

OFFICE OF SPECIAL MASTERS

(Filed: September 18, 2006)

DO NOT PUBLISH

PHILLIP WAY,)	
as parent of his daughter,)	
BAILEY WAY,)	
)	
Petitioner,)	
)	
v.)	No. 05-0588V
)	Involuntary Dismissal
SECRETARY OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

DECISION¹

Petitioner, Phillip Way (Mr. Way), as parent of his daughter, Bailey Way (Bailey), seeks compensation under the National Vaccine Injury Compensation Program (Program).² Mr. Way filed a Program petition on May 31, 2005. He alleged that Bailey suffers “acute demyelinating encephalomyelitis (ADEM)” that is related to a Hemophilus Influenzae type b (Hib) vaccination that she received on October 29, 2004. Petition (Pet.) at 1.

¹ 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 trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, “the entire decision” will be available to the public. *Id.*

² The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

THE STATUTORY SCHEME

The Act permits Mr. Way to establish causation by pursuing two distinct legal theories. First, Mr. Way can present what is commonly referred to as a Table case. The Act contains the Vaccine Injury Table (Table) that lists vaccines covered by the Act and certain injuries and conditions that may stem from the vaccines. *See* § 300aa-14; 42 C.F.R. § 100.3(a). If Mr. Way demonstrates by the preponderance of the evidence that following the administration of Bailey’s October 29, 2004 Hib vaccination, Bailey suffered the onset of an injury listed on the Table for Hib vaccine, within the time period provided by the Table for the injury, then Mr. Way is entitled to a presumption that the vaccine caused Bailey’s injury. §§ 300aa-11(c)(1)(C)(I); 300aa-13(a)(1)(A).³ Respondent may rebut the presumption of causation if respondent demonstrates by the preponderance of the evidence that the injury was “due to factors unrelated to the administration of” a vaccine. § 300aa-13(a)(1)(B); *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994).

However, the Table governing Mr. Way’s claim does not specify any injuries or conditions that may stem from the Hib vaccine. *See* 42 C.F.R. § 100.3(a)(IX). As a consequence, Mr. Way may not receive a presumption of causation in any circumstances. Rather, Mr. Way is limited to a second legal theory based upon traditional tort standards. *See, e.g.*, § 300aa-11(c)(1)(C)(ii)(I).

While “[t]he Act relaxes proof of causation for injuries satisfying the Table,” the Act “does not relax proof of causation in fact for non-Table injuries.” *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *See Grant*, 956 F.2d at 1148; *Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). To prevail under an actual causation theory, Mr. Way must demonstrate by the preponderance of the evidence that (1) “but for” the administration of Bailey’s October 29, 2004 Hib vaccination, Bailey would not have been injured, and (2) the administration of Bailey’s October 29, 2004 Hib vaccination was a “substantial factor in bringing about” Bailey’s injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The actual causation standard requires Mr. Way to adduce “a medical theory,” supported by “[a] reliable medical or scientific explanation,” establishing “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Grant*, 956 F.2d at 1148; *see also Knudsen*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)); *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Capizzano v.*

³ The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g., Thornton v. Secretary of HHS*, 35 Fed. Cl. 432, 440 (1996); *see also In re Winship*, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), quoting F. James, CIVIL PROCEDURE 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence standard. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff’d*, 73 F.3d 381 (Fed. Cir. 1995).

Secretary of HHS (Capizzano III), 440 F.3d 1317 (Fed. Cir. 2006). “The analysis undergirding” the medical or scientific explanation must “fall within the range of accepted standards governing” medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Mr. Way’s medical or scientific explanation need not be “medically or scientifically certain.” *Knudsen*, 35 F.3d at 549. But, Mr. Way’s medical or scientific explanation must be “logical” and “probable,” given “the circumstances of the particular case.” *Knudsen*, 35 F.3d at 548-49.

Congress prohibited special masters from awarding compensation “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a). Numerous cases construe § 300aa-13(a). The cases reason uniformly that “special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone.” *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, at *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998).

