

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-1541V

Filed: August 9, 2019

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PAUL L. COOPER,	*	
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Petitioner,	*	Vaccine Act; Fact Ruling;
v.	*	Six Month Residual Requirement;
	*	Influenza (Flu) Vaccine; Shoulder
SECRETARY OF HEALTH	*	Injury Related to Vaccine
AND HUMAN SERVICES,	*	Administration (SIRVA); Special
	*	Processing Unit (SPU)
Respondent.	*	
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*Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.*  
*Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for respondent.*

### **ORDER DENYING RESPONDENT’S MOTION TO DISMISS AND FACT RULING ON SIX MONTH REQUIREMENT <sup>1</sup>**

**Dorsey**, Chief Special Master:

On October 16, 2017, Paul L. Cooper (“Mr. Cooper” or “petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et. seq, (the “Vaccine Act” or “Program”). Petitioner alleges that he developed a left shoulder injury related to vaccine administration (“SIRVA”) as a result of receiving an influenza (“flu”) vaccine on October 16, 2014. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

After a review of the petition and supporting documents, respondent filed a combined report pursuant to Vaccine Rule 4(c) and Motion to Dismiss (“Motion to Dismiss”), asserting that petitioner had not established that he suffered from the

<sup>1</sup> The undersigned intends to post this order on the United States Court of Federal Claims’ website. **This means the order 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 order contains a reasoned explanation for the action in this case, the 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).

residual effects of his alleged vaccine-related injury for more than six months after vaccination as required by the Vaccine Act. Respondent's Motion to Dismiss (ECF No. 18). For the reasons discussed herein, respondent's Motion to Dismiss is **DENIED**.

**I. Procedural History**

Approximately one month after filing his petition for compensation, Mr. Cooper filed seven medical record exhibits and a Statement of Completion. (ECF Nos. 7-8). During the initial status conference, counsel for petitioner stated that this petition was filed due to the pending statute of limitations and that further investigation into petitioner's claims would be necessary. Scheduling Order dated Jan. 10, 2018 (ECF No. 9).

In April and May 2018, petitioner filed additional medical records, a supplemental affidavit, a letter from his physician and a second Statement of Completion. (ECF Nos. 12-16). On July 9, 2019, respondent filed a status report with a detailed list of records respondent believed to be outstanding. Respondent stated that "[b]ased on the current record, petitioner's claim lacks reasonable basis." Respondent's Status Report dated July 9, 2018 at 2. (ECF No. 18).

From July to September 2018, petitioner filed two additional medical record exhibits, a supplemental affidavit and another Statement of Completion stating that petitioner "now believes all relevant medical records have been filed in this matter." (ECF Nos. 20-21, 23).

On April 9, 2019, respondent filed his report pursuant to Vaccine Rule 4(c) and a Motion to Dismiss arguing that the "evidence does not support a finding that petitioner suffered the residual effects of his alleged injury for more than six months after the administration of the vaccine or that treatment of petitioner's alleged vaccine-related injury resulted in inpatient hospitalization and surgical intervention." Respondent's 4(c) Report and Motion to Dismiss ("Motion to Dismiss") at 1. Specifically, respondent asserted that petitioner did not seek treatment for his shoulder pain until almost three months after his vaccination, and nearly three years passed before petitioner again complained of shoulder pain. *Id.* at 5.

On June 28, 2019, petitioner filed a response to the Motion to Dismiss ("Response"). ECF No. 29. In it, petitioner argues that "[t]here is preponderant evidence to support Petitioner's claim that he suffered the residual effects of his vaccine injury for more than six months" citing to his medical records, affidavits, and a letter from his treating physician, Dr. Ellen Vaughney. *Id.* at 7. Petitioner argues that not only has he submitted preponderant evidence to support a finding that he suffered the residual effects or complications of his shoulder pain for more than six months, but he also submitted documentation from his treating provider "causally connect[ing] the vaccination to his shoulder pain." *Id.* at 3.

This order and fact-finding will only address whether petitioner has satisfied the six-month severity requirement of the Vaccine Act. The issue of causation will be not be addressed.

