In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-788V
(To be published)

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DANA STURDIVANT and	*	Filed: January 21, 2016
TROY STURDIVANT, natural parents	*	
and guardians of B.G.S., a minor,	*	
	*	
Petitioners,	*	Vaccine Act Entitlement;
	*	Causation-in-fact; Autism;
v.	*	Prevnar; Hib; Table Injury
	*	Encephalopathy
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES	*	
	*	
Respondent.	*	
	*	
* *		

Barrett J. Clisby, Oxford, MS, for the Petitioners.
Traci R. Patton, U.S. Department of Justice, Washington, DC, for the Respondent.

DECISION

HASTINGS, ***Special Master.***

This is an action in which the Petitioners, Dana and Troy Sturdivant, seek an award under the National Vaccine Injury Compensation Program (hereinafter the "Program"[1]), on behalf of their son, B.G.S. Petitioners allege that Hib and Prevnar vaccinations administered to B.G.S. on March 28, 2005, caused an encephalopathy in B.G.S., causing or contributing to his severe neurodevelopmental disorder, and perhaps other problems. B.G.S. has been diagnosed as having a neurodevelopmental disorder that falls within the category of an Autism Spectrum Disorder. For the reasons set forth below, I conclude that the Petitioners are *not* entitled to an award on behalf of B.G.S.

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa—10 *et seq.* (2012). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2012). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). ("Causation-in-fact" is also known as "actual causation.") In such a situation, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination initially caused, or significantly aggravated, the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination initially caused or aggravated the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or aggravation, but must demonstrate that the vaccination was at least a "substantial factor" in causing or aggravating the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" and the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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 proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id*. at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id*. at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11* v. HHS, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony

and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

BACKGROUND: 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 disorders" ("ASD")[2] were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning 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 contained 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*

[2] "Autism Spectrum Disorder" is a *general* classification which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term "autism" is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id*.) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the "DSM-V" as opposed to the prior "DSM-IV," revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs.

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).[3] 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).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g.*, *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 19, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. HHS*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by Hepatitis B vaccine); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No.

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

02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by combination of vaccines); *Allen v. HHS*, No. 02-1237V, 2015 WL 6160215 (Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS* (Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine) (not yet published), *aff'd* by Judge Braden on Dec. 18, 2015; *Hardy v. HHS*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines).

In addition, some autism causation claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Bushnell v. HHS*, No. 02-1648V, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Fesanco v. HHS*, No. 02-1770V, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014); *Canuto v. HHS*, No. 04-1128V, 2016 WL ____ (Fed. Cl. Spec. Mstr. Hastings Dec. 18, 2015) (on appeal). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g., Fesanco v. HHS*, 99 Fed. Cl. 28 (Judge Braden affirming).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.[4]

[4] I am well aware, of course, that during the years since the "test cases" were decided, in two cases involving vaccinees suffering from ASDs, Vaccine Act compensation was granted. But in *neither* of those cases did the Respondent concede, nor did a special master find, that there was any *"causation-in-fact"* connection between a vaccination and the vaccinee's ASD. Instead, in both cases it was conceded or found that the vaccinee displayed the symptoms of a *Table Injury* within the Table time frame after vaccination. (See Section I above).

In *Poling v.* HHS, the presiding special master clarified that the family was compensated because the Respondent conceded that the Poling child had suffered a *Table Injury--not* because the Respondent or the special master had concluded that any vaccination had contributed to causing or aggravating the child's ASD. See *Poling v.* HHS, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cir Spec. Mstr. Jan. 28, 2011) (a fees decision, but noting specifically that the case was compensated as a Table Injury).

Second, in *Wright v. HHS*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Vowell Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." (2015 WL 6665600 at *2.)

The compensation of those two cases, thus, does *not* afford any support to the notion that vaccinations can contribute to the *causation* of autism. In setting up the Vaccine Act compensation system, Congress forthrightly acknowledged that the Table Injury presumptions would result in compensation for some injuries that were *not*, in fact, truly vaccine-caused. H.R. Rept. No. 99-908, 18, 1986 U.S.C.C.A.N. 6344, 6359. ("The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.")

III

PROCEDURAL HISTORY OF THIS CASE

On November 9, 2007, Dana Sturdivant and Troy Sturdivant filed a petition ("Pet.") requesting compensation under the National Vaccine Injury Compensation Program, on behalf of their son, B.G.S. Various medical records were attached to that petition, identified as Petitioners' Exhibit A ("Pet. Ex. A"). The petition alleged that a measles-mumps-rubella vaccination administered to B.G.S. on November 29, 2004, acting either alone or in combination with the Hib (haemophilus influenza type B) and Prevnar (pneumococcal) vaccinations administered to B.G.S. on March 28, 2005, caused his neurological, gastrointestinal, metabolic, and allergy problems. (Pet., ¶1.) Petitioners filed additional medical records, identified as Petitioners' Exhibit B ("Pet. Ex. B"), on April 8, 2008.

Initially, the case was assigned to Special Master Richard Abell. (ECF No. 2.) Petitioners filed a request, on May 29, 2008, to transfer the case to the Omnibus Autism Proceeding ("OAP"). That request was granted on June 5, 2008, and the case was re-assigned to the docket of Chief Special Master Golkiewicz. (ECF Nos. 9-10.) However, on June 12, 2009, Petitioners filed a request for "Review of Case-Specific Proof of Causation," indicating that they did not want their petition linked to other cases. On July 10, 2009, Chief Special Master Golkiewicz granted their request, "de-coupled" this case from the OAP, and reassigned it to the docket of Special Master Sandra Lord. (ECF Nos. 11, 14.)

Petitioners filed additional medical records identified as Petitioners' Exhibit C ("Pet. Ex. C"), on August 3, 2009.

On November 2, 2009, Respondent filed Respondent's Report, contending that this claim is not eligible for compensation. (ECF No. 16, p. 2.)

On November 16, 2010, this case was reassigned to the docket of Special Master Patricia Campbell-Smith. (ECF No. 24.)

On January 17, 2011, Petitioners filed the medical records of Dr. John Shoffner, director of the Medical Neurogenetics ("MNG") laboratory.[5] Petitioners filed a Notice of their intent to remain in the Vaccine Injury Compensation Program, on June 21, 2011. On October 14, 2011, Petitioners filed an Amended Petition. In that Amended Petition, the Petitioners alleged that "the Hib vaccine is the cause-in-fact of [B.G.S.'s] current complications and deficiencies." (p. 2, ¶ 6.) Confusingly, however they also alleged that "as a direct result of one or combination" of the Prevnar and Hib vaccinations, B.G.S. suffered multiple neurological and gastrointestinal problems. (*Id.*, p. 3, ¶ 7.) Further, Petitioners contended that B.G.S. "reacted to the Hib within 72 hours" after receiving the vaccination. (*Id.*, p. 3, ¶ 8.) On June 28, 2012, Petitioners filed the expert medical opinion of Dr. Stephen Chevalier, Petitioners' Ex. D ("Pet. Ex. D.")

