

I

PROCEDURAL HISTORY

This case was assigned to the undersigned on July 1, 2013. Notice, ECF No. 2. The undersigned held an initial status conference in this case on July 24, 2013. Minute Entry, Jul. 24, 2013. After this status conference, the undersigned ordered Petitioner to file a Statement of Completion or Status Report on or before September 4, 2013; Respondent's Rule 4(c) Report deadline was set for 42 days after Petitioner's Statement of Completion. Order, ECF No. 6. Petitioner failed to comply with these deadlines; therefore, on January 15, 2014, the undersigned issued an Order to Show Cause, instructing Petitioner to show cause for that failure. Order, ECF No. 8.

Petitioner filed a Response to the undersigned's Order to Show Cause, stating that Petitioner's counsel had received electronic notifications in this case in his "spam" folder, and therefore court orders were not detected until after the filing of the Order to Show Cause. Response, ECF No. 10. Petitioner indicated in his Response that he still wished to continue with his claim, and subsequently filed outstanding medical records on January 29, 2014. Response, ECF No. 10; Records (Exs. 1-5), ECF No. 9. On April 10, 2014, the undersigned convened a status conference with the parties, and Petitioner's counsel "indicated that Petitioner's retained expert was no longer willing to participate in this case as the most recently filed medical records did not support his theory of causation." Order at 1, ECF No. 16. The undersigned thereafter ordered Respondent's counsel to file a Rule 4(c) Report by May 15, 2014, and Petitioner to file a Motion for a Ruling on the Record by May 29, 2014. *Id.*

On May 9, 2014, Petitioner's counsel filed an "Affidavit in Support of Claim." Pet'r's Aff., ECF No. 17. Respondent's counsel filed a Rule 4(c) Report on May 14, 2014, asserting that this case is not appropriate for compensation. Report, ECF No. 18. Petitioner filed a Motion for Judgment on the Administrative Record on June 6, 2014. Motion, ECF No. 19. Respondent's Response was filed on June 23, 2014. Response, ECF No. 20. This case is now ripe for a decision on the record.

II

FACTUAL HISTORY

Petitioner received an influenza vaccination in his left deltoid on October 18, 2011, at a Wal-Mart in Elizabethton, Tennessee. Pet. at 2. Petitioner averred that prior to receiving the vaccination, he did not feel "ill or light-headed," but afterward remained in the store for fifteen minutes, as instructed by the vaccine administrator, and then "he stood up, took two steps, and fainted." *Id.* at 2.

When Petitioner fell, he struck his head on the concrete floor of the store. *Id.* Petitioner lost one tooth and “chipped several others down to the nerve.” *Id.* Petitioner “had to have three other teeth surgically removed.” *Id.* Petitioner sustained “five facial fractures which required his jaw to be wired shut.” *Id.* Several “plates and screws were placed in his mandible during surgery.” *Id.*

Immediately following Petitioner’s fall on October 18, 2011, Petitioner was transported by ambulance to the Bristol Regional Emergency Room. The EMS Record indicates that Petitioner’s fasting blood sugar taken by EMS personnel at the scene was “50,” and Petitioner was described by EMS personnel as being “hypoglycemic.”³ EMS Record at 2, Oct. 18, 2011, filed Mar. 28, 2014. The ambulance record stated, “[p]atient’s vitals obtained along with blood sugar level checked showing patient was hypoglycemic. Patient stated that he was diabetic and had just taken his flu shot and approximately two minutes later patient passed out.” *Id.* Petitioner was administered oral glucose in the ambulance. *Id.*

Upon admission to the Emergency Room, Petitioner’s medical history noted that Petitioner was diabetic. Pet’r’s Wellmont Bristol Regional Medical Center Records at 3. It was also noted that Petitioner had a history of falls within the last three months. *Id.* at 7. The medical records indicated that Petitioner sustained injury to his head, neck and face. *Id.* at 3. On examination at Bristol Regional Medical Center, Petitioner was noted to have suffered a “comminuted nondisplaced fracture [] of the mandibular condyles bilaterally. Additionally, a fracture through the anterior mandible is present extending into the right mandibular body. There appears to be a fracture of the first molar . . .” *Id.* at 11-12.

Petitioner was transferred to Wellmont Holston Valley Medical Center to see a facial trauma surgeon. Pet’r’s Wellmont Holston Valley Medical Center Records at 1. Dr. Testerman, the attending physician, wrote that Petitioner became dizzy and fell while at Wal-Mart and was “found to be hypoglycemic.” *Id.* at 5. Dr. Testerman additionally noted that “[i]t was felt that the patient possibly became hypoglycemic and fainted, [] resulting in his injury.” *Id.*

A discharge summary from Bristol Regional Medical Center on October 22, 2011 stated that Petitioner underwent a surgical procedure on October 20, 2011, and had an “[o]pen reduction with internal fixation of his mandibular fracture.” Pet’r’s Wellmont Bristol Regional Medical Center Records at 23.

