

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

No. 06-392V

Filed: May 10, 2010

Not for Publication

ROBERTA BORN, *
 *
 Petitioner, * Failure to Produce Expert
 * Report; Medical Records
 v. * Inadequate to Demonstrate
 * a Medical Theory of
 * Causation.
 *
 SECRETARY OF THE DEPARTMENT *
 OF HEALTH AND HUMAN SERVICES, *
 *
 Respondent. *
 *

Michael T. McDonnell, III, Kutak Rock, LLP, Philadelphia, PA, for petitioner.

Traci R. Patton, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Special Master:

On May 11, 2006, Ms. Roberta Born [“Ms. Born” or “petitioner”] 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”], *pro se*. She secured representation in November, 2006, and her current attorney entered a formal written

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material 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 (2006).

appearance on December 7, 2006.

The petition ["Pet.,"] asserted that Ms. Born had received a tetanus vaccination on May 20, 2003, and thereafter suffered unspecified "neurologic injuries" caused by the vaccination. Pet. ¶¶ 1-3. The petition was filed without any of the statutorily required supporting documentation.³ Medical records pertinent to Ms. Born's vaccination (although not the vaccination record itself) and to the symptoms she claimed were caused by that vaccination were filed after many delays. However, Ms. Born has failed to produce an opinion of a medical expert causally linking her symptoms to the tetanus vaccine she received, and thus, **her petition for compensation is denied.**

I. Procedural History Summary.

The resolution of this case was significantly impeded by Ms. Born's repeated failures to comply with court orders. During the period that petitioner was *pro se*, the court and respondent assisted her in attempting to obtain records pertaining to the vaccination she claimed was causal of her injuries. Several orders memorialized these efforts. See Orders filed August 15, 2006, October 10, 2006, and October 31, 2006.

Difficulties in obtaining petitioner's cooperation persisted after she secured representation. In status conferences held on January 17, March 9, July 17, and October 22, 2007; on April 14 and Sept 10, 2008; and on February 13 and 19, June 26, and December 18, 2009, I emphasized the importance of petitioner's compliance with court orders to file medical records or other documents. I also emphasized the importance of making and keeping appointments for evaluation of her current medical condition and determining its cause. In view of Ms. Born's apparent difficulties in complying with the requests of her counsel and the orders of this court, some of these status conferences included both petitioner and her counsel. See, e.g., Scheduling Order, filed December 18, 2009 (documenting Ms. Born's presence at the status conference).

On July 9, 2009, I ordered petitioner to file an expert report. After several requests for extensions of time, on December 11, 2009, petitioner's counsel reported to the court that Dr. Marcel Kinsbourne had reviewed Ms. Born's case and had provided a report regarding causation, which had been furnished to Ms. Born, but the report was not filed with the court as an exhibit. See Status Report filed December 11, 2009. At the request of Ms. Born's counsel, I held a recorded telephonic status conference on December 18, 2009, with counsel for both parties and Ms. Born to discuss her options and to ensure that she understood the posture of her case. Although I was not provided

³ Section 300aa-11(c) of the Vaccine Act requires the petition to be accompanied by certain documentary evidence, including records pertaining to the vaccination and subsequent treatment. See also Vaccine Rule 2(e), RCFC, Appendix B.

with a copy of Dr. Kinsbourne's opinion regarding causation, some of the discussion at this status conference revealed that Dr. Kinsbourne could not opine favorably in Ms. Born's case. During the status conference, I indicated that Ms. Born would have one final opportunity to supplement the record with anything she wished me to consider before ruling on her case. See Order filed December 18, 2009. Nothing was filed by the January 19, 2010 deadline.

Because respondent's original Vaccine Rule 4(c) report was filed at a time before most of the medical records were filed in this case, I ordered respondent to file a supplemental Rule 4(c) report. Respondent complied, and on April 26, 2010, filed the ordered report and a motion to dismiss.

II. Failure to Establish Vaccine Causation.

In order to receive compensation, a petitioner must prove either a "Table" injury⁴ or that a vaccine listed on the Table was the cause in fact of an injury. Because the unspecified neurological injuries Ms. Born alleged are not listed on the Vaccine Injury Table with reference to the tetanus vaccination she received, Ms. Born cannot demonstrate a "Table" injury. Therefore, Ms. Born must demonstrate that the tetanus vaccine caused her injury. See § 300aa-11(c)(1)(C)(ii). No reliable evidence submitted links her vaccination as the cause in fact of any illness, disability, injury, or condition. I therefore hold that petitioner has failed to establish her entitlement to compensation.

