

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-896V

Filed: November 9, 2015

SCOTT WOODRING,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

UNPUBLISHED

Chief Special Master Nora Beth Dorsey

Entitlement; Ruling on the Record;
Decision Without a Hearing; Lack of a
Medical Opinion; Insufficient Proof of
Causation; Acute Inflammatory
Demyelinating Polyneuropathy ("AIDP");
Chronic Inflammatory Demyelinating
Polyneuropathy ("CIDP"); Guillain-Barré
Syndrome ("GBS"); Special Processing
Unit ("SPU")

Danielle Strait, Maglio Christopher and Toale, PA, (DC) Washington, DC, for petitioner.
Julia McInerny, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

On September 23, 2014, Scott Woodring filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.,² [the "Vaccine Act" or "Program"]. Petitioner alleges that he suffered "a severe neurological injury, likely an inflammatory demyelinating neuropathy" after receiving the influenza

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, 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). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. 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 National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

vaccine on September 23, 2011. Petition at 1. Petitioner alleges that his injury was “causally connected to an adverse reaction” to his vaccination. Petition at 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

Under the Vaccine Act, compensation may not be awarded “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). Petitioner has failed to file the report of a medical expert, and the medical records do not support petitioner’s claims. For the reasons discussed below, petitioner has failed to demonstrate that he is entitled to compensation. The petition is dismissed for insufficient proof.

I. Procedural History

Petitioner filed his petition without all relevant medical records due to the impending expiration of the Vaccine Act’s statute of limitations.³ Petitioner filed the last of his medical records on January 5, 2015, and the initial status conference was held telephonically on January 23, 2015.

During the call, respondent’s counsel expressed concern regarding the length of the time between vaccination and onset. See Order, issued Jan. 27, 2015, at 1. Petitioner’s counsel indicated she was aware of the issue and requested additional time for petitioner to file an affidavit and other documents to explain this lapse of time. See id.

Instead of any additional proof, petitioner filed a motion for a decision on the record pursuant to Vaccine Rule 8(d).⁴ In his motion, petitioner identified the exhibit and page number of the medical records he believes support his claim and indicated that he “considers the evidentiary record closed.” Motion for a Decision on the Record, filed Mar. 4, 2015, at 1. He further indicated that he “will not proffer the opinion of a medical expert and consequently elects not to pursue a formal causation hearing with expert witness testimony.” Id. at 2.

Respondent filed her response approximately two months later. Respondent argued that petitioner’s claim should not be compensated and instead, should be dismissed. Response, filed May 15, 2015, at 1.

The matter is now ripe for adjudication.

³ See Petition at 1 n.1. Petitioner included only his proof of vaccination with the petition. See Exhibit 1.

⁴ The Vaccine Rules, which can be found at Appendix B to the Rules of the Court of Federal Claims (“RCFC”), govern all Vaccine Act proceedings. Vaccine Rule 1(a). Under the Vaccine Rules, a special master may “decide a case on the basis of written submissions without conducting an evidentiary hearing.” Vaccine Rule 8(d).

II. Medical History

There is little information regarding petitioner's prior medical condition in the medical records filed. Lab results from 2010 indicate petitioner's cholesterol was high, and he was prescribed medication. Exhibit 2 at 25. Later provided medical histories indicate that he was a long time smoker. See, e.g., Exhibit 7 at 42.

On September 23, 2011, petitioner's hearing was evaluated due to a complaint of tinnitus in his left ear for the previous six months. Exhibit 2 at 47. It was reported that he suffered a hearing loss during childhood due to a fever. Id. The same day, September 23, 2011, petitioner received the influenza vaccination alleged as causal. Exhibits 1 and 5 (proof of vaccination).

Two months later on November 21, 2011, petitioner visited his primary care provider, Dr. Cox, for his tinnitus and for follow-up regarding his high cholesterol. Exhibit 2 at 97. It appears petitioner's blood pressure also may have been elevated but no other symptoms or complaints were noted.⁵

Petitioner first complained of moderate to severe back pain traveling down his right leg to his foot on February 8, 2012 (138 days after vaccination). Exhibit 2 at 47. He indicated he had been carrying equipment up and down stairs during the previous week but denied any particular injury. Id. Dr. Cox ordered a lumbar MRI.⁶ Exhibit 2 at 55. Performed on February 20, 2012, the MRI showed a pinched nerve on petitioner's right side, and Dr. Cox ordered pain medication and physical therapy. Id. at 100.

