

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-424V

(not to be published)

WILLIAM J. VOGLER,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Filed: April 25, 2014

Dismissal Without Hearing;
Influenza Vaccine; Six Month
Requirement; Althen Analysis;
Causation-in-fact

Firooz Namei, McKinney & Namei Co., Cincinnati, OH, for Petitioner.

Lynn Ricciardella, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT¹

On June 27, 2011, Petitioner William Vogler filed this action seeking compensation under the National Vaccine Injury Compensation Program ("the Program").² The petition alleges that Mr. Vogler suffered meningitis as a result of the influenza ("flu") vaccine he received on November 5, 2008. ECF No. 1 at ¶ 5.

Petitioner filed the relevant medical records he intended to rely upon to establish his entitlement to compensation, certifying completion of the record on April 23, 2012. ECF No. 18. Thereafter, on July 9, 2012, Respondent filed her Rule 4(c) Report. ECF No. 20 ("Resp't's Rep't"). In it, Respondent contended that based upon the then-existing record, Mr. Vogler could not satisfy the first two prongs of the test for establishing an entitlement to a Program award as set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In particular, Respondent argued that Mr. Vogler could not show by a preponderance of the evidence that the flu

¹ Because this decision contains a reasoned explanation for my action in this case, it will be posted 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 note (2006)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) provides that each party has 14 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 will be available to the public. *Id.*

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10-34 (2006) (hereinafter "Vaccine Act" or "the Act"). Subsequent references to the Vaccine Act will be by section.

vaccine as a general matter *can* cause the kind of injuries he experienced, and/or that the vaccination he received *did* cause his injury. Resp't's Rep't at 15.

After the filing of the Rule 4(c) Report, Petitioner repeatedly informed the special master previously responsible for this case of his intent to retain an expert to provide a report in support of his petition, and even went so far as to disclose the putative expert's name. *See* ECF Nos. 27, 28, 29. By August 2013, Mr. Vogler reported that he was instead considering retention of a different expert, and the special master accordingly gave him additional time to file that report. ECF No. 31. In January of this year, however, Petitioner stated that he no longer intended to submit an expert report, and instead asked that I rule upon the record as it now stands. ECF No. 40.

After considering the record as a whole, and for the reasons explained below, I find that Mr. Vogler has failed to carry his burden and therefore has not demonstrated an entitlement to compensation under the Vaccine Program.

I. The Record

The record in this case consists of Mr. Vogler's medical records plus two affidavits. I have reviewed the entire record as required by the Vaccine Act (§ 300aa-13(a)(1)). In this ruling I address the sufficiency of Petitioner's evidence in support of an award of compensation.

A. Petitioner's Relevant Medical Records

1. *Mr. Vogler's Personal Medical Records* - Petitioner received his flu vaccination³ on November 5, 2008 at the age of 33. *See* Pet'r's Ex. 2 at 4. Shortly thereafter, he presented to his primary care provider, Frederick Simpson, M.D., on November 12, 2008 complaining of myalgia, headaches, stiff neck, nasal congestion and drainage, testicular pain, and a rash on his feet. *See* Pet'r's Ex. 3 at 50. Dr. Simpson's contemporaneous notes state that these symptoms had occurred "since [Petitioner] got flu shot 1 [week] ago." *Id.* Dr. Simpson's differential diagnosis was "viral syndrome versus viral meningitis, possible influenza but less likely." *Id.*

Mr. Vogler was subsequently transferred to the emergency room ("ER") "for [a] lumbar puncture to further assess the possibility of meningitis, though likely viral." Pet'r's Ex. 3 at 50. At the ER, Petitioner complained of aching, fever, headaches, blurry vision, photophobia, and epistaxis⁴. *Id.* at 39. Petitioner's lumbar puncture showed elevated white blood cells. *Id.* at 51. The results were suggestive of possible bacterial meningitis, though this was viewed by the initial treating physicians to be unlikely. *Id.* at 43. The "final impression" of the attending physician was

³ Mr. Vogler received a trivalent influenza vaccination. Pet. Ex. 1 at 3. In the United States, all trivalent influenza vaccines are inactive, therefore the virus in his vaccination was incapable of reproducing. "Seasonal Influenza Vaccine Safety: A Summary for Clinicians, Ctrs. for Disease Control & Prevention" (Sept. 27, 2013), http://www.cdc.gov/flu/professionals/vaccination/vaccine_safety.htm#inactivated.

