## In the United States Court of Federal Claims office of special masters

No. 16-1248V

(Not to be Published)

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REOINALD OROSE,	*	Special Master Corcoran
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	*	Filed: May 11, 2018
Petitioner,	*	
v.	*	Motion for Ruling on Record;
	*	Dismissal of Petition; Vaccine
SECRETARY OF HEALTH	*	Act; Denial Without Hearing.
AND HUMAN SER VICES,	*	-
	*	
Respondent.	*	
	*	
* * * * * * * * * * * * * * * * * * * *	* *	

Amy S. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Claudia B. Gangi, U.S. Dep't of Justice, Washington, D.C. for Respondent.

## **DECISION DISMISSING CASE FOR INSUFFICIENT PROOF**<sup>1</sup>

On September 30, 2016, Reginald Grose filed a petition seeking compensation under the National Vaccine Injury Compensation Program.<sup>2</sup> The Petition alleges that the influenza ("flu") vaccine Mr. Grose received on October 7, <u>2013</u>, caused him to suffer right shoulder tendinitis, bursitis, and brachial neuritis. *See* Petition ("Pet.") (ECF No. 1) at 1. On January 19, 2017, Petitioner filed an Amended Petition alleging that he received a flu vaccine on October 7, <u>2014</u>, that caused him to suffer right shoulder tendinitis, bursitis, and brachial neuritis.

<sup>&</sup>lt;sup>1</sup> Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.* 

<sup>&</sup>lt;sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

aggravated pre-existing right shoulder injuries. Amended Petition (ECF No. 14) at 1-2. The Amended Petition contains no allegations relating to the flu vaccine received in 2013.<sup>3</sup>

After filing medical records from September 2016 to March 2017, the parties filed the Joint Statement of Completion on March 23, 2017 (ECF No. 22). Respondent then filed his Rule 4(c) Report on August 7, 2018, contesting Petitioner's right to damages (ECF No. 31). More specifically, Respondent's Report asserted that Petitioner had not offered preponderant evidence (medical or scientific) demonstrating a right to compensation with regard to his alleged initial injury (or a significant aggravation thereafter). *Id.* at 6. In addition, Respondent argued that Petitioner's post-vaccination diagnosis of amyotrophic lateral sclerosis ("ALS") was the more likely cause of Petitioner's right shoulder complaints. *Id.* 

Given the issues identified by Respondent in the Rule 4(c) Report, I held a status conference with the parties on September 5, 2017, at which time I discussed the overall viability of Petitioner's claim, and proposed a deadline for Petitioner to retain an expert to opine in this matter. *See* Non-PDF Order, dated Sept. 5, 2017. I specifically directed Petitioner to file an expert report on or before November 9, 2017. *Id.* Thereafter, Petitioner filed two motions for an extension of time to the file the report. *See* ECF Nos. 34, 35. According to Petitioner's second motion, counsel had retained Dr. Marko Bodor to conduct a medical review of his case, which he was still in the process of completing (ECF No. 35). Petitioner filed a third request for an extension of time on January 11, 2018, informing the Court that his expert could not offer a medical opinion in support of his claim, and requesting additional time to determine how he wished to proceed in this matter (ECF No. 36). Thus, in a Non-PDF Order, dated March 30, 2018, I directed Petitioner to file a status report on or before February 16, 2018, indicating if he intended to continue with his claim or request dismissal.

On February 16, 2018, Petitioner filed the present motion for a ruling on the record (rather than file an expert report), setting forth the medical facts in support of his claim and requesting a favorable ruling. *See* Motion for Ruling on the Record, dated Mar. 23, 2018 (ECF No. 39) ("Mot."). In his motion, Petitioner maintains that the flu vaccine he received on October 7, 2014,<sup>4</sup> caused him to suffer immediate right shoulder pain (citing Ex. 11 at 5) which resulted in a right shoulder tendinitis diagnosis roughly three months later on January 19, 2015, and a bursitis (and brachial neuritis) diagnosis roughly five months later on March 19, 2015. *Id.* at 2. Petitioner otherwise maintains that his ALS symptoms (beginning between April and June 2015) are unrelated to the symptoms he experienced post-vaccination in 2014. *Id.* 

<sup>&</sup>lt;sup>3</sup> According to Petitioner's affidavit, he originally thought he received a flu shot in his right arm on October 7, 2013, but later realized the 2013 vaccine was administered in his left shoulder without complications. Ex. 11 at 1.

<sup>&</sup>lt;sup>4</sup> Petitioner's motion contains no allegations relating to the flu vaccine he received on October 7, 2013.