## II. Medical History<sup>2</sup>

At the time of vaccination, Mr. Cooper was a 62 year-old self-employed musician. Petitioner's Exhibit ("Pet. Ex.") 3 at 2. Prior to vaccination, petitioner's medical history does not reflect any record of shoulder pain. *Id.*; see generally Pet. Ex. 6.<sup>3</sup>

On October 16, 2014, petitioner received a flu vaccine to his left deltoid at the Northern Virginia Pulmonary and Critical Care Associates, P.C. located in Arlington, Virginia. Pet. Ex. 1 at 7;<sup>4</sup> Pet. Ex. 7 at 2. Petitioner presented to this appointment for a pulmonary evaluation because he had been a pack-a-day smoker for the past 50 years and his wife insisted he be evaluated. *Id.* In the assessment by Dr. Ellen C. Vaughey, it was noted that Mr. Cooper had "no real pulmonary symptoms" and that he was able to play golf every day and was not limited in his activities. *Id.* The record of the physical examination did not note any abnormalities other than some diminished breath sounds. *Id.* at 5-6. Mr. Cooper was assessed with mild COPD without asthma and he was encouraged to stop smoking. *Id.* at 6.

In his affidavit, Mr. Cooper stated that he began feeling pain "within 24 hours of receiving the flu shot, but I figured that must be normal and it would subside and go away." Pet. Ex. 10 at 1. When that did not happen, "it only got worse, and I suffered through it." *Id.* Mr. Cooper averred that he contacted Dr. Vaughey's office to report his unusual reaction to the flu vaccine, but was told by Dr. Vaughey that she had no experience with negative reactions to the flu vaccine and had no treatment advice or recommendations.<sup>5</sup> *Id.* Mr. Cooper stated that he continued to suffer from left shoulder pain which was consistent and increasing. *Id.*

On January 12, 2015, nearly three months after receiving the vaccination, Mr. Cooper presented to Maurice T. Zagha, MD. While he states in his affidavit that the visit to Dr. Zagha was "specifically for the pain and suffering [he] was experiencing from the flu shot", pet. ex. 10 at 2, the medical notes from this visit document there were four

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<sup>2</sup> The undersigned notes that a total of 17 pages of medical records have been filed in this case, including one page which is a duplication of the vaccination record, and a one page letter from one of Mr. Cooper's treating physicians.

<sup>3</sup> Petitioner only filed one set of records that pre-date his October 16, 2014 flu vaccination. In his supplemental affidavit, petitioner states that he did not have any medical treatment between October of 2011 and October of 2014. Pet. Ex. 13. Petitioner's medical history includes a hernia operation in 2008, noting that he is a current one-pack a day smoker, and a family history of diabetes and heart disease.

<sup>4</sup> Although the record of vaccination does not set forth the site of vaccine administration, respondent does not appear to contest, based on the numerous subsequent medical histories, that it was administered in petitioner's left arm. Motion to Dismiss at 2.

<sup>5</sup> Petitioner did not file any medical records that note or otherwise document this conversation.

complaints that Mr. Cooper wanted addressed. Pet. Ex. 5 at 2. Mr. Cooper complained of a left-sided pain under a scar, back pain, “a sore [left] biceps where he got his flu shot”, and a golf cart hit. *Id.* For his shoulder, the assessment was “internal derangement of [left] shoulder.” In the medical notes, Dr. Zagha noted that Mr. Cooper should be excused for jury duty. *Id.*

The next set of medical records are dated October 12, 2017, two years and nine months after receiving the vaccination. Pet. Ex. 2 at 1. On this date, Mr. Cooper presented to the Virginia Sportsmedicine Institute for complaints of left shoulder pain. Pet. Ex. 2 at 1. He was diagnosed with left shoulder rotator cuff tendinosis and treated with hot/cold packs. *Id.*

One day later, on October 13, 2017, Mr. Cooper presented to Robert P. Nirschl, M.D., M.S., at the Nirschl Orthopaedic Center for Sports Medicine & Joint Reconstruction. Pet. Ex. 3 at 2. Mr. Cooper related that approximately three years prior, he received a flu vaccine injection in his upper lateral left arm and noted “more or less immediate pain and described as burning and intense in and about the area of the injection.” *Id.* Mr. Cooper stated that the pain “lingered for a matter of months and thereafter he has noted pain in and about the shoulder area.” *Id.* Dr. Nirschl stated that this report was “a rotator cuff story” of which the burning sensation had “more or less resolved.” *Id.* On examination, Mr. Cooper had no numbness or tingling to his left arm. *Id.* There was some moderate stiffness in his neck but no history suggestive of radiculopathy to the shoulder. *Id.* Dr. Nirschl noted a full range of motion to the left shoulder and a “minimally positive impingement sign at 90 degrees of forward flexion and abduction.” *Id.* at 2. There was no evidence of inflammation or atrophy. *Id.* There was a mildly diminished external rotation strength of the left shoulder. *Id.* An x-ray of the left shoulder revealed

a prominent exostosis<sup>6</sup> at the dorsal distal aspect of the distal clavicle. The remainder of x-ray examination of the shoulder including the glenohumeral joint and the greater tuberosity, and the proximal upper humerus were within normal range.

