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In the United States Court of Federal Claims Office of special masters No. 00-269V

Filed: August 22, 2014 Not to be Published

FILED

AUG 2 2 2014

U.S. COURT OF

ELAINE PIETRUCHA, mother of B.P., a minor,

Petitioner,

*

SECRETARY OF HEALTH AND HUMAN SERVICES,

v.

Respondent.

1

Autism; Decision Without a Hearing; Insufficient Proof; Dismissal

DECISION1

HASTINGS, Special Master

Petitioner filed a petition for Vaccine Compensation in the National Vaccine Injury Compensation Program ("the Program"), on May 8, 2000, alleging that her child, B.P., was injured by a vaccine or vaccines listed on the Vaccine Injury Table. See § 14.

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in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, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). 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 The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 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.

FACTS

Petitioner's son, B.P., was born by Cesarean section on April 28, 1996. (*See* Petitioner's Exhibit ("Pet. Ex.") D, p. 2.)³ During his first year of life B.P. received routine pediatric immunizations. (Pet. Ex. D, p. 1.) On November 14, 1996, B.P.'s development was described as normal for his age. (Pet. Ex. D, p. 9.). On February 11, 1997, the pediatrician noted that B.P. was able to take three steps and say the words "mama" and "dada." (Pet. Ex. D, p. 11.)

On May 9, 1997, the pediatrician recorded that B.P. had a "normal exam," was "walking well," and could say "kitty, dada, mama." (Pet. Ex. D, p. 12.) He received measles-mumps-rubella ("MMR") and chickenpox ("Varivax") vaccinations during this visit, when he was one year old. (Pet. Ex. D, pp. 1, 12.) Three months later, on August 11, 1997, the pediatrician's next entry characterized B.P. as a "well child," but noted that he had been suffering from loose stools for two weeks. (Pet. Ex. D, p. 13.) B.P. received diphtheria-pertussis-tetanus ("DPT") and bacterial meningitis ("Hib") vaccinations during this visit. (*Id.*)

Petitioner contacted the pediatrician's office by telephone on August 21, 1997, to report that B.P. had suffered from loose bowel movements for about five days, but he was well otherwise, and did not exhibit fever or chills. (Pet. Ex. D, p. 14.) Due to this ongoing diarrhea, a laboratory study of B.P.'s stool was performed, which did not detect any anomalies, and on August 29, 1997, the pediatrician noted that the diarrhea "was less." (Pet. Ex. D, pp. 14-16.)

Petitioner contacted the pediatrician's office by telephone on October 6, 1997, to report a bruise and a small cut on B.P.'s heel. (Pet. Ex. D, p. 17.) The next entry in the pediatrician's record, on November 24, 1997, included a notation that B.P.'s development was marred by "spotty speech" and that his mother was concerned about "temper tantrums." (Pet. Ex. D, p. 17.) B.P. received an oral polio vaccination during this visit, when he was about eighteen months old. (*Id.*) Further notations, on November 26 and 29, indicate that he suffered from fever, diarrhea, and crankiness. However, on November 29, 1997, he was characterized as playful and active, while his temperature had returned to normal. (Pet. Ex. D, pp. 17-19.)

Petitioner contacted the pediatrician's office on April 1, 1998, to report that B.P. had experienced an episode of shaking, but then returned to normal playful activity shortly thereafter. (Pet. Ex. D, pp. 19-20.) She recalled an identical episode that had occurred in January, 1998. (*Id.*) As a result, B.P. was referred to a neurologist, and MRI and EEG examinations were scheduled. On, May 26, 1998, Dr. Elliott Grossman, a neurologist, performed an extensive evaluation of B.P. to determine the cause of his "recent paroxysmal episodes." (Pet. Ex. E, p. 1-

³ Petitioner's Exhibits A through I, constituting the medical records in this case, were filed with the Amended Petition on September 4, 2001. Other medical records were filed on various occasions thereafter, but they appear to be duplicate copies of parts of the original Petitioner's Exhibits A-I.

