

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**E-Filed: October 17, 2012**

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HANNA GRACE HOLTZCLAW, a minor, by her mother and natural guardian, LAURA HOLTZCLAW,	*	UNPUBLISHED
Petitioner(s),	*	No. 02-395V
v.	*	Chief Special Master Campbell-Smith
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision on the Record; Dismissal of Claim for Insufficient Proof; Haemophilus Influenzae B ("HiB") Vaccine;
Respondent.	*	Encephalopathy; Autism
* * * * *	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.

Linda Renzi, Washington, D.C., for respondent.

**DECISION ON THE RECORD**<sup>1</sup>

On April 24, 2002, Laura Holtzclaw ("petitioner") filed a petition on behalf of her minor child, Hannah,<sup>2</sup> seeking compensation under the National Vaccine

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<sup>1</sup> Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this ruling 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 note (2006)). As provided by Vaccine Rule 18(b), 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).

Injury Compensation Program (“the Program”).<sup>3</sup> Petitioner alleged that Hannah developed autism after receiving a Haemophilus Influenzae B (“HiB”) vaccination on May 10, 1999. Pet. for Vaccine Comp. at 7, 8.

Petitioner’s claim is one of more than 5000 cases that were part of the Omnibus Autism Proceedings (“OAP”). In the OAP, a group of attorneys representing petitioners litigated six test cases presenting two theories exploring how administered vaccines could cause Autism Spectrum Disorders (“ASDs”). The first theory considered whether the MMR vaccine and thimerosal-containing vaccines in combination could cause autism. The second theory considered whether thimerosal-containing vaccines alone could cause autism. Three different Special Masters evaluated and ultimately rejected each of these theories.<sup>4</sup>

Following the resolution of the test cases, participants in the OAP could further pursue the vaccine claims with new evidence on causation or could withdraw their vaccine claim from the Program. Petitioner here decided to proceed on a new theory of causation alleging, by amended petition, that as a direct result of receiving a HiB vaccine in May of 1999, Hannah developed an encephalopathy “with characteristics of mild autistic disorder.” See Second Amend. Pet. for Vaccine Comp. at 8, 18.

The undersigned afforded petitioner a number of opportunities to file evidence supportive of her claim, including medical records documenting Hannah’s symptoms, an affidavit describing the onset of Hannah’s injury, and a medical opinion of vaccine-related causation. Petitioner failed to file evidence supporting the claims she set forth in her amended petition. Accordingly the undersigned issued an Order to Show Cause why the claim should not be

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<sup>2</sup> There is a discrepancy on the spelling of the minor child’s name. The undersigned used the spelling consistent with the medical records.

<sup>3</sup> The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter “Vaccine Act” or “the Act”). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

<sup>4</sup> The theory 1 cases are Cedillo v. Sec’y, HHS, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); Hazlehurst v. Sec’y, HHS, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); Snyder v. Sec’y, HHS, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Theory 2 cases are Dwyer v. Sec’y, HHS, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); King v. Sec’y, HHS, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Mead v. Sec’y, HHS, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

dismissed for a failure of proof. See Show Cause Order June 7, 2012. On August 13, 2012, petitioner responded by moving for judgment on the record as it now stands. See Pet'r's Amend. Mot. for J. on the R.

For the reasons discussed below, the undersigned **DENIES** the Motion for Judgment on the Record in petitioner's favor, and **DISMISSES** this case for insufficient proof.

