In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-049V
Filed: May 27, 2015
(Not to be published)

DIANE DAVIS and ANDREW DAVIS, as parents of LD, a minor,		
Petitioners,		Petitioners' Motion for a Ruling on the Record; Insufficient Proof of Causation; Vaccine Act Entitlement; Denial Without Hearing
v.		
SECRETARY OF HEALTH AND HUMAN SERVICES		
Respondent.		

Patricia A. Finn, P.C., Piermont, NY, for Petitioners.
Ann D. Martin, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*

This is an action seeking an award under the National Vaccine Injury Compensation Program ("the Program")[1] on account of an injury to the Petitioners' son, LD. For the reasons stated below, I conclude that the Petitioners are not entitled to such an award.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program ("Program"), compensation awards are made to individuals who have suffered injuries after receiving certain vaccines. There are two separate means of establishing entitlement to compensation. First, if an injury specified in the "Vaccine Injury Table" ("Table"), originally established by statute at §300aa-14(a) and later modified, occurred within the applicable time period after vaccination, as prescribed in the Table, then the injury may be *presumed* to qualify for compensation. §300aa-13(a)(1); §300aa-11(c)(1)(C)(i); §300aa-14(a). If a person qualifies under this presumption, he or she is said to have suffered a "Table Injury."

[1] The applicable statutory provisions governing the National Vaccine Injury Compensation Program are found in 42 U.S.C. § 300-10 *et seq*. (2006 ed.). Hereinafter, for ease of citation, all "U.S.C." references will be to 42 U.S.C. (2006 ed.).

Alternatively, if no Table Injury can be shown, the petitioner may gain an award by instead showing that the vaccine recipient's injury was *actually caused* by the vaccination in question. 42 U.S.C. §300aa-13(a)(1); §300aa-11(c)(1)(C)(ii).

II

THE OMNIBUS AUTISM PROCEEDING

This case concerning LD is one of more than 5,400 cases filed under the Program in which it has been alleged that a child's disorder known as "autism," or a similar disorder, was caused by one or more vaccinations. A brief summary of one aspect of that history is relevant to this Decision.

In anticipation of dealing with such a large group of cases involving a common factual issue--*i.e.*, whether vaccinations can cause autism--the Office of Special Masters ("OSM") devised special procedures. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the *Autism General Order # 1*,[2] which set up a proceeding known as the "Omnibus Autism Proceeding" (OAP). In the OAP, a group of counsel selected from attorneys representing petitioners in the autism cases, known as the Petitioners' Steering Committee ("PSC"), was charged with obtaining and presenting evidence concerning the general issue of whether those vaccines can cause autism, and, if so, in what circumstances. The evidence obtained in that general inquiry was to be applied to the individual cases. (*Autism General Order # 1*, 2002 WL 31696785, at *3, 2002 U.S. Claims LEXIS 365, at *8.)

Ultimately, the PSC elected to present two different theories concerning the causation of autism. The first theory alleged that the *measles* portion of the MMR vaccine can cause autism, in situations in which it was alleged that thimerosal-containing vaccines previously weakened an infant's immune system. That theory was presented in three separate Program "test cases," during several weeks of trial in 2007. The second theory alleged that the mercury contained in the thimerosal-containing vaccines can *directly affect* an infant's brain, thereby substantially contributing to the development of autism. The second theory was presented in three additional "test cases" during several weeks of trial in 2008.

On February 12, 2009, decisions were issued concerning the three "test cases" pertaining to the PSC's *first* theory. In each of those three decisions, the petitioners' causation theories were rejected. I issued the decision in *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Patricia Campbell-Smith issued the decision in *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Denise Vowell issued the decision in *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

[2] The *Autism General Order # 1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed.Cl.Spec.Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." An electronic version of that File is maintained on this court's website. This electronic version contains a "docket sheet" listing all of the items in the File, and also contains the complete text of most of the items in the File, with the exception of a few documents that are withheld from the website due to copyright considerations or due to § 300aa-12(d)(4)(A). To access this electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Select the "Vaccine Claims" page, then the "Autism Proceeding" page.

