# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS** 

No. 16-797V Filed: November 19, 2018 Not to be Published.

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TARA HURLEY,	*	
	*	
Petitioner,	*	
	*	Influenza ("flu") vaccine;
v.	*	SIRVA; onset in one month;
	*	no expert report; motion for
SECRETARY OF HEALTH	*	decision of dismissal
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
******	*****	

<u>Ronald C. Homer</u>, Boston, MA, for petitioner. <u>Linda S. Renzi</u>, Washington, DC, for respondent.

### MILLMAN, Special Master

## **DISMISSAL DECISION**<sup>1</sup>

Petitioner filed a petition on July 5, 2016, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that influenza ("flu") vaccine administered to her left shoulder on November 1, 2013, caused her a shoulder injury related to vaccine administration ("SIRVA").<sup>2</sup> Pet. Preamble and at ¶ 1.

On July 6, 2016, this case was initially assigned to the Special Processing Unit ("SPU"),

<sup>&</sup>lt;sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. **This means the decision will be available to anyone with access to the Internet.** When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

<sup>&</sup>lt;sup>2</sup> This is not a Table injury because the Vaccine Injury Table change making SIRVA a Table injury is effective only for petitions filed after March 21, 2017. Petitioner filed her petition before that date.

but failed to settle. The case was reassigned to the undersigned on March 6, 2017.

The undersigned held a factual hearing on January 18, 2018. Testifying for petitioner were petitioner, April Silva (petitioner's spouse), Collen Bedford (petitioner's sister), Carol Hurley (petitioner's mother), and Dustin Leahy (petitioner's childhood friend). The witnesses were sequestered.

On March 15, 2018, petitioner filed her posthearing brief.

On April 30, 2018, respondent filed his posthearing brief.

On May 15, 2018, petitioner filed her response to respondent's posthearing brief.

On August 20, 2018, the undersigned issued a finding of fact (onset), finding that petitioner's shoulder pain began in December 2013 and not immediately after her November 1, 2013 flu vaccination. The undersigned gave petitioner until September 19, 2018 to file either: (1) a motion for dismissal, or (2) a status report advising the undersigned how she would like to proceed.

On September 19, 2018, petitioner moved for an extension of time of 30 days until October 19, 2018, to determine how she wanted to proceed, which motion the undersigned granted.

On October 19, 2018, petitioner filed a status report and motion for an extension of time of 30 days until November 19, 2018 to determine how she wanted to proceed, which motion the undersigned granted. However, the undersigned stated in her Order of October 22, 2018 that if petitioner failed to file either a motion to dismiss or an expert report in support of her allegations by November 19, 2018, the undersigned would dismiss the petition on the basis of a failure to prosecute and a failure to make a prima facie case.

On November 19, 2018, petitioner filed a Motion for a Decision Dismissing the Petition, stating that she had chosen not to move forward with her petition.

The undersigned **GRANTS** petitioner's Motion for a Decision Dismissing the Petition and **DISMISSES** this petition.

#### FACTS

#### **Prevaccination Records**

Petitioner was born on August 6, 1976.

On October 25, 2011, petitioner saw Dr. Susan Weinman, a neurologist. Med. recs. Ex.

2, at 19. Petitioner had a history of complex partial seizures, dysthymia,<sup>3</sup> gastroesophageal reflux disease, and von Willebrand's<sup>4</sup> factor. Her mood was good. She was on Topamax<sup>5</sup> and Effexor.<sup>6</sup> <u>Id.</u> Petitioner had a history of depression and Dr. Weinman did not think it was secondary to Topamax. She recommended a psychiatric clinical nurse specialist. <u>Id.</u> at 20.

On October 19, 2010, petitioner saw Dr. Weinman. <u>Id.</u> at 15. She and her partner were thinking of having a baby, with the partner as the birth mother. Petitioner stopped smoking in August. <u>Id.</u>

On July 24, 2012, petitioner saw Dr. Weinman. <u>Id.</u> at 13. Petitioner had a history of complex partial seizures and recently seized on July 15, 2012. She lost consciousness briefly three times over a five-minute period. She denied recent stressors. She stopped taking Topamax in March, but that day said she was noncompliant even when she was taking it. Petitioner had been seizure-free since 2004. Dr. Weinman recommended restarting Topamax and she just did. Her mood was good. She also had stopped taking Effexor. She married her wife one year previously. Petitioner went on a modified diet, exercised, and lost some weight. Her weight was 191 pounds. <u>Id.</u>

On August 17, 2012, petitioner saw James D'Aquila, a chiropractor, for cervical rotation of her right C-3 post C-4. Med. recs. Ex. 25, at 1. Chiropractor Aquila also did a thoracic rotation of her right T10. Id.