[5] These medical records were not assigned an exhibit number or letter. I will refer to them as the "MNG records."

Respondent filed the expert report of Dr. Peter Bingham, Respondent's Exhibit A ("R. Ex. A"), on November 8, 2012.[6]

On March 8, 2013, this case was reassigned to my docket. (ECF No. 39.) I convened a telephonic status conference on May 20, 2013, to address the difficulties presented by certain illegible entries in Dr. Chevalier's office records. Petitioners were instructed to provide a legible transcript of these important entries. (*See* Order, May 20, 2013.)

It took over a year, but Petitioners finally filed the typewritten transcription of various medical notes recorded by Dr. Chevalier ("Pet. Ex. F"), and a supplemental expert report of Dr. Chevalier ("Pet. Ex. E"), on May 29, 2014.

After filing their exhibits E and F, Petitioners continued to seek additional medical records. (See ECF Nos. 52-63.) On January 20, 2015, Petitioners filed a status report indicating that they were ready to proceed to a trial in this case. (ECF No. 64.) During a status conference on January 27, 2015, and via documents filed over the next several months, the parties prepared for an evidentiary hearing to be held on July 31, 2015, at which the Petitioners themselves, other family members, Dr. Chevalier, and Dr. Bingham would testify. (ECF Nos. 65-74.)

However, during a status conference held on July 28, 2015, Petitioners' counsel informed me that Dr. Chevalier was no longer willing to testify in the case, and that Petitioners wished to submit the case to me without oral expert testimony. Respondent's counsel agreed. (ECF No. 76.)

Accordingly, during the evidentiary hearing on July 31, 2015, the only witnesses offered by Petitioners were the Petitioners and two of the grandparents of B.G.S. (Tr. 1-117.) At the conclusion of the hearing, Petitioners' counsel clarified that they were submitting the case to me, relying upon the testimony of the four lay witnesses who testified that day, plus the two written expert reports of Dr. Chevalier. (Tr. 119-20.) Petitioners' counsel waived the right to file post-hearing briefs (Tr. 120-21), instead electing to make a brief closing argument. (Tr. 121-23.)

IV

FACTS

Petitioners' son, B.G.S., was born on November 21, 2003. (Pet. Ex. A, p. 23.) His medical records indicate that B.G.S. received regular pediatric examinations and immunizations during his first 12 months of life. (Pet. Ex. A, pp. 25-28, 79.)

On November 29, 2004, when B.G.S. was 12 months old, he received his first MMR and varicella vaccinations, along with his fourth diphtheria-tetanus-acellular pertussis ("DTaP") vaccination. On that date, his pediatrician noted B.G.S.'s developmental progress as: "takes 3 steps, 4 words, feeds self well." (Pet. Ex. A, pp. 31, 79).

[6] Both Petitioners and Respondent used letters of the alphabet to identify their exhibits. Respondent's filing on November 8, 2012, included Respondent's Exhibits A, B, C, D, and E.

At 13 months of age, on December 23, 2004, B.G.S. was prescribed the antibiotic Augmentin, to treat an episode of left otitis media. He was re-examined six days later on December 29, when his mother reported that he had vomited several doses of the antibiotic. The examining nurse noted that B.G.S. would receive three more days of antibiotic treatment. (Pet. Ex. A, p. 32.)

Three months later, on March 28, 2005, B.G.S.'s developmental progress was described as "runs, climbs, 5-10 words, understands, follows commands, uses spoon, scribbles, stacks." According to the office notes, he "eats well" and he is "doing well." (Pet. Ex. A, p. 33; Pet. Ex. F, p. 1.) On that date, B.G.S. received his fourth Prevnar and his third Hib vaccinations. (Pet. Ex. A, pp. 33, 79.)

On March 30, 2005, B.G.S. returned to his pediatrician with a temperature of 100.9°, suffering from two days of fever up to 103°, nausea, vomiting, and diarrhea. His pediatrician noted that B.G.S. wanted to eat and drink, that his nausea and vomiting had decreased, and that he was "happy and not in acute distress." His oropharynx and tympanic membranes were described as "clear." The assessment by B.G.S.'s pediatrician indicated "gastroenteritis," which was treated with Motrin and Tylenol. (Pet. Ex. A, p. 34; Pet. Ex. F, p. 2.)

The following day, on March 31, 2005, B.G.S. returned to his doctor's office with a "3 day history of fever up to 104° [for] two days," and loose stools. He had "normal urine output" and, again, both of his ears were "clear," and his oropharynx was "benign." The assessment at that time was "viral illness – gastroenteritis," which was treated by the administration of appropriate fluids and nutrition. (Pet. Ex. A, p. 35; Pet. Ex. F, p. 3.)

Eleven days later, on April 11, 2005, B.G.S. returned to his pediatrician with a three-day history of fever, reaching a maximum of 103.9°, along with a cough, congestion and fussiness. His physical examination revealed bilateral otitis media, with bulging, dull tympanic membranes that exhibited zero movement. He received an injection of Rocephin, and a ten-day prescription of Augmentin. (Pet. Ex. A, p. 36; Pet. Ex. F, p. 4). On April 12 and 13, 2005, B.G.S. returned to his pediatrician's office to receive repeat injections of Rocephin. (*Id.*)

There are no further pediatric notes for seven months, until November 7, 2005, when B.G.S. received an influenza vaccination. On November 29, 2005, B.G.S. was examined by his pediatrician, who noted that he spoke only 5 to 6 words, and might have difficulty hearing. The pediatrician suspected "delayed speech," and made referrals for speech and hearing evaluations. One such referral, to the "First Steps" program for evaluation, was cancelled by B.G.S.'s mother. (Pet. Ex. A, pp. 37-38.)

On December 6, 2005, B.G.S. was seen at the ENT Clinic of the University of Mississippi Medical Center, where the physician performing the exam noted that the parents "do not feel that [B.G.S.'s] speech is normal for his age." The doctor also indicated that "[o]therwise, [B.G.S.] seems to be developmentally appropriate to his parents." (Pet. Ex. A, p. 61.) Dr. Kyle Gordon, a pediatric otolaryngologist at the Ear Nose & Throat Surgical Group, evaluated B.G.S. for possible hearing loss on December 15, 2005, when he was 25 months old.

