who told her that a physician would return her call. *Id*. at 2. Ms. Gill stated that she called Einstein Family Medicine a third time on October 1, 2014 and was told by the receptionist that the physician would call her back after the doctor was finished seeing his patients for the day. Again, Ms. Gill did not receive a return call. When Ms. Gill called back on October 6, 2014, she was able to make an appointment to see her physician, but the first available appointment she could schedule was for November 25, 2014. *Id*.; Tr. 13. Ms. Gill also stated in her affidavit that in the first few days after vaccination, she visited her school's nurse, Nurse Tiller, complaining of shoulder pain and to obtain ice packs to place on her left arm to help alleviate the pain. *Id*.

Approximately one month later, on October 24, 2014, Ms. Gill presented to the emergency room at Bryn Mawr Hospital with complaints of an injury to her left arm. Pet. Ex. 2 at 1. She reported that the injury "happened 2 weeks ago (Doctors office)." *Id*. The notes from this visit state that Ms. Gill was experiencing moderate pain to her left arm, noting that Ms. Gill "was given flu shot on 9/26." *Id*. The notes further indicate "[s]ince the injection, patient has been having intermittent pain in the L[eft] arm that she describes as throbbing." *Id*. Upon examination, there was no erythema, tenderness, swelling, laceration or abrasion noted in the left arm. *Id*. at 2. Ms. Gill underwent an x-ray and ultrasound of her left extremity, both of which were normal. Pet. Ex. 4 at 12, 14. Ms. Gill was not provided with any medication as she stated that her pain "comes and goes intermittently and that it is not currently present." Pet. Ex. 4 at 12. The clinical impression noted "acute pain in the left upper extremity (upper arm) … Rule out DVT in L upper extremity." *Id*. Ms. Gill was discharged with instructions to continue using over-the-counter medication to treat her pain and to follow up with her primary care physician the next week. *Id.*

On November 25, 2014, Ms. Gill presented to Dr. Kandasamy for continued complaints of left arm pain for the past two months. Pet. Ex. 3 at 32. Ms. Gill reported that her pain started after she received a flu vaccine. *Id*. Ms. Gill had noticed redness and a lump on her left arm after the vaccination that lasted for three weeks. *Id*. The notes from this visit state "started experiencing pain in the L arm 10/06/14 on and off throughout the day. Pain would last for 15-30 min and will occur every 1-2 hours." *Id.*

On physical examination, there was no swelling, redness or tenderness. Her range of motion was within normal limits. *Id*. at 34. Under impression and plan, it is noted that "subjective symptoms [do not] match with the exam." *Id*. Dr. Kandasamy wrote that she did not believe Ms. Gill's symptoms were caused by the flu vaccine, but that she would obtain the records from Bryn Mawr hospital. Dr. Kandasamy prescribed Motrin for discomfort and pain relief. *Id*.

One week later, on December 3, 2014, Ms. Gill was seen by physical therapist Jennifer Gulla at Moss Rehabilitation Center to begin physical therapy. Pet. Ex. 12 at 4. Ms. Gulla noted that Ms. Gill had a two "month history of [left] arm pain after getting flu shot on 09/27/2014 in L[eft] arm. With[in] 24 hours p[atien]t reported increase in pain with sleeping and constant pain. Pain in proximal left arm. N/T in left distal fingers (all 5/5)." Pet. Ex. 12 at 7. Ms. Gill had some reductions in her range of motion of the left shoulder as compared with the right. *Id*. at 8, 10. She also had a positive result on the Hawkins impingement test. *Id*. It was recommended that MS. Gill attend physical therapy twice weekly for eight weeks. *Id*. at 6. At her December 9, 2014 visit, Ms. Gill reported experiencing increased pain in her left shoulder and there was increased discomfort during the Active Range of Motion ("AROM") and at the end range of motion of her left shoulder. *Id*. at 6. Ms. Gill was only seen at Moss Rehabilitation for these two sessions and was discharged on December 11, 2014 at her request. *Id*. at 5. Ms. Gill stated that she wanted to try another facility that had "better hours." *Id.*; Tr. 24.