Petitioner began physical therapy to address his injury (diagnosed as lumbar nerve root compression) on March 2, 2012 at Cadillac Outpatient Rehabilitation Services. Exhibit 4 at 292. In those records, his date of onset is listed as January 1, 2012 (100 days after vaccination). Id. Described as suffering pain, decreased core strength, and limited range of motion, petitioner was prescribed therapy (to include aquatherapy) and heat packs. Id. at 292-293.

Based on a referral from Dr. Cox, petitioner saw Dr. Zimmerman on March 26, 2012 to determine if surgery was warranted. Exhibit 6 at 9. According to Dr.

⁵ The medical record contains an entry which is difficult to read but appear to indicate "elevated DBP," most likely an abbreviation for elevated diastolic blood pressure. Exhibit 2 at 97. Also, later medical records indicate a history of hypertension. See, e.g., Exhibit 2 at 42.

⁶ "MRI" stands for magnetic resonance imaging. MRI technology uses a magnetic field and radiofrequency signals to visualize internal structures of the body. See MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TEST'S ("MOSBY'S") at 1166 (4th ed. 2010).

Zimmerman's records, petitioner's symptoms began approximately six weeks prior to that visit.⁷ Id.

At the visit on March 26, 2012, Dr. Zimmerman reviewed petitioner's earlier MRI and agreed with the radiologist that the small hernia noted was not compressive. Exhibit 6 at 9. Observing that petitioner was suffering additional symptoms of weakness and clumsiness, he described petitioner's symptoms as "suggestive of myelopathy." Id. He speculated that petitioner may have suffered a disc rupture after his February 20, 2012 MRI. Id. He ordered additional MRIs which were performed on March 27, 2012. Id.; see id. at 3-6 (results of March MRIs).

After reviewing the MRIs done March 27, 2012, Dr. Zimmerman remained confused by petitioner's symptoms. Exhibit 6 at 2. The results of the MRIs were normal except for some bulging which Dr. Zimmerman assessed as minor and insignificant. Referencing, for example, some clumsiness in petitioner's hands, Dr. Zimmerman theorized petitioner suffered a myelopathy or degenerative disease. Concluding he could not help petitioner surgically, he recommended a neurology referral. Id.

On March 28, 2012, petitioner presented to the emergency room at Munson Medical Center⁸ with complaints of increasing pain, heaviness, weakness, coldness in his feet, and numbness in his fingers. Exhibit 7 at 393. He was admitted to the hospital for observation and an MRI and EMG were ordered. Id. at 395.

An electrodiagnostic specialist, Dr. Richardson, reviewed the findings of petitioner's EMG and concluded he suffered from acute demyelinating polyneuropathy, a presentation/variant of Guillain-Barré syndrome ("GBS").⁹ Exhibit 7 at 416-418.

⁷ Six weeks prior to the March 26, 2012 visit with Dr. Zimmerman would be February 14, 2012.

⁸ The medical records from Munson Medical Center indicate petitioner had seen a neurologist, Dr. Syring, earlier that day who advised that he go to the emergency room and recommended that he receive an MRI and EMG. See, e.g., Exhibit 7 at 400. "EMG" stands for electromyogram which is used to evaluate patients with muscle weakness. The test monitors the electrical activity of a muscle. MOSBY'S at 577-78.

⁹ GBS is a

Rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with parathesis of the feet. Followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs and face Variant forms include acute autonomic neuropathy, Miller-Fisher syndrome, acute motor axonal neuropathy, and acute motor-sensory axonal neuropathy."

Petitioner reported that he had been suffering his symptoms for three weeks but had been fatigued for several months. Id. at 416.

That same day, March 28, 2012, petitioner saw a neurologist, Dr. Lee, who agreed with Dr. Richardson's interpretation of the EMG results. Exhibit 7 at 419-21. During the visit with Dr. Lee, petitioner and his wife reported flu-like symptoms which began approximately a month before his symptoms (which would have been early January 2012). Id. at 419. Dr. Lee recommended "full admission" and ordered a five day course of IVIG.¹⁰ Exhibit 7 at 421. She indicated Dr. Salon would "assume neurological coverage." Id.