Those three decisions were later each affirmed in three different rulings, by three different judges of the U.S. Court of Federal Claims. *Hazlehurst v. HHS*, 88 Fed. Cl. 473 (2009); *Snyder v. HHS*, 88 Fed. Cl. 706 (2009); *Cedillo v. HHS*, 89 Fed. Cl. 158 (2009). Two of those three rulings were then appealed to the U.S. Court of Appeals for the Federal Circuit, again resulting in affirmances of the decisions denying the petitioners' claims. *Hazlehurst v. HHS*, 604 F. 3d 1343 (Fed. Cir. 2010); *Cedillo v. HHS*, 617 F. 3d 1328 (Fed. Cir. 2010).

On March 12, 2010, the same three special masters issued decisions concerning three separate "test cases" pertaining to the petitioners PSC's *second* causation theory. Again, the petitioners' causation theories were rejected in all three cases. *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); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar.12, 2010). None of the petitioners elected to seek review of any of those three decisions.

III

BACKGROUND

A. Facts

LD and his twin sister were born on November 26, 2001, by cesarean section. (Ex. 3, pp. 10-12.) LD received regular "well child" medical examinations at Renaissance Pediatrics during the first year of life: at three days of age (11/30/01), six weeks (1/8/02), two months (2/15/02), four months (4/5/02), six-and-one-half months (6/12/02), nine months (9/4/02), and twelve months (12/9/02). (Ex. 4; Ex. 5, pp. 34-40.) At each of these examinations, the notes of his pediatrician include a neurological assessment indicating "within normal limits." During each of these visits, LD received one or more of his routine pediatric vaccinations. (*Id.*, *see also* Ex. 4.) On December 9, 2002, when LD was twelve months old, he received a varicella vaccination, but not the usual MMR immunization. (Ex. 4; Ex. 5, p. 34.)

LD received medical care for minor childhood illnesses in January and December of 2003. (Ex. 5, p. 33.) On January 31 and December 3, 2003, his neurological assessment indicated "[without] deficits." (*Id.*) On January 5, 2004, there is a notation in the pediatric record stating: "2 YO chart audit completed. Needs 2 YO [well child care] (last WCC on 12/2) and needs DTAP #4, IPV #3, MMR #1, HIB #4. Letter mailed." (Ex. 5, p. 42.) On July 3, 2004, the medical records from Renaissance Pediatrics, in Chesapeake, Virginia, indicate that LD's mother brought him to the pediatrician's office for treatment of a rash. (Ex. 5, pp. 26-27.)

Dr. Sharon Tucker performed an examination characterized as a "2-year well-child visit," on July 20, 2004, when LD was about two years eight months old. (Ex. 5, pp. 24-25.) His developmental milestones at that time were listed as: "Kicks ball forward, Walks up stairs, Towers 4 cubes, 6 word vocabulary, Points to 2 pictures, 2 word sentences, Uses spoon/fork, Removes garment and Feeds doll." (*Id.*) However, he was not yet toilet trained. (*Id.*) His "mental status" was described as "alert" and "normal," and his "speech" was "normal," as were all the other categories listed in his "neurologic" assessment. (*Id.*) Nonetheless, he was referred to an audiologist to evaluate possible "speech delay." (*Id.*) Dr. Tucker noted that LD's last prior set of vaccinations had been administered when he was twelve months old, and that LD's mother

expressed concerns about allowing further vaccinations for her son. Dr. Tucker gave Mrs. Davis some explanatory materials about vaccines and obtained a signed statement from her indicating that she understood the potential risks of delaying immunizations. (*Id*.; *see also* Ex. 5, p. 23.)

Dr. Tucker examined LD again on August 23, 2004, due to a parental complaint of "autistic behaviors, not a lot of eye contact, not progressing with speech." (Ex. 5, p. 15.) More specifically,

> Mom is concerned with patient's behavior. Mom stated that the patient does not look her in the eye. Patient aligns his toys in perfect order. Does not like loud noises. Cannot tolerate baby crying. Patient ban[g]s his head repeatedly when he is having a tantrum. Mumbles often and jabbers to himself. Patient plays well by himself. Prefers to have someone feed him.

(*Id*.) Dr. Tucker recorded her assessment of LD as "developmental delay." (*Id*., p. 16.) She made referrals for audiological and neurological assessments. (*Id*.)