⁴ Epistaxis is a hemorrhage from the nose, or nosebleed. *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) ("Dorland's") at 635.

“[a]cute febrile illness,” and the plan was to keep Petitioner under “[o]bservation for meningitis.” *Id.* Mr. Vogler was thus admitted to Wilson Memorial Hospital.

On November 13, 2008, Mr. Vogler reported improvement of his symptoms. Pet’r’s Ex. 3 at 47. Dr. Simpson’s assessment was that Petitioner likely had viral meningitis rather than bacterial. *Id.* at 48. Since Petitioner reported improvement, the plan was to discharge him and allow him to return home. *Id.* That night, however, Mr. Vogler remained an inpatient in the hospital due to shortness of breath. *Id.* at 25. The results of Petitioner’s chest x-ray and computed tomography (“CT”) scan on November 14, 2008 suggested bilateral pneumonia. *Id.* at 41-42. The next day, neurologist Evelyn Brown, M.D., examined Mr. Vogler. *Id.* at 25. Her impression of Petitioner was “most likely a viral illness with mild meningeal involvement and now with severe pulmonary involvement with late onset.” *Id.* at 26.

On November 15, 2008, at Dr. Simpson’s request, Mr. Vogler presented to Dr. Ravi Kamepalli for an infectious disease consult. *See* Pet’r’s Ex. 3 at 25, 29. Dr. Kamepalli prescribed Tamiflu⁵ “given the proximity of [Petitioner’s] . . . symptoms to the date of [his] vaccination.” *Id.* at 29. Dr. Kamepalli’s impressions were “[v]iral syndrome . . . [p]ost fraction complication of influenza vaccination . . . [b]ilateral pneumonia . . . [and] [h]eadache.” *Id.* at 30. At Dr. Kamepalli’s suggestion, Dr. Simpson ordered “infection control to report [Petitioner] as [having] Post Vaccine complications of Influenza vaccination.” Pet’r’s Ex. 4 at 94.

Petitioner was subsequently discharged from the hospital on November 17, 2008. Pet’r’s Ex. 3 at 23-24. At discharge, the differential diagnosis given to Petitioner by Dr. Simpson was “[v]iral meningitis versus influenza vaccination reaction” *Id.* at 23. The discharge summary also noted that Petitioner’s condition “had begun following [his] influenza vaccination and [the] relationship to that is unclear.” *Id.*

On November 21, 2008, Mr. Vogler again presented to Dr. Kamepalli. *See* Pet’r’s Ex. 15 at 23. Dr. Kamepalli noted that Petitioner “ha[d] some problems with pneumonia for which he was put on IV Rocephin⁶ . . . at the time of discharge.” *Id.* Dr. Kamepalli also noted that “post influenza vaccine complications were suspected.” *Id.* Petitioner had received Tamiflu “[a]nd amazingly within 24 hours . . . he remarkably turned around and started to get better.” *Id.*

Petitioner followed up with Dr. Kamepalli several times in the immediate following months, and Dr. Kamepalli’s treatment notes repeat his initial supposition that the flu vaccine Mr. Vogler had received was related to his subsequent illnesses. Thus, in February 20, 2009, Dr. Kamepalli asserted that Petitioner “was suspected to have post vaccine complications” as of November 2008. Pet’r’s Ex. 3 at 3. Likewise, on March 6, 2009, Dr. Kamepalli saw Mr. Vogler and noted in his medical history that he had “had problems with his post vaccination.” *Id.* at 2. Dr. Kamepalli’s

⁵ Tamiflu is a trademark for a preparation of oseltamivir phosphate. *Dorland’s* at 1870. Oseltamivir is used to treat some types of flu infection in adults, children, and infants (older than 2 weeks of age), and also to prevent some types of flu in adults and children (older than 1 year of age) when they have spent time with someone who has the flu or when there is a flu outbreak. <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a699040.html>.