*Id.* at 3. The diagnoses were: (1) history of initial inflammatory response to the outer upper arm post flu shot injection, (2) presence of some mild rotator cuff tendinosis of the shoulder at this time, evidence of mild rotator cuff tendinosis of the shoulder, (3) evidence of a longstanding bony exostosis at the distal clavicle but no clear evidence of AC osteoarthritis at this time. *Id.* Mr. Cooper was prescribed Prednisone, over-the-counter NSAIDs and “a few sessions” of physical therapy. *Id.* at 4. Dr. Nirschl noted that Mr. Cooper requested a copy of the consultation because he had

communicated with a lawyer who informed him that there is a Government program which reimburses patients who have had evidences of symptoms

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<sup>6</sup> Exostosis is defined as “a benign bony growth projecting outward from the surface of a bone.” *Dorland’s Illustrated Medical Dictionary*, 660 (32d ed. 2012).

in reference to flu shots. Whether or not the current rotator cuff tendinosis is related to the flu shot is uncertain. I advised the patient and his wife who was present that there are many patients who have rotator cuff problems on the basis of attrition and did not have a history of a flu shot inflammatory response. There is no evidence currently of abnormality of the deltoid muscle but initially it might be presumed that there was an inflammatory response possible leaving a small amount of scar residual in the deltoid muscle. Currently however there is no clinical evidence of any major distortion of the deltoid.

*Id.* at 4.

On April 9, 2018, Mr. Cooper filed a letter from Dr. Vaughey (dated March 13, 2018), where Dr. Vaughey confirmed that petitioner received a flu vaccine on October 16, 2014. Pet. Ex. 8 at 2. Dr. Vaughey also confirmed that Mr. Cooper reported that he had spoken with his primary care physician about his shoulder pain and called Dr. Vaughey's office again on January 30, 2015 and February 3, 2015. Dr. Vaughey also noted that Mr. Cooper "communicated with us several times in April between 4/24/15 and 4/27/15." *Id.* Dr. Vaughey stated

[d]ue to the onset of symptoms after the vaccine, the lack of other possible etiologies, and the description by the patient, I think it is more likely than not that his symptoms were due to the flu shot.

*Id.* at 2. On April 27, 2015, a triage coordinator from Dr. Vaughey's office emailed the number of the advocacy line for Novartis to Mr. Cooper to "report his medical condition." Pet. Ex. 9 at 2.

### **III. Affidavit Testimony Regarding Six Month Requirement**

In his affidavit, Mr. Cooper describes that during his visit with Dr. Zagha in January 2015, Dr. Zagha was sympathetic but had no experience with treating adverse reactions to vaccines. Pet. Ex. 10 at 2. Mr. Cooper stated that he followed up with Dr. Zagha again shortly after the January 2015 visit to determine if Dr. Zagha had conducted any research on adverse reactions to vaccines, to which Dr. Zagha "said he had, named 4 or 5 possible injuries." *Id.* Mr. Cooper said that no physical therapy was prescribed, but rather he was encouraged to consult with an orthopedic surgeon. *Id.*

After consulting with Dr. Zagha in January 2015, Mr. Cooper stated that he returned to Dr. Vaughey and repeatedly called and emailed her office to notify her that he continued to experience shoulder pain from the flu shot. Pet. Ex. 10 at 2. He stated that he intended to report his reaction to the vaccine manufacturer about a possible "bad batch". *Id.* Mr. Cooper stated that Dr. Vaughey seemed "clueless on a cure" and "had no therapy to recommend." *Id.* At this point, after having consulted with "two [of the] most highly respected physicians, who had no experience in treating this flu

reaction”, Mr. Cooper stated that he continued to suffer, hoping that the pain would go away on its own, which it did not. *Id.*

Mr. Cooper stated that he could not stand the idea of surgery or even cortisone steroid injections to treat his pain. Pet. Ex. 10 at 2. He stated that he realized he would probably have to endure the pain for the rest of his life. *Id.* Mr. Cooper explained that as a concert guitarist, he needs full functional use of both of his arms and that this injury affected him negatively at a crucial point of his career. *Id.* He stated that he “refused gigs as I lost confidence that my arm would hold up through the evening’s concert. Never did that before. And my arm is hurting me now.” *Id.*