BACKGROUND

Bailey was born at 12:23 a.m., on July 21, 2003, at Rockford Memorial Hospital in Rockford, Illinois. *See* Petitioner’s exhibit (Pet. ex.) 2 at 440. She weighed seven pounds. *See id.* She measured 18½ inches in length. *See id.* Her APGAR scores were nine at one minute and nine at five minutes. *See id.*⁴

From July 29, 2003, to October 29, 2004, physicians associated with Rockford Health System monitored Bailey’s growth and development. *See generally* Pet. ex. 3 at 14-29. According to the physicians, Bailey was a normal child. *See generally id.* As an infant, Bailey received a full complement of childhood vaccinations, including a Hepatitis B vaccination on July 21, 2003; a diphtheria-tetanus-acellular pertussis (DTaP) vaccination, a Hib vaccination, inactive polio vaccine (IPV), a pneumococcal vaccination and a Hepatitis B vaccination on September 23, 2003; a DTaP vaccination, a Hib vaccination, IPV and a pneumococcal vaccination on November 19, 2003; a DTaP vaccination, a Hib vaccination, a pneumococcal vaccination and a Hepatitis B vaccination on January 21, 2004; and a measles-mumps-rubella (MMR) immunization and a varicella immunization on July 23, 2004. *See* Pet. ex. 3 at 13.

On October 29, 2004, Bailey presented to Rockford Health System for a 15-month “Pediatric Preventive Health” evaluation. Pet. ex. 3 at 28. Bailey’s parents reported that Bailey had been “spitting up milk” since October 26, 2004. *Id.* In addition, Bailey’s parents reported that Bailey had “slept all day” and had been “cranky” on October 28, 2004. *Id.*

⁴ An APGAR score is a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1670 (30th ed. 2003).

Upon examining Bailey, the physician observed that Bailey was “teething.” Pet. ex. 3 at 29. Otherwise, the physician described Bailey as “well.” *Id.* The physician recommended that Bailey’s parents “d[is]c[ontinue] milk” for a period. *Id.* Then, the physician recommended that Bailey’s parents “re-introduce” milk. *Id.* The physician advised Bailey’s parents to “try soy milk” if Bailey’s “vomiting” occurred again after the reintroduction of milk. *Id.* Bailey received a Hib vaccination and a pneumococcal vaccination. *See id.*; *see also* Pet. ex. 3 at 13. The physician instructed Bailey’s parents to “R[eturn]T[o]C[linic]” as needed and when Bailey was “18 mo[nths]” old. Pet. ex. 3 at 29.

Bailey “slept” apparently “throughout most of” the remainder of the day on October 29, 2004. Pet. ex. 5 at 7. In addition, Bailey “seemed to have some trouble walking.” *Id.* Bailey’s parents “attributed” Bailey’s “difficulty walking to pain or discomfort in” the area where Bailey received her vaccinations. *Id.* Bailey “did not have much to eat” before “[s]he went to sleep early” on October 29, 2004. *Id.*

Bailey “slept in” on October 30, 2004. Pet. ex. 5 at 7. When Bailey’s mother attempted to wake Bailey, Bailey’s “eyes” appeared ““rolled into the back of [Bailey’s] head.”” *Id.* In addition, Bailey “was stiff.” *Id.* Bailey’s mother “called 911.” *Id.*

The South Beloit Fire Department arrived at Bailey’s residence at 11:00 a.m., on October 30, 2004. *See* Pet. ex. 8 at 2. According to emergency medical services (EMS) personnel, Bailey appeared postictal. *See id.* EMS personnel transported Bailey to the Beloit Memorial Hospital Emergency Department. *See id.* Upon arriving at the hospital, Bailey “[b]egan to [f]lex and [a]ppeared to [s]hake as if [h]aveing [sic] a [s]iezure [sic].” *Id.*; *see also* Pet. ex. 5 at 8.