On August 21, 2012, chiropractor Aquila did a rotation of petitioner's left C4. Id.

On October 23, 2012, petitioner saw Dr. Weinman. Med. recs. Ex. 2, at 12. She had mild hand tingling as a side effect of Topamax. Her mood was more depressed and she was emotional. Her wife was pregnant after much effort. Petitioner had been on Effexor but stopped taking it. In the past, petitioner saw a psychiatric clinical nurse specialist and said she would like to see her again, which Dr. Weinman encouraged. Petitioner's weight was 184 pounds. She was tearful at one point. <u>Id.</u>

On February 12, 2013, petitioner saw Dr. Weinman. Id. at 10. Her mood was more

<sup>&</sup>lt;sup>3</sup> Dysthymia or dysthymic disorder is "a mood disorder characterized by depressed feeling (sad, blue, low), loss of interest or pleasure in one's usual activities, and by at least some of the following: altered appetite, disturbed sleep patterns, lack of energy, low self esteem, poor concentration or decision-making skills, and feelings of hopelessness." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 550 (32<sup>nd</sup> ed. 2012) (hereinafter "Dorland's").

<sup>&</sup>lt;sup>4</sup> Von Willebrand's disease "is a congenital bleeding disorder, usually of autosomal dominant inheritance, characterized by deficiency of von Willebrand factor, with prolonged bleeding time and often impairment of adhesion of platelets on glass beads, associated with epistaxis and increased bleeding after trauma or surgery...." <u>Dorland's</u> at 544.

<sup>&</sup>lt;sup>5</sup> Topamax is trademark for topiramate which is "a substituted monosaccharide used as an anticonvulsant in the treatment of partial seizures." <u>Dorland's</u> at 1940.

<sup>&</sup>lt;sup>6</sup> Effexor is trademark for venlafaxine hydrochloride which is "a serotonin-norepinephrine reuptake inhibitor [SSRI]; used as an antidepressant and antianxiety agent." <u>Dorland's</u> at 2046.

depressed and her wife had miscarried. They will continue with in vitro. Petitioner was back on Effexor and seeing a therapist for counseling. Petitioner was smoking again one-half a pack per day. Her weight was 185 pounds. <u>Id.</u>

On July 2, 2013, petitioner saw Dr. Weinman and told her that she wanted to taper off Topamax prior to donating her eggs to be fertilized in vitro and implanted in her partner. Med. recs. Ex. 2, at 8. She had a history of seizures and also wanted to stop taking Effexor as well. <u>Id.</u> Dr. Weinman counseled petitioner that with her history of depression, recent stressor and hormone therapy could impact her mood. <u>Id.</u> at 9. Dr. Weinman gave her the name of a psychiatrist who specializes in women's issues. <u>Id.</u> Petitioner refused to be weighed. <u>Id.</u> at 8.

On July 17, 2013, petitioner paid her first visit to Women and Infants Hospital of Rhode Island and spoke to Dr. Carol A. Wheeler after petitioner and her spouse April Silva signed informed consent forms for: (1) in vitro fertilization with donor eggs, (2) yearly freezing of preembryos, and (3) donor sperm. Med. recs. Ex. 3, at 4-9, 10-13, 14-15. Petitioner told Dr. Wheeler that she wanted to donate eggs for her partner. <u>Id.</u> at 1. Petitioner has von Willebrand's disease and her egg retrieval might need DDAVP.<sup>7</sup> <u>Id.</u> at 1. Petitioner also had a seizure disorder and was weaning off Topamax. <u>Id.</u>

On October 9, 2013, petitioner donated her eggs to her partner via transvaginal ultrasound guided oocyte aspiration with conscious sedation. Med. recs. Ex. 3, at 47. On October 9, 2013, petitioner weighed 209 pounds and was 5'4" inches tall. <u>Id.</u> at 101.

