

MAY 28, 2019

OSM

U.S. COURT OF FEDERAL CLAIMS

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 26, 2019

* * * * *
ODAINÉ TOMLINSON, a parent of,
and natural guardian of,
C.T., a minor
Petitioner,
v.
SECRETARY OF HEALTH
AND HUMAN SERVICES,
Respondent.
* * * * *

PUBLISHED
No. 19-431V
Special Master Gowen
Dismissal; Hepatitis B;
Seizure Disorder

Odainé Tomlinson, pro se, New Bern, NC, for petitioner.
Heather L. Pearlman, Department of Justice, Washington, D.C., for respondent.

DECISION DISMISSING PETITION¹

On March 18, 2019, Odaine Tomlinson (“petitioner”), acting pro se, filed a petition in the National Vaccine Injury Compensation Program.² Petitioner filed the petition on behalf of his minor child, C.T. Petition ¶ at 1. Petitioner alleged that on January 3, 2019 C.T. suffered from status epilepticus, a seizure disorder, encephalopathy, encephalitis, anaphylaxis (Type III hypersensitivity) and vasovagal syncope as a result of receiving the Hepatitis B vaccine on December 17, 2013. Id. at ¶ 3.

A. Procedural History

Petitioner initially filed the claim under his name only. I order the case caption be corrected to reflect that the claim was filed on behalf of his minor child, C.T. On April 11, 2019,

¹ Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims. The court’s website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting 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). “An objecting party must provide the court with a proposed redacted version of the decision.” Id. If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes. Id

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act.”). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

the undersigned held a status conference in the above-captioned matter to discuss petitioner's claim regarding the Hepatitis B vaccination his minor child, C.T. received on December 17, 2013. Petitioner is *pro se* and appeared on behalf of himself and the minor C.T. Ms. Traci Patton appeared on behalf of respondent. The status conference was recorded.

During the status conference, I described the Vaccine program, reviewed petitioner's filings and gave my preliminary thoughts on the case. As an initial matter, I advised petitioner that cases that come before this Court are often very sophisticated and the Office of Special Masters maintains a list of attorneys as a service to petitioners seeking compensation under the program.³

I reviewed the medical records petitioner filed with the petition. C.T. was born on December 17, 2013 by cesarean and weighed 7 lbs. 2.8 oz. Petitioner ("Pet.") Tab 2 at 13. She received the Hepatitis B vaccination the same day. *Id.* at 14. C.T. was discharged to home with her mother on December 20, 2013. *Id.* at 16. The next medical record included with the petition was from January 3, 2019. Pet. Tab 3. The medical records reveal that C.T. experienced a five-minute seizure, observed by her parents. Pet. Tab 3 at 40. She was taken by ambulance to Carolina East Emergency Department. *Id.* C.T. was subsequently intubated with rapid sequence sedation upon arrival at the hospital. Pet. Tab 3 at 26. C.T. was diagnosed with seizure and status epilepticus and transferred to the Pediatric ICU at Vidant Medical Center the same day. Pet. Tab 4 at 37. While in the hospital, C.T. underwent an MRI that showed minimal diffuse FLAIR hyperintensity in the right mesial temporal lobe. Pet. Tab 4 at 47. C.T.'s father described C.T. having a possible absence seizure about two years prior, when she was "unresponsive....with eyes open for about 20 minutes," but medical care was not sought. Pet. Tab 4 at 40. C.T. was discharged on January 6, 2019 with 5 mg of Diastat to be used as needed in case of future seizures. *Id.* at 39.

The next medical record is from a paramedic report on February 6, 2019, where C.T. may have been experiencing another seizure. Pet. Tab 3 at 32. C.T.'s mother called paramedics after she thought C.T. was having another seizure. *Id.* C.T. was seen by Radonna Carroll, FNP-C., on February 27, 2019. Pet. Tab 5 at 59. During this visit, it was noted that C.T. had never received any health care or preventative medical services since birth. *Id.* at 61.