At that time, his parents reported that "they do not feel that his speech is normal for his age…that he says a few words and babbles a lot." Based on evidence that B.G.S. possibly suffered from "conductive hearing loss bilaterally," Dr. Gordon discussed with his parents the possibility of inserting bilateral "PE tubes" (pressure equalization tubes) in his ears. However, B.G.S.'s parents were reluctant to do so at that time. (*Id.*, p. 60.)

Four months later, on March 31, 2006, B.G.S. received treatment for fever, coughing, and left otitis media (ear infection). (Pet. Ex. A, p. 39.) He later received another hearing evaluation from a clinical audiologist at the Jackson Ear Clinic, on April 3, 2006, at which time his mother reported that B.G.S. "had a severe ear infection in April 2005, and since that time [the mother] feels that hearing has not been as good, and he has quit talking." The audiologist stated that B.G.S. possessed "hearing sensitivity in the normal to near normal range for at least one ear" that would be "sufficient for normal speech and language development." (Pet. Ex. B, p. 3.)

Pediatrician Steven Chevalier referred B.G.S. to "Beyond Play Therapy" for evaluation of pervasive developmental disorder ("PDD") on July 18, 2006. On July 26, 2006, B.G.S. received approval for twice-weekly speech therapy. (Pet. Ex. A, pp. 39-40.)

The Rankin County School District performed a speech and development evaluation on B.G.S. on November 16 and December 7, 2006. At that time, his parents reported that he "was developing normally until approximately 18 months of age, when his language skills regressed significantly and he stopped using words." The evaluators concluded that B.G.S. exhibited "a 25% or more delay in the developmental areas of language, social and cognitive" performance. This developmental level "fell within the mild to moderate autistic range." (Pet. Ex. A, pp. 93, 96, 98.)

On March 30, 2007, B.G.S. suffered another episode of fever and bilateral otitis media that required treatment with antibiotics. He received further treatment for persistent fevers on April 1, 2007. His parents brought him to the Baptist Hospital Emergency Center in Jackson, on April 2, 2007, because he had a fever, was jaundiced, and his urine was brown colored. Medical personnel at Baptist Hospital concluded that B.G.S. suffered from hemolytic anemia, and treated him with intravenous fluids. On April 4, 2007, B.G.S. was transferred to the University of Mississippi Medical Center, in Jackson, for further evaluation. It was noted that B.G.S. had previously received two injections of Rocephin, but "he continued with increased temp [reportedly 104°]. He was then more lethargic and had '?convulsions' with fever." The hospital notes suggest that his urine discoloration might be attributed to weekly DMSA "chelation" treatments that he had been receiving. The hospital summary of B.G.S.'s treatment, dated April 5, 2007, lists his diagnoses as: "autism; autoimmune hemolytic anemia; febrile illness, resolved." (Pet. Ex. A, pp. 41, 55-56.)

On April 6, 2007, B.G.S.'s parents returned to their pediatrician, complaining that he still suffered from fever and urine problems. Dr. Chevalier closely monitored B.G.S.'s recovery from hemolytic anemia, recording his observations on April 6, 9, 12, and 19 of 2007. (Pet. Ex. A, pp. 43-44.)

Petitioners brought B.G.S. to the Mississippi Behavior Clinic to obtain a second opinion regarding his developmental problems. On August 20, 2007, these specialists described his symptoms in great detail and confirmed his diagnosis of "autism," specifically citing the diagnostic code for autistic disorder (299) from the DSM-IV-TR. This report briefly summarized an interview with B.G.S.'s parents, in which they indicated that, "after having received his immunizations at 16 months of age, progression of his milestones ceased… he stopped talking and began to display extreme social changes." (Pet. Ex. B, pp. 32-33.)

On May 14, 2008, a video-EEG examination was administered to B.G.S. to evaluate possible seizure activity. Certain "eye fluttering" events were reported, but these were not associated with any epileptiform discharges during the test. There were, however, "generalized epileptiform discharges during sleep." (Pet. Ex. C, p. 67.)

On June 10, 2008, Dr. Anne Yates, a pediatric allergy and immunology specialist at the University of Mississippi Medical Center, examined B.G.S. Dr. Yates noted the history reported by B.G.S.'s mother that: "within 7 weeks after his MMR, varicella and DTaP vaccines (given 11/29/04),[7] he began to have less social interaction, and less speech and language development" … and "[i]nitially, these changes were quite subtle." (Pet. Ex. C, p. 150.) Dr. Yates summarized her impressions, which included "autistic child, of unknown etiology," a history of mild rhinitis, rashes, occasional infections, and numerous food intolerances without any evidence of "true IgE-mediated allergic reaction." (*Id*., p. 153.) Based on laboratory testing, she confirmed that B.G.S. had protective titers to Hib, diphtheria, Polio, varicella, measles, rubella, hepatitis B and herpes virus 6. She noted inadequate titer levels for mumps and tetanus, and recommended administration of the pneumovax vaccine and a DTaP booster. (*Id*., pp. 107, 153.) However, B.G.S.'s mother indicated that she did not want him to receive further vaccinations. (*Id.*, p. 106.)

In April 2008, specialists at the Biochemical Genetics Laboratory of the University of Mississippi Medical Center performed extensive tests on B.G.S. to identify any potential genetic causes of his condition. Dr. Hans Bock's impression after the testing was, "I have documented no definite evidence to support a possible mitochondrial etiology." (Pet. Ex. C, pp. 64-65.)

Dr. Colette Parker, a pediatric neurologist at the University of Mississippi Medical Center, summarized B.G.S.'s medical status in a report on April 29, 2009. She recorded the impression that B.G.S. suffered from "static encephalopathy," "autistic spectrum disorder," and some epileptiform activity. She also noted that an extensive genetic evaluation of B.G.S. performed was "thus far negative." (Pet. Ex. C, pp. 61-62.)

[7] MMR, varicella, and DTaP vaccinations were administered on November 29, 2004, as noted in this quotation. The alleged onset of various "subtle" symptoms, "within seven weeks" of that date, would have occurred in late January, 2005. I note that there are no medical records pertaining to January and February 2005. The symptoms mentioned in this quote were not described in the office notes concerning the next medical examination, on March 28, 2005. The Prevnar and Hib vaccinations were administered on March 28, 2005.

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, Petitioners relied upon the expert reports of a single medical expert, as did Respondent. Initial prehearing discussions indicated that Petitioners' expert, Dr. Chevalier, would orally testify on behalf of Petitioners, but the Petitioners ultimately elected to rely only on his expert reports. Both parties were amenable to the reports of their experts being used in this manner. At this point, I will briefly summarize both the qualifications and the opinions of these expert witnesses.