Petitioner underwent another surgical procedure on October 27, 2011, where another tooth was removed, and bars, screws, and wires were inserted in Petitioner’s mouth and face. *Id.* at 31. Petitioner also had a subsequent surgery on December 22, 2011 for his remaining facial injuries. *Id.* at 218. Petitioner noted in his affidavit that he still experiences pain and physical disfigurement as a result of his fall on October 18, 2011. Pet’r’s Aff. at 4, ECF No. 17.

³ Hypoglycemia is defined as “an abnormally diminished concentration of glucose in the blood, which may lead to tremulousness, cold sweat, piloerection, hypothermia, and headache; when chronic and severe it may cause central nervous system manifestations that in rare cases can even be fatal.” Dorland’s Illustrated Medical Dictionary 902 (32nd ed. 2012).

III

DISCUSSION

To receive compensation under the Program, a petitioner must prove either: (1) that the petitioner suffered a “Table Injury” -- i.e., an injury included in the Vaccine Injury Table -- corresponding to his vaccination, or (2) that the petitioner suffered an injury that was actually caused by his vaccination. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). To establish causation-in-fact, the petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 300aa-13(a)(1)(A). The 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 v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). Pursuant to Vaccine Rule 8(d), “[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing.” *See* Vaccine Rule 8(d).

In the seminal case of *Althen v. Secretary of the Department of Health and Human Services*, the Federal Circuit set forth a three-prong test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). The *Althen* test requires the petitioner to set forth: “(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.” *Id.* To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Specifically, under the first prong of *Althen*, petitioners must offer a scientific or medical theory that answers in the affirmative the question “can the vaccine(s) at issue cause the type of injury alleged?” *See Pafford v. Sec’y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004) (emphasis added). This may be accomplished in a number of ways. *Id.* “Reliability and plausibility of pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory, so as to render it credible.” *Id.* In addition, epidemiological studies and an expert’s experience, while not dispositive, lend significant credence to the claim of reliability; articles published in respected medical journals, which have been subjected to peer review, are also persuasive. *Id.* However, publication “does not necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593–94 (1993).

In addition to showing that the vaccine at issue can cause a particular injury, a petitioner must also prove that the vaccine actually *did* cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4 (emphasis added); *Althen*, 418 F.3d at 1279. A petitioner does not meet this obligation by showing a temporal association between the vaccination and the injury; petitioner must explain how and why the injury occurred. *Pafford*, 2004 WL 1717359, at *4.

While a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. For example, if petitioner's theory involves a process that takes several days to develop after vaccination, an injury that occurred within a day of vaccination would not be temporally consistent with that theory. Conversely, if the theory is one that anticipates a rapid development of the reaction post-vaccination, the development of the alleged injury weeks or months post-vaccination would not be consistent with that theory. The special master cannot infer causation from temporal proximity alone. In fact, it has been held that where a petitioner's expert views the temporal relationship as the "key" indicator of causation, the claim must fail. *See, e.g., Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144 (Fed.Cir. 1992); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) (stating that inoculation is not the cause of every event that occurs within a ten-day period following it); *Thibaudeau v. Sec'y of Health & Human Servs.*, 24 Cl. Ct. 400, 403 (Fed. Cl. Oct. 23, 1991).

A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation, unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994).

In this case, Petitioner sought redress for his injury under the Vaccine Act's compensatory provision for off-Table injuries. The Petition alleges that Petitioner suffered facial injuries as a result of fainting after receiving a trivalent influenza vaccination on October 18, 2011. Pet. at 2. The undersigned examined Petitioner's medical records and did not find any evidence that satisfies the three elements of causation set forth above. The undersigned concludes that the medical records filed in this case provide preponderant evidence that Petitioner's fainting episode stemmed from his hypoglycemia, secondary to his Type 1 diabetes, not his influenza vaccination. The undersigned will outline below why Petitioner failed to satisfy all prongs of *Althen* and is not entitled to compensation under the Program.

A. Althen Prong I

Under the first prong of *Althen*, Petitioner is required to set forth a reliable medical theory, explaining how a particular vaccination *can* cause a particular injury. *Althen*, 418 F.3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (indicating 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 accepted by a special master must be supported by a "sound and reliable" medical or scientific explanation. *Knudsen*, 35 F.3d at 548.

Petitioner has not provided a sound or reliable medical theory, causally connecting his vaccination with his injury. Instead, Petitioner cites the close temporal proximity between

Petitioner's fainting spell and the receipt of his influenza vaccine as evidence of a vaccine-caused injury. Pet'r's Motion at 1-4, ECF No. 19. Petitioner offers no scientific explanation for the alleged correlation between the influenza vaccine and his fall. Absent a valid scientific theory connecting the influenza vaccination to Petitioner's injury, an asserted temporal association alone is insufficient to establish entitlement to compensation under the Vaccine Program. *Moberly*, 592 F.3d at 1323.