On October 21, 2013, three of petitioner's eggs were transferred to April Silva but she subsequently did not become pregnant. <u>Id.</u> at 56. They would do one more cycle for the partner. <u>Id.</u>

On November 1, 2013, Nancy Donahue, who worked with Dr. Wheeler, spoke with petitioner who said she would like to move forward with another donor egg cycle to her partner April Silva before the end of the year. <u>Id.</u> at 57.

#### **Postvaccination Records**

The vaccine record notes petitioner received flu vaccine in her right arm, not her left arm, on November 1, 2013. Med. recs. Ex. 1, at 1. An undated handwritten note at the bottom of the Screening Questionnaire and Consent Form reads: "Note to MD: RPh. that administered vaccine circled right arm[;] however patient recalls vaccine given in left arm + Rite Aid system agrees." This is followed by a circled "MI" and the number 434-1333. Id. Petitioner filed additional records from Rite Aid showing that the vaccination site was the left deltoid. Med. recs. Ex. 16, at 2.

<sup>&</sup>lt;sup>7</sup> DDAVP is desmopressin acetate, "a potent synthetic analogue of vasopressin, used . . . to increase coagulation factor VIII activity before surgical procedures in patients with . . . von Willebrand disease." <u>Dorland's</u> at 500.

On November 7, 2013, Nancy Donahue wrote a note that she anticipated petitioner would have another egg retrieval around December 17, 2013 and transference of eggs to April Silva on December 20, 2013. Med. recs. Ex. 3, at 58.

On November 19, 2013, petitioner called Nancy Donahue with one day of menses. <u>Id.</u> at 61. Ms. Donahue advised petitioner to start oral contraceptives that day, continue through November 29, 2013, and then discontinue. <u>Id.</u>

On November 29, 2013, petitioner and her partner signed another consent form for in vitro fertilization with donor eggs. <u>Id.</u> at 67-72.

On December 16, 2013, Dr. Wheeler performed oocyte retrieval of petitioner's eggs with transvaginal ultrasound guided oocyte aspiration under conscious sedation. <u>Id.</u> at 91. On December 16, 2013, petitioner weighed 218 pounds and was 5'4" tall. <u>Id.</u> at 105.

Almost three months later, on March 4, 2014, petitioner saw her chiropractor James D'Aquila. Med. recs. Ex. 15, at 1. (This is a transcription of the handwritten records of Exhibit 8, at 1.) Petitioner did not give him a history or, if she did, he did not write one down. He did a left shoulder adjustment. She came back for further adjustments on March 8, 2014, March 11, 2014, and March 20, 2014. Id.

On March 18, 2013, petitioner saw Dr. Weinman, her neurologist. Med. recs. Ex. 2, at 5. Petitioner remained off Topamax. Her partner was pregnant. Petitioner denied episodes of loss of consciousness, staring spells, or déjà vu. Her mood had been good recently and she preferred to stay off Effexor. On physical examination, petitioner had normal muscle bulk and tone, strength of 5/5 throughout, and symmetrical fine motor movements. Her sensory examination was intact and symmetrical. The medical record for this visit does not note petitioner telling Dr. Weinman that her left shoulder hurt. Dr. Weinman advised her to go back on Topamax as petitioner would soon be taking care of and driving an infant as she and her partner were expecting a baby soon. Dr. Weinman told petitioner to continue to get adequate sleep. Id.

On March 21, 2014, petitioner had cervical spinal x-rays done at the request of chiropractor D'Aquila. Med. recs. Ex. 12, at 1. Dr. Donnella S. Corneau wrote next to "history" that petitioner had a history of neck pain extending to her left shoulder. <u>Id.</u> at 1-2. The x-ray showed straightening of cervical lordosis, which can be seen with spasm or pain, and mild anterior osteophytic spurring of the cervical spine. <u>Id.</u> at 1.