A. Petitioners' expert

1. Qualifications of Steven Chevalier, M.D.

Dr. Chevalier is a board-certified pediatrician who provided medical care for B.G.S. from birth through mid-2012. (Pet. Exs. D, E.) Petitioners did not file a *curriculum vitae*, or a description of Dr. Chevalier's qualifications.[8]

2. Summary of the opinion of Steven Chevalier, M.D.

Petitioners filed their Amended Petition on October 14, 2011, introducing various changes in their theory of vaccine causation. One change of particular significance is that "petitioners aver that Hib vaccine is the cause-in-fact of [B.G.S.'s] current complications and deficiencies." (Am. Pet., pp. 2-3, ¶ 6.) Further, B.G.S. "reacted to the Hib within 72 hours." (*Id*., ¶ 8.) Thus, the Amended Petition does **not** implicate the MMR vaccine as a cause of B.G.S.'s condition, and petitioners now allege vaccine "causation-in-fact" rather than a "Table Injury."

In support of that Amended Petition, two affidavits of Dr. Chevalier were filed: Petitioners' Exhibit D and E. Neither of Dr. Chevalier's affidavits (expert reports) includes mention of a "Table Injury."

According to his first report, filed on June 28, 2012, Dr. Chevalier was B.G.S.'s pediatrician from birth until mid-2012, when the family moved to Florida. Dr. Chevalier stated that B.G.S.'s development from birth until late March 2005 "was on a completely normal course." Dr. Chevalier also stated that, following B.G.S.'s vaccinations on March 28, 2005 - -

> [B.G.S.] developed a fever up to 104 and an acute rash. Within (3) days he continued to appear ill and was admitted [to] the Mississippi Baptist Medical Center appearing jaundiced, lethargic and experiencing abnormal urine. All of

[8] I note that the first expert report of Dr. Chevalier, filed June 28, 2012, states that "a *curriculum vitae* is included in Exhibit "A" which contains a report outlining Steven P. Chevalier, M.D., FAAP qualifications and expertise." (Pet. Ex. D, p. 2.) However, there are no page numbers cited, and my review of Pet. Ex. A did not reveal a *curriculum vitae*.

> this started and progressed within seventy-two (72) hours of the injection and has continued… Following his hospitalization for acute changes, [B.G.S.'s] development slowed, his speech regressed, and his socialization skills severely regressed. From this time forward, [B.G.S.] has had significant issues consistent with a severe pervasive developmental disorder. It is my professional opinion, stated to a reasonable degree of medical certainty, that the Encephalopathy commenced within seventy-two (72) hours of the DTaP/Hib injection and persisted for more than twenty-four (24) hours in this child.

(Pet. Ex. D, p. 2.)

The second report of Dr. Chevalier, filed on May 19, 2014, is largely a repetition of his earlier report, but contained a few modifications. Dr. Chevalier wrote:

> On March 28, 2005, [B.G.S.] received a Prevnar vaccine and a Hib vaccine (haemophilus influenza type B). Immediately after the shots were administered [B.G.S.] began to show raised, red bumps around the injection sites. That night, he was reported as restless with a high fever, which continued the next day along with diarrhea. [B.G.S.'s] fever reached 104 within three days of receiving the vaccinations and the injection sites had become an acute rash. [B.G.S.] also had some convulsions, seizures and other forms of ataxia in that short time frame as well. Spiking fever, rash, and seizures are three large red flags of encephalopathy, which I diagnosed in this child. Within three (3) days he continued to appear ill and was admitted to Mississippi Baptist Medical Center on March 30, 2005 appearing lethargic, with decreased appetite, and high fever. All of this started and progressed within seventy-two (72) hours of the injection and has continued.

(Pet. Ex. E, p. 2.)

Dr. Chevalier described B.G.S.'s gradually worsening developmental delay following March of 2005. He stated that:

> It is undeniable, to a reasonable degree of medical certainty, that this child experienced irreversible injury which occurred proximate to the Hib and Prevnar vaccinations with onset of symptoms within a less than four hour time frame.

(*Id.*) Dr. Chevalier concluded with his professional opinion stating, with a reasonable degree of medical certainty, that "the encephalopathy commenced within seventy-two (72) hours of the Hib and Prevnar injections and persisted for more than twenty-four (24) hours in this child." (*Id.*, p. 3.)

Thus, in both of Dr. Chevalier's affidavits, it appears that his theory of vaccine causation amounts to a suggestion that the vaccinations administered on March 28, 2005, caused B.G.S. to have an "encephalopathy" that manifested within seventy-two hours following those

vaccinations. The report also suggests that such encephalopathy resulted in an unspecified "irreversible injury" to B.G.S. thereafter. (Ex. E, p. 2.)

B. Respondent's expert

1. Qualifications of Peter Bingham, M.D.

In 1981, Peter Bingham graduated, *cum laude*, from Harvard College with a bachelor's degree in biology. Dr. Bingham received his medical degree from the Columbia College of Physicians & Surgeons, in New York, in 1987. He performed a pediatrics residency at the Children's Hospital of Philadelphia from 1987 to 1989. From 1989 until 1992, he served as a Neurology Resident at the Children's Hospital of Philadelphia and the Hospital of the University of Pennsylvania, in Philadelphia. In 1994, he completed a one-year neuromuscular disease research fellowship at the Hospital of the University of Pennsylvania. (R. Ex. B, p. 1.)

Between 1994 and 2000, Dr. Bingham was an Assistant Professor of Neurology and Pediatrics at the University of Pennsylvania School of Medicine. Concurrently, he served as a staff physician at the Children's Hospital of Philadelphia, where he participated in inpatient services and the general child neurology clinic. He was appointed Associate Professor of Neurology and Pediatrics at the University of Vermont, in August 2000, and became a staff physician in pediatric neurology at Fletcher Allen Health Care/University of Vermont, at the same time. As of November 2012, Dr. Bingham continued to serve in both of those positions. Dr. Bingham has been board-certified in Neurology and Child Neurology since 2005. (R. Ex. B, pp. 1-2.)

Dr. Bingham has published thirty peer-reviewed medical articles. He has also written or co-authored all or parts of more than ten textbooks concerning neurology or pediatrics. (R. Ex. B, pp. 3-6.)

2. Summary of the opinion of Peter Bingham, M.D.

Respondent filed the expert report of Dr. Peter Bingham on November 8, 2012. Dr. Bingham opined that although B.G.S. has a form of autism, his neurodevelopmental difficulties did not result from vaccinations that he received on March 28, 2005. (R. Ex. A, p. 4.) In his initial review of the facts of this case, Dr. Bingham noted that B.G.S. had a history of benign "macrocrania" (an unusually large head) for the first three months of life and beyond. (*Id.*, p. 1, citing Pet. Ex. A, p. 66.) He contended that this unusual head growth was the antecedent of autism, suggesting a genetic or pre-natal origin of B.G.S.'s condition. (*Id.*, p. 5.)