During the status conference, Mr. Tomlinson advised that he and his wife tried to analyze what could have caused C.T.'s seizures. He explained that she had not received any other medical care after birth and she did not have any significant illnesses. Further, he explained that his other two children did not have seizures and they have not received any vaccines. Thus, he and his wife concluded that hepatitis B vaccine administered to C.T. shortly after birth was the cause of her seizures, as they could not identify any other cause.

I discussed that neurological disorders are extremely complex and seizure disorders are not fully understood. I explained that sometimes seizure disorders have a genetic basis. For

³ A list of attorneys who have expressed a willingness to accept vaccine injury cases and is offered as a convenient reference to *pro se* petitioners and potential petitioners in the program can be accessed: <http://www.cofc.uscourts.gov/vaccine-programoffice-special-masters>.

example, a neurologist may look to whether an individual has a mutation such as in the SCN1A gene. According to the National Institute of Health Genetics Home Reference, “Hundreds of mutations in the SCN1A gene have been found to cause genetic epilepsy with febrile seizures plus (GEFS+), which is a spectrum of seizure disorders of varying severity. These conditions include simple febrile (fever-associated seizures, which start in infancy and usually stop by age 5, and febrile seizures plus (FS+), including those not related to fevers (afebrile seizures).”⁴ Respondent’s counsel stated that Dravet syndrome, a seizure disorder that often begins at infancy, is associated with a mutation of the SCN1A gene. I indicated that while the SCN1A gene mutation is better known, other types of seizure disorders, may have genetic components that are not well understood.

I observed that the medical records included a note describing a “seizure disorder in maternal great grandmother and maternal aunt.” Pet. Tab 3 at 44. The limited medical records do not indicate if C.T. had a genetic test for a possible gene mutation. While some seizure disorders have a genetic basis, such as Dravet syndrome, others do not, and the field of neurology continues to evolve and seeks to find more answers. Because the causes of seizure disorders are not well understood and can be quite complex, vaccine cases involving seizure disorders often involve extensive disagreements between medical experts analyzing the cases.

Then I explained that a petitioner has the burden of proof to establish that the vaccine was the cause of the alleged injury. For a petitioner to prevail, there must be sufficient record that consists of either medical records or the opinion of a competent physician, and in most cases, both are necessary. Further, a Special Master cannot award compensation based solely on the petitioner’s claims. I explained that the limited medical evidence in this case would make it extremely hard for petitioner to prevail. Further, the four-year period between when C.T. received the Hepatitis B vaccine and the onset of seizure (even if at the earlier date described by C.T.’s father) makes it extremely difficult for petitioner to prove there is a proximate temporal relationship between the vaccination and the injury (*Althen* prong three).

B. Legal Standard and Dismissing the Petition

In order to prevail, a petitioner must prove either a “Table” injury or that a vaccine listed on the Table was the cause-in-fact of an injury. § 11(c)(1)(C). The Table identifies the vaccines covered under the program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination.⁵ 42 U.S.C. §14(a).

An “off-Table” injury is initially shown when the petitioner demonstrates, by a preponderance of the evidence: (1) that she received a vaccine set forth on the Vaccine Injury Table; (2) that she received the vaccine in the United States; (3) that she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months or that resulted in death. § 13(a)(1)(A). Petitioner must establish each of the three *Althen* factors by preponderant evidence: (1) a medical

⁴ National Institute of Health, Genetics Home Reference, SCN1A-gene, <https://ghr.nlm.nih.gov/gene/SCN1A#conditions> (last accessed April 16, 2019).

⁵ The most recent version of the Table can be found at 42 C.F.R. §100.3.