Respondent filed a responses on April 19, 2018, asserting that he relies on the arguments set forth in his Rule 4(c) Report in maintaining that the present matter should be dismissed. Respondent reiterates that the current record does not provide sufficient evidence of vaccine causation based on the lack of support in Petitioner's medical records and his onset of ALS post-vaccination (ECF No. 40).

## **Analysis**

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of his vaccinations, or (2) that he suffered an injury that was actually caused by a vaccine. *See* Sections 13(a)(1)(A) and 11(c)(1). An examination of the record, however, does not uncover preponderant evidence that Mr. Grose suffered a Table injury. Accordingly, Petitioner seeks to establish entitlement via a causation-in-fact, non-Table claim - meaning he must meet the test for such a claim set forth by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005).

Although Petitioner submitted evidence of tendinitis/bursitis/brachial neuritis diagnoses, there is no evidence in the record that any treater linked Petitioner's vaccine to either of his diagnoses thereafter, or to a significant aggravation of any pre-existing injury. At best, the record suggests that at least one of Petitioner's treaters made reference to his shoulder pain starting following vaccination (Ex. 12 at 15).<sup>5</sup> However, upon review, this record appears to establish only that Petitioner <u>himself</u> informed treaters of this fact, or that treaters (accepting his medical history as true) assumed the correlation had been noted in the past, and accordingly recorded those in Mr. Grose's past medical history (Ex. 12 at 15). Such evidence does not establish a causal link between an injury and a vaccination. Overall, the treater opinions contained in the medical record do not support Petitioner's assertion that he suffered a vaccine-induced injury, and it is otherwise undeniable that he was never so diagnosed around the time of the vaccination – or later for that matter.

Petitioner's inability to obtain an expert report to support his claim is also a significant barrier to his claim's overall tenability. Petitioner has offered no medical or scientific support for a theory in which the flu vaccine could be deemed causal of the tendinitis/bursitis/brachial neuritis (or a significant aggravation of a pre-existing injury) that Petitioner experienced. Certainly many Vaccine Program petitioners succeed in alleging a vaccine-induced tendinitis/bursitis injury (or SIRVA-type injuries) and vaccine-induced brachial neuritis. In order to succeed however, Petitioner would have needed some combination of (a) medical or scientific literature

<sup>&</sup>lt;sup>5</sup> Notably, the physician's note cited in this record states that Petitioner developed right shoulder pain following a flu shot in <u>2013</u> (a vaccination that Petitioner specifically amended his petition to exclude, and one that he specifically denies caused him any right shoulder problems). *See* Ex. 11 at 2; Ex. 12 at 15.

corroborating his claim that flu vaccine can cause injuries akin to what he experienced, (b) treater support for the conclusion that the flu vaccine was the cause of his injury, and/or (c) a persuasive, reliable expert opinion explaining how Mr. Grose's course of post-vaccination symptoms is consistent with the pathogenesis of a vaccine-caused disease. Here, however, Petitioner has offered no such evidence of any kind.

In addition, even if I assume some causal link existed between Petitioner's flu vaccine and his subsequent diagnoses, Petitioner has not offered evidence demonstrating that onset of his shoulder injury occurred in a medically acceptable timeframe. In this case, Petitioner argues that his shoulder pain began immediately following his October 2014 vaccination. Mot. at 1.<sup>6</sup> Petitioner cites to a doctor's office visit in January 2015 (over three months post-vaccination) as the time of initial diagnosis of tendinitis following his vaccination (Ex. 2 at 19). This record, however, does not support Petitioner's assertion that his pain began immediately (i.e. within hours or perhaps days) following his October 2014 flu vaccine. Rather, the record cited by Petitioner appears to assert that he had previously been diagnosed with arthritis/tendinitis prior to the visit, and does not purport to assess onset of any post-vaccination symptoms. Furthermore, subsequent visits with treaters indicate that Petitioner reported his shoulder pain began prior to his October 2014 flu vaccine. See, e.g., Ex. 2 at 14 (2/17/2015 office visit stating pain started "over the last year"); Ex. 9 at 65-68 (3/19/2015 office visit stating pain started approximately two years prior to visit); Ex. 12 at 15, 27 (11/3/2015 office visit stating right shoulder pain developed two years ago after a 2013 flu vaccine he received in his left arm); Ex. 12 at 33, 79 (4/21/2014 office visit stating shoulder pain began two years prior and patient denied any particular inciting event or trauma).