Dr. Bingham strongly contested the factual basis for Petitioners' assertion that B.G.S. suffered an acute encephalopathy in the days and weeks following his vaccinations of March 28, 2005. He explained that the medical records following that date do *not* contain any mention of a rapid decrease in consciousness (that is, lethargy, stupor or coma), disorientation, or seizures, which are the clinical characteristics of an acute encephalopathy. Dr. Bingham alleges that there are multiple inaccuracies in the summaries of B.G.S.'s medical history that were provided in the Petitioners' affidavits and the assumptions made by Dr. Chevalier. (R. Ex. A, pp. 4-5.)

Dr. Bingham also observed that Petitioners and their expert have not set forth any description of *a biological mechanism* that might link any of B.G.S.'s vaccinations to developmental impairment or autism. (R. Ex. A, p. 5, ¶ 3.) He also contended that the medical records do not support Petitioners' contentions regarding B.G.S.'s gastrointestinal or metabolic disturbances. (*Id*., ¶ 5.) Dr. Bingham concluded with a sharp disagreement with Dr. Chevalier's understanding of the events following B.G.S.'s vaccination, which was not supported by contemporaneously-recorded medical records. (*Id*., pp. 5-6.)

VI

ISSUES TO BE DECIDED

Unfortunately, it is not completely clear exactly what Petitioners are arguing in this case. For example, as will be detailed below (*see* Section VII of this Decision), Petitioners' counsel was not even completely clear as to *what vaccinations* he alleged to have harmed B.G.S. Also, while Dr. Chevalier's two reports do not even mention a "Table Injury," Petitioners' counsel at the conclusion of the hearing seemed to argue briefly, though confusingly, that B.G.S. suffered a "Table Injury encephalopathy." Further, it is not even clear *what injury* of B.G.S. it is that Petitioners seek compensation for. That is, their counsel insisted during his brief closing argument that this case "is not an autism case" and that "autism is not a problem with this child." (Tr. 122.) Yet, the most basic point of the Petitioners' case seems to be to seek compensation for B.G.S.'s *severe neurodevelopmental disorder* (*see* Petitioners' Amended Petition and Petitioners' Prehearing Memorandum), which disorder has in fact been diagnosed as falling *within the autism spectrum*. (*See, e.g.*, Pet. Ex. A, pp. 55-56, 96.) In addition, while Petitioners have asserted that his vaccinations of March 28, 2005, caused not only his neurological deficiencies, but also "gastrointestinal disorders," "metabolic disorders," and "food allergies" (*see* their Petition, Amended Petition, and Prehearing Memorandum), their expert's two reports said *nothing* about the latter three types of disorders, asserting only that B.G.S. suffered from "encephalopathy."

This Decision, accordingly, will be organized according to the two general theories of vaccine causation which *seem* to have been advocated by Petitioners, in their expert's two reports and in their counsel's closing argument. Specifically, the two primary issues to be decided here are: 1) whether B.G.S. suffered a "Table Injury encephalopathy;" and 2) whether, as Petitioners alternatively argue, B.G.S.'s vaccinations of March 28, 2005, played any role in "causing-in-fact" his neurodevelopmental disorder (or any other injuries).

VII

TABLE INJURY

Petitioners' counsel very briefly argued orally that B.G.S. suffered a "table injury" based upon the administration of the Prevnar and Hib vaccinations, on March 28, 2005. (Tr. 121.) However, I find this argument to be completely without merit.

First, counsel's two-paragraph argument about an alleged "table injury" was far from clear, as to even what counsel was arguing. (Tr. 121, lines 7-22.) Counsel did not even specify *what* Table Injury he alleged to have occurred. In his second sentence, counsel accurately stated that B.G.S. received, on March 28, 2005, Prevnar and Hib vaccinations. But in his first and third sentences counsel mentioned a "DTP-Hib" shot and a "DTP and Hib simultaneously." (Tr. 121, lines 7-9, 13-16).

This argument was simply incoherent. But if counsel was arguing that B.G.S. actually received a *DTP* shot on March 28, 2005, he was flatly wrong, as the records make clear. (Pet. Ex. A, p. 34; Pet. Ex. F, p. 1.)

Guessing at what counsel was suggesting, he *may* have been acknowledging in his first paragraph that B.G.S. did *not* receive a DTP vaccination on March 28, 2005, but arguing that I should, for unexplained reasons, treat B.G.S.'s case *as if* a DTP vaccination had occurred on that day. (Tr. 121, lines 7-16.) Note that in his following paragraph, counsel states that Dr. Chevalier opined that B.G.S. had suffered an "encephalopathy" commencing within 72 hours of his March 28 vaccinations. (Tr. 121, lines 17-22.) Note also that "encephalopathy" *is* listed on the applicable Vaccine Injury Table as a Table Injury for the DTP vaccine, but is *not* listed as a Table Injury for the Hib or Prevnar (pneumococcal) vaccinations. (*See* 42 C.F.R. § 100.3 - - compare section (a) II (encephalopathy listed as a Table Injury for DTP vaccine) to sections IX and XII (*no* Table Injuries at all listed for the Hib and pneumococcal vaccines).)[9]

But if that was, in fact, what petitioners' counsel meant to suggest, I must reject that argument completely. Encephalopathy is simply *not* a Table Injury for either the Hib or Prevnar vaccines, so by law I cannot apply the "Table Injury encephalopathy" standards to B.G.S.'s case.

[9] The statute itself contains a version of the Vaccine Injury Table that applied to vaccinations administered prior to the enactment of the Program and for several years after that enactment. *See* § 300aa-14(a). However, the Vaccine Injury Table was administratively modified with respect to Program petitions, such as this one, that were filed after March 24, 1997. *See* 62 Fed. Reg. 7685, 7688 (1997); *O'Connell v. Shalala,* 79 F.3d 170 (1st Cir. 1996). That Table modification, along with an earlier administrative modification of the Table in 1995 (see 60 Fed. Reg. 7694 (1995)), significantly altered the "Table Injury" categories, with respect to pertussis-containing or measles-containing vaccinations, from the version of the Table contained in the statute. The revised Table, listing "encephalopathy" as a Table Injury for the pertussis-containing (DTP) vaccinations, but not Hib or pneumococcal vaccinations, appears at 42 C.F.R. § 100.3 (2015 edition of C.F.R.). (I note also that in each Program case, the version of the Vaccine Injury Table applicable to the case is the version that was in effect on the date on which the petition was filed. (§ 14(c)(4).) The petition in this case was filed on November 9, 2007, so the version of the Vaccine Injury Table applicable to this case is the one that existed in the Code of Federal Regulations on that date. That is the version that I describe in the text above.)