Dr. Salon monitored petitioner during his IVIG treatment, providing several written updates regarding his progress. Exhibit 7 at 407-415. On March 30, 2012, Dr. Salon agreed that petitioner suffered from AIDP,¹¹ noting that petitioner's spinal fluid showed elevated protein levels. He reported that petitioner's symptoms began as long as eight weeks after "a likely viral illness." Exhibit 7 at 413. Petitioner improved and was transferred to the inpatient rehabilitation unit on April 3, 2012 after finishing IVIG treatment. Id. at 405.

The medical records from petitioner's inpatient physical therapy (from April 3-9, 2012) reflect a diagnosis of the AIDP variant of GBS. E.g., Exhibit 7 at 71, 76. The records also reference the "24 hour flu-like syndrome" occurring one month prior to his symptoms which were reported to Dr. Lee on March 28, 2012. Id. at 71. Petitioner was discharged on April 9, 2012 (id. at 31) with instructions to continue outpatient physical therapy (see Exhibit 4 at 207). On April 17, 2012, petitioner began physical therapy at the same provider he visited in March 2012. Id. at 208. He underwent a second course of IVIG in May 2012. See Exhibit 2 at 19-22.

On October 15, 2012, petitioner returned to his primary care provider, Dr. Cox, complaining of weakness and soreness after a fall. Exhibit 2 at 39. Two months later, he visited a different neurologist, Dr. Galinas, for a second opinion. Exhibit 3 at 65. He complained of "weakness, poor balance and frequent falls." Id. For the first time, petitioner mentioned his vaccination when providing his medical history. He attributed his illness to the influenza vaccination but mistakenly indicated he received the vaccination in November 2011. Id. (Petitioner received the influenza vaccination on September 23, 2011.)

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32d ed. 2012) ["DORLAND'S"] at 1832.

¹⁰ "IVIG" stands for intravenous immunoglobulin. Neil M. Davis, MEDICAL ABBREVIATIONS, 15th Edition, at 178 (2011).

¹¹ "AIDP" stands for acute inflammatory demyelinating polyradiculoneuropathy. Neil M. Davis, MEDICAL ABBREVIATIONS, 15th Edition, at 42 (2011). Polyradiculoneuropathy is "any disease of the peripheral nerves and spinal nerve roots." AIDP is a variant of GBS.

Dr. Galinas ordered an EMG, the results of which were abnormal. Exhibit 3 at 33. After reviewing the EMG results and noting petitioner's history of AIDP with poor recovery after IVIG treatment, Dr. Galinas diagnosed petitioner with chronic inflammatory demyelinating polyneuropathy ("CIDP").¹² Id.

Petitioner returned to Dr. Galinas in early January 2013 for additional lab work. Exhibit 8 at 27. At that visit, Dr. Galinas advised him to undergo another course of IVIG and increase his nightly dose of gabapentin. Id. at 28. After finishing IVIG treatment, petitioner reported some improvement in his numbness but Dr. Galinas questioned the benefit of the IVIG treatment. Id. at 25-26. Dr. Galinas prescribed prednisone, outpatient therapies, and a home exercise program in March 2013. Id. at 24. Petitioner reported much improvement in numbness, tingling, and strength in May 2013. Id. at 21. He continued his outpatient physical therapy until March 10, 2014. See Exhibit 4 at 5. At that time, it was noted that petitioner had returned to exercising at a local fitness center and could climb stairs independently. He was instructed to continue his exercise program at home. Id. at 16.

III. Applicable Legal Standards

Under the Vaccine Act, petitioner may prevail on his claim if the vaccinee for whom he seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove his claim by preponderant evidence. § 13(a)(1)(A). This standard is "one of . . . simple

¹² CIDP is

a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by a progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid. It occurs most commonly in young adults, particularly males, and is related to [GBS]. Presenting symptoms often include tingling or numbness of the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations.

DORLAND'S at 1491.

preponderance, or ‘more probable than not’ causation.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing Hellebrand v. Sec’y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir. 1999). Id. at 1352. The received vaccine, however, need not be the predominant cause of the injury. Id. at 1351.

The Circuit Court has indicated that petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352-53 (quoting Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” Id. The Federal Circuit subsequently reiterated these requirements in its Althen decision. See 418 F.3d at 1278. Althen requires a petitioner

to 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.

Id. All three prongs of Althen must be satisfied. Id. Close calls regarding causation must be resolved in favor of the petitioner. Id. at 1280.