5.) Dr. Grossman reported that the EEG was slightly abnormal and the MRI showed a significant cyst in the cerebellum that would require monitoring in the future. Dr. Grossman recorded his own observations that B.P. was non-verbal and interacted poorly with others, and his parents reported that B.P. abruptly lost speech and behavioral skills at about one-and-one-half years of age. (*Id.*) Dr. Grossman was unable to identify a specific cause for the occasional tremors. He arrived at an overall diagnosis of "autism." (Pet. Ex. E, pp. 4-5.)

A second neurologist, Dr. Donald Younkin, evaluated B.P. on August 21, 2000. Dr. Younkin concluded that the cyst detected in B.P.'s brain was benign, and unrelated to his ongoing behavioral abnormalities. Dr. Younkin opined that B.P. had never experienced a definite seizure. Finally, Dr. Younkin recorded his impression that B.P. exhibited "classic signs of infantile autism." (Pet. Ex. F, pp. 1-2.)

II

PROCEDURAL BACKGROUND

The original petition in this case was filed by the *pro se* petitioner, and accompanied by a limited number of medical records. Thereafter, Petitioner retained counsel to represent her, and on February 26, 2001, attorney David Lewis became counsel of record. On March 1, 2001, a status conference was convened, during which Mr. Lewis was instructed to complete the medical record and file an amended petition that clearly identified Petitioner's theory of the case. (*See* Order, March 1, 2001.) On September 4, 2001, Petitioner filed an "Amended Petition" along with various medical records. (*See* Pet. Exs. A through I.)

Petitioner requested that case-specific proceedings be deferred pending completion of the Omnibus Autism Proceeding ("OAP") (see Notice, filed Aug.13, 2002.). (See Section III below for further discussion of the OAP.) On August 30, 2002, proceedings in this case were stayed, and it was reassigned to my docket. (See Order, filed Aug. 30, 2002.)

Proceedings resumed in 2008, when Petitioner was directed to file medical records sufficient to determine the date of the first symptom or manifestation of onset of B.P.'s condition. (*See* Order, filed Jan. 15, 2008.) On December 11, 2008, I issued an Order noting that Petitioner had failed to file the required medical records, but allowing additional time for Petitioner to comply. (*See* Order, filed Dec. 11, 2008.) On March 31, 2009, Petitioner was again ordered to file the requisite medical records, and warned that failure to file a response would lead to a dismissal due to either a failure to prosecute this claim, or an inability to document this claim. (*See* Order, March 31, 2009.) Thereafter, Petitioner contacted members of my staff directly, on several occasions, to report that her counsel was not representing her properly. (*See* Orders, filed Nov. 20, 2009, Jan. 14, 2010). On January 14, 2010, Petitioner's counsel was relieved of his duties and replaced by the Petitioner, acting *pro se*. (*See* Order, filed Jan. 14, 2010.)

On February 16, 2010, I issued an Order requiring Petitioner to file *all* of the medical records relevant to causation of B.P.'s injuries. (*See* Order, filed Feb. 16, 2010.) On September 14, 2010, Petitioner was ordered to file an expert medical opinion in support of her claim. (*See* Order, filed Sept. 14, 2010.) On December 2, 2010, I issued an Order directing Petitioner to file a statement identifying her theory of how vaccines caused B.P.'s injury, and the opinion of a medical expert in support of her claim. That Order stated that

The legal requirements for proving that a vaccine or vaccines actually caused injury are the same in every case under the Vaccine Act, regardless of the vaccine involved or the nature of the injury.

First, a person seeking compensation must establish a reliable theory connecting vaccination to injury.

Second, the person seeking compensation must establish a logical sequence of cause and effect showing the vaccination was the reason for the injury.

Third, a person seeking compensation must establish that the injury followed the vaccination within a time frame that is appropriate...

You must present an expert medical opinion or other reliable evidence to establish the three requirements of *Althen* listed above.

(Order, filed Dec. 2, 2010, p. 2, citing Althen v. HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005.)

