

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 13-683V

Filed: July 31, 2015

(Not to be published)

BARBARA FARLEY,	*	
	*	Ruling on Record; Influenza Vaccine;
Petitioner,	*	Transverse Myelitis [TM];
v.	*	Temporal Relationship
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

John Robert Howie, Esq., Howie Law, P.C., Dallas, TX, for petitioner.
Justine Walters, Esq., U.S. Dep't of Justice, Washington, DC for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Gowen, Special Master:

On September 16, 2013, Barbara Farley [“petitioner”] timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 [“Vaccine Act”]². The petition alleges that, as a result of her influenza vaccination on September 15, 2010, petitioner suffered from Longitudinally Extensive Transverse Myelitis [“TM”]. The petition further alleges that petitioner’s injuries persisted for more than six months.

On January 20, 2015, petitioner filed a motion for a ruling on the record. Petitioner’s Motion for Ruling on the Record [“Motion”], filed Jan. 20, 2015. Respondent filed a response to petitioner’s Motion on January 30, 2015. Respondent’s Response to Petitioner’s Motion for Ruling on the Record [“Response”], filed. Jan. 30, 2015.

This case is now ripe for decision. For the reasons stated herein, I find that the petitioner has failed to establish entitlement to an award and thus, the case is dismissed.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 and note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). 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 Background

The Petition was filed in this matter on September 16, 2013. Subsequently, petitioner filed petitioner's medical records. Petitioner's Exhibits [hereinafter Pet. Exs.] 2-14, filed Nov. 4, 2013. Petitioner also filed her affidavit on November 19, 2013. Pet. Ex. 1, filed Nov. 19, 2013. On December 5, 2013, petitioner filed an Amended Petition, additional medical records and her Statement of Completion. Amended Petition, Pet. Ex. 15, and Statement of Completion, filed Dec. 5, 2013. Additional medical records were filed on January 7, 2014. Pet. Ex. 17.

Respondent filed her Rule 4(c) Report [hereinafter R.4 Report] on March 26, 2014, indicating the Division of Vaccine Injury Compensation's position was that this case was not appropriate for compensation. R.4 Report, filed Mar. 26, 2014. Additional medical records were filed on April 15, 2014. Pet. Ex. 18, filed Apr. 15, 2014. Petitioner requested a subpoena, which was granted on May 6, 2014. On July 11, 2014, a fact hearing was tentatively scheduled for September 4, 2014 to determine the timing of onset. Order, filed July 11, 2014. Further, petitioner filed numerous declarations from various individuals regarding the timing of onset. Pet. Exs. 19-28, filed May 15, 2014; Pet. Exs. 31-32, filed Aug. 4, 2014.

After a status conference on August 27, 2014, the parties requested that the fact hearing be cancelled and petitioner was ordered to file petitioner's MRI films from January 6, 2011, and January 13, 2011, and an expert report addressing the *Althen*³ factors and also if possible, the date of onset or aging of petitioner's lesion(s). Order, filed Sept. 3, 2014. Petitioner filed her MRI report and films on November 3, 2014, via compact disc, which was received by the clerk's office on November 4, 2014. Pet. Ex. 33, filed Nov. 3, 2014; Pet. Ex. 34, filed Nov. 4, 2014.

On November 3, 2014, petitioner also filed an unopposed motion for extension of time to file her expert report. Petitioner's Motion for Extension of Time, filed Nov. 3, 2014. Her motion was granted and her expert report was ordered to be filed by January 5, 2015. Non-pdf Order, filed Nov. 4, 2014. On January 5, 2015, petitioner filed an additional motion for extension of time for 14 additional days to file her expert report. Petitioner's Motion for Extension of Time, filed Jan. 5, 2015. This motion was granted by non-pdf order on January 5, 2015. Non-pdf Order, filed Jan. 5, 2015 (setting petitioner's expert report deadline for Jan. 20, 2015). On January 20, 2015, petitioner filed a motion for ruling on the record. Motion, filed Jan. 20, 2015. Respondent filed her response to the motion for ruling on the record on January 30, 2015. Response, filed Jan. 30, 2015.