⁶ Rocephin is the trademark for a preparation of ceftriaxone sodium, an antibiotic. *Dorland’s* at 1651.

diagnosis of Petitioner was “[v]iral syndrome status post influenza vaccination with symptoms appearing to have clinically resolved.” *Id.* This was Mr. Vogler’s last doctor’s visit until almost a year later on January 8, 2010, when he again saw Dr. Kamepalli, this time complaining of nasal drainage issues. Pet’r’s Ex. 15 at 19. Dr. Kamepalli noted from Petitioner’s medical history that he had had “significant problems with viral syndrome post influenza vaccination,” among other things. *Id.*

Several months later, Mr. Vogler (who was in the process of identifying a new primary care physician) went to Roger Goodenough, M.D., on September 9, 2010. Pet’r’s Ex. 15 at 7. Dr. Goodenough recorded in Petitioner’s history that Petitioner had been hospitalized in November 2008 after receiving a flu vaccine, and (relying upon Mr. Vogler’s medical record) noted Dr. Kamepalli’s opinion that “the influenza vaccine had caused the meningitis which led to all the other complications.” *Id.* Dr. Goodenough’s assessment was a flu vaccine reaction, among other things. *Id.*

Petitioner next had a consultation with Ronal Manis, M.D., an infectious disease specialist, on September 27, 2010. Pet’r’s Ex. 15 at 16. After reviewing the records from Petitioner’s November 2008 E.R. stay, Dr. Manis opined - contrary to Dr. Kamepalli’s earlier opinion - that there was in fact no “evidence that the flu vaccine accounted for [Petitioner’s] illness in [2008].” *Id.* According to Dr. Manis, “[t]he antibody response level to the flu vaccine would not have been present for perhaps 3 weeks or so after the time of the injection,” making onset of Mr. Vogler’s symptoms too early, and that it was therefore possible that Mr. Vogler had been “incubating a viral illness at the time of his flu vaccine which later caused his illness.” *Id.* Ultimately, Dr. Manis believed, Mr. Vogler “had a viral illness in ’08 with apparent viral meningitis with secondary bacterial pneumonia” but that he did “not see evidence suggesting this was due to the flu vaccine.” *Id.*

Petitioner returned to Dr. Goodenough on October 7, 2010 for a health maintenance physical suggested by his work place. Pet’r’s Ex. 15 at 6. Dr. Goodenough noted that since the time Mr. Vogler had last visited, he had undergone a cardiology consultation with his tests coming back normal. *Id.* He also recorded Mr. Vogler’s infectious disease consult with Dr. Manis, reiterating Dr. Manis’s opinion that Petitioner’s problems did not originate from the flu vaccine he had received in November 2008. *Id.* Dr. Goodenough’s final assessment of Mr. Vogler was that he was a healthy male. *Id.*

2. Family Medical Records - In addition to his treatment records, Mr. Vogler filed medical records pertaining to his three children (Amanda Vogler, Tyler Renner, and William “Trey” Vogler)⁷ and his wife (Nichole Vogler). ECF Nos. 10 & 12. The majority of these records consist of (a) the immunization histories of Petitioner’s children and wife, or (b) treatment records pertaining to doctors’ visits that significantly pre- or post-date Petitioner’s November 2008

⁷ Mr. Vogler filed Exhibits 1 through 7 with the petition. *See* ECF No. 1. However, Petitioner subsequently filed his children’s medical records labeling them as Exhibits 1 through 4. *See* ECF Document No. 8 attachments 1-4. Respondent’s October 13, 2011 status report pointed out Petitioner’s usage of duplicative exhibit numbers, and Petitioner subsequently re-filed his children’s records on October 20, 2011 but this time as Exhibits 8-11.

immunization. Although nothing in the procedural history of this case explains Mr. Vogler's view of the relevance of such evidence in establishing his claim, it appears the records may have been offered to shed some light on other potential causes of Petitioner's various illnesses around the time of his vaccination or a little while thereafter.

Thus, the records submitted pertaining to Mr. Vogler's youngest child, Trey, indicate that he visited his primary care physician on October 7, 2008 (almost a month before Mr. Vogler received the flu vaccine) complaining of fever, cough, and nasal congestion, and was diagnosed as having allergies and a coexisting viral upper respiratory infection. Pet'r's Ex. 10 at 60. In addition, the medical records for Mr. Vogler's oldest child, Tyler, indicate that on November 9, 2008 it was determined that he should be given a prophylactic vaccination and inoculation against flu, and that in fact he received a Fluvirin vaccine that same day. Pet'r's Ex. 9 at 16.