On April 28, 2014, petitioner saw Dr. Thomas Bliss, an orthopedist, and filled out a questionnaire. Med. recs. Ex. 7, at 1. She wrote that her left shoulder was killing her and it started about six months earlier, which would be the end of November 2013. However, she wrote in the questionnaire that she received flu vaccine on September 14, 2013, putting the onset of her pain about two months after her flu vaccination. <u>Id.</u> She wrote that the pain was intermittent. <u>Id.</u> She recorded her height as 64 inches and weight as 195 pounds. <u>Id.</u> at 2. She told Dr. Bliss, "Nothing specific started this [pain] off." Id. at 3. She told Dr. Bliss that the pain

was quite bad for the past three months or so. She said in November 2013, she had an IVF procedure lasting about four hours under anesthesia and, after that, she had some aching in her neck and jaw. That gradually improved but was replaced by pain in her left shoulder which got significantly worse and, over time, she noticed she had difficulty moving her shoulder. On physical examination, Dr. Bliss noted a somewhat increased cervical lordosis<sup>8</sup> and thoracic kyphosis.<sup>9</sup> X-rays of petitioner's cervical spine and left shoulder appeared normal to him. He diagnosed petitioner with adhesive capsulitis of her left shoulder secondary to a chronic cervical strain. He injected Marcaine and Kenalog-40 and prescribed physical therapy. Id.

On May 1, 2014, petitioner went to physical therapy and gave a history to Alexander Neal, DPT. Med. recs. Ex. 9, at 1. She said that she had surgery for IVF in November and December 2013. She noted "that while under anesthesia, [she] had difficulty breathing and had to be lifted by her neck to assist breathing that left bruising of her neck. Since then, [she] has had shoulder pain that began in January 2014 and states that she thinks a nerve was pinched while being under [anesthesia]." Id. Chiropractic treatment only caused more pain. Id. Mr. Neal diagnosed petitioner with adhesive capsulitis of her left shoulder. Id. at 2.

On August 7, 2014, petitioner returned to Dr. Bliss and stated that she remembered "she had a flu shot in December" and thought that her left arm pain might have started after the flu shot. Med. recs. Ex. 7, at 5.

On August 8, 2014, petitioner had an MRI of her left shoulder, showing mild thickening of the inferior capsule with surrounding edema which can be seen in adhesive capsulitis. <u>Id.</u> at 4.

On August 19, 2014, petitioner filled out a Medical History and Review of Systems Questionnaire for Dr. Andrew Green, an orthopedic surgeon. Med. recs. Ex. 6, at 8. She wrote that the onset of her problem in her left shoulder began in December 2013. <u>Id.</u> She gave a history to Dr. Green that the onset of anterior left shoulder pain with intermittent radiation to her wrist and decreased range of motion began in December 2013 with no associated trauma. <u>Id.</u> at 3. Dr. Green diagnosed petitioner with left shoulder adhesive capsulitis. <u>Id.</u>

On August 26, 2014, petitioner saw Dr. Weinman, her neurologist. Med. recs. Ex. 2, at 3. Petitioner told Dr. Weinman that she had had a frozen shoulder since she received a flu shot in December 2013. Id.

On September 2, 2014, petitioner received Tdap vaccine in her left deltoid. Med. recs. Ex. 10, at 33.

On March 18, 2016, petitioner had arthroscopic capsular release and debridement surgery for adhesive capsulitis. Med. recs. Ex. 6, at 11-12.

<sup>&</sup>lt;sup>8</sup> Cervical lordosis is "the dorsally concave curvature of the cervical vertebral column when seen from the side." <u>Dorland's</u> at 1074.

<sup>&</sup>lt;sup>9</sup> Thoracic kyphosis is "the dorsally convex curve formed by the thoracic vertebral column when seen from the side." <u>Dorland's</u> at 993.

#### **Affidavits**

On July 11, 2016, petitioner filed her affidavit. Ex. 13. She gives a graphic description of immediate pain after flu vaccination, a pain she "had never experienced before," resulting in blood gushing out and running down her arm. Ex. 13, ¶ 3, at 2. Petitioner states the pharmacist applied pressure with some gauze and then put on a Band-Aid. <u>Id.</u> Petitioner states she expected the pain to go away, but it instead intensified. <u>Id.</u> at ¶¶ 4 and 5, at 2. She "would get a sharp pain that felt like a knife in the center of her shoulder joint for a few seconds" which would then go away. <u>Id.</u> at ¶ 5, at 2. Over time, "the pain became increasingly intense and more frequent." <u>Id.</u>

