

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

No. 12-768V

Filed: August 20, 2014

(Not to be published)

ROSWELL PEREZ,

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Petitioner,

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v.

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Mindy Michaels Roth, Esq., Britcher, Leone & Roth, L.L.C., Glen Rock, NJ for petitioner.
Justine Daigneault, Esq., U.S. Dept. of Justice, Washington, DC for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION¹

Gowen, Special Master:

On November 13, 2012, Roswell Perez filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2006) (“Vaccine Act”). Petition at 1. In the petition, Mr. Perez alleged that he received an influenza and a swine flu vaccine on November 23, 2009, and that the following day he developed muscle aches, primarily in the back.² *Id.* Mr. Perez then alleged that he later developed numbness and tingling in his left leg, then in his left arm, in the succeeding days following his vaccinations. *Id.* Mr. Perez complained of experiencing an array of symptoms over the following nine months and saw multiple physicians. *Id.* Petitioner

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal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 Under the Vaccine Act, a petition for vaccine compensation must contain documentation demonstrating that the vaccine injured person “received a vaccine set forth in the Vaccine Injury Table.” 42 U.S.C. § 300aa-11(c)(1)(A). The Vaccine Injury Table, located at 42 C.F.R. § 100.3(a), does not include the H1N1 vaccine, a monovalent influenza vaccine, only the trivalent seasonal influenza vaccine. 42 C.F.R. § 100.3(a). Therefore, the H1N1 vaccine is not covered under the Vaccine Injury Compensation Program. Rather claims of injury resulting from the H1N1 vaccine are covered by the Countermeasures Injury Compensation Program. See <http://www.hrsa.gov/cicp/index.html>.

filed a motion for a ruling on the record on November 21, 2013. Petitioner's Motion for Decision on the record ("Motion"), filed Nov. 21, 2013. The undersigned now finds that the information in the record does not show entitlement to an award under the Act.

1. Procedural Background

Petitioner filed affidavits and medical records from multiple providers. Petitioner's Exhibits ("Pet. Ex(s).") 1-18. Several extensions of time were granted in order to facilitate the obtaining of additional medical records for ongoing treatment and to obtain an expert report for the petitioner. See Joint Status Report (petitioner requested and was granted 45 days to file an expert report), filed March 22, 2013; Joint Status Report (petitioner requested and was granted 60 days to file an expert report), filed May 18, 2013; Petitioner's Motion for Extension for Time (petitioner requested and was granted 90 days to file an expert report), filed June 28, 2013.

Petitioner filed a motion for a decision on the record on November 21, 2013.³ Motion at 1-2. Respondent, after an appropriately requested expansion of time, filed a response to the Motion for a Decision on the Record and a Rule 4 report on December 13, 2013. Response to Motion for a Decision on the record and Rule 4 report, filed Dec. 13, 2013.

This matter is now ripe for adjudication.

2. Factual History

Mr. Perez was employed as a crisis counselor in the emergency room of Rutgers and Mountainside Hospital in New Jersey, where he received an H1N1 vaccine and a seasonal flu vaccine in the hospital's Occupational Medicine Department on November 23, 2009. Pet. Ex. 1 at 1; Pet. Ex. 2, pp. 11-14. Mr. Perez received the vaccines in different arms: the H1N1 in the left deltoid, and the seasonal flu in the right deltoid. Pet. Ex. 2, pp. 11-14. At the time he received the vaccinations he was thirty years old. Pet. Ex. 1, p. 1; Petition at 1.

Within the following 24 hours he began to experience muscular pain, primarily in the back. Pet. Ex. 1, p. 2. On November 25, 2009, Mr. Perez was examined by Dr. Richard Cirello, a doctor at the Mountainside Family Practice, who apparently told him that he was fine and that he did not have Guillain-Barré syndrome. Pet. Ex. 15, p. 216-17. Mr. Perez alleges that he later became nauseous, began to have diarrhea, and felt numbness of his left leg from the toes to the knee; a few days later, on November 27, 2009, he alleges he awoke with pronounced numbness of his left leg, left arm and face. Pet. Ex. 1, p. 2.