B. Affidavits

Besides his own affidavit (Pet. Ex. 6), Mr. Vogler filed an additional affidavit from his wife, Nichole Vogler (Pet. Ex. 7). Both affidavits substantiate Petitioner's receipt of the flu vaccine on November 5, 2008 and claim that his symptoms continue to this day. They also state that Petitioner incurred his alleged illnesses almost immediately after being vaccinated, and confirm the Voglers' joint belief that the flu vaccine is to blame for his illness. *See* Pet'r's Ex. 6 at 3; Pet'r's Ex. 7 at 2.

II. Respondent's Contentions

Respondent filed her Rule 4(c) Report on July 9, 2012. In it, Respondent contends that because Mr. Vogler does not allege a "Table injury" (meaning a vaccine-specific injury as listed on the Vaccine Injury Table (42 C.F.R. § 100.3 (2011)), he was obligated to establish, by a preponderance of the evidence, that his flu vaccination was the cause-in-fact for his subsequent illness. Resp't's Rep't at 15. Respondent asserts that Petitioner cannot carry this burden, for a number of reasons.

First, Respondent maintains that the treating physicians' notations relating to Mr. Vogler's initial illness as well as his follow-up visits are insufficient to meet the first prong of the *Althen* test – that is, while the treating physicians' observations and speculations as to the relationship between Petitioner's vaccination and subsequent illness may have probative value as to the issue of whether the vaccine "did cause" his injuries (*Althen* prong two), they are not sufficient to establish that the vaccine "can cause" such injuries (*Althen* prong one). Resp't's Rep't at 14.

Second, Respondent argues that the statutory requirement of proving that Petitioner suffered from the residual effects of his injury for more than six months after the vaccine's administration has not been met. Resp't's Rep't at 15 (citing § 300aa-11(c)(1)(D)). Respondent states that undisputed evidence in the medical records shows that in less than six months, Petitioner's immediate post-vaccine symptoms had cleared. *Id.* (citing Pet'r's Ex. 3 at 2).

Third, Respondent notes the absence of any posited medical or scientific theory that would establish the “can cause” *Althen* prong.⁸ Resp’t’s Rep’t at 15. And indeed, although after the filing of the Respondent’s Rule 4(c) Report in July of 2012, Petitioner repeatedly indicated his intent to obtain an expert opinion for this purpose (*see, e.g.*, ECF Nos. 28, 29) he ultimately did not provide such a report.

Finally, Respondent observes that the mere fact that a treating physician’s opinion has probative value with respect to the “did cause” inquiry does not, as a matter of law, carry the day on that issue for a petitioner - especially where the treating physician seems to have largely based his conclusion on the temporal relationship between the vaccination and the petitioner’s subsequent illness. Resp’t’s Rep’t at 14. Respondent further points out that Petitioner’s treating physicians are not all in agreement as to the relationship between his flu vaccination and illnesses. *Id.* at 14-15.

As noted above, after the filing of Respondent’s Rule 4(c) Report, Mr. Vogler reported to this forum that he intended to obtain and file an expert report in support of his claim. However, in January of this year, Petitioner indicated he no longer intended to file an expert report, and instead asked that I render a decision based on the existing record.⁹

III. Applicable Legal Standards.

To receive compensation under the 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 the vaccinations in question, or (2) that his illnesses were actually caused by a vaccine (a category of claim often generically referred to as a “non-Table injury”). *See* §§ 300aa-13(a)(1)(A) and 11(c)(1); § 300aa-14(a); § 300aa-11(c)(1)(C)(ii)(I); 42 C.F.R. § 100.3; *see also Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).¹⁰

The Vaccine Act requires a petitioner to establish his entitlement to a Program award by a preponderance of the evidence. § 300aa-13(a)(1). Under this evidentiary standard, a petitioner must demonstrate that the injury claimed was “more likely than not” caused by the alleged vaccine.

⁸ This refers to what is often termed *Althen* prong one - “a medical theory causally connecting the vaccination and the injury,” (*Althen*, 418 F.3d at 1278) – and which requires a Petitioner to prove that the received vaccine(s) can cause the alleged injury (or injuries).