Petitioner is not required to eliminate alternative causes when establishing his prima facie case. Doe 11 v. Sec’y Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); de Bazan v. Sec’y, Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). To support an argument regarding causation, petitioner may, however, introduce evidence of the lack of an alternative cause. Walther v. Sec’y, Health & Human Servs., 485 F.3d 1146, 1149-50 (Fed. Cir. 2007). Respondent also may introduce evidence of the lack of an alternative cause to rebut evidence regarding causation. Doe 11, 601 F.3d at 1358; de Bazan, 639 F.3d at 1353.

Once petitioner has established a prima facie case, the burden shifts to respondent to show by preponderant evidence that petitioner’s injury was “due to factors unrelated to the administration of the vaccine.” § 13(a)(1); see also DeBazan, 639 F.3d at 1352-54; Walther, 486 F.3d at 1150.

IV. Analysis of Petitioner's Claim

Petitioner alleges that the influenza vaccination he received on September 23, 2011 caused him to suffer a demyelinating polyneuropathy later diagnosed as CIDP. Motion for a Decision on the Record at 1. To support his claim, petitioner relies solely on the medical records filed and arguments made in his petition and motion.

Respondent opposes compensation in this case arguing that petitioner has not established that he suffered the injury claimed and even if he had, has not proved causation. Response at 6. She maintains petitioner has failed to satisfy any of the Althen prongs. Id. at 7-8.

The undersigned finds petitioner has provided evidence sufficient to establish that he suffered the alleged injury (demyelinating polyneuropathy later diagnosed as CIDP) but has failed to prove causation. Specifically, petitioner has failed to satisfy all three Althen prongs. He has not provided sufficient evidence to establish a medical theory of causation, a logical sequence of cause, and effect showing the vaccination caused his injury and a proximal temporal relationship between vaccination and injury.

1. The Alleged Injury

Although his primary care physician, Dr. Cox, initially thought petitioner's back pain was due to a compressed nerve, in March 2012, Dr. Zimmerman questioned this diagnosis. An EMG was administered to petitioner in March 2012, the results of which were consistent with AIDP, a variant of GBS. After that date, none of petitioner's treating physicians questioned his diagnosis, and he received treatment consistent with that diagnosis. Petitioner did not respond well to IVIG treatment and was later deemed to have CIDP.

2. Causation

The Secretary has proposed adding the injury of GBS following receipt of seasonal influenza vaccines to the Vaccine Injury Table. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45,132-01 (July 29, 2015) (to be codified at 42 C.F.R. pt. 100). As described by the Secretary, this change would apply to GBS which presents as AIDP when the petitioner's first symptom or onset occurs within 3 to 42 days after vaccination. Id. at 45,145-46.

Nevertheless, this change has not been finalized and even if it were, petitioner's onset occurred more than 42 days after vaccination. Thus, petitioner must prove causation in this case. He must satisfy all three Althen prongs.

a. A Medical Theory Causally Connecting Vaccine and Injury.

To satisfy the first Althen prong, petitioner must show that the vaccine in question **can** cause the injury alleged. See Pafford v. Sec'y, Health & Human Servs., No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), aff'd, 64 Fed. Cl. 19 (2005), aff'd, 451 F.3d 1352 (Fed. Cir. 2006). Petitioner must offer a medical theory

which is reputable and reliable. See, e.g., Pafford v. Sec'y, Health & Human Servs., 451 F.3d 1352, 1355 (reputable); Moberly v. Sec'y, Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). Petitioner must prove this prong by preponderant evidence. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

Petitioner has not filed the report of a medical expert or offered a medical theory. He has not established that the influenza vaccine can cause CIDP.

Although the Secretary has proposed adding GBS to the Vaccine Injury Table, she indicates that the “scientific evidence is inadequate to accept or reject a causal relationship between seasonal influenza vaccines and GBS.” Revisions to the Vaccine Injury Table, 80 Fed. Reg. at 45,135. She bases her recommendation on studies showing a causal connection between earlier strains of the seasonal influenza vaccination but asserts “there is no evidence demonstrating that current formulations of the seasonal influenza vaccine can cause GBS.” Id. at 45,146. Moreover, here petitioner has been diagnosed with CIDP, and that injury is not identified as an injury on the proposed Table changes. In fact, CIDP is specifically excluded. Id. at 45,145.