Mr. Perez then presented to his family physician, Sabato Lombardo, M.D., complaining of numbness and tingling in the leg. Pet. Ex. 3, p. 30. Dr. Lombardo

³ The Motion for a Decision on the record is captioned Affidavit of Mindy Michaels Roth, petitioner's counsel.

referred Mr. Perez to Abraham Morganoff, M.D., a neurologist. Pet. Ex. 3, pp. 62-63. Dr. Morganoff examined him and reported to Dr. Lombardo that the patient presented “with normal, objective neurological full evaluation and assessment and that the patient’s clinical and subjective complaints are consistent with post-reaction flu-H1N1, question of mild underlying hypokalemia.” Pet. Ex. 4, pp. 97-99. Dr. Morganoff indicated that there was “no evidence of Guillain-Barré syndrome” and that there was “no evidence of neurodegenerative presentation.” *Id.*, p. 99. Dr. Morganoff also indicated that he tried to assure Mr. Perez that his complaints were probably a benign reaction to the flu shots which should be self-resolving. *Id.*

According to petitioner, the symptoms did not resolve, and throughout the next month petitioner continued to experience pain in the middle and lower sections of the left side of his back, as well as numbness and tingling in both extremities which awakened him at night. Pet. Ex. 1, p. 3. Mr. Perez then consulted another neurologist, Dr. Matthew Menken, at Princeton & Rutgers Neurology, on December 4, 2009. Pet. Ex. 3, p. 61. Dr. Menken advised him to report his apparent reaction to the flu vaccine to the CDC. *Id.* Additionally, Dr. Menken ordered an MRI of Mr. Perez, which was normal and showed “no evidence of demyelination.” Pet. Ex. 4, pp. 100-01.

On January 19, 2010, Mr. Perez consulted Dr. Liviu C. Craciun, M.D., Ph.D., a board certified neurologist and clinical neurophysiologist. Pet. Ex. 3, pp. 22-24. Dr. Craciun reviewed petitioner’s medical history, essentially as recited above, with the addition that that the tingling that had occurred once a night and three times a week had not occurred in the past week. *Id.* Dr. Craciun also noted that Mr. Perez had diagnosed himself with obsessive compulsive disorder and anxiety. Pet. Ex. 3, p. 22; Pet. Ex. 7, pp. 118-120. Dr. Craciun performed a neurological exam, and his assessment was post vaccination syndrome, possible mild form of Parsonage-Turner syndrome, or thoracic radiculopathy and anxiety. Pet. Ex. 7, p. 120. Dr. Craciun did not elaborate on the basis for his post vaccination syndrome or Parsonage Turner Syndrome opinions. *Id.* He did not explain either the criteria for these diagnoses or how petitioner’s symptoms satisfied those criteria. *Id.*

Petitioner returned to Dr. Lombardo in March 2010 for a pain in his right shoulder. Pet. Ex. 1, p. 4. Between July and August of 2010, petitioner consulted with three different doctors regarding symptoms of neck pain. Pet. Ex. 8, p. 131; Pet. Ex. 10, p. 188. Petitioner reported enlarged lymph nodes in his neck, for which he sought treatment in August of 2010 from Deepak Jain, M.D. Pet. Ex. 9, pp. 168-172. Dr. Jain described two small but tender lymph nodes in the left posterior chain. Pet. Ex. 9, p. 168. Dr. Jain recorded that Mr. Perez attributed these to the H1N1 flu vaccine he had received the prior November. *Id.*, p. 169.