⁹ On August 21, 2013, Mr. Vogler moved to dismiss his claim entirely on the grounds that he had decided to seek expert testimony from “another expert at Stanford University Medical School,” rather than from the individual he had previously identified as his most likely expert. ECF No. 31 at 1. The special master denied the motion, observing that it was more properly styled as a motion for an extension of time in which to file an expert report, and instead ordered the Petitioner to provide his long-overdue expert report by September 13, 2013. ECF No. 32 at 1.

¹⁰ In this decision, I reference published decisions of other special masters, which constitute persuasive but not binding authority. *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). I also cite Federal Circuit decisions, which are binding on special masters. *Guillory v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff’d*, 104 Fed. App’x 712 (Fed. Cir. 2004); *see also Spooner v. Sec’y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Once a petitioner is deemed to have satisfied this burden, he is entitled to compensation unless Respondent can rebut the showing by preponderant proof that the vaccinee’s injury is “due to factors *unrelated* to the administration of the vaccine.” § 300aa-13(a)(1)(B) (*emphasis added*).

In satisfying his burden, a petitioner is required to prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed.Cir.2006). Before finding in favor of the party with the burden to prove a fact’s existence, the special master must “believe that the existence of a fact is more probable than its nonexistence.” *Moberly*, 592 F.3d at 1322 n.2 (internal citations omitted). The special master must assess “the record as a whole” and may not find that a petitioner has established an entitlement to compensation “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1).

Mr. Vogler has not alleged a Table injury in this case (and in fact there are no Table injuries specified for influenza vaccines). I must therefore consider the requirements needed to prove an off-table injury. A petitioner alleging such a claim must satisfy (by a preponderance of the evidence) the three prongs set forth by the Federal Circuit in the *Althen* decision: (1) a medical theory causally connecting the vaccination to the injury (*i.e.*, that the vaccine “can cause” the injury); (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury (*i.e.*, that in this case the vaccine “did cause” the injury); and (3) a proximate temporal relationship between the vaccination and the injury. *Althen*, 418 F.3d at 1279. A petitioner who successfully does so is entitled to compensation, unless the Respondent can then demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *Id.*

In attempting to substantiate a Program claim, petitioners may rely on a variety of evidence, and may satisfy their burden with circumstantial proof. *Althen*, 418 F.3d at 1280. This includes the opinions of treating physicians. *Moberly*, 592 F.3d at 1325 (holding that “treating physician evidence . . . [can] support[] the claim of causation”); *see also Carter v. Sec’y of Health & Human Servs.*, 2007 WL 415185, at *21 n. 25 (Fed. Cl. Spec. Mstr. Jan. 19, 2007). Contemporaneous medical records are also especially useful in establishing Petitioner’s claim. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed.Cir.1993).

Petitioners also need not offer expert testimony to satisfy their burden. *See* § 300aa-13(a)(1) (petitioners may be awarded Program compensation based on “medical records *or* . . . medical opinion” (*emphasis added*)); *see also Althen*, 418 F.3d at 1279-80. Although expert testimony may be helpful and may be considered, there are no “hard and fast *per se* scientific or medical rules” for finding causation under the Vaccine Act. *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Accordingly, a special master may determine that a Petitioner has carried his or her burden of proof sufficient to receive a Program award even where his or her claim is not supported with conclusive medical literature, epidemiological studies, and/or general acceptance in

the scientific or medical communities. *See Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

IV. Analysis

Mr. Vogler has offered some probative evidence to substantiate his claim. Nevertheless, based on my review of the record as a whole, I find that Petitioner has failed to establish by a preponderance of the evidence that he was injured by the flu vaccine he received on November 5, 2008.

There is no dispute that Mr. Vogler received a flu vaccination in November 2008 (Pet’r’s Ex. 2 at 3 and 5), or that such a vaccine can be the basis for a compensable injury claim under the Act. *See* § 300aa-14(a) and 42 C.F.R. 100.3. Similarly, the record establishes that Petitioner did experience illness that occurred temporally after administration of the vaccine. *See, e.g.*, Pet’r’s Ex. 3 at 50. However, to establish an entitlement to compensation under the Vaccine Program, Petitioner (like all petitioners asserting claims pursuant to the scheme set forth by the Act) must do more. He has not done so based upon the record before me.

A. *Althen* Prongs

I cannot find based on the existing record that Petitioner has shown causation-in-fact since he has failed to carry his burden of proof under any of the *Althen* prongs.

