In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 08-108V
(To be published)

HAROLD HARDY, III, and TIFFANY ANN HARDY-BELL, legal representatives of HH, a minor,	*	Filed: November 3, 2015
Petitioners,	*	
v.	*	Autism; Vaccine Act Entitlement; Causation-in-fact; Significant Aggravation; DTaP; Prevnar; Table Injury Encephalopathy
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	

Michael L. Cave, Baton Rouge, Louisiana, for Petitioners.
Darryl R. Wishard, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

HASTINGS, *Special Master.*

This is an action in which the Petitioners, Harold Hardy and Tiffany Ann Hardy-Bell, seek an award under the National Vaccine Injury Compensation Program (hereinafter the "Program"[2]), on behalf of their daughter ("HH"). Petitioners allege that certain vaccinations administered to HH on August 26, 2005, contributed to the causation of her severe neurodevelopmental disorder, either by initially causing, or by significantly aggravating, that disorder. HH has been diagnosed as having a neurodevelopmental disorder that falls within the

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[1] Because I have designated this document to be published, this document will be made available to the public unless the petitioners file, within fourteen days, an objection to the disclosure of any material in the decision that would constitute, "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." *See* 42 U.S.C. § 300aa—12(d)(4)(B); Vaccine Rule 18(b).

[2] 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."

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 HH.

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.

The Petitioners in this case appear to allege at times that the vaccinations that HH received on August 26, 2005, *initially caused* her neurodevelopmental disorder. (Petition, ¶ 23: Amended Petition, ¶ 23.) Alternatively, at times the Petitioners have alleged that those vaccinations *significantly aggravated* a pre-existing condition, causing it to worsen. (*E.g.*, Amended Petition, ¶ 21.) According to *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013), "the National Vaccine Injury Compensation Program *** allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had *significantly aggravated*' a vaccine-related 'illness, disability, injury, or condition.'" *Id*. at 1355-56, *quoting* 42 U.S.C. § 300aa-11(c)(1)(C)) (emphasis added.) In *Whitecotton v. HHS*, 81 F.3d 1099, 1103 (Fed. Cir. 1996), the U.S. Court of Appeals for the Federal Circuit stated that "the statutory requirements to make out a *prima facie* significant aggravation claim are analogous to those required to make out a *prima facie* initial onset claim." The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." § 300aa-33(4).

The elements of an off-Table *significant aggravation* case are set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). There, the court combined the test from *Althen*, above, which defines off-Table causation cases, with the test from *Whitecotton v. HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resultant test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims").

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")[3] 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* 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).[4] 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);

[3] "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.

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

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. 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*, (not yet published) (Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine).

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. 02-1648, 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. 02-1770, 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 4338058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014). 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.[5]

III

FACTS

HH was born on February 23, 2005. (Ex. 1, p. 8.)[6] In her initial medical examination, HH was assessed with a possible heart murmur. (*Id*., p. 9.) On February 24, 2005, HH received a Hepatitis B vaccination and was discharged from the hospital. (*Id*., pp. 8-9.)

Rachel Chatters, M.D., performed an evaluation on March 11, 2005, when HH was two weeks of age. (Ex. 2, p. 47.) At that time, Dr. Chatters noted that there had been "no problem since last visit," and that HH's developmental assessment was within normal limits. During the next assessment, on March 31, 2005, Dr. Chatters referred HH to a specialist for further

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[5] 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 (Fed. Cl. Spec. Mstr. 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." (Decision at 2-3).

The compensation of these 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.")

[6] At various times, Petitioners filed medical records and other evidence identified as Petitioners' Exhibits 1 through 29. I will refer to these items as Ex. 1, 2, 3, etc.

evaluation of a heart murmur. (Ex. 2, p. 48.) At a follow-up visit on April 13, 2005, HH's mother reported that HH was experiencing choking episodes and a feeding problem. (Ex. 2, p. 49.) Dr. Chatters diagnosed HH with gastroesophageal reflux disease (GERD), and prescribed treatment with Zantac. (*Id*.)

On April 28, 2005, when HH was two months of age, Dr. Chatters reported that she was "doing well," and her developmental assessment was within normal limits. (Ex. 2, p. 50.) At this visit, HH received several vaccinations. (Ex. 2, pp. 21, 50.)

On June 6, 2005, HH's parents took her to the Children's Clinic of Southwest Louisiana, because they were concerned that HH was congested, had little appetite, and had trouble sleeping. (Ex. 2, p. 5.) Dr. Bryan Karriker diagnosed HH with a viral infection. (*Id*.) One month later, on June 23, 2005, HH had a "well visit" at the same clinic, where it was noted that she was developing normally, exhibiting "coos, kicks, smiles." (Ex. 2, p. 33.) On June 29, 2005, HH received several more vaccinations. (Ex. 2, pp. 21, 41.)

No irregularities were noted at HH's check-up at six months of age, on August 26, 2005. (Ex. 2, p. 6.) HH received DTaP (diphtheria, tetanus, acellular pertussis), Hepatitis B, IPV (inactivated polio vaccine), and Prevnar (pneumococcal) vaccinations. (Ex. 2, p. 21.)

On September 7, 2005, HH's mother brought her to the Children's Clinic again, and reported that HH had been suffering from congestion, runny nose, and fever, off and on for the previous 1½ weeks. (Ex. 2, p. 9.) It was also noted that HH had exhibited increased sleeping and decreased appetite. (*Id*.) The pediatrician diagnosed right otitis media (ear infection) and an upper respiratory infection. (*Id*.) At a follow-up visit one month later, on October 7, 2005, HH was diagnosed with acute sinusitis and prescribed an antibiotic treatment. (Ex. 2, p. 11.)