On December 17, 2014, Ms. Gill underwent an initial evaluation by occupational therapist, Tarre Ferrell, at Novacare Rehabilitation. Pet. Ex. 4 at 17. In the summary, Ms. Gill reported "that on 9/26/14, she visited MD office to receive flu vaccination. Patient stated that the next day, her L arm throbbed and ached." *Id*. She reported that the severity of her left shoulder had reached an 8/10, and at best her pain level was a 6/10. Ms. Gill stated that her current level of pain was 8/10. She also reported numbness and tingling throughout her left forearm and fingers. *Id*. On physical examination, there was a reduced range in her active range of motion ("AROM") to the left shoulder. Pet. Ex. 4 at 17. The goals for physical therapy were to decrease the pain levels to her left shoulder, including the abnormal sensations, and to increase AROM and improve the strength of her left upper extremity so Ms. Gill could engage in activities of daily living and work-related tasks without difficulty or discomfort. Pet. Ex. 4 at 19. Ms. Gill was scheduled to attend physical therapy three times a week for four weeks. *Id*.

Ms. Gill attended physical therapy from December 30-31, 2014, January 7, 13, 15 (records note that "[p]atient may be over-exaggerating symptoms as she does not appear inhibited during ROM and strengthening exercises in therapy"), 16, 19, 20, 26, 27, and February 4, 11, 13, 2015. She was discharged on February 13, 2015 to a home exercise program ("HEP"), and her prognosis on discharge was rated as "good." Pet. Ex. 4 at 64.

Ms. Gill was reevaluated by Ms. Ferrell at NovaCare Rehabilitation on March 17, 2015. Pet. Ex. 4 at 66. It was noted that Ms. Gill's subjective complaints of pain were unchanged. Her shoulder abduction range of motion decreased to 45 degrees and remained "fairly unchanged in other planes of motion, with patient indicating pain as a

limiting factor." *Id*. at 68. It was recommended that Ms. Gill continue with physical therapy twice weekly, for the next four weeks. *Id*. at 69.

Ms. Gill attended physical therapy on March 17, 18, 24, 26, and April 1, 3, 7, 2015. On April 6, 2015, she called her physical therapist and requested to be discharged. The next day, April 7, 2015, she returned to Novacare Rehabilitation for her final session and was discharged with a "good" prognosis. Ms. Gill was instructed to continue with her home exercise program. The majority of her goals for physical therapy were listed as "Goal Abandoned Apr 07, 2015. d/c [discharge] per patient request."[4] Pet. Ex. 4 at 90.

Ms. Gill presented for her annual wellness exam on February 16, 2016. Pet. Ex. 3 at 19. She had a normal exam and there was no mention of any shoulder problems during this visit. *Id*.

Ms. Gill was not seen again for her left shoulder until February 23, 2016, where she presented to orthopedist Dr. Katharine Criner "[c]omplaining of left shoulder pain that started after a flu shot in the fall of 2014 as well as intermittent numbness and tingling of the left hand." Pet. Ex. 5 at 30. Ms. Gill reported that she had attended physical therapy which provided some relief as did application of ice to the shoulder. *Id*. at 31. Dr. Criner noted that Ms. Gill had not yet undergone a nerve conduction study or received any cortisone injections. *Id*. Dr. Criner's impression was calcific tendinitis of the left shoulder and carpal tunnel of the left wrist. *Id*. Ms. Gill was given a left wrist splint to wear during the night and an EMG/nerve conduction study was ordered. Ms. Gill was instructed to continue with her NSAIDS and with her home exercise program to strengthen her rotator cuff. *Id*.

On February 24, 2016, Ms. Gill presented to orthopedist, Dr. Katharine Theresa Woozley, "[c]omplaining of left shoulder pain that started after a flu shot in the fall of 2014 as well as intermittent numbness and tingling of the left hand." Pet. Ex. 3 at 23. Dr. Woozley noted that Ms. Gill had previously attended physical therapy for her left shoulder which gave her some relief. However, Ms. Gill continued to complain of intermittent numbness and tingling of the left hand which also occurred during the night. On examination, Ms. Gill had "[f]ull painless ROM cervical spine… Shoulder range of motion: Bilateral UE: Full symmetric, painless ROM shoulders (forward flexion 180, abduction 180, IR 60, ER 50), elbows, forearms, wrists, hands. Internal rotation to T12 (no pain)." The notes further state "[n]o tenderness to palpation bilateral sternoclavicular joint, clavicle, posterolateral/lateral/ anteriolateral aspect acromion, coracoid, acromioclavicular joint. She has some tenderness to palpation at the left deltoid muscle. Negative belly press, liftoff, speed's, yeagerson's, Neer's Hawkin's, empty can." *Id*. at 25. Under "Impression and Plan" the diagnosis is listed as calcific tendinitis of left shoulder, carpal tunnel syndrome, left." *Id*. EMG nerve conduction studies of the bilateral upper extremities were ordered. Ms. Gill was instructed to