On September 24, 2004, an audiologist at the Eastern Virginia Medical School in Norfolk noted LD's history of speech and language delay, but examined his hearing and concluded that he displayed "normal peripheral auditory sensitivity." (Ex. 5, p. 14.)

On September 27, 2004, LD was examined by Ralph Northam, M.D., a neurologist at the Division of Child & Adolescent Neurology at Children's Hospital of The King's Daughters. (Ex. 6, pp. 1-2.) Dr. Northam recorded the following history:

> Developmentally, he walked at around 1 year of age but has never really used meaningful language. He makes very poor eye contact and tends to not mingle with other kids. He often stays in his own little world. He is very routine and order oriented. He has an aversion to loud noises and especially other children crying. He perhaps uses one or two words that mother can understand; however, the rest of it is gibberish. He does not have any echolalia. Thus far, he has not been evaluated by Speech Therapy. He has not shown any interest in potty training.

(*Id*.) Dr. Northam concluded that LD had "autistic tendencies," and that he certainly had a "communication disorder." (*Id*.)

Officials of the Chesapeake Public School System, in Virginia, performed a developmental evaluation of LD on December 13, 2004, when he was two years old. (Ex. 8, pp. 5-15; Ex. 9, pp. 8-12.) Psychologist Jill Lewis reported that LD's scores on various tests indicated a "developmental age of 12 months overall." (Ex. 8, p. 7.) He exhibited significant delays in fine motor, cognitive, and language development. (*Id*., p. 12.) During his speech and language evaluation, LD demonstrated only "a very limited vocal and verbal repertoire." (*Id*., p. 25.) Based on these observations, the school district authorized special speech and occupational therapies for LD. (Ex. 8. p. 3; Ex. 9, p. 3.)

Mary Megson, M.D., examined LD and recorded a summary of her findings on December 20, 2004. (Ex. 7, pp. 17-19.) She noted that:

> [LD] is a 3 year old seen for evaluation of his autism * * *. Mom started him on a gluten free/casein free diet in October and noticed decreased stims, less toe walking, better eye contact and less hand flapping. He does tend to line things up, gets up close to the TV, looks at things out of the corner of his eye. After mom began the GF/CF diet he regained the use of ten words. He also engages in some spinning behavior, which has persisted. She began using NDF [a chelating agent], after which he showed increased attention. The first year of life his language development was normal with cooing at 3 months, babbling at 6 months, saying "mama" and "dada" at 10 months. He did hand flap some but had a lot of non-verbal vocalizations. He does like to be held, likes to be active, is described as affectionate.

(*Id*.) Dr. Megson opined that LD suffered from autism, ADHD, yeast of the intestines, "metals," and gluten/casein sensitivity. (*Id*., pp. 18-19.)

Between May 15, 2006 and January 10, 2010, medical personnel at Renaissance Pediatrics provided medical services for LD, as needed. (Ex. 15, pp. 3-12.) He suffered from episodes of "strep throat" in 2009. (*Id*., pp. 4-7.) Also in 2009, LD's pediatric neurologist administered an EEG exam, due to his staring spells, and noted certain aberrations, but concluded that his symptoms were "not classically epileptic." (Ex. 19, pp. 34-35.) On February 3, 2011, a neurologist at the Children's Hospital of The King's Daughters, in Norfolk, Virginia, Joseph Dilustro, M.D., identified a "developmental venous anomaly [in LD's] left cerebellar hemisphere." (Ex. 11, p. 18.) However, this condition was not threatening, and no intervention or treatment was indicated. (Ex. 19, p. 39.)

Virginia Proud, M.D., who specializes in genetics at the Eastern Virginia Medical School in Norfolk, examined LD on July 11, 2012. (Ex. 10, pp. 1-5.) The case history recorded by Dr. Proud includes the following:

> Mom was concerned by 6 months when he had a fever, irritability, and diarrhea reportedly associated with immunizations and subsequently lost some skills with a change in his behavior. He began to sit up and lost that skill. By 2 years of age, in 2003, he saw Dr. Northam who diagnosed him with autism and he was given Early Infant evaluation and services.