Petitioner did not respond to these Orders, and therefore, I issued an Order to Show Cause as to why this petition should not be dismissed for failure to prosecute the case. (*See* Order, filed Dec. 8, 2011.) In response, Petitioner filed a lengthy narrative letter discussing various potential theories of causation, along with some medical records and medical literature. (*See* Response, filed Jan. 9, 2012.)

One month later, Petitioner filed the letter of Lisa Rankin, M.D., on February 13, 2012 ("Letter #1"). In that letter, Dr. Rankin expressed her opinion that "it does appear that the circumstances under which [B.P.] was vaccinated played a role in his development of this chronic encephalopathy," and, "[B.P.] may have an underlying mitochondrial disorder or dysfunction that played a role by making him less able to deal with the numerous vaccines that are given during a short period of time." (Letter #1, filed Feb. 13, 2012.) On February 22, 2012, I issued an Order indicating that the letter of Dr. Rankin was not sufficient to satisfy the statutory requirements for compensation. I directed Petitioner to file a supplementary expert report clearly opining "that one or more vaccinations **more probably than not** played a substantial role in **causing** B.P.'s injury." (See Order, filed Feb. 22, 2012.)

⁴ As there are several letters/reports from Dr. Rankin filed in support of this claim, each addressed "To Whom It May Concern," I will number them for ease of reference, as Letter #1, #2, #3, etc.

Petitioner filed another letter from Dr. Rankin on March 26, 2012, which described B.P.'s medical history as follows:

It is very clear that there was a series of poor decisions that were made on the part of the providers combined with the use of several vaccines that are known to be associated with adverse reactions, including Encephalopathy... As you follow through the notes you can see reactions with each set of [B.P.'s] vaccines getting progressively worse and culminating in seizures. This leaves no room for doubt that [B.P.'s] chronic Encephalopathy is a vaccine-related injury.

(Expert Report, filed March 26, 2012.)("Letter #2.") In response, I directed Respondent to file a "Rule 4 report" and an expert report. (Order, filed April 19, 2012.)

Respondent's Report ("Resp. Rep."), filed on June 15, 2012, contended that Dr. Rankin's opinion letters were vague and conclusory, contained factual inconsistencies, and did not provide a theory of vaccine causation. (Resp. Rep., pp. 16-17.) Respondent noted, in particular, that Dr. Rankin herself had acknowledged the lack of evidence to support a finding that B.P. had a mitochondrial disorder. [Id., p. 17.] Respondent countered Dr. Rankin's allegation regarding repeated adverse reactions to vaccines, in Letter #2, by observing that the medical records mention only one incident of a post-vaccinal reaction, consisting only of several hours of fussiness and redness at the injection site. (Id.) Further, the incidents described by the treating neurologists as "tremors" (Petitioner's Ex. E, pp. 4-5, and Ex. F, p. 2) did not have any temporal association with a vaccination, nor were they diagnosed as seizures by the neurologists. (Resp. Rep., p. 18.) Respondent's Report concluded that the record in this case lacks preponderant support of vaccine causation of B.P.'s injury, and should, therefore, be dismissed. (Id.)

Respondent summarized those contentions in a Motion for Appropriate Relief, arguing that due to the insufficiencies of Petitioner's expert reports, Respondent should not be required to provide a responsive expert report. (*See* Motion, filed June 15, 2012.) Further, Respondent's Motion requested the issuance of an order directing Petitioner to show cause why this case should not be dismissed due to insufficient proof. (*Id.*)

A digitally-recorded status conference was held to discuss these issues, on July 10, 2012, with the participation of Petitioner, Elaine Pietrucha, and Respondent's counsel, Ann Martin. Petitioner was instructed to discuss with her expert witness "the preparation of an expert report that explains in detail how one or more specific vaccines caused [B.P.'s] injuries." (Order, filed July 11, 2012.)