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 proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Proving an “off-table,” injury allows some flexibility in onset of injuries post-vaccination, but petitioner bears the burden for showing a proximate temporal relationship. This requires that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact. *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

In the Omnibus Hepatitis B vaccine-demyelinating injury cases, a three to sixty-day time frame between the hepatitis B vaccine and the onset of Guillain-Barré Syndrome (“GBS”), transverse-myelitis (“TM”), multiple sclerosis (“MS”) and chronic inflammatory demyelinating polyneuropathy (“CIDP”) has been found to be medically appropriate. *See Pecorella v. Sec'y of Health & Human Servs.*, No. 04-1781, 2008 WL 4447607 (Fed. Cl. Spec. Mstr. Sept. 17, 2008); *See also Stevens v. Sec'y of Health & Human Servs.*, No. 99-594, 2006 WL 659585 (Fed. Cl. Spec. Mstr. Feb. 24, 2006); *Gilbert v. Sec'y of Health & Human Servs.*, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006); *Werderitsh v. Sec'y of Health & Human Servs.*, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006); and *Peugh v. Sec'y of Health and Human Servs.*, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007). But the medically accepted time frames established in the hepatitis B vaccine injury cases are the upper bounds between vaccination and onset of symptoms. In *Nussman*, the Claims Court upheld the Special Master’s finding that a Hepatitis B vaccine given forty-one days prior to petitioner’s initial seizure was outside the appropriate time frame for proving a proximate temporal relationship. *Nussman v. Sec'y of Health & Human Servs.*, 83 Fed.Cl. 111, 123 (Fed. Cl. 2008). In the current case, the time elapsed between C.T. receiving the vaccine and her recorded seizure is five years.

As discussed above, C.T. received the vaccination in question when she was born, on December 17, 2013. Pet. Tab 2. The first symptom of seizures recorded in her medical records was not until five years later, on January 3, 2019. While petitioner’s father indicated to medical professionals that C.T. may have suffered seizures two years before January 2019, there are no corresponding medical records associated with his statements. *See* Pet. Tabs 4 & 5. Petitioner’s father told Dr. Hassan that a year before she was admitted to the hospital, C.T. had one-minute episodes where her entire body would get stiff and it would appear as though she was clenching her body. Pet. Tab 4 at 44. He stated that they would shake C.T. and she would snap out of it and go to the bathroom to urinate. *Id.* The episodes lasted for four months and they did not seek medical attention. *Id.*

During the status conference I inquired whether petitioner had any additional medical records or vaccination records that could be submitted that were closer in time to the onset of C.T.’s symptoms. Petitioner stated that no other vaccines were administered, and no medical records existed between the time of vaccine administration and C.T.’s hospitalization in January 2019. This is consistent with the statements made to medical professionals by petitioner that appear in the medical records. *See* Pet. Tabs 2 through 3.

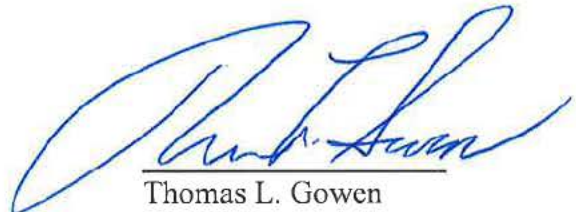
In the present case, petitioner does not allege a Table injury. Thus, to prevail on entitlement, petitioner must establish that the Hepatitis B vaccine is the actual cause of C.T.'s injuries. Under the Vaccine Act, a petitioner may not be awarded compensation based solely on the petitioner's claims. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. §300aa-13(a)(1).

Petitioner has not submitted medical records or other evidence sufficient to establish entitlement to compensation, nor do additional medical records exist between C.T.'s discharge from the hospital after birth and January 2019. Petitioner has not submitted the opinion of a competent physician linking C.T.'s alleged injury to the Hepatitis B vaccine she received on December 17, 2013. Even if the onset of C.T.'s seizures began at three, as the father thought they may have, the Vaccine Program has yet to consider a case that has found vaccine causation for a condition with onset even close to three years after vaccination.

Viewing the facts in the light most favorable to the petitioner I can see no plausible avenue for proving any connection between the vaccine and the child's seizure disorder.

Therefore, in accordance with the reasoning stated above, **the petition is DISMISSED for insufficient proof. The Clerk of the Court shall enter judgement accordingly.**⁶

IT IS SO ORDERED.



Thomas L. Gowen
Special Master

⁶ Entry of judgment is expedited by each party's filing notice renouncing the right to seek review. Vaccine Rule 11(a).