(Ex. 10, p. 2.) Dr. Proud opined in a report dated July 18, 2012, that LD "has a probable Mitochandrial Disorder with molecularly confirmed Complex-I defect." (Ex. 10, p. 1.) Dr. Proud also reported that LD had

> a history of staring spells and an abnormal EEG for spike and slow wave in 2009, diagnosis of autism when he was approximately 3 and an MT-DNA mutation while it is homoplastic, it can be pathogenic. It [the mutation] does not have a strong likelihood of being the sole cause of his autism; however, it could certainly contribute to autism spectrum disorder.

(*Id*., p. 4.)

B. Procedural history

Diane and Andrew Davis (hereinafter, "Petitioners") filed a "Short-Form Autism Petition for Vaccine Compensation on January 19, 2007. That filing constituted an allegation that their son, LD, developed an autism spectrum disorder or a similar neurodevelopmental disorder that was caused by either the measles-mumps-rubella vaccination ("MMR"), or by the thimerosal ingredient in other vaccinations covered by the Vaccine Program. See *Autism General Order #1*, 2002 WL 31696785, at *4, *8 (Fed. Cl. Spec. Mstr. July 3, 2002).

On January 31, 2007, individual proceedings in this case were stayed pending the conclusion of the Omnibus Autism Proceeding ("OAP"). (Order, filed Jan. 31, 2007.) As the OAP neared completion, Petitioners were directed to file all of the medical records relevant to their claim, pursuant to 42 U.S.C. §300aa-11(c)(2). (Order, filed Oct. 15, 2009.) Petitioners requested, and were allowed, a 90-day enlargement of time to file those records. (Order, filed March 29, 2010.) Petitioners filed a Notice regarding the format of the medical records, on April 13, 2010, along with a Statement of Completion indicating that all the available relevant records were included. (Notice and Statement, filed April 13, 2010.) On April 19, 2010, Petitioners filed Exhibits 1-9, in the form of a "compact disc."

Respondent filed a Statement, in response, indicating that, based on Exhibits 1-9, Respondent was unable to determine the date of onset of LD's condition, or whether Petitioners' claim had been timely filed. (Statement, filed May 25, 2010.) Respondent also alleged that there were significant gaps in the medical record and specific records that were lacking. (*Id*.)

Petitioners did not file any supplemental information, or any response to Respondent's Statement, for eighteen months. On November 10, 2011, I filed an Order in this case noting the outcome of the OAP "test cases," as described above in Section II, and directing Petitioners to inform the court if they wished to proceed with their case. If so, Petitioners were ordered to file, within 30 days, an amended petition that was fully compliant with § 300aa-11(c), and which clearly explained their theory of vaccine causation in this case. (Order, filed Nov. 10, 2011.) There was no response.[3] On December 13, 2011, I filed an Order to Show Cause, indicating that this case would be dismissed if Petitioners failed to file an appropriate response to my Order of November 10, 2011. On January 6, 2012, I granted Petitioners' request for a 30-day extension of time to file an appropriate response. Instead, on February 6, 2012, Petitioners' counsel, Herbert Waichman, filed a motion to withdraw as counsel of record,[4] and another request for additional time. Further enlargements of time were allowed, thereafter, until Mr. Waichman was ultimately relieved of his duties as counsel. (*See* Orders filed Feb. 7, Feb. 23, and May 21, 2012, and Jan. 3, 2013.) On January 3, 2013, I filed an Order directed to the now *pro se* Petitioners, ordering Petitioners to file, within 30 days, an amended petition that was fully compliant with § 300aa-11(c), and which clearly explained their theory of vaccine causation in this case.

On January 28, 2013, Petitioners filed a Statement indicating that they were trying to replace their counsel so that they could continue pursuit of their claim. Petitioners were allowed additional enlargements of time to file all of the medical records required by § 300aa-11(c), and

[3] Petitioners have never filed an amended petition in response to that order.

[4] It is notable that the Motion to Withdraw as Attorney of Record, filed on Feb. 2, 2012, included the following statement: "In petitioner's counsel's view, there is no reasonable basis to proceed forward with petitioner's case. To do so would, in counsel's view, be wasteful of Program resources."

a Statement of Completion. (*See* Orders filed Feb. 6, May 8, and July 1, 2013.) Each of these orders allowing enlargements of time included the following instruction: "You must file within 90 days of the date of this Order all available medical records of [LD's] well-child visits between twelve and thirty one months of age; records pertaining to the diagnosis of [LD's] ASD, any records discussing the cause of [LD's] ASD, and specialist treatment records." (*Id.*, pp. 1-2.) However, nothing was filed.