At one point in the case, Petitioner seemed prepared to offer expert testimony, establishing a scientific theory under *Althen* prong one. However, during a status conference convened on April 10, 2014, Petitioner's counsel indicated that "Petitioner's retained expert was no longer willing to participate in this case as the most recently filed records did not support his theory of causation." Order, ECF No. 16. The undersigned asked Petitioner's counsel whether he was referring to the EMS record that indicated that Petitioner was a diabetic and that he was hypoglycemic at the time he fainted, and Petitioner's counsel affirmed that this was the issue. *Id.* Without a credible medical expert, promulgating a sound and reliable medical theory of causation, supportive medical records, or a sound and reliable medical theory itself, there is no evidence in the record that provides any theory of vaccine causation sufficient to meet *Althen* prong one. As such, Petitioner does not meet his burden under the first prong of *Althen*.

B. *Althen* Prong II

Under the second prong of *Althen*, Petitioner is required to establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1280; *see Capizzano*, 440 F.3d at 1327 ("[t]here may well be circumstances where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine.").

In this case, the evidence submitted by Petitioner consists of his affidavit and the submission of Petitioner's medical records, which Petitioner alleges show that his facial and dental injuries, sustained after fainting, were caused-in-fact by his receipt of an influenza vaccination on October 18, 2011. The undersigned finds no such causal relationship between Petitioner's injury and vaccination.

Petitioner received the influenza vaccination on October 18, 2011. Pet. at 1. Petitioner was transported by ambulance the same day to the Bristol Regional Hospital Emergency Room after fainting and sustaining facial injuries. The ambulance record states:

[p]atient's vitals obtained along with blood sugar level checked showing patient was hypoglycemic. Patient stated he was diabetic, and had just taken his flu shot and approximately two minutes later patient passed out.

EMS Medical Record at 2. A fasting blood sugar taken by EMS personnel at the scene was 50, and Petitioner was described by EMS personnel as "hypoglycemic." *Id.* Petitioner was then administered oral glucose in the ambulance. *Id.*

Petitioner's attending physician at Holston Valley Medical Center, Dr. Testerman, affirmed that Petitioner became dizzy and fell while at Wal-Mart and was "found to be hypoglycemic." Pet'r's Wellmont Holston Valley Medical Center Records at 5. Dr. Testerman additionally noted that "[i]t was felt that the patient possibly became hypoglycemic and fainted, [] resulting in his injury." *Id.* Dr. Testerman's notes make no mention of the vaccine as a possible cause of Petitioner's fainting episode.

The undersigned does not doubt that Petitioner carefully monitors his blood sugar levels, eats regularly, and administers himself insulin appropriately. Pet'r's Ex. 17 at 1. That does not change the fact that when the EMS personnel responded to the Wal-Mart because Petitioner had fainted, they found Petitioner's blood sugar to be very low; they described Petitioner as "hypoglycemic," with a blood sugar level of 50. EMS Medical Record at 2. Petitioner's retained expert declined to participate in this case when he learned of the information set forth in these treatment records (suggesting the significance of such facts). Order, ECF No. 16. Based on the evidence provided in the medical records in this case, the undersigned finds that Petitioner's fall stemmed from his hypoglycemia as a result of his low blood sugar, not his influenza vaccination. Under prong two of *Althen*, Petitioner must provide preponderant evidence that his vaccination *did* cause his alleged injury. In this case, Petitioner has failed to meet his burden. Since Petitioner has provided no evidence that his influenza vaccine *did* cause his resulting injuries, through either the medical records or the opinion of a credible medical expert, Petitioner's claim fails under the second prong of *Althen*.

C. Althen Prong III

Under the third prong of *Althen*, Petitioner is required to show that there was a proximate temporal relationship between vaccination and injury that comports with Petitioner's prong one theory of causation. *Althen*, 418 F.3d at 1279. Petitioner submitted records that purport to establish a temporal association between when Petitioner received the influenza vaccination and the timing of this fainting spell, resulting in Petitioner's facial and dental injuries. As previously discussed, however, though the events of vaccine receipt and subsequent injury occur in close temporal proximity, Petitioner has provided no theory against which to evaluate the temporal nexus of his claim. In the absence of that nexus, Petitioner's claim fails under the third prong of *Althen*.

IV

CONCLUSION

Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1). In this case, because there are insufficient medical records supporting Petitioner's claim, a medical expert opinion must be offered in support, establishing a sound and reliable medical theory, linking vaccination to injury, and

demonstrating a logical sequence of cause and effect between said vaccination and injury. Petitioner has offered no such opinion.

The undersigned is sympathetic to the fact that Petitioner suffers from facial injuries. However, under the law, the undersigned can authorize compensation only if a medical condition or injury either falls within one of the “Table Injury” categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. No such proof exists in the record. **Thus, this case is dismissed for insufficient proof. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.**

IT IS SO ORDERED.

s/Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master