#### **IV. Discussion**

Under the Vaccine Act, a petition for compensation must contain “supporting documentation, demonstrating that the person who suffered [a vaccine related injury] ... suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa–11(c)(1)(D)(i). The burden is on the petitioner to establish, by a preponderance of the evidence, the persistence of a vaccine-caused injury for longer than six months. *Song v. Sec’y of Health & Human Servs.*, 31 Fed. Cl. 61, 65–66, *aff’d*, 41 F.3d 1520 (Fed.Cir.1994). However, dismissal is not appropriate if it appears the parties reasonably contest the length of time that petitioner has suffered from the effects of his alleged vaccine injury. *See, e.g., Faup v. Sec’y of Health & Human Servs.*, No. 12-87V, 2015 WL 443802, at \*4 (Fed. Cl. Spec. Mstr. Jan. 13, 2015).

Although a petitioner cannot establish the length or ongoing nature of an injury merely through his self-assertion, the fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from his alleged injury. *See, e.g., Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at \*3 (Fed. Cl. Spec. Mstr. July 18, 2014) (finding that petitioner suffered from residual symptoms that, due to their mild nature, did not require medical care).

Here, there appears to be no dispute that petitioner received the flu vaccine on October 16, 2014 and he must therefore show that his alleged injuries continued through April 16, 2015. *Herren*, 2014 WL 3889070, at \*2; *see also Hinnefeld v. Sec’y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at \*4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012)(dismissing case where medical history revealed that petitioner’s Guillain-Barré syndrome resolved less than two months after onset).

The medical records and Mr. Cooper’s own affidavit demonstrate that he first presented to a medical professional for treatment for his shoulder injury on January 12, 2015. Pet. Ex. 5 at 2. Although Mr. Cooper averred that he contacted Dr. Vaughney’s office shortly after the vaccination to report his reaction to the flu vaccine, there are no medical records that corroborate this statement.

However, Dr. Vaughey's March 13, 2018 letter supports Mr. Cooper's statement that he called her office in April 2015 to report his continuing shoulder pain. Pet. Ex. 8 at 2. In his affidavit, Mr. Cooper stated that he continued to call and email Dr. Vaughey's office to report his continuing shoulder pain and also to obtain information regarding the vaccine manufacturer in order to report his reaction. Pet. Ex. 10. Dr. Vaughey's letter confirms that Mr. Cooper "communicated with us several times in April between 4/24/15 and 4/27/15." Pet. Ex. 8 at 2. In addition, petitioner's exhibit 9, page 2, is an email from Dr. Vaughey's triage coordinator to Mr. Cooper dated April 27, 2015, providing him with the advocacy line for Novartis, the vaccine manufacturer. *Id.*

"In the Vaccine Program, petitioners are accorded the benefit of close calls." *Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at \*10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013). What favors a ruling in petitioner's favor is not only his affidavit testimony, but also the medical records and Dr. Vaughey's own letter documenting Mr. Cooper's calls and emails to Dr. Vaughey's office from April 24, 2015 to April 27, 2015, more than six months after he received the October 16, 2014 flu vaccine. The undersigned finds that these records provide preponderant proof that Mr. Cooper continued to suffer his alleged vaccine injury for more than six months.

## V. Conclusion

Thus, the undersigned finds, based on the record as a whole, that petitioner has established that he suffered the residual effects of his vaccine-related injury for at least six months as required by the Vaccine Act. Therefore, Respondent's Motion to Dismiss is **DENIED**.

The undersigned notes that the medical record evidence in this case appears incomplete.<sup>7</sup> Therefore, in order to proceed and to ensure the record is complete, petitioner is ORDERED to file a complete set of records from all of his medical providers from three years prior to the October 16, 2014 vaccination to the present. Petitioner shall specifically request a certified and complete set of records from each provider and shall also file copies of each of these requests. The filing of incomplete records will result in delays in adjudicating petitioner's claim. It is imperative that all relevant records are filed in order to proceed.

The following is **ORDERED**:

- (1) Petitioner shall file a complete and certified set of medical records by **Tuesday, October 1, 2019**. When these records have all been filed (and certified by a custodian of records as complete), petitioner shall file **a Statement of Completion**.

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<sup>7</sup> As previously noted, only 17 pages of medical records have been filed. The records appeared to have been faxed to petitioner's counsel's office and no copies of the actual requests for these records were filed.

- (2) Within **30 days of the filing of the Statement of Completion**, the parties shall confer and file **a joint status report** stating how the parties propose proceeding with this matter, i.e., settlement discussions, filing a Rule 4 report, or proceeding to a hearing.
- (3) Additional proceedings will be set after the information in this Ruling and Order is filed.

**IT IS SO ORDERED.**

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