[4] Around this time frame, Ms. Gill was diagnosed with breast cancer. Tr. 27. She testified that treating her breast cancer became a priority and she stopped treating her shoulder. *Id*. Ms. Gill also testified that while she still experienced shoulder discomfort during this time, her symptoms decreased. *Id*.

continue with her home exercise program for her left shoulder and strengthening for her rotator cuff calcific tendinitis. *Id*.

On May 9, 2016, Ms. Gill underwent a nerve conduction and needle EMG study on her left arm. Pet. Ex. 10 at 1. The results of both studies were within normal limits. *Id*.

Ms. Gill filed the affidavit of Bernadette Abraham, the mother of the special needs child that Ms. Gill cares for. Pet. Ex. 17. Ms. Abraham also testified during the fact hearing. Ms. Abraham testified that Ms. Gill takes cares for Ms. Abraham's daughter who was born with microcephaly and is severely handicapped. Tr. 90. Ms. Abraham explained that her daughter is in a wheelchair and is unable to eat or drink except through a G-tube. Tr. 90. Ms. Gill cares for Ms. Abraham's daughter on a daily basis from 4 p.m. to 8 p.m. and changes, bathes and generally cares for her during this time. *Id*. Ms. Abraham averred and testified that on September 26, 2014 (the date of vaccination), Ms. Gill told Ms. Abraham that she had just received a flu shot and that her left arm was still in pain. Ms. Abraham testified that her daughter is 21 years old and approximately 150 pounds and she recalls having to assist Ms. Gill with moving her daughter on the day Ms. Gill received the vaccination, September 26, 2014. Tr. 92. Ms. Abraham also recalled Ms. Gill having hard time getting in touch with her doctor to be seen for her shoulder pain. Ms. Abraham stated that she advised Ms. Gill to go to the emergency room if she could not reach her physician. Ms. Abraham also stated that she recalled Ms. Gill having difficulty pushing the wheelchair for Ms. Abraham's child and having to taking frequent breaks. Ms. Abraham stated that she felt compelled to help Ms. Gill with caring for her daughter during this time because Ms. Gill could not afford to take time off from work. *Id*.

Regarding her current status, Ms. Gill testified that her arm "has gotten better." Tr. 31. She stated that her shoulder pain is still present and it "comes and goes" but that overall, the pain has decreased. *Id*. She testified that the pain usually increases with activities that involve lifting or pulling. Tr. 31. Ms. Gill confirmed that she has not sought treatment for her shoulder since February 2016. *Id.* At the time she was experiencing the highest level of pain, Ms. Gill stated that she was frightened that the injury would impact her livelihood and her ability to earn an income. Because her job involves caring for children which involves lifting and substantial use of her arm, Ms. Gill stated that she was concerned that she would not be able to perform her job duties. Tr. 33.

Ms. Gill testified that her shoulder injury impacted the activities that she normally participated in such as Zumba, swimming and crochet class. Tr. 28. Her shoulder injury has also impacted her ability to do household chores such as mopping, vacuuming, and sweeping. Tr. 29. Ms. Gill also has four young grandchildren and her shoulder injury made it difficult for her to lift and care for them. Tr. 30.

During her testimony, Ms. Gill referenced a calendar book where she kept dates of certain appointments, including her physical therapy appointments. Tr. 37. These calendar entries were filed as petitioner's exhibit 18. (ECF No. 35). These pages contain monthly views of September-December 2014, and February and April of 2015. On the September 2014 monthly calendar page, Ms. Gill noted an appointment with Dr.

Kandasamy on September 26, 2014. Pet. Ex. 18 at 1. On the October 2014 page, Ms. Gill noted that she was "out w/arm" on October 6-7, 2014. *Id*. at 2. On October 24, 2014, she noted "Bryn Mawr Hospital for arm x-ray ultrasound." *Id.* In November and December 2014, Ms. Gill noted the dates of several of her physical therapy appointments and her appointments with Dr. Kandasamy. *Id.* at 3-4. Likewise, the February and April 2015 pages, noted the dates of additional physical therapy and medical appointments. *Id*. at 5-6.