On January 15, 2013, Petitioner filed another letter from Dr. Rankin, which stated that "there is no room for doubt that [B.P.'s] chronic encephalopathy had a clear causative event that

⁵ Respondent cited Dr. Rankin's statement that B.P. "may have an underlying mitochondrial disorder," followed by the acknowledgement that B.P. "has never had any workup along those lines." (Resp. Rep., pp. 16-17, *citing* Letter #1, Feb. 13, 2012.)

was unfortunately exacerbated multiple times by a series of poor choices made by his medical providers." (See Response, filed Jan 15, 2013, p. 2.) ("Letter #3.") This letter did not include any statement that B.P.'s injuries were caused by a vaccination. I authorized an additional six months for Petitioner to obtain an adequate expert report. (See Order, filed Jan. 18, 2013.) When nothing was filed in response, on August 22, 2013, I issued an Order directing Petitioner to show cause why this case should not be dismissed for failure to prosecute. Petitioner responded on September 20, 2013, requesting more time to comply. An additional thirty day enlargement of time was allowed. (See Order, filed Sept. 25, 2013.)

Petitioner then filed another letter from Dr. Rankin, which reviewed B.P.'s medical history from 1996 to 1998, and opined that B.P. "was transformed from a Neurotypical child to the very affected adolescent he is today as a result of a vaccination schedule that was used in a child who was obviously suffering from its detrimental effects." (See Notice, filed Oct. 25, 2013, p.3.) ("Letter #4.") After reviewing this document, I filed an order indicating that Dr. Rankin's report again was not sufficient to satisfy Petitioner's burden of proving that B.P. was injured by a vaccination. (See Order, filed Nov. 1, 2013.) In this Order, I provided specific instructions regarding what an appropriate expert report must include, and allowed Petitioner another three months to file a supplementary expert report. (Id.)

On February 3, 2014, Petitioner filed a response that did not include the required supplemental expert report. On February 5, 2014, I issued an Order indicating that Petitioner's response was not sufficient to satisfy Petitioner's burden of proving that B.P.'s injuries were caused by a vaccination. That Order required Petitioner to file a supplemental expert report within 30 days, and again provided explicit instructions as to what that report must contain. Petitioner has not filed anything in response to my Order of February 5, 2014.

Ш

THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorder" ("ASD") were caused by one or more vaccinations. A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in *King v. HHS*, No. 03-584V, 2010 WL 892296, at *5-10 (Fed. Cl. Spec. Mstr. Mar 12, 2010), and will not be repeated here.

Ultimately, the Petitioners' Steering Committee ("PSC"), an organization formed by

⁶ I note that in Letter #3 Dr. Rankin stated that she had provided care for B.P., "for several years." (Letter #3, filed Jan. 15, 2013) However, Dr. Rankin's own medical records concerning B.P. during those years have not been filed into the record of this case.

attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of ASDs. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury in thimerosal-containing vaccines could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). Thus, the proceedings in these six test cases concluded in 2010.

IV

ANALYSIS

To receive compensation under the Program, Petitioner must prove either 1) that B.P. suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of B.P.'s vaccinations, or 2) that B.P. suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Vaccine Act, a special master cannot find that Petitioner has proven her case by a preponderance of the evidence, based upon "the claims of a Petitioner alone, unsubstantiated by medical records or by medical opinion." §300aa-13(a) (2006). Petitioner has failed to file sufficient evidence in this case.

The contemporaneous medical records of B.P.'s pediatrician document a normal infancy and the administration of routine infant vaccinations. There are several notations indicating that he sometimes suffered from episodes of "loose stools" or diarrhea. (Pet. Ex. D, pp. 13-16.) There were no aberrant neurological symptoms noted until November 24, 1997, when the pediatrician recorded that Petitioner expressed concerns about B.P.'s "spotty speech" and "temper tantrums." (Ex. D, p. 17.) Thus, symptoms of the condition later identified as "autism" began to manifest in B.P. during the final months of 1997.