II. Medical History Summary

³ The factors include (1) a medical theory casually connecting the vaccination to injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between the vaccination and the injury. *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

While the undersigned reviewed the record in its entirety, given the overwhelming issue with the timing of onset the undersigned's medical history summary is focused on the events prior to and culminating with petitioner's transverse myelitis diagnosis.

Prior to vaccination petitioner complained of her left wrist hurting since January [2008] and was diagnosed with De Quervain tenosynovitis during a March 26, 2008, office visit. Pet. Ex. 3, p.1. Later she developed similar symptoms in her right wrist in 2009. Pet. Ex. 5, p. 3. Petitioner also complained of right knee pain, which stemmed from a knee injury while exercising on December 18, 2009. Pet. Ex. 3, pp. 28-37. She had a knee MRI performed on December 20, 2009, where the impression was "small knee joint effusion. Otherwise, essentially negative right knee MRI." Pet. Ex. 3, p. 62. Petitioner also had a history of hysterectomy, high blood pressure, hair loss and thinning and benign breast calcifications and was taking Armour Thyroid for a thyroid problem. Pet. Ex. 3, pp. 3-4, 8-9, 20, 42-43.

Petitioner received a flu shot in her left deltoid on September 15, 2010. Pet. Ex. 2. On November 1, 2010, petitioner went to Dr. Raymond Kazmar, a rheumatologist, for follow-up on labs and a nodule on her right index finger. Pet. Ex. 6, p.10. Her labs, which were drawn on October 22, 2010, indicated an elevated sed rate and ACE level. Pet. Ex. 6, p.10; Pet. Ex. 15, p.6. Petitioner previously had an elevated sed rate and ACE level prior to vaccination. Pet. Ex. 15, pp.8-9; Pet. Ex. 16, p.10. Her later recounted history of present illness indicated that there was some thought that she may suffer from rheumatoid arthritis, however testing was negative. Pet. Ex. 4, p.7.

It was not until January 3, 2011, over three months after vaccination that petitioner went to her physician with complaints of lower back pain and being wobbly standing. Pet. Ex. 6, p.10. Subsequently, on January 4, 2011, petitioner presented to Ingalls Memorial Hospital emergency department with complaints of back and leg pain for the past two days. Pet. Ex. 7, pp. 24-32. Petitioner also complained of her legs being sensitive to touch, "feels like pins and needle in mid to lower back down legs." Pet. Ex. 7, p. 24. Petitioner was admitted to the hospital for further evaluation, and mentioned that "recently she had an upper respiratory infection with some cough, running of her nose, and low-grade fever." Pet. Ex. 7, p. 2; *But see* Pet. Ex. 7, p.8 (patient history the next day stating "no associated headache, visual changes, vertigo, hearing loss, fever rash and recent upper or lower respiratory tract infections"). It was during this hospital admission that she was assessed as having transverse myelitis, after she underwent CT of head ("no acute intracranial process"), CT of lumbar spine ("degenerative changes in lower lumbar spine"), and MRI of thoracolumbar spine ("multilevel degenerative changes, diffuse disk bulging at L3-L4, with mild indentation of the ventral margin of thecal sac"). Pet. Ex. 7, pp. 5-7. While petitioner put forth affidavits to support an earlier onset of symptoms of back pain, the affidavits and declarations, even if accepted fully, place the onset of her TM symptoms in December 2010, which is still approximately three months post-vaccination. Pet. Exs. 19-28, 31-32.

III. Summary of Parties' Arguments

Petitioner has submitted her case for a decision on the medical records alone, without offering an expert report to set forth a reliable medical theory of causation or to explain a logical sequence of cause and effect showing that the vaccine in question was the cause of the alleged injury. See *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Neither has petitioner submitted evidence addressing a medically appropriate timeframe, as is also required under *Althen*. Petitioner was ordered to file her expert report by January 20, 2015, and instead filed her motion for ruling on the record. See Non-pdf Order, filed Jan. 5, 2015 (granting petitioner's second motion for extension of time to file her expert report). Petitioner's support for her motion consisted of the following four statements and cites to the record:

1. Exhibit 2, p. 1-Petitioner received an influenza vaccine on 9/15/10.
2. Exhibit 4, p. 7 –Petitioner developed pain in her back between the shoulder blades that spread to her lower back on 12/12/10.
3. Exhibit 7, p. 8 – Petitioner's back pain progressed, and she began to develop weakness, numbness, and tingling in her lower extremities by the first few days of January 2011.
4. Exhibit 7, pp. 5-7 – After a spine MRI reflected extensive abnormal signal in the spinal cord from C4 to the upper thoracic spine, Petitioner was diagnosed with transverse myelitis.