## I. FACTUAL HISTORY

Petitioner's daughter, Hannah, was born on December 16, 1997. Second Amend. Pet. for Vaccine Comp. at 5. Petitioner alleges that shortly after her daughter's first birthday, on May 10, 1999, Hannah received a HiB vaccine at her pediatrician's office. Pet'r's Ex. 2 at 47. Prior to this vaccination, Hannah was a well baby and was appropriately meeting her developmental milestones. Second Amend. Pet. for Vaccine Comp. at 6. The day after vaccination, Hannah developed a fever, began to shake and jerk, and became inconsolable. Second Amend. Pet. for Vaccine Comp. at 9. Hannah's pediatric records reveal that on May 15, 1999, five days after she received her HiB vaccination, her mother telephoned the pediatrician, described Hannah's symptoms, and asked whether the administered vaccine was responsible. Pet'r's Ex. 2 at 47. The pediatrician responded that Hannah "probably" had a cold and advised petitioner to give her a children's cold medicine. See id.; see also Second Amend. Pet. for Vaccine Comp. at 11 (stating that Hannah's jerking and shaking had stopped by the time petitioner called the pediatrician).

Hannah's next documented pediatric visit occurred on December 10, 1999, seven months after her HiB vaccination. Pet'r's Ex. 2 at 42. Hannah returned to the pediatrician's office for treatment of a rash and a cold. Id. She was almost twenty-four months of age at that time.

Between eighteen and twenty-four months of age, Hannah began to lose her language skills and began to exhibit odd behaviors that included walking on her tip-toes, flapping her arms, watching spinning wheels, and "lining up her toys" repeatedly. Pet'r's Amend. Mot. for J. on the R. at 10; Second Amend. Pet. for Vaccine Comp. at 13, 16. As a result of Hannah's emerging language and behavioral issues, she received speech and occupational therapies in April of 2000. Pet'r's Ex. 5 at 46-49. Two months later, Hannah was referred to a development and genetics center for psychological and behavioral evaluations. Pet'r's Ex. 6 at 15.

When Hannah was nearly twenty-nine months of age, an evaluation at the genetics center revealed that she was exhibiting characteristics that were consistent with autism. Pet'r's Ex. 5 at 9. A separate behavioral evaluation revealed that

Hannah was “a very social child” who enjoyed attention and “initiated games with her parents.” Pet’r’s Ex. 6 at 13. But, her “speech was obviously delayed,” and “interspersed with jargon and jabber.” Id.

On December 5, 2000, Hannah was diagnosed with an ASD by a psychologist at the center where she received speech and occupational therapy. Pet’r’s Ex. 5 at 18. Three months later, in March of 2001, Hannah’s pediatric neurologist wrote that her symptoms and history supported a “diagnosis of encephalopathy with features of an autistic spectrum disorder within the mild range.” Pet’r’s. Ex. 6 at 7. The neurologist added that Hannah’s prognosis was good since she exhibited “functional use of language.” Id.

## II. LEGAL STANDARD

Petitioner may prove entitlement to Program compensation by proving that Hannah either: (1) suffered an injury listed on the Vaccine Injury Table within the requisite time period (a “Table” injury), or (2) sustained her injury as a direct result of receiving a covered vaccine (an “off-Table” injury). See Vaccine Injury Table set forth at § 14(a), as amended by 42 C.F.R. § 100.3; Off table § 11(c)(1)(C)(ii)(I); see also Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).

A rebuttable presumption of causation attaches to a Table injury, while an off-Table injury imposes the burden of proving causation on the petitioner. §14(a). Petitioner must show by preponderant evidence that the vaccine in question was a “substantial factor” in causing the injury, and that the injury would not have occurred “but for” the received vaccination. Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006) (citing Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999)). Petitioner proves causation by providing: “(1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury; and (3) a proximate temporal relationship between the vaccination and the injury.” Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Since Hannah’s alleged injury of encephalopathy is not an injury listed on the Vaccine Injury Table for the HiB vaccine, petitioner’s claim is an “off-Table” one, and she must establish causation as prescribed by the Althen case. Id.

## III. DISCUSSION

Petitioner's claim for compensation must be supported by the medical records or the opinion of a medical expert. §13(a)(1).

### **A. The Dearth of Factual Support for Petitioner's Claim**

The medical records establish that Hannah received a HiB vaccination on May 10, 1999. The records further establish that twenty-two months later, Hannah was diagnosed with an ASD. But the records offer no causal link between the received vaccine and Hannah's autistic condition. None of Hannah's treating physicians causally associated Hannah's condition with the HiB vaccination she received. Nor has petitioner offered an expert opinion in support of her claim.