The strongest record evidence supporting the first *Althen* prong (that a vaccine “can cause” an illness along the lines experienced by Petitioner) is provided by Dr. Kamepalli’s contemporaneous medical treatment notes. Unquestionably a treating physician’s observations and deductions have probative value in establishing a petitioner’s theory for how a vaccine injured him. But *how much* value such treatment notes have depends upon their depth – and in particular, whether they include some plausible explanation for how the vaccine at issue could have caused a similar injury.

Here, Dr. Kamepalli’s treatment notes provide little to no detail in explaining what led him to deduce a relationship between Mr. Vogler’s illness and the flu vaccination he had just received. Dr. Kamepalli’s conjecture as to the existence of such a relationship is not without any probative significance. However, something to suggest that his conclusion is reliable is lacking. In order to find that *Althen* prong one has been met, evidence establishing the medical or scientific grounds upon which such conjecture could reasonably be based is needed. Dr. Kamepalli’s personal but unsubstantiated suppositions as to what might have caused Petitioner’s symptoms, standing alone, are not enough. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993) (“[c]onjectures . . . are of little use, however, in the project of reaching a quick, final, and binding legal judgment - often of great consequence - about a particular set of events in the past”).

In instances where petitioners have met their burden under *Althen* prong one, they have often done so by offering proof, such as expert reports or corroborative medical literature, that outlined a theory as to how the vaccine might have caused the alleged injury. *See, e.g., Nash*, 2002 WL 1906501, at *19; *Ebenstein v. Sec’y of Health & Human Servs.*, No. 06-573V, 2010 WL 5113185, at *9 (Fed. Cl. Spec. Mstr. Sept. 1, 2010). Evidence explaining how an inactive flu vaccine can cause meningitis would be helpful, but has not been provided in this case. Even an explanation from one of Petitioner’s treating physicians detailing why he/she believed a connection existed between the flu vaccine and Petitioner’s meningitis would have been useful - again the medical records reflect no such opinion.

Without that sort of evidence, I am left with only the medical record notations setting forth a supposition that itself seems rooted in the temporal association between Mr. Vogler’s vaccination and his illness. But, as has been noted often by the Federal Circuit, a temporal relationship alone between vaccine and injury cannot establish the degree of “but for” causation required to establish an entitlement to Program compensation. *Moberly*, 592 F.3d at 1323. The record as it exists is therefore insufficient to establish by a preponderance of the evidence that the flu vaccine can cause Mr. Vogler’s meningitis-like illness.

There is similarly a lack of evidence supporting the second *Althen* prong — that the flu vaccine “did” cause Mr. Vogler’s injuries. The second prong requires proof of a logical sequence of cause and effect usually supported by facts from a petitioner’s medical records. In the instant case, Petitioner’s medical records fail to provide the necessary evidentiary support for the second *Althen* prong and are in fact inconsistent on this point. Petitioner’s contemporaneous medical records do indicate that in Dr. Kamepalli’s estimations Petitioner’s subsequent illness was caused by his flu vaccination. *See* Pet’r’s Ex. 3 at 30. At the same time, however, Petitioner’s discharge summary from the Wilson Memorial Hospital states that the relationship between his vaccination and illness is unclear. *See* Pet’r’s Ex. 3 at 23. Additionally, Dr. Manis, an infectious disease specialist, clearly stated that in his view, Petitioner’s illness was *not* caused by the flu vaccine but was instead attributable to other factors. *See* Pet’r’s Ex. 15 at 16. Mr. Vogler has provided no reasons why Dr. Kamepalli’s estimations should be given more weight than his other doctors, and so I am left with a record which reflects that the doctors involved with Petitioner’s care were unsure what had caused his sickness.

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. That term has been equated to the phrase “medically-acceptable temporal relationship” as employed in the *Althen* decision. *Althen*, 418 F.3d at 1281. In determining what is considered to be a medically acceptable time frame, the temporal relationship mentioned in *Althen*’s prong three must coincide with the theory of how a vaccine can cause an injury mentioned in prong one. *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008); *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (Fed. Cl. 2011) *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, 11-355V, 2013 WL 3214877 (Fed. Cl. May 30, 2013), *motion for review denied* (Fed. Cl. Dec. 3, 2013), *appeal docketed* (Fed. Cir. 2014).