In the Beloit Memorial Hospital Emergency Department, Bailey exhibited a “rectal” temperature of 101.9° Fahrenheit. Pet. ex. 5 at 8. Although Bailey “was not actively ‘shaking,’” she appeared to be “seizing.” *Id.* Bailey received two intravenous doses of Ativan, “with good results.” *Id.* The Emergency Department physician consulted Bailey’s pediatricians, one of whom “recommended complete evaluation.” *Id.*

Bailey underwent a “[l]umbar puncture.” Pet. ex. 5 at 8. During the procedure, Bailey “went into a seizure again.” *Id.* She received additional Ativan. *Id.* A physician completed the procedure without further incident. *See id.* The lumbar puncture results were “abnormal.” Pet. ex. 5 at 9.

Bailey underwent other diagnostic tests, including a complete blood count and a “[g]ram stain.” Pet. ex. 5 at 9. Several of the results were “abnormal.” *Id.* In particular, the gram stain showed “gram positive cocci in pairs, possibly staph or strep.” *Id.* The Emergency Department physician suspected “[b]acterial meningitis.” *Id.*; *see also* Pet. ex. 5 at 12. The Emergency Department physician arranged to transfer Bailey to Rockford Memorial Hospital “for hospitalization.” Pet. ex. 5 at 9.

At Rockford Memorial Hospital, Bailey's "working diagnosis was bacterial meningitis." Pet. ex. 2 at 5; *see also* Pet. ex. 2 at 12. Bailey endured a complicated course, remaining hospitalized until November 19, 2004. *See generally* Pet. ex. 2 at 3-7. On November 19, 2004, Bailey entered the Rehabilitation Institute of Chicago with a diagnosis of "[a]cute hemorrhagic leukoencephalopathy." Pet. ex. 2 at 4, 7; *see also* Pet. ex. 9 at 183 ("The patient is status post meningoencephalitis.").

Bailey remained at the Rehabilitation Institute of Chicago until December 23, 2004. *See generally* Pet. ex. 9 at 182-84. She "participated daily in physical therapy, occupational therapy, and speech therapy with occasional recreational therapy." Pet. ex. 9 at 183. Upon discharge from the Rehabilitation Institute of Chicago, Bailey received orders for "occupational therapy, physical therapy and speech therapy." Pet. ex. 9 at 184.

PROCEDURAL BACKGROUND

Mr. Way did not provide with his petition any of the medical, educational and therapeutic records required by § 300aa-11(c)(1) & (2) and by Vaccine Rule 2(e). Therefore, the special master directed initially the development of the documentary record. *See, e.g., Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. June 29, 2005); *Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. July 19, 2005). On October 4, 2005, Mr. Way represented that he had filed complete medical, educational and therapeutic records. *See* Petitioner's Status Report (Status Report I), filed October 4, 2005. Then, the special master directed the submission of an amended petition and a medical expert's opinion supporting the amended petition by no later than November 14, 2005. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. Oct. 12, 2005).

On November 17, 2005, Mr. Way informed the special master that Mr. Way's "original choice for a medical expert" could not "offer an opinion" because of "health reasons." Petitioner's Status Report and Request for Enlargement of Time to Submit Amended Petition and Medical Expert Opinion (Status Report II), filed November 17, 2005, ¶ 2. Mr. Way indicated that he had "engaged a new medical expert." *Id.* Mr. Way requested "an enlargement of 45 days to submit an amended petition and medical expert opinion." *Id.*, ¶ 3. Therefore, the special master directed the submission of an amended petition and a medical expert's opinion supporting the amended petition by no later than January 6, 2006. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. Nov. 18, 2005).

On January 6, 2006, Mr. Way informed the special master that Mr. Way's expert had "submitted a draft report" to Mr. Way's attorney of record, Ronald C. Homer, Esq. (Mr. Homer).⁵ Petitioner's Status Report and Request for Enlargement of Time to Submit Amended Petition and Medical Expert Opinion (Status Report III), filed January 6, 2006, ¶ 2. Mr. Way indicated that Mr.

⁵ Mr. Homer is a highly-qualified attorney with substantial Program experience.