The records also do not support a finding that Hannah suffered an encephalopathy. Symptoms of an "off-Table" encephalopathy may be informed by the Qualifications and Aids to Interpretation (QAI) of a "Table" encephalopathy. See 42 C.F.R. § 100.3(b). As described in the QAI, an acute encephalopathy is a serious medical event, sufficient to merit hospitalization even if none occurs. 42 C.F.R. § 100.3(b)(2)(i). The QAI instructs that symptoms of mere fussiness, even fever and seizures, without more, do not establish an encephalopathy. 42 C.F.R. § 100.3(b)(2)(i)(E). Such symptoms must be accompanied by a "significantly decreased level of consciousness" to merit Program compensation, 42 C.F.R. § 100.3(b)(2)(i)(A), and that decreased level of consciousness must persist for more than 24 hours. Id.

Petitioner alleges that Hannah developed a fever and cried inconsolably after receiving the HiB vaccine in May of 1999. Petitioner reported these symptoms to Hannah's pediatrician five days after her vaccination, and the pediatrician concluded that the symptoms were suggestive of a cold. Nothing in the record suggests that Hannah's symptoms were sufficiently severe to indicate that an acute encephalopathy had occurred.

According to petitioner, Hannah also began shaking and jerking the day after her vaccination. But petitioner did not report these symptoms to the pediatrician when she called four days later. The symptoms of shaking and jerking described in petitioner's amended petition and her motion for judgment on the record are not documented in Hannah's medical records. This lack of documentation persuades the undersigned that either the symptoms did not occur during the time period petitioner alleges now, or that the symptoms were not striking enough to warrant mention to the pediatrician four days later. The medical records do reflect a phone call on May 15, 1999—five days after Hannah's HiB vaccination—to Hannah's pediatrician reporting cold symptoms only. Without more, the record provides no factual support for a finding that Hannah suffered an acute encephalopathy after receiving the HiB vaccine.

The record before the undersigned does show that Hannah exhibited characteristics of autism as early as eighteen months of age. She was diagnosed with the disorder in December of 2000, and she has received treatment for her ASD as recently as 2009. See Pet. Ex. 5 at 3. An ASD is described in broad medical terminology as an “encephalopathy,” which means “any disorder of the brain.” Stedman’s Medical Dictionary 636 (28<sup>th</sup> ed. 2006). This characterization of an ASD, without more, is not dispositive of the question whether the condition was caused by received vaccines. Nor is a vaccinee’s manifestation of characteristic symptoms of an ASD determinative of whether an encephalopathy, that is compensable under the Program, has occurred. Encephalopathic injuries are entitled to compensation under the Program when they present with certain features, commonly abrupt and striking in onset. See Waddell v. Sec’y of Health & Human Servs., No. 10-316V, slip op. at 10-19 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). Such features are missing in this case.

### **B. No Supporting Opinion Offered**

Program compensation cannot be awarded “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” §13. The record in this case contains only petitioner’s claims of a causal link between Hannah’s HiB vaccination and her injury. None of Hannah’s treating doctors have attached such an opinion; nor has petitioner presented a supportive opinion from a medical expert.

## **IV. CONCLUSION**

This record does not provide a factual basis for petitioner’s claims. Nor does it contain any medical opinion linking Hannah’s received vaccine to her injury.

For the reasons more fully detailed above, the undersigned **DENIES** petitioner’s Motion for a Decision on the Record and **DISMISSES** the claim for insufficient proof. The clerk shall enter **JUDGMENT** accordingly.<sup>5</sup>

### **IT IS SO ORDERED.**

s/Patricia E. Campbell-Smith  
Patricia E. Campbell-Smith  
Chief Special Master

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<sup>5</sup> Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties’ joint filing of notice renouncing the right to seek review.