On February 27, 2017, petitioner filed a supplemental affidavit. Ex. 17. She reiterates that she experienced immediate pain in her left shoulder after her flu vaccination on November 1, 2013. Id. at 1, ¶ 2. She explains that her December 16, 2013 egg retrieval procedure should have taken one hour, but took four hours. Id. She says that she continued to have shoulder pain and assumed it would go away. Id. at 2, ¶ 3. Her chiropractor Dr. Jim [James D'Aquila] told her in March 2014 that he thought petitioner had neck pain that radiated out to her left shoulder as a result of the way she was placed on the table during her December 2013 egg retrieval. Id. at 2-3. ¶ 5. Dr. Jim told her that her neck was strained. Id. at 3, ¶ 5. She saw Dr. Thomas Bliss, an orthopedist, in April 2014, and told him what Dr. Jim said about her egg retrieval. Id. at 3, ¶ 6. Dr. Bliss diagnosed her with frozen shoulder. Id. Only when she read on the Internet that other people had frozen shoulder from flu vaccinations did she recall that her flu shot hurt and her arm bled significantly afterward. Id. at 3, ¶ 7. Until then, she found it hard to believe that a flu vaccination could cause severe and sustained pain. Id.

On February 27, 2017, petitioner filed the affidavit of her wife April Silva. Ex. 18. On November 1, 2013, she and her wife received flu vaccinations. Id. at 1,  $\P$  2. The technician appeared to jam the needle in petitioner's arm and when the needle came out, clear liquid and blood trickled down her arm. Id. Petitioner's arm felt sore immediately. Id. As the weeks passed, petitioner's pain worsened. Id. at 2,  $\P$  3. Petitioner saw a chiropractor in March 2014. He suggested her shoulder pain could be coming from her neck and related to her egg retrieval procedure. Id. at 3,  $\P$  6.

On February 27, 2017, petitioner filed the affidavit of her mother Carol Hurley. Ex. 19. She states that during the 2013-2014 winter, petitioner had terrible left shoulder pain and could not shovel snow. Id. at 1,  $\P$  2. Ms. Hurley had the snow removal company she used for her business go to petitioner's and April's home each time it snowed. Id. Ms. Hurley does not say anything about the timing of the onset of petitioner's left shoulder pain.

On February 27, 2017, petitioner filed the affidavit of her sister Colleen Bedford. Ex. 20. She states that during the holiday season in 2013, she remembers noticing a change in petitioner. She complained of shoulder pain and stopped using her left arm. Id. at 1,  $\P$  2. Ms. Bedford does not say anything about the timing of the onset of petitioner's left shoulder pain.

On February 27, 2017, petitioner filed the affidavit of her childhood friend Dustin Leahy. Ex. 21. In December 2013, he visited petitioner's store to buy a ring for his girlfriend Katie as a Christmas present. Id. at 1,  $\P$  2. Petitioner told him she had a lot of pain in her left shoulder. He came back to petitioner's store the next day to give her pain patches. Id. at  $\P$  3. Mr. Leahy does not say anything about the timing of the onset of petitioner's left shoulder pain.

On December 20, 2017, petitioner filed her second supplemental affidavit. Ex. 22. She reiterates her prior statements and states, "I did not know that my shoulder pain could have been caused by my flu vaccination. I did not know it was possible for a vaccination to cause the kind of pain I felt in my left shoulder." Id. at 2-3, ¶ 3. She explains she wrote that she received flu vaccine on September 14, 2013 in the questionnaire in conjunction with her April 28, 2014 visit to Dr. Thomas Bliss, an orthopedist, because she did not recall exactly when she received flu vaccine. Id. at 3-4, ¶ 5. She states, "At the time I filled out the questionnaire, I did not associate my pain with my flu vaccination." Id. at 4. In addition, Dr. Jim [D'Aquila] told her that her pain could have been related to her egg-retrieval procedure. Id. She states that her "shoulder pain never went away following [her] flu vaccination." Id. at 5-6, ¶ 8.