Homer and the expert were “working on a final report.” *Id.* Mr. Way requested “an enlargement of 30 days to submit an amended petition and medical expert opinion.” *Id.*, ¶ 3. Therefore, the special master directed the submission of an amended petition and a medical expert’s opinion supporting the amended petition by no later than February 8, 2006. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. Jan. 10, 2006).

On February 13, 2006, Mr. Way informed the special master that Mr. Way’s expert had “formulated a preliminary opinion.” Petitioner’s Status Report and Motion for Extension of Time (Status Report IV), filed February 13, 2006, ¶ 2. Mr. Way requested “a thirty-day extension allowing time for counsel and the medical expert to discuss the expert’s preliminary opinion with [Mr. Way] before filing a written opinion and amended petition.” *Id.*, ¶ 3. Therefore, the special master directed the submission of an amended petition and a medical expert’s opinion supporting the amended petition by no later than March 10, 2006. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. Feb. 14, 2006).

On March 13, 2006, Mr. Way reiterated that his expert had “formulated a preliminary opinion.” Petitioner’s Motion for Extension of Time (Status Report V), filed March 13, 2006, ¶ 2. However, according to Mr. Way, his expert had not been able “to finalize his opinion due to obligations associated with his clinical practice.” *Id.*, ¶ 3. Mr. Way requested “a sixty-day extension for submission of a medical expert’s opinion and amended petition.” *Id.*, ¶ 4. Therefore, the special master directed the submission of an amended petition and a medical expert’s opinion supporting the amended petition by no later than May 5, 2006. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. Mar. 15, 2006).

On May 8, 2006, Mr. Way reiterated that his expert had “formulated a preliminary opinion and medical theory.” Petitioner’s Motion for Extension of Time (Status Report VI), filed May 8, 2006, ¶ 2. Mr. Way informed the special master that Mr. Way was “working with” the expert “to develop the medical theory in the case” by conducting “further research.” *Id.*, ¶ 3. Mr. Way estimated that he required 30 days “to complete” the research. *Id.* Mr. Way requested “a forty-five day extension for submission of a medical expert’s opinion and amended petition.” *Id.*, ¶ 4. Therefore, the special master directed the submission of an amended petition and a medical expert’s opinion supporting the amended petition by no later than June 9, 2006. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. May 9, 2006).

Mr. Way did not proffer by June 9, 2006, an amended petition and a medical expert’s opinion supporting the amended petition. Rather, on June 16, 2006, Mr. Homer moved to withdraw his appearance. *See Motion to Withdraw as Attorney of Record (Motion to Withdraw)*, filed June 16, 2006. On June 20, 2006, the special master granted Mr. Homer’s Motion to Withdraw. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. June 20, 2006).

On June 21, 2006, the special master issued his first order to show cause. *See Way v. Secretary of HHS*, No. 05-0588V, Order to Show Cause (Fed. Cl. Spec. Mstr. June 21, 2006). The

special master announced: “The case is now at an extremely critical juncture.” *Way v. Secretary of HHS*, No. 05-0588V, Order to Show Cause at 2 (Fed. Cl. Spec. Mstr. June 21, 2006). The special master explained that “despite adequate opportunity,” Mr. Way had “not produced yet a medical expert’s opinion supporting the case.” *Id.* The special master directed Mr. Way to file by no later than July 21, 2006, an amended petition and a medical expert’s opinion, as the special master had “required in numerous previous orders,” or to “show cause why the special master should not dismiss the petition.” *Id.*

On July 12, 2006, Mr. Way requested “a continuance” for 60 days. Letter, filed July 12, 2006, at 1. Mr. Way stated that he was awaiting receipt of the case file from Mr. Homer. *See id.* According to Mr. Way, he required additional time “to seek the necessary medical expert’s opinion” demanded by the special master’s June 21, 2006 order to show cause. *Id.* (emphasis added). The special master granted Mr. Way’s continuance, enlarging to September 15, 2006, Mr. Way’s time within which to file an amended petition and a medical expert’s opinion, or to show cause why the special master should not dismiss the petition. *See Way v. Secretary of HHS*, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. July 17, 2006). Noting that Mr. Way had “been pursuing a medical expert’s opinion since at least October 12, 2005,” the special master proclaimed: “[T]he special master does not contemplate any further enlargements of time.” *Id.*