⁷The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

In the months preceding November 1997, B.P. received DPT and Hib vaccinations on August 11, 1997, and Varivax and MMR vaccinations on May 9, 1997. During these six months, May through November of 1997, there were various occasions when Petitioner contacted the pediatrician to report B.P.'s diarrhea (Pet. Ex. D, pp. 14-15), and a minor cut on his heel (*Id.*, p. 17). If behavioral symptoms of B.P.'s developmental problems actually occurred earlier than November 1997, then they were not of such severity that they were reported by Petitioner at the time, or recorded by the pediatrician.

A. Table Injury

Neither petitioner's Amended Petition, filed on September 4, 2001, nor the four opinion letters of Dr. Rankin specifically allege that B.P. suffered a "Table Injury" in this case. However, Dr. Rankin contends that "B.P.'s chronic Encephalopathy is a vaccine-related injury." (Letter # 2, filed March 26, 2012.) Dr. Rankin modified this contention in Letter #3, by suggesting that B.P. suffered a chronic encephalopathy that was "exacerbated multiple times by a series of poor choices made by his medical providers." (Letter #3, filed January 15, 2013.) The "poor choices" alluded to in this statement presumably were the choices to administer vaccinations. In Letter #4, Dr. Rankin opines that B.P. was "transformed from a Neurotypical child into one suffering from a chronic Encephalopathy," as the result of "a series of poor decisions made by his medical providers." (Letter #4, filed Oct. 25, 2013, p. 3.) Again, the "poor decisions," alluded to in this letter, seem to be the decisions to administer vaccines. Thus, although Dr. Rankin's letters are rather vague, she appears to hold the opinion that B.P.'s neurological condition is the result of an encephalopathy that was either caused or exacerbated by a series of vaccinations that are included in the Vaccine Injury Table.

For the purpose of awarding compensation under the Program, the Vaccine Injury Table ("Table") defines the circumstances in which causation of an injury may be presumed to be vaccine-related; that is, those circumstances which determine the existence of a "Table Injury." *See Turner v. HHS*, 268 F.3d 1334, 1337 (Fed. Cir. 2001); §300aa-11(c)(1); §300aa-14.

An "encephalopathy" is defined in the Table as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." §300aa–14(b)(3)(A). The Table includes a section entitled Qualifications and Aids to Interpretation ("QAI"), which further limits the meaning of the term "encephalopathy." According to the QAI, a vaccinee is considered to have suffered a Table encephalopathy if the vaccinee manifests an injury consistent with the definition of an *acute* encephalopathy, within the appropriate time period, and if a *chronic* encephalopathy persists for more than 6 months after the immunization. 42 C.F.R. §100.3(b)(2). Thus, a Table encephalopathy is an acute encephalopathy that is followed by a chronic encephalopathy that lasts more than six month.

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⁸ The QAI section of the Vaccine Injury Table, 42 C.F.R. § 100.3(b), contains definitions for the terms used in the Table. *See Althen v. HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the Table).

An "acute" encephalopathy is defined as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i). For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. § 100.3(b)(2)(i)(A). Section 100.3(b)(2)(i)(D) of the QAI further states that a "significantly decreased level of consciousness" is indicated by "the presence of at least one of the following clinical signs for at least 24 hours or greater":

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

100.3(b)(2)(i)(D). The QAI also sets forth symptoms that the Table identifies as *not sufficient* to prove an acute encephalopathy:

The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

§ 100.3(b)(2)(i)(E).

In this *Pietrucha* case, Dr. Rankin makes reference to B.P.'s "encephalopathy" in her Letters #2, #3, and #4. There are two reasons why this characterization by Dr. Rankin does not support a "Table Injury" claim.

First, Dr. Rankin, who is the only medical professional who opines that B.P. suffered an "encephalopathy," always referenced a "chronic" encephalopathy. The term "encephalopathy" is very specifically defined in the QAI of the Vaccine Injury Table as beginning with an "acute" event. 42 C.F.R. §100.3(b). There is no acute event described anywhere in B.P.'s medical records that resembles a "significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. §100.3(b)(2)(A). Thus, even if I were to accept Dr. Rankin's written opinion regarding an alleged "chronic" encephalopathy, that would still not satisfy the criteria required by the Vaccine Injury Table.