Petitioner has failed to provide a medical theory causally connecting the influenza vaccination to his injury. He has failed to satisfy the first Althen prong.

b. A Logical Sequence of Cause and Effect

To satisfy the second Althen prong, petitioner must prove that the vaccine he received **did** cause his injury. Pafford, 2004 WL 1717359, at *4. He must provide preponderant evidence of causation. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Opinions of a treating physician who determines a vaccination caused the petitioner's injury should be considered when determining if petitioner has met his burden of proof under the second Althen prong. See id. Any diagnosis, conclusion, or medical judgment contained in the record should be considered when determining if compensation is appropriate. § 13(b)(1).

Petitioner has not provided evidence that the influenza vaccination he received on September 23, 2011 caused his injury. None of petitioner's treating doctors attributed his condition to the vaccination he received, and petitioner was unable to obtain a medical opinion supporting causation from his treating doctors or another expert. A review of the medical records filed revealed that none of petitioner's treating physician's offered any opinion as to the cause of his illness.

The only evidence regarding causation is found in medical histories provided by petitioner and his wife. In the majority of those medical histories, they did not link petitioner's injury to his vaccination but rather a flu-like illness suffered approximately one month prior to onset. See, e.g., Exhibit 7 at 419. It was not until ten months after onset and more than a year after vaccination that petitioner first mentioned any relationship between his influenza vaccination and his injury. When doing so, he misstated the vaccination date, indicating it was two months later and thus, closer in time to his onset. See Exhibit 3 at 65 (history provided to Dr. Galinas in December

2012). Prior to that time, petitioner and his wife linked his injury only to a flu-like illness they indicated he suffered in January 2012.

Moreover, as other special masters have observed, there is a difference between a medical history provided by petitioner and reported in his medical records and a statement regarding causation offered by the treating physician. See, e.g., Caves v. Sec'y, Health & Human Servs., 2010 WL 5557542, at *20 (Fed. Cl. Spec. Mstr. Nov. 29, 2010).

For all these reason, petitioner has not established a logical sequence of cause and effect showing that the vaccination was the reason for the injury. He has failed to satisfy the second Althen prong.

c. A Proximate Temporal Relationship between Vaccination and Injury

The third Althen prong requires that petitioner provide preponderant evidence that the first symptom or onset of his injury “occurred within a timeframe for which . . . it is medically acceptable to infer causation-in-fact.” de Bazan, 539 F.3d at 1352. Petitioner must show that his injury did not occur too soon or too long after vaccination. Id.

The medical records show that petitioner’s first symptom or onset most likely occurred in late January or early February 2012 more than four months after his September 23, 2011 vaccination.¹³ The earliest possible onset would be January 1, 2012 which is still 100 days after vaccination, and this date appears only in the records from petitioner’s February 2012 physical therapy. See Exhibit 4 at 292.

The Secretary’s proposal to add the injury of GBS after receiving the influenza vaccine includes a timeframe for onset between 3 to 42 days. Revisions to the Vaccine Injury Table, 80 Fed. Reg. at 45,146. In petitioner’s case, 42 days after vaccination would be November 4, 2011. The fact that the Secretary has proposed this time frame does not mean that a petitioner may not obtain compensation for a claim involving a later onset (even one that is substantially later) but the petitioner must provide evidence establishing that the later onset is medically acceptable to infer causation.

In petitioner’s case, even based on the earliest date of onset (January 1, 2012), the time between vaccination and onset is at least 100 days (more than twice the length of time set forth in the proposed table change), and petitioner has provided no evidence that an onset occurring that long after vaccination is medically acceptable to infer causation. Petitioner has failed to provide evidence of a proximate temporal relationship between vaccination and injury, and thus, has failed to fulfill the requirements of the third Althen prong.

¹³ See, e.g., Exhibit 2 at 45. When he first complained of back pain on February 8, 2012, petitioner indicated the pain’s duration was one week. This statement identifies petitioner’s first symptom or onset as occurring on February 1, 2012.

V. Conclusion

Petitioner has failed to offer the opinion of a medical expert, and the medical records filed do not support his allegations. He has failed to demonstrate that his injury was caused the vaccination he received. Specifically, petitioner has failed to satisfy the requirements of the Althen prongs.

This case is not a close call. Petitioner has failed to establish that he is entitled to compensation under the Vaccine Act. **This case is dismissed for insufficient proof.**

The clerk of the court is directed to enter judgment in accordance with this decision.¹⁴

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

¹⁴ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.