#### TESTIMONY

Petitioner testified first. Tr. at 4. On November 1, 2013, April and petitioner went to Rite Aid for flu vaccinations. <u>Id.</u> at 8. The woman who injected petitioner "hit" her with a really high shot, almost in the corner of her shoulder, not where the fatty part is. "It hurt immediately really bad. And when she took the needle out, some of the flu vaccine or whatever, and then blood came out, really far down my arm like it was almost pouring out. And the lady went and got something to clean it up. So it was really painful when she first did it." <u>Id.</u>

Petitioner said that her shoulder hurt for a couple of days, and then the pain was intermittent. <u>Id.</u> Petitioner did not remember specifically having shoulder pain on Thanksgiving which was at her sister's house. <u>Id.</u> at 9. Petitioner said that except for a day or two after the vaccination when she thought about her shoulder pain after the flu vaccination, she "didn't really think about it because it wasn't like I got the shot and then I was in immense pain forever." <u>Id.</u> at 10. She did not report her left shoulder pain to the ultrasound technician when she was undergoing multiple ultrasounds for her December 16, 2013 egg retrieval. <u>Id.</u> at 10-11.

Petitioner described the December 16, 2013 egg retrieval procedure. <u>Id.</u> at 11. She said, "They knocked me out. I had had it done before and last time it was only like a half-hour thing or an hour. This time, they knocked me out and I was—when I came through [sic], they said that they nicked me and so I had a lot of [vaginal] pain." <u>Id.</u> She does not recall whether she had left shoulder pain at this time. <u>Id.</u> at 12.

She remembers Dustin Leahy buying a ring from her store right before Christmas. <u>Id.</u> She did not connect her shoulder pain to her vaccination. Her pain intensified. <u>Id.</u> When she spoke to her chiropractor Dr. Jim in March 2014, he asked if there were anything unusual that happened to her recently and she told him about the egg retrieval. <u>Id.</u> at 16. She did not remember her flu vaccination at the time. Then she saw Dr. Bliss who told her about adhesive capsulitis. <u>Id.</u> at 16. She wrote in the questionnaire at Dr. Bliss's office that she received flu vaccine on September 14, 2013, but she was not sleeping well then and could not recall any dates. <u>Id.</u> at 18. She did not at that time associate her left shoulder pain with the flu vaccination. <u>Id.</u>

She remembered when she had the egg retrieval in December 2013, she had a bruise on her cheek. <u>Id.</u> at 20. When she told the chiropractor, he said that she probably strained her neck and that pain radiated out into her shoulder. <u>Id.</u> As soon as Dr. Bliss diagnosed petitioner with adhesive capsulitis, she went on the Internet. <u>Id.</u> at 21. She continued:

[T]he one thing that I did notice – because when I was doing the research, it was saying that most people that had this adhesive capsulitis were women that were over 60 that had diabetes and everything, and I didn't have any of that stuff. And then I ended up on some chat board and it was people that were younger and they related it back to the flu shot. So then I started thinking, I was like, yeah, I remember getting the flu shot now. It was like a light went off [sic] and I remembered getting the flu shot and having the pain then.

#### <u>Id.</u> at 21-22.

Petitioner said this was the first time she related the flu vaccine to her shoulder pain and mentioned her Internet research to Dr. Bliss. <u>Id.</u> at 22. However, she told Dr. Bliss that she received flu vaccine in December 2013. <u>Id.</u> at 22-23. Petitioner's counsel asked her to explain why she told Dr. Bliss that she received flu vaccine in December 2013. Petitioner responded, "It's hard to remember backwards. So I just – I don't know why I said December. I said – probably just didn't have any sleep and I couldn't remember." <u>Id.</u> at 23.

Petitioner's counsel asked petitioner why, when she filled out a questionnaire for her second orthopedist Dr. Green, she wrote that her problem began in December 2013. Petitioner replied, "I don't know. I just didn't remember correctly." <u>Id.</u> Petitioner's counsel asked petitioner why she told her neurologist Dr. Weinman that she had a frozen shoulder since her flu shot in December 2013. <u>Id.</u> at 24. Petitioner replied, "I think it's the same thing as – as I just didn't remember if I had it in December or November." <u>Id.</u> Petitioner said she gave the history to the radiologist on March 21, 2014 who took x-rays of her cervical spine that she had a history of neck pain extending to her left shoulder. <u>Id.</u> at 30-31. Petitioner agreed that she told P-T Alexander Neal on May 1, 2014 that she believed her left shoulder pain was associated with her egg retrieval procedure in December 2013. <u>Id.</u> at 34. Petitioner said she had never given a medical history to any provider that her shoulder pain occurred in November 2013 immediately following a flu vaccination. <u>Id.</u> at 37. She does not think any of her treating physicians attributed her left shoulder pain to flu vaccination. Id. at 37-38.