## III. Discussion

### a. Applicable Legal Standard

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. 42 U.S.C. § 300aa–13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like 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."); *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl.Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Valenzuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or

court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

### b. Onset period for a SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, 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). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria 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.; see also* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052). The criteria at issue in this case is whether Ms. Gill's pain occurred within the specified time-frame of 48 hours or less after administration of her September 26, 2014 flu vaccination. The undersigned finds that it does.

> Section 42 U.S.C.A. § 300aa-13(b)(2) provides that:
>
> The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

42 U.S.C.A. § 300aa-13(b)(2). Although this petition was filed prior to most recent changes to the Vaccine Injury Table, this section of the statute provides relevant guidance to the issue in this case.

### c. Evaluation of the Evidence

The parties dispute whether petitioner has satisfied her burden of proof as to the second SIRVA criteria: "[pain occur[ring] within the specified time-frame." To meet this criterion, petitioner must show by preponderant evidence that her left shoulder pain began within 48 hours of her September 26, 2014 flu vaccination. 42 U.S.C. § 300aa–13(a)(1)(A); 42 C.F.R. § 100.3(c)(10). Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). In light of all of the above record evidence and for the reasons described below, the undersigned finds that there is preponderant evidence that the onset of petitioner's alleged shoulder pain occurred within 48 hours of petitioner's September 26, 2014 flu vaccination.

It is undisputed that Ms. Gill was not formally seen by a healthcare provider until October 24, 2014, approximately 28 days after her September 26, 2014 flu shot. However, the medical records provide preponderant evidence demonstrating that the onset of her shoulder pain began within 48 hours of the administration of the flu vaccine. Ms. Gill states in her affidavit that she called her primary care physician's office four times between September 29, 2014 and October 6, 2014, to discuss the pain in her left shoulder. Ms. Gill filed her telephone records which provide some support for her claim. *See* Pet. Ex. 15 (petitioner's affidavit), Pet. Ex. 16 (petitioner's phone records).

On October 24, 2014, Ms. Gill went to the emergency room at Bryn Mawr Hospital with complaints of an injury to her left arm. Pet. Ex. 2 at 1. She reported that the injury "happened 2 weeks ago (Doctors office)." *Id*. The notes from this visit state that Ms. Gill was experiencing moderate pain to her left arm, noting that Ms. Gill "was given flu shot on 9/26." *Id*. The notes further indicate "[s]ince the injection, patient has been having intermittent pain in the L[eft] arm that she describes as throbbing." *Id*. Pet. Ex. 3 at 72. This is the most contemporaneous medical record filed, and while Ms. Gill was a couple weeks off in estimating the timeframe of when her left shoulder pain began, she was able to provide a specific date of when she received the flu shot, placing the onset of her shoulder injury as occurring within 48 hours of vaccination.

There are also a large number of references in the filed affidavits and medical records which place the onset of Ms. Gill's shoulder pain within 48 hours of vaccination administration. *See* Pet. Ex. 14 at 1 (Ms. Gill states in her affidavit that her left arm pain began "immediately after vaccination"); Pet. Ex. 2 at 1 (record dated October 24, 2014, where Ms. Gill reports that her left shoulder pain started "since" injection she received on 9/26 (sic – the vaccination date was 9/24/14)); Pet. Ex. 3 at 32 (record dated November 25, 2014 where Ms. Gill reported that she believed her pain started after she received a flu injection); Pet. Ex. 12 at 4 ("Ms. Gill had a two "month history of [left] arm pain after getting flu shot on 09/27/2014 in L[eft] arm. With[in] 24 hours p[atien]t

reported increase in pain with sleeping and constant pain); Pet. Ex. 4 at 17 (Ms. Gill reported "that on 9/26/14, she visited MD office to receive flu vaccination. Patient stated that the next day, her L arm throbbed and ached"); Pet. Ex. 5 at 30 (Ms. Gill was "[c]omplaining of left shoulder pain that started after a flu shot in the fall of 2014"); Pet. Ex. 3 at 23 ("[c]omplaining of left shoulder pain that started after a flu shot in the fall of 2014).[5]

The undersigned also credits the testimony of both Ms. Gill and Ms. Abraham who during the hearing describe how Ms. Gill was in pain on the evening she received her vaccination. Ms. Abraham specifically recalls that Ms. Gill had difficulty lifting and moving Ms. Abraham's daughter during the evening of September 26, 2014. Tr. 90-92.