And in any event, even if "encephalopathy" *was* a Table Injury applicable to B.G.S.'s case, the evidence would still not show that B.G.S. suffered a "Table Encephalopathy." That is, for Vaccine Act petitions, such as this one, filed after the modifications to the Vaccine Injury Table in effect since 1995 and 1997, "encephalopathy" exists as a Table Injury for several vaccinations (pertussis-containing or measles–containing), but a lengthy, precise definition of a "Table encephalopathy" is specified. 42 C.F.R. § 100.3(b)(2). The regulation, to summarize, requires a "significantly decreased level of consciousness" that lasted at least 24 hours. As noted in *Waddell*, by then-Chief Special Master Campbell-Smith, that regulatory definition implies "a state of diminished alertness that is much more than mere sleepiness or inattentiveness . . . [It] requires markedly impaired--or strikingly absent--responsiveness to environmental or external stimuli, for a sustained period of at least twenty-four hours." *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291, at *7 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). Special Master Campbell-Smith added that the symptoms of a "Table Injury encephalopathy" are not "subtle." (*Id*. at *6.)

The medical records of this case, however, show *no such injury*. To the contrary, the records show that on March 30, 2005, B.G.S., while feverish and having suffered from some nausea and vomiting, was "happy and not in acute distress." (Pet. Ex. A, p. 34; Pet. Ex. F, p. 2.)

Accordingly, Petitioners' argument that B.G.S. suffered a Table Injury must be rejected.[10]

VIII

PETITIONERS HAVE NOT SHOWN THAT B.G.S. SUFFERED ANY INJURY THAT WAS "CAUSED-IN-FACT" BY HIS VACCINATIONS OF MARCH 28, 2005

Second, I conclude that Petitioners have failed to demonstrate that it is "more probable than not" that B.G.S. suffered any injury that was "caused-in-fact" by his vaccinations of March 28, 2005 (or any other vaccinations). There are several reasons for this conclusion.

A. Petitioners' and Dr. Chevalier's conclusions are based on incorrect assumptions as to B.G.S.'s medical history.

As noted above, Dr. Chevalier opined, in both of his written reports, that B.G.S. suffered an "encephalopathy," and "irreversible injury," within 72 hours of his vaccinations of March 28,

[10] In this regard, I note that, though Petitioners' counsel never referred to it in the Petition, the Amended Petition, the Prehearing Memorandum, or his closing argument, I found in the medical records of B.G.S. a document which mentions a "Table Injury." That is, the records include a letter of a medical doctor, Jerry Kartzinel, who opined that B.G.S. had suffered a "TABLE INJURY following his March 28, 2005 vaccinations, which resulted in vaccine induced encepahalopathic changes." (Pet. Ex. C, p. 154) (capitals in the original.) However, Dr. Kartzinel, also did not explain *what* Table Injury he was describing, nor explain *why* he believed that B.G.S suffered any Table Injury. Again because, as explained above, the Vaccine Injury Table does not even list any Table Injuries for the Hib or Prevnar vaccines, I find no merit to this reference of Dr. Kartzinel.

2005.[11] (Pet. Ex. D, p. 2; Pet. Ex. E, pp. 2-3.) Dr. Chevalier based his conclusion of "encephalopathy" on his assumption that B.G.S., in the days immediately following those vaccinations, suffered from a high fever, "convulsions, seizures, and other forms of ataxia," and was limp, and lethargic. (Pet. Ex. D, p. 2; Pet. Ex. E, p. 2.) He also wrote that at one point during those days B.G.S. was "generally unresponsive to any external stimuli." (Pet. Ex. E, p. 2.)

However, while, B.G.S. clearly *did* suffer from a high fever of up to 104° (Pet. Ex. A, pp. 34-35), those other statements are *not* confirmed by the medical records of Dr. Chevalier's own office, created when B.G.S. visited on both March 30 and 31, 2005. Those medical records make *no mention* of seizures, convulsions, or unusual seizure – like movements. The records do *not* mention that B.G.S. was limp, lethargic, appeared to suffer from ataxia, or was unresponsive to stimuli. (Pet. Ex. A, pp. 34-35; Pet. Ex. F, pp. 2-3.) Thus, Dr. Chevalier seems to have based his conclusion of an "encephalopathy" upon severely *mistaken* assumptions of fact as to B.G.S.'s symptoms.

Moreover, Dr. Chevalier also relied upon the allegation that B.G.S. was *admitted to a hospital* with the symptoms alleged above, on March 30, 2005. (Pet. Ex. D, p. 2; Pet. Ex. E, p. 2.) But again, B.G.S.'s medical records show *no such hospitalization*. To the contrary, Dr. Chevalier himself wrote on March 30 that B.G.S. was "happy and not in acute distress." (Pet. Ex. A, p. 34; Pet. Ex. F, p. 2.)

It appears, in this regard, that Dr. Chevalier may have been confusing *two different* incidents and dates. That is, on March 30 of 2*007*, Dr. Chevalier examined B.G.S. due to a recurrence of bilateral otitis media that had caused a two-day fever. (Pet. Ex. A, p. 41.) And associated with that record is a hospital discharge summary from April 5, 2007. (Pet. Ex. A, pp. 55-56.)

Likewise, the Petitioners' own contentions in their Petition, Amended Petition, Prehearing Memorandum, and their attorney's closing argument, concerning B.G.S.'s alleged symptoms in the days immediately after the vaccinations of March 28, 2005, were generally mistaken in the *same way* as the two reports of Dr. Chevalier.

Concerning this point, I have studied the affidavits of both the Petitioners (Ex. A, pp. 1-2) and B.G.S.'s grandparents (filed on July 23, 2015), as well as the oral testimony given by all four of those individuals during the evidentiary hearing on July 31, 2015. I do *not* find that the four witnesses were *intentionally* misstating the facts as they remembered them. However, when I compare the allegations of those four witnesses, given years after the vaccinations in question, to the *actual medical records* made on March 30 and March 31, 2005, I must credit the *records* as accurate, not the testimony.

In this regard, I note that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed.Cir.1993).

[11] At one point in his first report, Dr. Chevalier incorrectly stated that B.G.S. had received a "DTaP/HiB injection" on March 28, 2005. (Ex. D, p. 2.) However, in his second report, Dr. Chevalier correctly described the vaccinations of that day as Prevnar and Hib. (Ex. E, p. 2.)

Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters usually accord more weight to the medical records. *See, e.g.*, *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

To be sure, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. H.H.S.*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992).