On September 10, 2013, I filed another Order to Show Cause, stating that Petitioners' claim would be dismissed if they failed to file the required medical records within 30 days. Petitioners filed a Response on October 3, 2013, requesting additional time to comply with the Order to Show Cause. Additional time was allowed. (Order, filed Oct. 24, 2013.)

On January 10. 2014, Petitioners filed a Motion to Substitute Attorney Patricia Finn in place of the *pro se* Petitioners. That Motion was granted on January 17, 2014, and Petitioners were again ordered to file the required medical records. On April 1, 2014, Petitioners filed Exhibit 10, a medical record of geneticist Virginia Proud, M.D. Petitioners also filed a separate Statement of Completion indicating that all of the relevant medical records had been filed. (Statement, filed April 1, 2014.)

On May 19, 2014, Respondent filed a Supplemental Rule 4(c) Report and Motion to Dismiss, which again detailed the alleged failure by Petitioners to file all of the documentation required by § 300aa-11(c). Respondent also objected that Petitioners had never attempted to establish that their Petition was timely filed, or filed an amended petition articulating Petitioners' theory of vaccine causation. (Motion to Dismiss, filed May 19, 2014, p. 14.)

On June 3, 2014, counsel for both parties participated in a status conference to discuss identification of medical records relevant to Petitioners' claim. (*See* Order, filed June 4, 2014.) Petitioners were instructed to file a status report within 60 days, describing their efforts to file those records. Petitioners were also instructed to provide basic information regarding their claim in that status report, including: "the vaccination that allegedly injured their son, the date it was administered, the first symptoms of the injury, and the date when those symptoms appeared." (*Id*.) Petitioners filed a status report on July 31, 2014, which did not contain the required information, but argued that an additional ninety days were needed to "provide the Court with an amended complaint setting forth the allegations of the petition and responding to the Court's June 4th Order." (Status Report, filed July 31, 2014.)

Respondent filed a Response, on July 31, 2014, noting that Petitioners had been provided with an explicit list of medical records that remained outstanding. However, Respondent also contended that this case lacked "reasonable basis" to proceed, and should, therefore, be dismissed immediately. (Response, filed July 31, 2014.) Nonetheless, I decided to grant Petitioner's request for additional time. (Order, filed Aug. 7, 2014.)

On October 30, 2014, Petitioners filed various medical records, consisting of Exhibits 11 through 16, along with a request for additional time to file the other outstanding records and to provide Petitioners' answers to the specific questions propounded by the court. On October 31, 2014, I filed an Order allowing a two-week enlargement of time. That Order included the following instructions:

> Petitioners' counsel shall study the recently-filed medical records and determine whether this case was timely-filed. On or before November 13, 2014, petitioners' counsel shall file the outstanding medical records, and a status report addressing the timeliness issue. That status report shall specifically identify: 1) the vaccination that allegedly injured L.D., 2) the date it was administered, 3) the first symptoms of the injury, and 4) the date when those symptoms appeared.

(Order, filed Oct. 31, 2014.) Petitioners filed medical records identified as Exhibits 17, 18 and 19, on November 11, 2014. Also on November 13, 2014, Petitioners filed a Status Report addressing the issues set forth in my previous orders.

> With regards to the questions set out by the Court in the June 4, 2014 Order it is petitioner's position that the varicella vaccine administered on December 9, 2002 is the vaccine that allegedly caused LD's injuries. LD's speech issues were first noted at a well child visit on July 20, 2004 when the minor petitioner was 2 years 8 months old. ***. The petition in this case was filed on January 19, 2007 and the onset of symptoms did not occur until July 2004, therefore this petition is timely and should not be dismissed.

Thus, Petitioners alleged specifically that LD's injury was caused by the varicella vaccination administered on December 29, 2002, and that the first symptom of that injury appeared about eighteen months later, in July of 2004. Petitioners also explained the change in their theory of the case, as follows:

> Although this case was originally filed in the OAP, this was an error. The two theories presented in the OAP cases were (1) that the measles portion of the measles, mumps, rubella vaccine could cause ASDs and (2) that the mercury contained in thimerosal-containing vaccines could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. LD has never received an MMR vaccination and the varicella vaccination alleged to have caused LD's injuries does not contain thimerosal.