As I explained above, Mr. Vogler has failed to offer a theory as to how the flu vaccine can cause meningitis. No expert opinions or peer reviewed medical literature have been filed, and the one treating physician who drew a connection between Petitioner's vaccination and subsequent illness did not provide an explanation for the purported connection. Without a theory as to how the flu vaccine can cause meningitis in the time frame evidenced in this case, it is not possible for me to determine whether Petitioner's first symptoms appeared in a medically acceptable temporal relationship to his vaccination.

In considering whether Mr. Vogler has met this final prong of the *Althen* test, it is also important to note that Dr. Manis - the one treating doctor who looked closely at the significance of the temporal relationship between Petitioner's symptoms and his flu vaccine - concluded that the relationship did not support causation. After seeing Petitioner in September 27, 2010 for an infectious disease consult, Dr. Manis's notes state that "[t]he antibody response level to the flu vaccine would not have been present for perhaps 3 weeks or so after the time of the injection." Pet'r's Ex. 15 at 16. Dr. Manis also discounted an allergic reaction to the vaccine as a cause of Mr. Vogler's illness, stating that if in fact Petitioner had experienced an "allergy to the egg component of the vaccine . . . he would have had a more immediate reaction than 3 days [later]." *Id.* Because the actual temporal relationship between Petitioner's vaccination and symptoms did not match what Dr. Manis considered to be medically cognizable, Dr. Manis was of the opinion that Petitioner's illness was not caused by the flu vaccine he received on November 5, 2008. *Id.* There is nothing in the record to question his logic or contradict his conclusion.

In sum, the record lacks sufficient reliable and probative evidence for me to conclude that it is more likely than not that the flu vaccine *could* cause the illnesses experienced by Petitioner after his vaccination - let alone that the vaccination *did* cause his illnesses - or that there is a medically acceptable temporal relationship between the vaccination Mr. Vogler received and his illness.

B. Vaccine Act Six Month Requirement

It is well established in the Vaccine Court that in order to qualify for a compensation award, a petitioner must have suffered from the alleged injury for more than six months after receiving the vaccine. § 300aa-11(c)(1)(D)(i)¹¹; *see also Song v. Sec'y of the Dep't of Health & Human Servs.*, 31 Fed. Cl. 61, 65-66, *aff'd*, 41 F.3d 1520 (Fed.Cir.1994); dated *Boley v. Sec'y of the Dep't of Health & Human Servs.*, 05-420V, 2008 WL 4615034 (Fed. Cl. Spec. Mstr. Sept. 9, 2008) *aff'd sub nom. Boley v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 294 (Fed. Cl. 2009) *Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109 (Fed. Cl. Spec. Mstr. Oct. 11, 2013); *Parsley v. Sec'y of Health & Human Servs.*, No. 08-781, 2011 WL 2463539 (Fed. Cl. Spec. Mstr. May 27, 2011); *Anderson v. Sec'y of Health & Human Servs.*, No. 06-168V, 2006 WL 5626962 (Fed. Cl. Spec. Mstr. Oct. 13, 2006);

¹¹ Alternatively, a petitioner may advance her claim if the alleged injury or illness she suffered from the administration of the vaccine resulted in (a) inpatient hospitalization and surgical intervention or (b) death. § 300aa-11(c)(1)(D)(ii) - (iii).

In this case, however, the existing medical records (bulwarked to some extent by the Vogler affidavits) do not sufficiently establish that the six month requirement has been met. Rather, the record suggests that Mr. Vogler experienced an illness following the receipt of the vaccine that subsequently resolved itself within four months.

The history of Mr. Vogler's doctor visits alone highlights his inability to meet the six month requirement. Mr. Vogler's first symptoms occurred in November 2008, soon after he received the flu vaccine. *See* Pet'r's Ex. 3 at 50. But his last documented visit to a physician during which he complained of a vaccine-related complication was in March 2009 (*see* Pet'r's Ex. 3 at 2). There is a subsequent gap in the medical record - Petitioner did not see a physician again until ten months later, in January 2010. *See* Pet'r's Ex. 15 at 19. It thus appears that Petitioner stopped experiencing any clinical symptoms of his illness four months after he received the vaccination (since it is reasonable to conclude that he otherwise might have continued to seek treatment).