However, in balancing these considerations, special masters in this Program have traditionally declined to credit later testimony over contemporaneous records. *See, e.g., Stevens v. H.H.S*, 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. 1990); see also *Vergara v. H.H.S.*, 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") *See also*, *Cucuras v. H.H.S.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

Accordingly, the Petitioners' causation-in-fact" allegation in this case must be rejected, in the first place, for the simple reason that such allegation is based upon basic, very significant *misassumptions* of fact as to what symptoms B.G.S. displayed during the days in question.[12]

B. Respondent's expert was far more qualified, as to the particular medical issues at hand, than Petitioners' expert.

My discussion logically could end after Section VIII(A) above, since, as explained, Petitioners' causation theory is built upon significant *misassumptions of fact*. However, in the interest of completeness, I will list some *additional* reasons why Petitioners' causation theory is clearly devoid of merit.

A *second* reason why Petitioners' "causation-in-fact" theory is without merit, is simply that I found Respondent's expert, Dr. Bingham, to be far *more* qualified than the expert upon whom Petitioners relied, Dr. Chevalier, to opine as to the *particular* medical issues involved in this case.

Dr. Chevalier wrote that he is a board-certified pediatrician (Pet. Exs. D, E), which makes him at least *somewhat* qualified to opine as to the issues here. But Dr. Bingham is much *better* qualified. Dr. Chevalier's theory is that B.G.S. suffered an *encephalopathy*, which is a

[12] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

neurological injury. And Dr. Bingham, unlike Dr. Chevalier, has had a long career as a pediatric *neurologist*. (See Section V(B)(1), above.)

C. The written report of Petitioners' expert did not even actually allege that B.G.S.'s vaccines caused him any injury.

A close reading of the two written reports of Petitioners' expert reveals that those reports did not even actually allege that any vaccines caused B.G.S. any injury.

To be sure, Dr. Chevalier, in both his reports, opined clearly (if unconvincingly – see Section VIII(D) of this Decision below) that B.G.S. suffered an "encephalopathy," that the first signs of that encephalopathy commenced within 72 hours of his vaccinations of March 28, 2005 (Pet. Ex. D, p. 2; Pet. Ex. E, p. 3), and that B.G.S. suffered "irreversible injury" which occurred "proximate" to his Hib and Prevnar vaccinations of March 28 (Pet. Ex. E, p. 2).

But, Dr. Chevalier never stated explicitly that the *vaccinations caused* the "encephalopathy," and/or the "irreversible injury." Nor did Dr. Chevalier ever state explicitly that the *encephalopathy caused* B.G.S.'s autism, or his unspecified "irreversible injury," or any other condition.

I do conclude that one can plausibly *infer*, as I do, that Dr. Chevalier was *implying* that the vaccinations of March 28, 2005, caused the "encephalopathy"/"irreversible injury" that Dr. Chevalier alleged. I also infer that Chevalier was implying that the alleged encephalopathy in turn caused B.G.S.'s severe neurodevelopmental disorder (*i.e.,* his autism), and that Dr. Chevalier meant "irreversible injury" to mean that neurodevelopmental disorder.

But, it is still noteworthy that Dr. Chevalier for some reason failed even to make a straightforward statement to that effect in either of his written opinions.

D. Dr. Bingham's opinion was more persuasive than that of Dr. Chevalier.

As I noted in Section VIII(C) of this Decision immediately above, based upon the totality of Dr. Chevalier's two written reports, it is fair to *infer* that Dr. Chevalier was opining that the vaccinations of March 28, 2005, caused B.G.S. to suffer an "encephalopathy"/"irreversible injury," which, in turn, caused his tragic neurodevelopmental disorder, which has been diagnosed as a disorder within the autism spectrum. But even inferring that that is Dr. Chevalier's opinion, I must *reject* that opinion, for several reasons. First, as explained above in Section VIII(A) of this Decision, Dr. Chevalier's opinion was based on *gross misassumptions of fact* concerning B.G.S.'s symptom history. Second, explained above in Section VIII(B) of this Decision, Dr. Chevalier's *qualifications* concerning this issue are inferior to those of Respondent's expert, Dr. Bingham. And third, I found Dr. Bingham's written report to be substantially more persuasive than Dr. Chevalier's written reports. Dr. Bingham found that there was no support in the medical records to indicate that an encephalopathy had occurred soon after the vaccinations of March 28, 2005. (R. Ex. A, pp. 4-6.) Dr. Bingham, for example, found no mention in the records of the hospitalization that Dr. Chevalier assumed. (*Id*. at 5.) Additionally, Dr. Bingham noted the presence of an abnormally rapid head growth in the 97th percentile in B.G.S.'s first

year of life, as a recognized marker of possible abnormal brain development, often seen in the setting of autism. (*Id.* at 5.)

Dr. Bingham also highlighted the marked inconsistencies in symptomatology experienced by B.G. S. as reflected in the medical records, as compared to Dr. Chevalier's assumptions. (R. Ex. A, pp. 5-6.)

Dr. Bingham's review of the medical records also found no notes regarding developmental or neurological concerns until July 2006, more than one year after the vaccinations of March 28, 2005.

Further, Dr. Bingham opined that in the medical records, he saw no evidence of vaccine-caused injury to B.G.S. (R. Ex. A, pp. 4-6). Dr. Bingham noted that a biochemical genetic diagnostic evaluation done by Dr. Bock on April 7, 2009, "did not imply any consideration of vaccine-related encephalopathy." On April 29, 2009, pediatric neurologist Dr. Parker saw B.G.S., with her impression being "static" encephalopathy, which, Dr. Bingham noted, did not imply that B.G.S. had ever experienced an *acute* encephalopathy. (*Id.*, pp. 3-4.)

In short, Dr. Bingham's analysis of the case was much more persuasive than that of Dr. Chevalier.

E. Other injuries

In their Petition, Amended Petition, and other documents, Petitioners have alleged that B.G.S. suffered from not only a neurodevelopmental disorder, but also gastrointestinal problems, metabolic disorders, and food allergies.

Dr. Chevalier's opinions, however, did not address those other alleged disorders. Petitioners have filed no evidence at all linking such disorders to any vaccinations. Accordingly, I conclude that Petitioners have *failed* to demonstrate that B.G.S. suffers from *any* vaccine-caused injury.

IX

PETITIONERS HAVE FAILED THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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 the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government]

> shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does *not* satisfy the *Althen* test.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question can cause the *type* of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the *particular* vaccination did cause the *particular* condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that B.G.S. received

contributed to the causation or aggravation of B.G.S.'s tragic neurodevelopmental disorder, or any other injury.

