IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
Filed: June 12, 2014

FRED BROCK,	*	No. 12-756
Petitioner,	*	Special Master Gowen
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Influenza (Flu) Vaccine; Guillain Barré syndrome; Motion for Decision on the Record; Vaccine Act Entitlement; Denial Without a Hearing.
Respondent.	*	

Danielle Strait, Maglio, Christopher & Toale, PA, Washington, D.C., for Petitioner.
Justine Daigneault, United States Department of Justice, Washington, D.C., for Respondent.

UNPUBLISHED DECISION DENYING COMPENSATION[1]

On November 5, 2012, Fred Brock filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. (2006) ("Vaccine Act"). In the petition, and in the amended petition that he filed on November 12, 2012, Mr. Brock alleged that a September 14, 2010 influenza vaccine he received caused him to suffer from Guillain Barré syndrome. Petition ("Pet.") at 1-2; Amended Petition ("Am. Pet.") at 1-2. The undersigned now finds that the information in the record does not show entitlement to an award under the Act.

1. Procedural Background

After the petition, an amended petition, and several exhibits had been filed, an initial status conference was held during which the parties, having agreed to attempt to resolve this case informally, requested that it be placed on an expedited settlement track. See Order, dated January 9, 2013, at 1. Accordingly, Chief Special Master Vowell, the special master previously assigned to the case, suspended the Rule 4(c) deadline indefinitely and ordered the parties to file

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal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.

status reports every 30 days, beginning on April 9, 2013, updating the court on their settlement discussions. See Fast Track Order, dated January 9, 2013, at 1.

Thereafter, Petitioner continued to file medical records, ultimately filing his last medical record exhibits on May 9, 2013. The parties also continued to submit periodic status reports in which they documented their attempts to settle the case. After engaging in settlement negotiations for over eight months, the parties agreed that informal resolution of the case would not be possible. See Joint Status Report, dated September 30, 2013, at 1. Accordingly, they requested that the case be transferred from a settlement track to a litigation track, and Petitioner proposed to file an expert report by December 30, 2013. Id. Petitioner was ordered to do so. Non-PDF Order, dated October 4, 2013.

On December 20, 2013, Petitioner filed a status report in which he stated that he would not, in fact, be filing an expert report. Petitioner stated that he now "consider[ed] the record complete," and he proposed that a deadline be set for submission of Respondent's Rule 4 report.

On December 27, 2013, Chief Special Master Vowell ordered Petitioner to file either an expert report or a motion for ruling on the record by January 21, 2014, and ordered Respondent to file her Rule 4(c) report by February 19, 2014. On January 21, 2014, Petitioner filed a Motion for a Decision on the Record ("Motion"), in which he continued to allege that "[p]etitioner's past and continuing injuries from [Guillain Barré] are causally related to the influenza vaccination administered on September 14, 2010." Motion at 1. Petitioner confirmed that he has filed "all relevant records and affidavits pertaining to this Petition and consider[ed] the evidentiary record closed." Motion at 2. Because he did not proffer the opinion of a medical expert, Petitioner "elect[ed] not to pursue a formal causation hearing with expert witness testimony." Id.

On February 19, 2014, Respondent filed a "Rule 4(c) Report and Response to Petitioner's Motion for a Decision on the Record" ("Response"). In her Response, Respondent argues that "the record fails to establish a more likely than not causal connection between Petitioner's September 14, 2010 flu vaccination and his axonal [Guillain Barré]." Response at 13. Respondent further argues that Petitioner has not provided a medical or scientific report, or a medical or scientific theory, causally connecting the vaccine and Petitioner's injury. Id. According to Respondent, "a preponderance of treating physician statements suggest that Petitioner's axonal [Guillain Barré] was secondary to an intervening diarrheal illness, presumably C. jejuni, which has been directly associated with [Guillain Barré] in the medical literature." Id. at 14. Moreover, the Respondent contends, "[t]he special master is authorized to consider such evidence of an alternative cause in determining whether Petitioner has met his burden of proving a *prima facie* case." Id.

On March 5, 2014, this case was reassigned to the undersigned. Petitioner's Motion is now ripe for review.