3. Summary of the Parties’ Arguments

Petitioner has submitted his case on the medical records, without offering an expert report to set forth a reliable medical theory of causation or to explain the logical sequence of cause and effect as required by *Althen* prongs one and two. Petitioner

contends that he has ruled out other causes and that the early onset of the symptoms after the vaccinations is consistent with a vaccine injury. Motion at 5. Petitioner does acknowledge that the Program has not awarded compensation based upon those two factors alone. *Id.*

Respondent contends that petitioner has not set forth a medical theory, nor presented a medical explanation, as to how the seasonal flu vaccine caused the harm, and that petitioner therefore is not entitled to compensation. For the reasons set forth below, the undersigned concludes that petitioner has failed to prove, by a preponderance of the evidence, that the requirements of *Althen* have been met.

4. 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. Based on the record as a whole, the undersigned finds that petitioner has not established that he suffered a Table injury. Therefore, he must prove that the seasonal influenza vaccine caused-in-fact his alleged injuries without the benefit of a presumption in his favor.

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 his burden of proving causation-in-fact, petitioner must “show by preponderant evidence that the vaccination brought about [his] 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). He 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, 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) he received a vaccine set forth on the Vaccine Injury Table; (2) he received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness,

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.

disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months.⁵

Petitioner does present verification of having received an H1N1 vaccine and a seasonal vaccine in New Jersey on November 23, 2009. Pet. Ex. 1 at 1; Pet. Ex. 2, pp. 11-14. He reports that his symptoms are ongoing, that he has continued to seek treatment from multiple physicians, and that he continues to experience a host of symptoms daily, which include muscle aches and back pain, enlarged painful lymph nodes, sporadic numbness and tingling from his toes that travels up his legs, and numbness and tingling in his arms, hands, neck, face and head. Pet. Ex. 1 at 9. He asserts that these symptoms began shortly after the vaccinations and have continued, and that he does not consider this to be a “simple coincidence.” *Id.*

5. Analysis

A. *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).

Fundamental to the presentation of a reliable medical theory to explain the way in which the vaccine can cause the *injury* is a basic definition of the injury itself. In this case, petitioner has reported a significant array of symptoms, but has offered no explanation as to how the body is producing these symptoms or of how they are linked. He has offered no evidence that defines any discrete diagnostic entity to explain symptoms that ranged from back pain, to left sided numbness and tingling in the lower limb then the upper, to right sided numbness, to swollen lymph nodes and facial pain. Some of these symptoms occurred in the days and weeks after the vaccines and others, like the swollen lymph nodes, did not occur for months after the vaccine. Yet the petitioner claims they are all caused by the vaccine.

“An off-table petitioner, who does not benefit from a presumption of causation, must specify his vaccine-related injury and shoulder the burden of proof on causation.” *Broekelschen v. Sec’y, HHS*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). The Federal Circuit in that opinion also noted that *Althen* prong one ties the required medical theory

⁵ Section 13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)....” Section 11(c)(1) contains the four factors listed above, along with others not relevant in this case.

to an *injury* and prong two links the cause and effect analysis to a specific injury as well. *Id.* at 1346.

In this case, the closest that any of the physicians come to defining a disease entity is in Dr. Craciun's listing of "post vaccination syndrome" in his differential diagnosis. Pet. Ex 7, p. 120. While this term does give a name to the compilation of symptoms petitioner described to Dr. Craciun, the record contains no description of this diagnosis or the criteria necessary to make it. It should also be noted that when Dr. Craciun saw petitioner, his neurological exam was completely normal, and the symptoms had actually subsided over the prior week. Pet. Ex 7, p. 118.⁶ Dr. Craciun also listed possible Parsonage Turner Syndrome on the differential, again without setting forth any basis for that possible diagnosis. *Id.*, p. 120. Indeed, Parsonage Turner, which is an acute brachial neuropathy or brachial radiculitis, would hardly explain symptoms in the lower extremities.