Regarding her delay in seeking treatment, the undersigned finds Ms. Gill's explanation to be credible in light of her circumstances and situation at the time. The undersigned credits Ms. Gill's statement and testimony that she called her primary physician's office four times in order to speak to her physician about her left shoulder pain.

Based on the medical record evidence, the affidavit testimony of petitioner and other fact witnesses, and the testimony during the fact hearing, the undersigned finds that there is preponderant proof that the onset of Ms. Gill's left shoulder pain occurred within 48 hours of her September 26, 2014 flu vaccination.

Finally, to address respondent's statement in the Rule 4(c) report that on examination, petitioner's left arm showed no redness, swelling, tenderness and her range of motion was normal, the undersigned notes and finds that petitioner did exhibit a reduced range of motion in her initial physical therapy visit to Moss Rehabilitation as is noted in petitioner's exhibit 12 at 7. These physical therapy notes document an extensive examination of Ms. Gill's left shoulder by qualified physical therapists and specific tests to examine her range of motion. The undersigned finds this information to be persuasive. Indeed, respondent also acknowledges that the medical records show that Ms. Gill exhibited a limited range of motion of her left shoulder. *See* Respondent's Report at 4 (citing petitioner's exhibit 11 at 22 ("The therapist's upper extremity exam showed some ROM limitations on the left"). The Vaccine Injury Table provides that the first symptom or manifestation of onset of the condition occurs within forty-eight hours of vaccination. See 42 C.F.R. § 100.3(a)(XIV)(B). As stated in the Table's qualifications and aids to interpretation, "SIRVA manifests as shoulder pain and limited range of

[5] The undersigned acknowledges that there are two references in the medical records that place the onset of petitioner's shoulder injury outside of the 48-hour onset period. In petitioner's exhibit 2 at 1, dated October 24, 2014, Ms. Gill states that her injury "happened 2 weeks ago" which would place the onset around October 10, 2014. However, in the next sentence, it states that Ms. Gill was experiencing pain "since" the injection which took place on 9/26/2014, which corrects the previous deficiency. Also, petitioner's exhibit 3 at 32 states that Ms. Gill "started experiencing pain in the L arm 10/06/14 on and off throughout the day." However, also in that same note, Ms. Gill states that she had been experiencing "L arm pain x 2 months… believes it all started after she had gotten the flu vaccine." This would place the onset of her left arm pain at approximately the date of vaccination, September 26, 2014. Ms. Gill also testified that she did not know why Dr. Kandasamy recorded that she started experiencing pain in her left arm on 10/6/2014. Tr. at 18. Ms. Gill testified that she told Dr. Kandasamy she began experiencing pain "after the vaccine." Tr. at 19.

motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm." 42 C.F.R § 100.3(c)(10). Thus, the onset of petitioner's shoulder pain must be within 48 hours of vaccination. There is no such timing requirement for a limited range of motion.

In the Rule 4(c) report, respondent also noted that one physician stated that petitioner's subjective symptoms were not consistent with the examination and doubted any relationship to the flu vaccine. Respondent's Report at 6-7. The undersigned acknowledges that the physician made these statements, however, the objective tests and examinations show that Ms. Gill was experiencing some limitations in her range of motion where none existed prior to examination, and Ms. Gill consistently reports an increase of pain in the left shoulder that persisted after examination. The undersigned finds that Ms. Gill has provided preponderant evidence to show that the onset of her left shoulder pain began within 48 hours of vaccination and that she manifested a limited range of motion of her left shoulder after vaccination.

## IV. Conclusion

**The undersigned finds, based on the record as a whole, that the onset of petitioner's left shoulder pain was within forty-eight (48) hours of her September 26, 2014 influenza vaccination.**

The parties have previously indicated that even if the issue of onset is resolved in petitioner's favor, the issue of damages (specifically pain and suffering) would continue to be in dispute. *See* Scheduling Order dated Oct. 20, 2017 (ECF No. 19). Nevertheless, the parties are encouraged to consider an informal resolution of this claim. Petitioner shall file a joint status report by **Friday, March 8, 2019,** updating the Court on the status of the parties' discussions to resolve this claim. If the parties are still unable to reach a resolution of damages, then the status report shall state which items of damages are in dispute and how each party would like to resolve those issues, either by hearing or by submitting briefing.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**
Nora Beth Dorsey
Chief Special Master