Petitioner's affidavit states that he contacted his physician to schedule his January 2015 appointment in November 2014 (Ex. 11 at 2). Thus, even if I assume Mr. Grose's pain began in November 2014 (between one to two months post-vaccination), the onset of his symptoms is more likely than not too long to be causal. *See, e.g., Cooper v. Sec'y of Health & Human Servs.*, No. 16-1387V, 2018 WL 1835179, at \*11 (Fed. Cl. Spec. Mstr. Jan. 18, 2018) (finding entitlement where tendinitis/SIRVA injury occurred 48 hours post-vaccination); *Jewell v. Sec'y of Health & Human Servs.*, No. 16-0670V, 2017 WL 7259139, at \* 3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (finding entitlement where bursitis/SIRVA injury occurred within 72 hours of vaccination). My concerns about the timing issue would be the same even if Mr. Grose's injury were properly characterized as brachial neuritis (given the acute nature of the disease). *See, e.g., Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *mot. for review den'd*, 133 Fed. Cl. 140 (2017) (categorizing brachial neuritis as acute and suggesting severe pain should begin within *days* following vaccination). In addition, Petitioner has otherwise cited no case law or medical or scientific literature supporting his assertion that his shoulder injury

<sup>&</sup>lt;sup>6</sup> In support, Petitioner cites to his affidavit (Ex. 11 at 5). Mot. at 1. However, Petitioner's affidavit is only three pages in length--and in fact does <u>not</u> support his assertion that his pain started immediately following his October 2014 vaccination. Rather, the affidavit states that Petitioner used pain medication "over the following months" post-vaccination and then scheduled a doctor's appointment for January 2015. Ex. 11 at 2.

(or significant aggravation of a pre-existing shoulder injury) occurred in a medically appropriate timeframe.

It is also well documented in the medical record that Petitioner suffered from a shoulder injury in 2013 prior to receiving his October 2014 flu vaccine. Petitioner himself acknowledged this fact in his motion (Mot. at 1), and stated that it completely resolved, with no pain prior to receiving the flu vaccine in 2014 (Ex. 11 at 2). Mr. Grose's treaters (who evaluated him specifically for shoulder problems in 2013) noted that Mr. Grose attributed his 2013 shoulder symptoms to various causes. *See* Ex. 8 at 6, 8 (12/11/2013 appointment stating right shoulder injury occurred "years ago in a car accident" and reoccurred three months ago while doing pushups). Although, in his affidavit, dated February 21, 2017, Mr. Grose attributed the 2013 shoulder injury to a different cause. Ex. 11 at 2 (2/21/2017 affidavit stating right shoulder injury occurred while "installing a video surveillance system for a friend"). Although Petitioner asserts that his prior shoulder pain resolved prior to his October 2014 flu vaccine (Ex. 11 at 1-2), the medical records (as noted above) do not support this assertion. Petitioner has thus failed to offer persuasive evidence distinguishing his pre-existing shoulder problems from the pain he allegedly experienced immediately following his 2014 vaccination.

Finally, as Respondent pointed out, Mr. Grose was subsequently diagnosed with ALS postvaccination around October 4, 2016 (although it appears his symptoms may have started as early as April 2015) *See* Ex. 12 at 11; Ex. 2 at 7, 78. According to Respondent, symptoms including muscle weakness, back pain, joint pain, extreme weight loss, and fasciculation (some of which Mr. Grose experienced) were more likely attributable to his onset of ALS post-vaccination. Although Mr. Grose directly disputes any assertion that his ALS caused his symptoms, he offered no additional medical or scientific support analyzing the medical facts of his case and distinguishing his symptoms from those typically experienced by ALS patients.

Ultimately, a combination of the medical record itself and Petitioner's failure to obtain an expert are fatal to his claim. The record itself contains unexplained and unrebutted facts that suggest either that Petitioner's injuries predated vaccination, or that they are attributable to an entirely different illness that he unquestionably experienced. An expert opinion could have helped address such factual concerns, and was also needed in this case to provide some basis for Petitioner's *Althen* prong one and/or three showing. The plain record itself, without such further supplementation or substantiation, does not support Petitioner's claim, and therefore I cannot rule in his favor based solely upon it.

Under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on his claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent medical expert. Section 13(a)(1). In this case, however, there is insufficient evidence in the record for Petitioner to meet his burden of proof, and no expert opinion has been offered. Petitioner's claim therefore cannot succeed and must be dismissed. Section 11(c)(1)(A).

Thus, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

<u>/s/ Brian H. Corcoran</u> Brian H. Corcoran Special Master