Motion at p. 1.

Respondent's position is that petitioner's claim for compensation should be denied because the record fails to establish a more likely than not causal connection between petitioner's September 15, 2010 flu vaccination and her condition. Response at 1, filed Jan. 30, 2015. Further, respondent argues that petitioner has not shown, nor does the record contain, any proof that the time frame of onset, of approximately three months after vaccination, is medically acceptable to infer causation-in-fact. Response at 2, filed Jan. 30, 2015. Respondent further states, "petitioner has not offered an expert medical opinion or theory that advances a causal connection or logical sequence of cause and effect between her alleged TM and the flu vaccination, and the medical records fail to demonstrate preponderant proof of a vaccine-related injury." Response at 3, filed Jan. 30, 2015.

IV. Analysis

a. Applicable Legal Standard

In order to prevail under the Program, petitioner must prove either a "Table" injury⁴ or that a vaccine listed on the Vaccine Table was the cause-in-fact of an injury. Petitioner did not allege that she suffered a Table Injury, nor does the record support such a

⁴ A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

contention. Therefore, petitioner must prove that the influenza vaccine caused-in-fact the alleged injury.

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of petitioner alone, unsubstantiated by medical records or medical opinion. See § 13(a)(1). To satisfy her burden of proving causation-in-fact in this case, petitioner must “show by preponderant evidence that the vaccination brought about her injury by providing: (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.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); see also *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). She must show “that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.” *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the *Althen* prongs. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). However, mere temporal association is not sufficient to prove causation in fact. See *Grant v. Sec’y of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

When a petitioner alleges an “off-Table” injury, eligibility for compensation is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) a vaccine set forth on the Vaccine Injury Table was received; (2) the vaccine was received in the United States; (3) the person in question sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months or resulted in death. See § 11(c).

Petitioner has established that she did receive a covered vaccine under the Vaccine Injury Table and that it was received in the United States. Pet. Ex. 2. However, petitioner has failed to establish that her TM was caused by the flu vaccination at issue.

b. *Althen* Prong One

Under the first prong of *Althen*, petitioner is required to set forth a reliable medical theory that explains how a particular vaccination can cause the injury in question. *Althen*, 418 F.3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (holding that the purpose of the Vaccine Act’s preponderance of the evidence standard “is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body”). However, a causation theory or mechanism must be proposed and supported by a sound and reliable medical or scientific explanation. *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed Cir. 1994).

In this case, petitioner has failed to proffer a theory explaining how the flu vaccine can cause TM, including what is an appropriate timing of onset based on petitioner’s theory. Without a medical theory to explain the circumstances by which a vaccine can cause a particular injury, there is hardly a basis to form a decision on causation. Especially when, as in the case here, the timing of onset of petitioner’s alleged TM was

not until approximately three months post-vaccination. Petitioner has not provided an expert opinion to indicate how the flu vaccine could cause TM. Nor do the medical records provide support that the flu vaccine can cause TM. As petitioner has not provided a theory to preponderate the evidence in her favor, *Althen* prong one fails.

c. *Althen* Prong Two

The second *Althen* prong requires petitioner to establish that the vaccine was the reason for the injury—not only a but-for cause of the injury but also a substantial factor in bringing about the injury. See *Shyface v. Sec’y of HHS*, 164 F.3d 1344, 1352 (Fed. Cir. 1999). Impressions from treating physicians can be probative when evaluating the second *Althen* factor, as “treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