A. Medical Records.

Ms. Born's medical records contain reports⁵ of a tetanus vaccination on May 24, 2003,⁶ after stepping on a nail (see Pet. Ex. 6, p. 229), but do not include records pertaining to the actual vaccination. She was seen at the Community Health Center on June 3, 2003, with reported weakness in both legs, accompanied by numbness and

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. The tetanus vaccine is listed on the Table; however petitioner's medical condition is not an injury specified for compensation for that vaccine.

⁵ Ms. Born failed to file a copy of her vaccination record, but she made a number of attempts to obtain her medical records from the physician who administered the tetanus vaccination. Relatively contemporaneous medical records refer to the vaccination. See, e.g., Petitioner's Exhibit ["Pet. Ex."] 6, p. 229. Section 11(c)(1)(A) of the Vaccine Act requires supporting documentation demonstrating that a vaccine on the Vaccine Injury Table was actually administered. A vaccine record or a chart entry reflecting administration of a vaccination is not required. See *Centmehaiey v. Sec'y, HHS*, 32 Fed. Cl. 612, 621 (1995). I am satisfied that Pet. Ex. 6, p. 229 adequately documents the fact of Ms. Born's vaccination.

⁶ The petition alleges that the vaccination was received on May 20, 2003. In view of the lack of a vaccination record, I find that the medical record from August 7, 2003 (Pet. Ex. 6, p. 229) is the most reliable evidence of when the vaccination was received, and adopt May 24, 2003, as that date.

tingling all over her legs, and headache. She reported that the symptoms began within 24 hours of the vaccination. Pet. Ex. 6, p. 228.

On August 7, 2003, Ms. Born reported to Shannon Rio, a nurse practitioner, that she was experiencing leg and joint pain and tingling all over, and believed that she was having a reaction to the tetanus vaccination. She also complained of shoulder and neck pain, and some vision changes that made her reluctant to drive. Pet. Ex. 6, p. 229. Ms. Born requested a neurology consultation. *Id.* Unspecified laboratory results were within normal limits. Pet. Ex. 6, p. 230.

On August 14, 2003, Ms. Born reported to a neurologist, Dr. Kevin Sullivan, that the morning after the vaccination, she experienced stiff legs, blurry vision, slurred speech, and difficulty walking. These symptoms improved, but she developed muscle and joint pains, burning sensations, and shooting pain in her arms and had headaches, malaise, and tingling in her neck and shoulders. She investigated her symptoms on the internet and found others had reported similar symptoms after tetanus vaccinations, "suggesting a vaccine reaction." Pet. Ex. 2, p. 132. Doctor Sullivan noted that the usual reactions associated with tetanus toxoid are Guillain-Barré or brachial neuritis, and Ms. Born's symptoms did not match those two conditions. He did not doubt Ms. Born's report of her symptoms. He commented that "she may well have had some peculiar reaction to her tetanus toxoid," but had no "neurological abnormalities whatsoever." He assessed her as having joint pain and paresthesias. Pet. Ex. 2, p. 134.

Seven months later, on March 4, 2004, Ms. Born saw Dr. Ruth Lowengart, a specialist in Orthopedic Medicine and Occupational Health. She reported to Dr. Lowengart essentially the same symptoms after her vaccination as she had reported to Dr. Sullivan. See Pet. Ex. 3, p.143. The joint pain, muscle stiffness, and fatigue had persisted since the visit to Dr. Sullivan. Ms. Born indicated that an herbal remedy had relieved the pain, but she could not afford to take it. Doctor Lowengart described her symptoms as nonspecific and vague. *Id.*

Doctor Lowengart's diagnoses were not definite. She suggested that Ms. Born may have had a "[p]ossible Guillain-Barr[é] variant post vaccination" but that there was no evidence of one on examination. Both multiple sclerosis and fibromyalgia were "a possibility," but she did not have enough tenderness for a fibromyalgia diagnosis. Ms. Born had symptoms of chronic fatigue, but did not have a sore throat. Doctor Lowengart concluded: "In summary, I have no real diagnosis for her and no recommendations that are likely to help." Pet. Ex. 3, p. 143. She saw "no objective evidence of disability at this time." Pet. Ex. 3, p. 144.

In May, 2005, Ms. Born was seen at Morningstar Healing Arts by a physician whose signature is illegible. She reported joint pain, fatigue, and digestive problems that started after a tetanus vaccination two years earlier. This physician also recorded a history of depression, and that Ms. Born believed she had "chronic candida." Ms. Born described feeling tired, chronic loose stools, fecal incontinence, frequent urination,

tingling in her toes, trouble sleeping, and bloating. Pet Ex. 4, p. 146. She had a history of asthma, with some wheezing on examination. Pet. Ex. 4, p. 146. The physician's impressions included possible fibromyalgia, "CDSA," connective tissue problems, or Lyme disease. *Id.* There was little change at a follow up visit in June, 2004. Ms. Born had not followed suggestions regarding her bowel problems because of a fear of fasting, and refused to use Albuterol, because "it is a bad drug." She had no swollen or tender joints. *Id.* at 148. At a July, 2005 follow up visit, Ms. Born still had muscle stiffness. Laboratory testing did not reveal any problems, other than some food allergies. Pet. Ex. 4, p. 148.