B. Petitioners have failed to establish Prong 1 of Althen in this case

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Petitioners' primary theory is that the vaccinations B.G.S. received on March 28, 2005, resulted in various neurological, gastrointestinal, metabolic, and allergic conditions. However, as described above in Section VIII, Dr. Chevalier has *not* demonstrated that the vaccinations *can* cause any such injuries. Thus, Petitioners' claim clearly fails under *Althen* Prong 1.

C. Petitioners have failed to establish Prong 2 of Althen in this case

Under Prong 2, the Petitioners need to show that it is "more probable than not" that one or more of B.G.S.'s vaccinations *did* cause B.G.S.'s *own* condition. But this they have failed to do, for all of the reasons detailed above, again in Section VIII. Dr. Chevalier did not even provide a theory as to how the vaccinations in question might have caused B.G.S.'s alleged encephalopathy. Further, as described in Section VIII(A) above, Dr. Chevalier relied upon gross *misassumptions* concerning the facts of B.G.S.'s case. In addition, as described in Section VIII(D), Dr. Bingham persuasively refuted Dr. Chevalier's arguments concerning B.G.S.'s case. Thus, Petitioners have failed to establish Prong 2 of *Althen* in this case.

D. Petitioners have failed to establish Prong 3 of Althen in this case

Since I have explained why Petitioners have failed to satisfy the first and second prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong. However, Dr. Chevalier's above-described factual misassumptions mean that Petitioners have not been able to establish any proximate temporal relationship between any vaccination and any injury, as required under *Althen* Prong 3.

E. This is not a close case

In *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I found that Dr. Chevalier's opinion and Petitioners' arguments were *not at all* persuasive, while Respondent's expert was *far* more persuasive.

X

NOTATION CONCERNING "REASONABLE BASIS" OF CASES ALLEGING THAT VACCINATIONS AFFECTED AUTISM SPECTRUM DISORDERS (ASDs)

In this case Petitioners' counsel may or may not ultimately seek an award of attorneys' fees and costs. If counsel does so, I will *then* decide whether there was a reasonable basis to file *this case* and to prosecute it through trial to a decision.

My notation here, rather, concerns the *general issue* of whether future Vaccine Act cases involving ASDs, prosecuted to the point of a special master decision, will be found to have a "reasonable basis," so as to qualify for an award of attorneys' fees and costs. I note that there currently exist on my docket a number of cases in which it is alleged that a vaccinee's ASD was caused or aggravated by a vaccination. In many similar cases, in light of the "test cases" described on pp. 4-5 above, either the petitioner filed a "Motion for a Decision Dismissing the Petition," or the attorney withdrew from the case. In such situations, I have been inclined to find that the petition had a "reasonable basis" at the time of filing, and that it was reasonable to *prosecute the petition up to a certain point in time*.

However, in many other cases since the "test cases" became final in 2010, petitioners have elected to proceed to an evidentiary hearing, or have sought a "Ruling on the [written] Record," requiring a special master to spend a large amount of time evaluating the petitioner's theory and deciding the case. See decisions listed at pp. 5-6, above. In *all* of those cases, the petitioners have fallen *far short* of presenting a viable theory that one or more vaccines of any kind can contribute to causing or aggravating an ASD. Those failures have included cases in which the petitioner's theory is that the vaccination caused an "encephalopathy" (brain injury), which encephalopathy in turn allegedly affected the ASD; and cases in which the petitioners have alleged that the vaccinee had a "mitochondrial disorder" or "mitochondrial dysfunction," which allegedly made the vaccinee more susceptible to injury by vaccination.

In short, since the "test cases," *all* efforts in Vaccine Act cases to causally connect vaccines to ASD have fallen *far short* of plausibility.[13] The cases have presented no plausible evidence at all that vaccines can contribute to the causation of autism.

However, those cases have absorbed a huge amount of time of several special masters, time that could have been spent on other, more potentially viable, Vaccine Act cases. For example, in one case, *R.K. v. HHS*, Special Master Vowell was required to prepare two separate opinions, one of 161 pages and one of 58 pages (both single-spaced).

[13] I am not ignoring the *Poling* and *Wright* cases discussed at footnote 4 above. In each of those unusual cases, as explained in footnote 4, the vaccinee was shown to have suffered a Table Injury, *presumed* to be vaccine-caused under the Vaccine Act. But *no finding* of causation was made. Indeed, in the *Wright* case, while finding a Table Injury, Special Master Vowell remarked that the petitioner's alternative "causation-in-fact" theory in that case was "absurd."

Therefore, Vaccine Act counsel are hereby put on notice that if counsel pursue, to a decision, theories allegedly linking vaccines causally to ASDs,[14] and their evidence proves to be highly unpersuasive, I will *not* be inclined to conclude that there was a "reasonable basis" to pursue such cases to a decision. At this point, I cannot ethically award government funds to compensate counsel for pushing clearly unpersuasive theories to a decision.

In other words, I strongly advise counsel in Vaccine Act cases to carefully *scrutinize*, for *credibility*, any cases in which a petitioner or an expert witness asserts a theory that a vaccination significantly contributed to the causation or aggravation of an ASD. If after deciding such a case, I am not persuaded that there was a "reasonable basis," under all of the circumstances, for pushing the case to a special master decision, *I will be unlikely to award fees and costs, including the cost of experts,* for the evidentiary hearing or the final stages of the proceeding.

XI

CONCLUSION

The record of this case demonstrates plainly that B.G.S. and his family have been through a tragic ordeal. I had the opportunity, during the evidentiary hearing, to observe B.G.S.'s parents. I have also studied the records describing B.G.S.'s medical history, and the efforts of his family in caring for him. Based upon those experiences, the great dedication of B.G.S.'s family to his welfare is readily apparent to me.

Nor do I doubt that B.G.S.'s parents are sincere in their belief that B.G.S.'s vaccinations played a role in causing B.G.S.'s autism and/or other medical conditions. B.G.S.'s parents have heard the opinion of Dr. Chevalier, and perhaps other physicians, who profess to believe in a causal connection between vaccines and autism. After studying the extensive evidence in this case, I am convinced that the opinion provided by Petitioners' expert in this case, advising the Sturdivant family that there is a causal connection between the vaccinations B.G.S. received and B.G.S.'s medical condition, was *quite wrong*. Nevertheless, I can understand why B.G.S.'s parents found such opinion to be believable under the circumstances. I conclude that the Petitioners filed this petition in good faith.

Thus, I feel deep sympathy for the Sturdivant family. Further, I find it unfortunate that my ruling in this case means the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to families of *all* autistic children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of individual whose injuries or deaths can be linked causally, either by Table Injury presumption or by

[14] This includes theories alleging a Table Injury in which the *medical records* contain no significant evidence of a Table Injury.

preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on B.G.S.'s behalf.[15]

IT IS SO ORDERED.

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

[15] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.