In this case, petitioner did not provide a medical theory or opinion on how the flu vaccination can cause TM. The medical records alone do not provide support of a causal link between the flu vaccination and petitioner’s TM, which occurred approximately three months post-vaccination. Petitioner does not assert, nor does the evidence support that petitioner’s treating doctors attributed her TM to the flu vaccination she received on September 15, 2010. In fact, the record demonstrates that her doctors felt her TM was possibly viral. Pet. Ex. 8, p. 4 (“It is possible the patient has viral transverse myelitis.”). The underlying etiology of petitioner’s TM was also noted to be unknown. Pet. Ex. 9, p. 25. Under the Impressions section of her notes, Dr. Yilmaz, M.D., Ph.D. noted “[a]t this time the etiology is unknown. She [petitioner] raised the concern of possible flu vaccination causing transverse myelitis. I stated to her that I am not aware of any scientific evidence to support that.” Pet. Ex. 9, p. 26.

Given that petitioner put forth no theory to indicate how the flu vaccine can cause TM three months post-vaccination there is no theory for which to compare to the facts of this matter to then determine if indeed the flu shot caused petitioner’s TM. Further, after review of the records the undersigned did not find supportive evidence of a causal link of the flu vaccine to petitioner’s TM based on the facts of this case. Thus, petitioner fails to meet prong two of *Althen*.

d. *Althen* Prong Three

The third *Althen* prong requires the petitioner to demonstrate that the injury “occurred within a medically acceptable time frame.” *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1358 (Fed. Cir. 2006). Petitioner must establish a proximate temporal relationship, which “requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The appropriateness of timing of the onset of symptoms may be fairly specific to the diagnosis and the alleged vaccine.

In petitioner’s Motion, in terms of the timing of onset, she indicated that she

received the flu vaccine on September 15, 2010, and that she “developed pain in her back between the shoulder blades that spread to her lower back on 12/12/10.” Motion at line 1 and 2.⁵ Respondent raises the issue both in her R.4 Report and her Response that there is no evidence to support that the onset of TM approximately three or more months post-vaccination “is a medically-appropriate time frame for the onset of TM.” R.4 Report at 13; Response at 3. Petitioner was aware of the argument concerning the need for support of the temporal relationship prior to filing her Motion as respondent’s R.4 Report was filed March 26, 2014, and petitioner’s Motion was not filed until the following year on January 20, 2015. Moreover, the undersigned discussed with petitioner concerns regarding the timing of onset occurring approximately three months post-vaccination. See Order, filed Sept. 3, 2014. The undersigned ordered petitioner to file petitioner’s MRI(s) and an expert report that should address, if possible, the date of onset or aging of petitioner’s lesion(s) to determine if petitioner’s onset could be placed any earlier than December 2010. Order, filed Sept. 3, 2014. While petitioner filed her MRI reports, she did not supply an expert report or any evidence discussing her MRIs and any date of onset or aging of her lesion(s). Pet. Ex. 33, filed Nov. 3, 2014.

The undersigned agrees that there is no evidence in the record to aptly support the appropriateness of onset approximately three months after vaccination. Further, petitioner has not put forth evidence to adequately support a timing of onset prior to December 2010. Without any support that the timing of onset is appropriate for inferring a causal relationship between the vaccination and petitioner’s TM, petitioner has not satisfied the requirements of *Althen* prong three. Accordingly, petitioner has failed to meet her burden under *Althen* prong three.

V. Conclusion

Petitioner has failed to satisfy any of the *Althen* factors, and has thus failed to establish by a preponderance of the evidence that the influenza vaccine caused petitioner’s Transverse Myelitis. Petitioner has failed to demonstrate entitlement to compensation. **I therefore hold that petitioner’s claim is dismissed. The clerk shall enter judgment accordingly.**⁶

IT IS SO ORDERED.

/s Thomas L. Gowen
Thomas L. Gowen
Special Master

⁵ While petitioner put forth affidavits to support an earlier onset of symptoms of back pain than her January 2011 office visit and subsequent hospital admission, the affidavits and declarations, even if accepted fully, place with onset in December 2010, which is still approximately three months post-vaccination. Pet. Exs. 19-28, 31-32.

⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.