Second, I note that neither of the neurologists who examined B.P. in 1998 and 2000

diagnosed any sort of "encephalopathy," with either an acute, or a chronic manifestation. (*See* Pet. Exs. E and F.) Both doctors were asked to examine B.P. after he began to exhibit adverse neurological symptoms in late 1997. Dr. Elliott Grossman recorded the assessment "Autism" (Pet. Ex. E, p. 4), and Dr. Donald Younkin opined that B.P. exhibited "classic signs of infantile autism." (Pet. Ex. F, p. 2.)

There is insufficient evidence to show that B.P. suffered an acute encephalopathy qualifying as a Table injury.

B. Causation in fact

The medical opinion letters of Dr. Lisa Rankin do not provide persuasive evidence indicating that B.P.'s autism spectrum disorder was vaccine-caused. Dr. Rankin's opinions in these letters are conclusory, and they do not provide: 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 causation and injury.

C. Decision without hearing

The petition in this case was filed on May 8, 2000, almost fourteen years ago. Proceedings were stayed for about six years to allow the OAP test cases to be fully litigated, as described in Section III. Despite the great similarities between the issues presented in those OAP test cases and the issues in this case, Petitioner elected to continue with her claim after the resolution of the test cases. Since 2008, Petitioner has been allowed ample opportunity to file new evidence to support her claim. Petitioner has filed four expert reports, none of which stated a theory of vaccine causation with enough clarity to necessitate a responsive expert report from Respondent. Petitioner has received explicit instructions, on several occasions, as to what an expert report must include. On February 5, 2014, my most recent procedural Order repeated those instructions and allowed Petitioner an additional 30 days to file a supplemental expert opinion letter. Petitioner has not done so.

D. Conclusion

Although I have given Petitioner years in which to file an adequate expert report, she failed to do so, and now has made no response to my Order of February 5, 2014. I will therefore rule on the record as it now stands. It is clear from the record in this case that Petitioner has

⁹ Special Masters may adjudicate cases based upon the written record without conducting an evidentiary hearing. §12(d)(3)(B)(v); Vaccine Rule 8(d): *see also, Plummer v. HHS*, 24 Cl.Ct. 304, 307 (1991). Before deciding a case based upon a written record, the special master must ensure that both parties have a full and fair opportunity to present their cases. *Hovey v. HHS*, 38 Fed. Cl. 397, 400-01 (1997) (affirming special master's decision denying petitioner's request for an evidentiary hearing). Further, the special master must ensure that, even without a hearing, a record is created which is sufficient to allow review of the ultimate decision on compensation. *See Campbell v. HHS*, 69 Fed. Cl. 775, 778 (2006); *Hovey*, 38 Fed.Cl. at 401; *Dickerson v. HHS*, 35 Fed.Cl. 593, 598 (1996); *Murphy v. HHS*, 23 Cl.Ct. 726, 730, *aff'd*, 968 F.2d 1226 (Fed.Cir.1992), *cert. denied*, 506 U.S. 974 (1992).

failed to demonstrate either that B.P. suffered a "Table Injury" or that B.P.'s injuries were "actually caused" by a vaccination. This case is dismissed for insufficient proof and for failure to prosecute. The clerk shall enter judgment accordingly. 10

IT IS SO ORDERED.

George L. Hastings, Jr.

Special Master

¹⁰ This document constitutes my final "Decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). If petitioner wishes to have this case reviewed by a Judge of the United States Court of Federal Claims, a motion for review of this decision must be filed within 30 days. After 30 days the Clerk of this Court shall enter judgment in accord with this decision. If petitioner wishes to preserve whatever right petitioner may have to file a civil suit (that is a law suit in another court) petitioner must file an "election to reject judgment in this case and file a civil action" within 90 days of the filing of the judgment. 42 U.S.C. § 300aa-21(a).