

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-668V

March 13, 2014

Not to be Published

GERALD LEONARDI, III,

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Petitioner,

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v.

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Tdap vaccine; eight-week
onset to seizure; petitioner
moves for dismissal; petitioner's
expert Dr. Blitshteyn prefers not
to offer an opinion

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Jeffrey S. Pop, Beverly Hills, CA, for petitioner.

Ryan D. Pyles, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on September 11, 2013, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012). Petitioner alleges that his Tdap vaccination on October 14, 2010, caused a seizure one week later. All the medical histories petitioner gave to

¹ Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

treating doctors show an eight-week onset. Petitioner submitted an expert report from Dr. Svetlana Blitshteyn, a neurologist, saying that Tdap vaccine caused petitioner's seizures. Ex. 9, at 4. Dr. Blitshteyn relied on petitioner's and his wife's affidavits that the onset was one week, and remarked that "the first medically documented episode of loss of consciousness after dizziness" occurred about eight weeks after vaccination. Id. at 1, 3.

On January 8, 2014, the undersigned held a telephonic status conference with petitioner and respondent, explaining that Dr. Blitshteyn's report does not answer the question whether she would support causation if she assumed the onset of seizures was eight weeks as medically documented, and not one week as petitioner and his wife wrote in their affidavits. Petitioner's counsel did not know if Dr. Blitshteyn would support causation if she accepted an eight-week onset. In an Order dated January 8, 2014, the undersigned ordered petitioner to file a supplemental expert report from Dr. Blitshteyn answering that question.

On March 14, 2014, petitioner filed the supplemental report of Dr. Blitshteyn, in which she states that if she were to rely on the medical records alone, which consistently note onset was eight weeks after vaccination, that timeline would be "less compatible with vaccination-related seizure disorder. . . ." Ex. 19, at 1. Dr. Blitshteyn concludes: "Given the uncertainty about the timeline, I would prefer not to offer an opinion connecting Petitioner's seizures to the Tdap vaccination administered on October 14, 2010." Id.

On March 13, 2014, the undersigned held another telephonic status conference with petitioner and respondent and asked petitioner's counsel if petitioner is dismissing in light of Dr. Blitshteyn's refusal to support causation in this case. Petitioner's counsel orally moved to dismiss.

The undersigned grants petitioner's motion and dismisses his case.

FACTS

Petitioner was born on November 19, 1985.

On October 14, 2010, he received flu vaccine and Tdap vaccine. Med. recs. Ex. 2, at 1, 3. (Petitioner does not allege that he had a reaction to flu vaccine.)

On December 8, 2010, petitioner saw his personal care physician, Dr. Allan Wohl, and stated that he had fainted at work on December 7, 2010, but refused to go to the hospital. Med. recs. Ex. 2, at 2.

On December 8, 2010, on referral from Dr. Wohl, petitioner saw Dr. Craig Frankil, a cardiologist, for a cardiovascular consultation. Id. at 4. Petitioner gave Dr. Frankil a history that he had no real significant past medical history. Id. At work earlier that week, he had a documented syncopal event. Id. He was unconscious for five minutes. Id. He did not have chest pain, pressure, burning, or lightheadedness, but he did have dizziness. Id. Petitioner

denied that he had any prior syncopal event in the past. Id. Dr. Frankil diagnosed petitioner with syncopal event, smoking disorder, and obesity. Id. at 5.

On December 22, 2010, petitioner was taken to Aria Health Emergency Department by ambulance, where he told Dr. Bakhshish S. Sandhu that he had been at McDonald's when he felt lightheaded and woke in an ambulance. Id. at 15. Petitioner said he had a shaking episode, which lasted about five minutes. Id. Afterward, he felt confused. Id. Petitioner told Dr. Sandhu that he had a similar episode about two weeks ago but refused to be evaluated at that time, although he did follow up with his family doctor who sent him to a cardiologist for an evaluation. Id. Dr. Sandhu diagnosed petitioner with seizure vs. syncope and prescribed Topamax. Id.

Also on December 22, 2010, petitioner saw Dr. Robert Quinby, who wrote a history. Med. recs. Ex. 5, at 64. Petitioner had an apparent seizure that morning at McDonald's when he became lightheaded and then woke up in an ambulance. Id. He was told he had a shaking episode that lasted about five minutes. Id. Afterward, he felt confused and noted mild discomfort in the back of his head. Id. He had a similar episode about two weeks ago, but refused medical evaluation at that time. Id. He did follow up with his PCP, who sent him to a cardiologist for evaluation. Id. Petitioner's symptoms began as noted and he did not have a prior history of a similar problem. Id.

On December 23, 2010, petitioner saw Dr. Jay Klazmer, a neurologist. Med. recs. Ex. 2, at 19. Petitioner told Dr. Klazmer that his initial episode began two weeks earlier, associated with a transient mental foggy and sphincter incontinence. Id. On December 22, 2010, while at McDonald's, petitioner suddenly became lightheaded and fell to the ground. Id. He woke in an ambulance and was taken to Virtua Hospital Mt. Holly, where he refused to be treated. Id. He walked back to his car several blocks away. Id. His mother-in-law brought him to Atria ED, and he was admitted. Id. He recalled feeling foggy mentally after the episode, which gradually remitted. Id. An EEG showed generalized theta slowing without focal or epileptiform features. Id. at 20. Dr. Klazmer diagnosed petitioner with either convulsive syncope or recurrent seizures. Id.

DISCUSSION

To satisfy his burden of proving causation in fact, petitioner must prove by preponderant evidence: “(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 of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by

“reputable medical or scientific explanation[.]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Althen, 418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioner’s affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

The Vaccine Act does not permit the undersigned to rule for petitioner based on his claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1) (2012). His affidavit and that of his wife are not sufficient legally to support his allegation of causation from Tdap vaccine.

The medical records do not support his allegation that Tdap vaccine caused his seizure disorder. Petitioner told five different doctors that the onset of his dizzy spells was December 7, 2010, or two weeks before December 22, 2010, which is about eight weeks after vaccination on October 14, 2010. When asked by various doctors if he had any syncopal episodes before early December, petitioner answered in the negative.

Petitioner’s expert Dr. Svetlana Blitshteyn initially supported petitioner’s allegation because she assumed a one-week onset after Tdap vaccine, based solely on petitioner’s and his wife’s affidavits, while she recognized in her expert report that the first medical documentation of a seizure was in December 2010, eight weeks after vaccination. When asked if she would support an eight-week onset as causative from the vaccine, Dr. Blitshteyn demurred in her supplemental report and said that was less compatible for causation. In the last sentence of her supplemental report, she stated she preferred not to offer an opinion on causation in this case.

Without either medical record or expert support that Tdap vaccine can cause seizure disorder eight weeks later, petitioner has failed to satisfy prong one of Althen.

Because petitioner has failed to prove that Tdap vaccine can cause seizure disorder eight weeks later, he has also failed to prove that Tdap vaccine did cause his seizure disorder eight weeks later. Petitioner has failed to satisfy prong two of Althen.

In addition, petitioner has failed to prove that eight weeks is an appropriate time interval to support a holding of causation of seizure disorder from Tdap vaccine. Thus, he has failed to satisfy prong three of Althen.

Petitioner has failed to make a prima facie case. The undersigned **GRANTS** his oral motion for dismissal. This petition is hereby **DISMISSED**.

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

Dated: March 13, 2014

s/Laura D. Millman

Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.