2. **Applicable Legal Standard**

In order to prevail under the Program, Petitioner must prove either a "Table" injury[2] or that a vaccine listed on the Vaccine Table was the cause-in-fact of an injury. Based on the record as a whole, Petitioner has not established that he suffered a Table injury. Therefore, he must prove that the influenza vaccine caused-in-fact his Guillain Barré, 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 a 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) she received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months.[3]

3. **Factual History**

The medical records that have been filed in this case reflect the following: Petitioner received the flu vaccination at an Arizona Wal-Mart on September 14, 2010. Pet. Ex. 10 at 1. Thereafter, but prior to the apparent onset of his Guillain Barré, Petitioner was seen by treating physicians three times for treatment of his persistent diarrhea. On September 21, 2010, Petitioner presented to Dr. Jared Berkowitz with a three-day history of diarrhea and fever. Pet. Ex. 15 at 130-32. On September 24, 2010, Petitioner presented to Dr. Michael S. Drury with a 7-10-day history of diarrhea, mild nausea, and malaise (but no fever). Pet. Ex. 9 at 43. On

[2] 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.

[3] 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.

September 27, 2010, Petitioner was treated by family nurse practitioner Julie Hellige for persistent diarrhea. Pet. Ex. 9 at 39-42.

The onset of petitioner's Guillain Barré appears to have occurred by October 16, 2010, when Petitioner was seen at the emergency room of John C. Lincoln Hospital in Phoenix, Arizona for chief complaints of weakness, gait incoordination, and confusion. Pet. Ex. 2 at 23-25. An initial exam revealed mild bilateral lower extremity edema with no evidence of confusion. Id. at 9, 24-25. Within two days, Petitioner's weakness rapidly progressed to a "nearly complete flaccid paralysis of all extremities." Id. A lumbar puncture was performed on October 18, 2010, and revealed an elevated protein level in Petitioner's cerebrospinal fluid consistent with a diagnosis of Guillain Barré. Id. at 75.

Because of the history of diarrhea in the preceding weeks, a gastroenterology consult was requested upon admission to John C. Lincoln. Dr. Juan Teran, a gastrointestinal specialist, opined that Petitioner suffered from persistent diarrhea and "[f]laccid paralysis of extremities suggestive of [Guillain Barré], which can be associated with Campylobacter jejuni." Pet. Ex. 2 at 19. Dr. Teran noted that C. jejuni can be contracted through contact with animal stools and that Petitioner had recently been assisting his daughter at her dog breeding company, cleaning the dog kennels. Id. at 17-19; Pet. Ex. 18 at 48.[4] Dr. Jason Reinhart, a neurologist who consulted with Petitioner upon his admission to the hospital, noted Petitioner's history of "a flu shot 1 month ago" and "diarrhea for 3 weeks." Pet. Ex. 2 at 20-21. Dr. Reinhart ultimately concluded that Petitioner "presumably [had] a fulminant axonal form of Guillain Barré that occurred as sequelae to a Campylobacter jejuni GI infection." Pet. Ex. 14 at 5.

Similarly, Dr. Brian Porvin, a pulmonologist, observed following a consultation that Petitioner "ha[d] a significant GI illness with diarrhea just after his influenza vaccination 6 weeks ago." Pet. Ex. 2 at 15. According to a consulting neurologist who examined Petitioner on October 25, 2010, Petitioner had "[Guillain Barré], suspect[ed] axonal variant [and] source as C. jejuni, fulminant." Pet. Ex. 3 at 202. According to Petitioner's October 28, 2010 hospital discharge paperwork, authored by Dr. Mark Stivers, Petitioner's diagnosis was "Guillain-Barr[e] syndrome again presumably secondary to his infectious diarrhea." Pet. Ex. 2 at 9. Dr. Stivers noted elsewhere that Petitioner suffered "[f]laccid paralysis secondary to Guillain-Barre syndrome, status post-intravenous immunoglobulin (IVIg). This followed 4 weeks of diarrhea and was presumably secondary to Campylobacter infection that was previously treated." Pet. Ex. 2 at 5.[5] Neurologist Dr. Erik Ortega, who treated Petitioner after he had been released to an assisted living facility, also concluded that Petitioner's Guillain Barré "seems to have been related to a diarrheal illness." Pet. Ex. 4 at 4.

[4] A stool sample collected on October 18, 2010 was unremarkable. Pet. Ex. 2 at 83.