Evidence of Mr. Vogler's specific treatment course further bolsters my conclusion that his illness lasted for less than six months from the time his first symptoms appeared. As noted above, a week after the vaccination Petitioner presented to his primary care physician on November 12, 2008 complaining of myalgia and headaches, among other things. Pet'r's Ex. 3 at 50. But by the next day Mr. Vogler's condition had so improved that his doctors were considering discharging him from the hospital, keeping him longer as an inpatient only to keep him under observation. *Id.* at 48. Dr. Brown's subsequent November 14, 2008 neurologic consult noted that Petitioner "is feeling better with oxygen therapy," and that "[t]he patient's h[e]ad has not worsened, in fact he says that it is better with the pain medication he is receiving." *Id.* at 25. By November 17, 2008, he was considered to have recovered enough to be discharged home. *Id.* at 23.

The treatment notes of Dr. Kamepalli (who, as discussed above, is the source for the bulk of record evidence suggesting a connection between the vaccine and Mr. Vogler's illness) also reflect an uneven but improving course of an illness that eventually subsided. Thus, as early as November 15, 2008, Dr. Kamepalli noted that after receiving a couple of doses of Tamiflu Mr. Vogler was "otherwise starting to feel better" and even his "headaches are slightly better." *Id.* at 29. Dr. Kamepalli saw Petitioner again on November 21, 2008, and similarly noted that within 24 hours of receiving Tamiflu, Mr. Vogler had made a remarkable recovery. Pet'r's Ex. 3 at 10. Dr. Kamepalli also noted that Petitioner had no specific complaint, but was merely there for a follow up visit. *Id.*

Mr. Vogler next saw Dr. Kamepalli on February 20, 2009 – another follow-up visit that had been rescheduled to a later date because Petitioner had felt fine but was now experiencing new aches and pains. *Id.* at 3. Petitioner was not on any medications at the time, so Dr. Kamepalli's plan was to run more tests and follow Mr. Vogler's progress on an outpatient basis. *Id.* However, after Petitioner's next visit on March 6, 2009 (his final physician visit in 2009), Dr. Kamepalli concluded that although in his opinion Petitioner had suffered from a "[v]iral syndrome status post influenza vaccination," Mr. Vogler's "symptoms appear[ed] to have clinically resolved." Pet'r's Ex. 3 at 2. Petitioner was still not taking any medications, and the plan was for Petitioner to return only as needed. *Id.*

It thus appears from the existing medical records that the illness Petitioner experienced beginning in November 2008 had largely resolved by March 2009. There is nothing in the record that demonstrates that Petitioner suffered any further medical complications until January 2010, almost one year later.¹² Accordingly, even assuming Mr. Vogler's flu vaccine was causative of his illness, I find that he did not "suffer[] the residual effects or complications of [an] . . . illness, disability, injury or condition for more than 6 months after the administration [of the vaccine]" as required under the Act. § 300aa-11(c)(1)(D)(i).

CONCLUSION

The record clearly indicates that Mr. Vogler experienced a significant illness, and I have the greatest of sympathies for his suffering. However, based on the records filed, I cannot conclude that Petitioner is entitled to an award of compensation in this case. The Act permits me to award compensation only if a petitioner alleging an "off-Table injury" can show by medical records or competent medical opinion that his injury was more likely than not vaccine-caused. Here, both due to the absence of an expert report or medical literature theorizing as to the relationship between the vaccine and Mr. Vogler's illness, as well as inconsistencies in the medical records submitted in support of Mr. Vogler's claim, there is insufficient evidence to support an award of compensation. Moreover, Petitioner did not suffer the effects of his injury for more than six months as required by § 300aa-11(c)(1)(D)(i) of the Vaccine Act. All of the above leaves me no choice but to dismiss this claim.

The petition is hereby DISMISSED. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

IT IS SO ORDERED.

/s/Brian H. Corcoran
Brian H. Corcoran
Special Master

¹² I note that Petitioner's January 2010 visit was for a complaint of nasal drainage and that the severe headaches, body aches, fatigue and shortness of breath Petitioner had suffered in 2008 were not mentioned as being present at this visit. Pet'r's Ex. 15 at 19. Accordingly, it is likely that the nasal drainage was unrelated to Mr. Vogler's earlier illness.