(Status Report, filed Nov. 13, 2014.)

> On November 18, 2014, I filed an Order, which contained the following specific instructions:
>
> In Petitioners' status report filed on November 13, 2014, Petitioners assert that (1) the varicella vaccine of December 9, 2002, caused L.D.'s injury, but that (2) the first symptoms of that injury occurred when L.D. was around 2½ years to 2 years and eight months old, which would have been between April and July of 2004. However, that assertion leaves a gap of about a year and one half between the vaccination in question and the onset of symptoms. Petitioners are hereby given 90 days from the date of this order in which to file an expert report that draws a causal connection between that varicella vaccination and J.D.'s autism.

(Order, filed Nov. 18, 2014.) A status conference was convened on December 3, 2014, with the participation of counsel for both parties. During that conference, I notified Petitioners' counsel that, given Petitioners' representations in the status report filed in this case on November 13, 2014, I had grave doubts whether there existed a "reasonable basis" for spending further attorney time or costs on this case. (Order, filed Dec. 3, 2014.)

In response to my Order filed on November 18, 2014, Petitioners did not file an expert report to support their claim that the varicella vaccination caused an injury to LD. Instead, on February 16, 2015, Petitioners filed a "Motion for Ruling on the Record," alleging again that LD's varicella vaccination of December 9, 2002, caused his "behavioral issues, communication disorders, and autism." Accordingly, I will now rule on the existing record.

C. Issue for decision

The timeliness of this Petition need not be resolved. The only issue that I will decide is whether the varicella vaccination administered to LD on December 9, 2002, *caused* LD's autism and related conditions.

III

DISCUSSION

In order to qualify for an award under the Program, Petitioners must prove either: 1) that LD suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table--corresponding to one of his vaccinations, or 2) that he suffered an injury that was "actually caused" by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1).

Petitioners do not claim that LD suffered a "Table Injury," and in my examination of the filed medical records, I did not find in the record any evidence that LD suffered a "Table Injury."[5]

The legal standard to establish "actual causation" of an injury by a vaccine requires that a petitioner must present "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 proximal temporal relationship between vaccination and injury." *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed.Cir. 2005).

Under the statute, a petitioner may not be given 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. 42 U.S.C. § 300aa-13(a)(1). In this case, the records do not contain a medical expert's opinion, or any other evidence, indicating that LD's condition was caused by the varicella vaccine. No physician expressed such an opinion in the records that I reviewed, and the Petitioners have not pointed to any place in the records where any physician stated such an opinion. Thus, because the medical *records* do not seem to support the Petitioners' claim, a medical *opinion* must be offered in support. Petitioners, however, have offered no such opinion.

Further, none of the three prongs of the *Althen* standard to establish causation have been satisfied. Petitioners have not offered a medical theory causally connecting the varicella vaccination to autism or any other condition from which LD suffers; nor have Petitioners presented a logical sequence of cause and effect showing that the varicella vaccine caused an injury to LD. Finally, Petitioners have failed to even try to demonstrate that the eighteen-month interval between the administration of LD's varicella vaccination and the alleged date of onset of

[5] The "varicella" vaccine that is alleged to be the cause of LD's condition, is listed on the Vaccine Injury Table, but there are no "Table Injury" conditions identified regarding the varicella vaccine. 42 C.F.R. § 100.3(a)(X).

LD's symptoms constitutes the "proximal temporal relationship" that is required by the third prong of the *Althen* standard.

IV

CONCLUSION

It is, of course, tragic that LD suffers from significant neurological problems. He and his family are certainly deserving of sympathy for those difficulties. However, under the law I can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or competent medical opinion to be vaccine-caused. No such proof exists in the record before me. Accordingly, it is clear from the record in this case that Petitioners have not demonstrated either that LD suffered a Table Injury, or that his autism or any other condition was "actually caused" by a vaccination. Therefore, I have no choice but to hereby DENY this claim. In the absence of a timely-filed motion for review of this decision, the Clerk shall enter judgment in accord with this decision.

s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master