Although she saw her primary care physician, Dr. Sylvia Chatroux, on several occasions after her vaccination, Ms. Born did not discuss the vaccine injury at these visits. See, e.g., Pet. Ex. 5, pp. 165, 184-85.

A cervical spine MRI, with and without contrast, was performed on January 16, 2007. There were no significant findings. Pet. Ex. 6, p. 224. The brain MRI performed on the same date revealed "[m]ild generalized atrophy for patient age," but was "[o]therwise unremarkable." Pet. Ex. 6, p. 225. These tests were characterized as negative for multiple sclerosis. Pet. Ex. 6, p. 233.

B. Affidavits.

Ms. Born filed a number of affidavits temporally linking her symptoms to the time period surrounding her vaccination. See, e.g., Affidavit of Silas Smith, dated December 19, 2007; Affidavit of Andrew Oser, dated November 19, 2007. All were written and filed several years after the vaccination in question.

C. Opinions of Medical Professionals.

Ms. Born did not file any expert report. Thus, evidence that the tetanus vaccine caused an injury must be found in the medical records in order for Ms. Born to prevail, because her claim alone is insufficient. § 300aa-13(a)(1).

The opinions of treating physicians consist primarily of comments on the temporal connection between Ms. Born's reports of various neurological symptoms and her tetanus vaccination. During an emergency room visit on April 2, 2007, the history of chronic illnesses included the comment: "Notable for a vaccine injury following tetanus immunization with muscle weakness and joint issues." Pet. Ex. 1, p. 93. Based on the other data in the medical record, it appears that the information regarding the vaccine injury was part of the patient history. After a motor vehicle accident on August 29, 2007, a similar entry from the same hospital indicated that a vaccine reaction had caused leg weakness. Pet. Ex. 5, p. 153.

Several treating physicians noted the lack of any objective findings to support Ms. Born's claims of a vaccine injury. See, e.g., Pet. Ex. 2, p. 134 (Dr. Sullivan); Pet.

Ex. 3. pp. 143-44 (Dr. Lowengart).

On April 15, 2009, a rheumatologist, Dr. Rudy Greene, opined that Ms. Born's presentation was consistent with fibromyalgia.⁷ He noted that Ms. Born informed him that she was "possibly part of a class-action suit because of her vaccination" and "wants us to have a note prepared that this may be related to her vaccination." Doctor Greene's assessment was that Ms. Born's fibromyalgia "may have been precipitated by the vaccine, but nobody can say this definitely."

III. Analysis.

To receive compensation under the Program, petitioner must prove either 1) that she suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of her vaccinations, or 2) that she suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). There is no evidence that Ms. Born suffered a "Table Injury." Further, the record does not contain a medical expert's opinion or any other persuasive evidence indicating that her alleged injury was vaccine-caused.

A petitioner may not receive 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. § 300aa-13(a)(1). In this case, because there are insufficient medical records supporting petitioner's claim, a reliable medical opinion must be offered in support. Petitioner, however, has offered no such opinion. At best, Dr. Greene indicated that the vaccine "may have" precipitated Ms. Born's symptomology, but his comment does not constitute a medical opinion that rises to the level of preponderant evidence. He does not say that the vaccine was the probable cause, nor does he offer preponderant evidence of a medical theory by which a vaccine can cause fibromyalgia, what logically connects any theory of vaccine causation to Ms. Born's presentation, or why the temporal relationship between her vaccination and symptoms is anything more than a *post hoc, ergo proper hoc* analysis. See *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1323-24 (Fed. Cir. 2010) (concluding that a showing of temporal association between vaccination and injury, together with the absence of another identified cause, is insufficient to establish causation); see also *Andreu v. Sec'y, HHS*, 569 F.3d 1367, 1375 (analyzing how the treating physicians' testimony supported a causation-in-fact analysis); *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (explaining petitioner's three-prong causation burden); *Bradley v. Sec'y, HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (concluding special master was reasonable in finding that medical opinions based primarily on the petitioner's testimony did not qualify to substantiate petitioner's testimony).

⁷ Doctor Greene's records were not assigned an exhibit number. Instead, they appear as docket entry 59, filed on July 10, 2009, which is entitled "Status Report," followed by the entry "Medical Records."

IV. Conclusion.

Ms. Born has failed to demonstrate either that she suffered a “Table Injury” or that her injuries were “actually caused” by a vaccination. **Thus, respondent’s motion to dismiss this case is granted, and the case is dismissed because petitioner has failed to establish that a vaccine caused her injury. The clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Special Master