The following colloquy occurred:

BY THE COURT:

Q. You have mentioned that after you saw Dr. Bliss on April 28, 2014, and he diagnosed you with adhesive capsulitis, you then went to the Internet to look up the illness for purposes of treatment, but also to find out more about it, is that correct?

A. Yes.

Q. All right. And when you saw that older people who had obesity and diabetes had it, that didn't seem to help you understand your condition, is that right?

A. Yes.

Q. And so when you saw that there were younger people who had received flu vaccinations and then complained of adhesive capsulitis, that's when the lightbulb went off, that's when you connected flu vaccine to shoulder pain, is that right?

A. Yes.

Q. And you told a multitude of doctors and others that your pain began in December after a flu shot, isn't that right?

A. Yes.

Q. And the reasons that you said December was that's when you remembered your shoulder pain beginning, isn't that correct?

A. I remember it beginning around that, so, yeah, I probably said December.

Q. And the one thing you couldn't remember, which I can perfectly understand why, is you didn't know when your flu shot had been administered, is that correct?

A. Yes.

<u>Id.</u> at 40-41.

April Silva testified next for petitioner. <u>Id.</u> at 42. On November 1, 2013, she and petitioner received flu vaccinations at a pharmacy. <u>Id.</u> at 45. The pharmacist seemed to jab petitioner's arm really hard. Clear liquid started running down which she thought was the vaccine, and blood started pouring down. <u>Id.</u> Petitioner had some pain and aching. <u>Id.</u> Ms. Silva did not relate petitioner's pain to her vaccination because she had never heard of any shoulder pain from a vaccination and never heard of frozen shoulder until petitioner was diagnosed. <u>Id.</u> at 46. She carried all the bags for visiting their families at Thanksgiving. <u>Id.</u> at 47. She did not connect petitioner's initial pain with the vaccination because there were so many things going on. Petitioner went to the gym and could have pulled a muscle. <u>Id.</u> at 46. She remembers petitioner being in pain during Ms. Silva's pregnancy and before that. <u>Id.</u> at 48. At Christmas, Ms. Silva carried all the bags to visit her and petitioner's families. <u>Id.</u>

When she and petitioner researched frozen shoulder on the Internet, "a lightbulb went off and we were like, oh, my God, that flu shot that you got was so horrible, it must have been that." <u>Id.</u> at 51.

Colleen Bedford testified next for petitioner. <u>Id.</u> at 55. Ms. Bedford is petitioner's sister. <u>Id.</u> at 56. She held Thanksgiving dinner for the family in 2013. <u>Id.</u> at 58. She cannot say specifically that petitioner had left shoulder pain during Thanksgiving 2013. <u>Id.</u> at 59. Petitioner mentioned she had received her shot and that her arm was sore and bled really badly. Ms. Bedford said she visually observed symptoms of petitioner's left shoulder pain immediately after the shot but just thought it would be sore, but did not know for how long. <u>Id.</u> Around Thanksgiving, petitioner was doing exercises for her arm and using a moist heat sock on her arm. <u>Id.</u> at 60. Ms. Bedford went Christmas shopping in early December 2013 with petitioner, but petitioner could not pick up Ms. Bedford's two small children or strap them into car seats. <u>Id.</u> at 60-61. She does not know if this was before or after the December egg retrieval. Id. at 61.

Carol Hurley testified next for petitioner. <u>Id.</u> at 65. She is petitioner's mother. <u>Id.</u> She recalled petitioner in a lot of pain during Thanksgiving 2013. <u>Id.</u> at 67. Petitioner would heat up a sock with rice in it and put it on her shoulder. <u>Id.</u> At Christmas, petitioner would not carry any bags of presents into the house. <u>Id.</u> at 67-68. Ms. Hurley said that after petitioner had her flu shot, she progressively got worse. <u>Id.</u> at 70.

Dustin Leahy testified next for petitioner. <u>Id.</u> at 75. He grew up with petitioner and had gone to school with her since they were 13 years old. <u>Id.</u> at 76. That would be 25 years. <u>Id.</u> He went to petitioner's shop the week before Christmas to buy a ring for his girlfriend. <u>Id.</u> at 77, 79. Petitioner told him she had sharp pains in her shoulder. <u>Id.</u> at 78. He brought her pain patches three to five times. <u>Id.</u> at 79.