[5] Dr. Stivers also noted that "[s]tool tests were performed by the GI consultations that did not reveal any useful infectious agent, although again, the patient had previously been treated as an outpatient." Pet. Ex. 2 at 5.

4. **Discussion**

Petitioner presented to the emergency department at John C. Lincoln Hospital on October 16, 2010 with difficulty with balance and walking. Pet. Ex. 2 at 23-25. This rapidly progressed through ascending paralysis to full blown quadriplegia, without facial or significant respiratory impairment. Id. at 9. The diagnosis of fulminant axonal Guillain Barré syndrome was made. Id.; Pet. Ex. 14 at 5.

Petitioner has brought a claim asserting that his Guillain Barré was caused by the flu vaccine that he had received on September 10, 2010. Am. Pet. at 1-2. Petitioner has not submitted an expert report to articulate a theory or mechanism as to the causal relationship between the flu vaccine and the Petitioner's Guillain Barré. He has submitted the case on the medical records alone. While several treating physicians noted that Petitioner had had a flu vaccination within approximately a month of the onset of his Guillain-Barre symptoms, none of them articulated an opinion that the vaccination caused the Guillain-Barre.

Four days after his flu vaccine, Petitioner began to suffer with a persistent watery diarrhea for which he saw several physicians. His family physician treated with antibiotics and Lomotil. Pet. Ex. 15 at 132. The diarrhea diminished but was still present when he presented to John C. Lincoln with the prominent presentation of Guillain Barré syndrome. Because of the diarrheal history, a gastroenterology consult was requested. Dr. Juan C. Teran, M.D. examined him and based on the history of Petitioner's work at his daughter's dog breeding facility, but without confirmatory lab work, concluded that Campylobacter jejuni was the likely cause of the diarrhea and the subsequent Guillain Barré.

Respondent has filed a study entitled "Guillain Barré Syndrome Associated with *Campylobacter jejuni* Infection in England, 2000-2001." Resp. Ex. A at 1.[6] This study indicated that Campylobacter jejuni could represent as many as 13.7% of Guillain Barré hospitalizations after a multiplier of 10.3 was applied to the actual reported data to account for unreported cases of Campylobacter. Id. at 1-2. Actual data showed 1.3%. Id. at 2.

All other references by treating physicians to a causal relationship to diarrhea appeared to follow what Dr. Stivers' discharge summary from John C. Lincoln referred to as speculation by the gastroenterology consult. Pet. Ex. 2 at 9-11. There was no laboratory confirmation that Petitioner had actually contracted Campylobacter jejuni, although this could possibly be explained by the treatment with antibiotics before cultures were taken. See id. at 5, 83.

Despite the lack of laboratory confirmation, Dr. Teran made a reasonable clinical diagnosis based upon the history of persistent diarrhea and the occupational exposure of Petitioner to dog feces. He noted that Guillain Barré could be associated with Campylobacter, which could be contracted from animal waste. Ex. 2 at 17-19. Respondent's literature submission is supportive of this conclusion. In contrast, Petitioner has not submitted a medical opinion to explain why the flu shot was the more likely causal agent of the unquestioned Guillain Barré syndrome. Petitioner has the burden under Althen to articulate a theory as to how the

[6] The full cite for this article is Clarence C. Tam, et al., "Guillain-Barré Syndrome Associated with *Campylobacter jejuni* Infection in England, 2000-2001," CID 37, 307-10 (2003).

disease can be caused by the vaccine and a logical explanation as to why it is more likely than not that it was caused by the vaccine in this case. Petitioner has submitted the case for decision on the medical records without a supportive expert opinion.

The medical records do not articulate a theory as to how the flu vaccine can cause Guillain-Barre or the mechanism by which it occurred in this patient. On the other hand, the medical records on which Petitioner relies do contain a working diagnosis of diarrhea caused by unconfirmed Campylobacter jejuni, which could have been occupationally contracted and which Respondent's medical literature indicates can be a causal factor in producing Guillain Barré.

Thus, the undersigned finds that Petitioner has failed to present preponderant evidence that his flu vaccine was a substantial factor in causing his Guillain Barré. If anything, the presence of the intervening case of persistent diarrhea makes the alleged causal relationship less likely. As such, Petitioner has failed to make the required showing under Althen, and his petition must be dismissed.

5. **Conclusion**

In accordance with the foregoing, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

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