On September 12, 2006, Mr. Way requested “a continuance” for 90 days. Letter, filed September 12, 2006, at 1. Describing Bailey’s “records and notes” as “numerous,” Mr. Way asserted that “review” of the case “requires the time and availability of the physicians.” *Id.* And, Mr. Way asserted, he is “subject to” the physicians’ “schedule.” *Id.*

DISCUSSION

The special master has canvassed thoroughly the record. He determines that Bailey’s medical records alone do not reflect an independent basis for him to conclude more likely than not that Bailey’s October 29, 2004 Hib vaccination caused-in-fact Bailey’s condition, as Mr. Way alleges. Likewise, the special master determines that Bailey’s medical records alone do not reflect an independent basis for him to conclude more likely than not that Bailey’s October 29, 2004 pneumococcal vaccination caused-in-fact Bailey’s condition. Although most, if not all, of Bailey’s treating physicians during Bailey’s hospitalization for Bailey’s devastating neurological condition understood clearly the temporal relationship between Bailey’s October 29, 2004 vaccinations and the onset of Bailey’s devastating neurological condition, *see, e.g.*, Pet. ex. 2 at 4, 10, 14, 70, 80, 88, 96, 102, 108, 117, 122, 214; Pet. ex. 5 at 7, 19; Pet. ex. 9 at 177, 182, none of the physicians concluded ever that Bailey’s vaccinations were in any way responsible for Bailey’s devastating neurological condition. Instead, most, if not all, of Bailey’s treating physicians during Bailey’s hospitalization for Bailey’s devastating neurological condition believed that based upon “results of the Gram stain,” Bailey’s devastating neurological condition was related to “bacterial meningitis.” Pet. ex. 2 at 12; *see also* Pet. ex. 2 at 2; Pet. ex. 5 at 9. As a consequence, Mr. Way must proffer unquestionably a medical expert’s opinion to establish his claim. *See* § 300aa-13(a).

The special master has afforded Mr. Way an exceedingly generous, “full and fair opportunity to present” his case. Vaccine Rule 3(b). The record reflects absolutely that Mr. Way has consulted at least two medical experts in his effort to obtain a relevant opinion. *See* Status Report II; Status Report III. Indeed, after reviewing ostensibly Bailey’s medical records, one of the experts prepared a “draft report,” Status Report III; discussed apparently the “preliminary opinion” with Mr. Way, Status Report IV; and performed additional research with the intent “to finalize” the opinion. Status Report V; *see also* Status Report VI. For whatever reason, Mr. Way has not provided the medical expert’s opinion.

Now, it appears that Mr. Way is soliciting an opinion from a different expert, or possibly, from different experts. *See* Letter, filed September 12, 2006. Yet, given the protracted period during which Mr. Way obtained obviously—but did not file—an opinion from one expert, the special master is not at all confident that Mr. Way will ever submit a medical expert’s opinion supporting the petition. *Moreover, considering the six enlargements of time that he had already granted to Mr. Way, the special master signaled plainly in his July 17, 2006 order that he would not grant to Mr. Way additional enlargements of time. See Way v. Secretary of HHS, No. 05-0588V, Order of the Special Master (Fed. Cl. Spec. Mstr. July 17, 2006).*

CONCLUSION

The special master *denies* Mr. Way’s request for a continuance. Despite more than adequate opportunity to submit a medical expert’s opinion supporting his claim, Mr. Way has failed wholly to advance his case. On the record before him, the special master determines that Mr. Way is not entitled to Program compensation.

In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Mr. Way’s copy of this decision to Mr. Way by overnight express delivery.

John F. Edwards
Special Master