This failure to describe a diagnostic entity and to explain how the symptoms fit the criteria of that diagnosis, as a prerequisite to the application of *Althen* prong one, is a critical but not necessarily fatal shortcoming in the proof. "Medical recognition of the injury claimed is important and by definition a 'vaccine related injury,' i.e., illness, disability, injury or condition, has to be more than just a symptom or manifestation of an unknown injury." *Broeklschen* at 1349.

Neither did any of petitioner's multiple physicians describe a medical theory to explain how the multiple symptoms could be caused by the vaccine. Problematically as well, none of them, even when they acknowledged petitioner's belief that the vaccines caused the injury, were willing to attribute the symptoms to one vaccine or the other. Because the H1N1 vaccine is not covered by the Vaccine Act any harm attributable to it would not be compensable. The proof in this case requires a medical theory and logical cause and effect to describe how the seasonal flu vaccine was the "but for" cause of the harm. As a general, but not invariable, rule, it is necessary to provide expert testimony or opinion to explain how the covered vaccine could cause the injury alleged. No such opinion or testimony was offered in this case, and petitioner's medical records by themselves are not sufficient to satisfy the *Althen* prongs.

Petitioner's counsel acknowledges in his motion for a ruling on the record that the Program has not yet accepted the theory of a diagnosis by exclusion such as she suggests this case presents. Motion at 5. A diagnosis of exclusion generally refers to a diagnostic methodology whereby physicians reach a conclusion as to the nature of a disease or injury by eliminating other potential entities which could cause similar signs and symptoms. The methodology may also be used to reach a conclusion as to the cause of the disease or injury. In this case, it is difficult to say that a diagnosis of exclusion has been made when no disease entity has been identified to explain petitioner's symptoms. It is further difficult to say that a diagnosis of exclusion has been made when no physician's testimony was offered to state that the vaccine caused

⁶ Dr. Morganoff also stated that the patient's clinical and subjective symptoms are "consistent with post-reaction flu –H1N1," but did not enunciate a theory for a causal connection.

petitioner's symptoms, even by process of exclusion. As counsel also acknowledges, with none of the multiple physicians consulted by petitioner being willing to state an opinion as to causation, there is no evidence that would satisfy the *Althen* prongs. Thus, I have concluded that petitioner failed to prove, by a preponderance of the evidence, a theory sufficient to satisfy prong one of *Althen*.

B. *Althen* Prong Two

Petitioner has not presented an expert explanation of the biological cause of his injury, either through the records or by expert report, much less an explanation of how the seasonal flu vaccine could be that cause. Without presentation of a scientifically reliable theory to explain how the vaccine can cause the harm, he cannot prove a logical cause and effect as to how a scientifically known mechanism could have been triggered by the vaccine and caused the symptoms alleged. Petitioner essentially contends that he has ruled out other causes of the symptoms and that the timing of their onset shortly after the vaccine, at least for some of them, is more than a coincidence. It is questionable whether petitioner has actually ruled out other causes, but even if he had, the coincidental timing and rule-out of other causes, without the presentation of an explanation of how the vaccine could cause the injury and how in this case it did, is insufficient to satisfy the *Althen* criteria.

C. *Althen* Prong Three

The appropriateness of timing of the onset of symptoms is largely a function of the causal mechanism. Some mechanisms may cause symptoms immediately and others not for days to weeks. Without specificity as to a diagnosis and cause of injury it is not possible to conclude that the timing of the onset of symptoms was related to the vaccine.

6. Conclusion

The medical records do not provide adequate support for, or an explanation of, a medical theory to explain petitioner's symptoms. None of petitioner's physicians stated an opinion as to a causal relationship between the seasonal flu vaccine and the symptoms. No other expert was presented. Accordingly, petitioner has failed to present the preponderant evidence necessary to satisfy the *Althen* prongs. As such, the case must be dismissed.

The Clerk shall enter judgment accordingly.⁷

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

⁷ Entry of judgment can be expedited by each party's filing of a notice renouncing the right to seek review. See Vaccine Rule 11(a).