At the close of the hearing, respondent's counsel reiterated respondent's position that there was no reasonable basis to bring this case. <u>Id.</u> at 81.

#### DISCUSSION

The Vaccine Act, 42 U.S.C. § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion.

The medical records do not support petitioner's allegation of onset of shoulder pain on November 1, 2013. None of petitioner's treating doctors attributed her left shoulder pain to vaccination. Her chiropractor thought her shoulder pain was due to the manual repositioning of petitioner's body when she was under anesthesia in mid-December 2013, which resulted in her having an achy neck and jaw. The achy neck and jaw improved but was replaced by a painful left shoulder. Dr. Bliss, petitioner's first orthopedist, diagnosed her adhesive capsulitis as secondary to cervical (neck) strain. She told Dr. Bliss that nothing specific started her pain. Even when petitioner, having educated herself on the Internet about flu vaccination and SIRVA, told Dr. Bliss and Dr. Weinman, her neurologist, that her left shoulder pain began in December 2013 right after a flu shot, neither one diagnosed her with SIRVA due to flu vaccination. Petitioner also informed her second orthopedist Dr. Green that the onset of her left shoulder pain was in December 2013. The overwhelming objective evidence from the contemporaneous histories petitioner gave was that her left shoulder pain began in December 2013.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. <u>United States v. United States Gypsum</u> <u>Co.</u>, 333 U.S. 364, 396 (1948); <u>Burns v. Sec'y of HHS</u>, 3 F.3d 415 (Fed. Cir. 1993); <u>Ware v.</u> <u>Sec'y of HHS</u>, 28 Fed. Cl. 716, 719 (1993); <u>Estate of Arrowood v. Sec'y of HHS</u>, 28 Fed. Cl. 453 (1993); <u>Murphy v. Sec'y of HHS</u>, 23 Cl. Ct. 726, 733 (1991), <u>aff'd</u>, 968 F.2d 1226 (Fed. Cir.), <u>cert. denied sub nom. Murphy v. Sullivan</u>, 113 S. Ct. 263 (1992); <u>Montgomery Coca-Cola</u> <u>Bottling Co. v. United States</u>, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Sec'y of HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

A discussion of the other witnesses at hearing is appropriate here. The undersigned was surprised to hear petitioner's sister and mother giving detailed onset information that is completely absent from their affidavits. Because the undersigned does not find petitioner's or her wife's testimony on onset credible, the undersigned similarly finds petitioner's sister's and mother's testimony on onset not credible. Petitioner's childhood friend Dustin Leahy's testimony was consistent with his affidavit, i.e., he has no idea when petitioner's left shoulder began to bother her. The contemporary medical records and the histories petitioner gave to all her treaters are that either there were over two months between her flu vaccination and the onset of her pain (her questionnaire answers on April 28, 2014 for her first visit to Dr. Bliss) or that her

arm pain began in December 2013 (Dr. Bliss, Dr. Weinman, Dr. Green). These consistent contemporaneous histories outweigh the fact witnesses' attempt at hearing to persuade the undersigned that petitioner's left shoulder pain began on November 1, 2013 and continued episodically until it worsened in January 2014.

The undersigned ruled on August 20, 2018 that petitioner's onset of left shoulder pain occurred in December 2013, at least one month after her November 1, 2013 flu vaccination. The undersigned gave petitioner the opportunity to file an expert report in support of a flu vaccination causing pain one month later, but petitioner did not do so.

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(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." <u>Althen v. Sec'y of HHS</u>, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In <u>Althen</u>, the Federal Circuit quoted its opinion in <u>Grant v. Secretary of Health and Human Services</u>, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" <u>i.e.</u>, "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." <u>Grant</u>, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. <u>Id.</u> at 1148.

Petitioner must show not only that but for flu vaccine, she would not have left shoulder pain, but also that flu vaccine was a substantial factor in causing her left shoulder pain. <u>Shyface</u> <u>v. Sec'y of HHS</u>, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The undersigned **DISMISSES** this petition for failure to make a prima facie case of causation of fact.

#### CONCLUSION

This case is now **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment herewith.<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.

# IT IS SO ORDERED.

Dated: November 19, 2018

/s/ Laura D. Millman Laura D. Millman Special Master