HH and her mother returned to the pediatrician's office on December 21, 2005, with a renewed complaint of "earache." (Ex. 2, p. 13.) HH was diagnosed with an upper respiratory infection and "otalgia." (*Id*.) However, during this visit, the pediatrician also indicated that HH's development should be monitored, because she was not "scooting" or "crawling." (*Id*.) It was also noted that HH was able to express a "few words." (*Id*.)

On January 10, 2006, the pediatrician performed a general check-up and noted HH's ongoing constipation. (Ex. 2, p 14.) He also noted significant "developmental concerns" about HH, such as "not sitting alone, only reaches for things occasionally, slow response if any to stimuli." (*Id*.) HH reportedly remained lethargic after napping, had a slow facial expression, and would not get on her hands and knees. (*Id*.) She also exhibited esotropia of the right eye. (*Id*.) The physician recorded his diagnoses as "developmental delay" and "esotropia." (*Id*.) He referred HH to an ophthalmologist, and ordered an MRI of the brain, a CMP (comprehensive metabolic panel) test, and other testing. (*Id*.) More notes of the visit indicated that HH's mother had already contacted "Early Steps," an early childhood disability program. (Ex. 2, p. 15.) The CMP and chromosomal test results for HH were normal. (Ex. 2, pp. 4, 24.) The MRI report indicated "negative" for any abnormalities. (Ex. 2, pp. 26-27.) On January 23, 2006, Dr. Karriker requested an EEG examination for HH, due to "developmental delay" and to rule out "absence" seizures. (Ex. 2, p. 35.)

HH was evaluated by Dr. Duane Superneau, a geneticist, on January 26, 2006. (Ex. 6, p. 1.) Dr. Superneau diagnosed HH with neurodevelopmental delay, but he could not identify any specific syndrome. (*Id*., pp. 1-2.*)* The parents reported to him that "by nine months of age" they had realized HH was behind in her development. (Ex. 6, p. 1.) Further, HH's parents were "worried about her losing skills." (*Id*.) At this time, Dr. Superneau noted that HH's "head circumference is at the lower limits of normal and outside the range of expected for family average." (Ex. 6, p. 2.) Dr. Superneau recorded the following assessment: "Neurodevelopmental delay; [Rule out] seizure disorder; Relative microcephaly." (*Id.*) He also recommended that HH receive an EEG test and be examined by a neurologist, to determine "whether the spells she seems to exhibit reflect a seizure disorder." (*Id*.) The EEG result was normal. (Ex. 14, p. 8.)

On January 27, 2006, HH was seen again by Dr. Karriker because she was "not crying, not eating." (Ex. 2, p. 16.) Dr. Karriker noted that HH's "eyes [were] dazing off," that she was "always tired," that she would not sit up by herself, would not crawl, would not grab things and that she was experiencing a decrease in appetite. (*Id*.)

On February 23, 2006, when HH was 12 months old, she was examined by Dr. Stephanie Cave. (Ex. 7, p. 53.) Based on her initial discussion with a parent, Dr. Cave recorded that HH had "stopped progressing" at six to seven months of age, then "regressed" at ten months of age. (Ex. 7, p. 60.) Dr. Cave diagnosed HH's condition as: 1) hypotonia, 2) cow milk intolerance, 3) constipation, and 4) developmental delay. (Ex. 7, p. 53.) Dr. Cave also made a series of recommendations concerning medicines, nutrition, liver detoxification, and laboratory testing. (*Id*., pp. 54-59.)

Dr. Robert P. Cruse, a pediatric neurologist, evaluated HH on June 22, 2006. (Ex. 14, pp. 7-9.) Dr. Cruse recorded the history of HH's condition, as provided by her parents, including their belief that HH suffered seizures ("spells of getting tense") shortly after her birth. (*Id*., p. 7.) The parents felt that HH was "normal" for the first six months of life. (*Id*.) At about that time, "she received a hepatitis immunization, and the mother reports that two hours after the shot she had a seizure which was described as staring and unresponsiveness. From that time on, she was felt to show regression[7] and/or lack of progression in her development." (*Id*.)

The neurological examination of HH by Dr. Cruse had an outcome characterized as "abnormal" in many ways. (Ex. 14, p. 9.) Dr. Cruse considered the possibility that HH had a combined central and peripheral nervous system disorder based on her symptom presentation. (*Id*.) He described HH's series of head circumference measurements, from birth until one year of age, which showed a gradually slowing rate of growth, and by one year of age resulted in a head size below the 2nd percentile. (*Id*., pp. 8-9.) He summarized the following impressions:

> Abnormal neurological exam. Microcephaly with head circumference below the 2nd percentile. Of concern is that her head circumference has decreased over time and crossed percentile lines; it was initially at the 50th percentile up to about 3 *months of life* * * *.

[7] I note that the alleged "regression" was the parents' opinion, not the opinion of Dr. Cruse. His later comment regarding regression involved a "regression in head circumference." (Ex. 14, p. 9.)

(Ex. 14, p. 9, emphasis added.) Thus, Dr. Cruse indicated that soon after *age 3 months* HH had a declining head growth which indicated a neurologic disorder.

On July 19, 2006, HH received an electromyography (EMG) and a nerve conduction test, which revealed no evidence of peripheral neuropathy or a myopathy. (Ex. 14, p. 101.) On July 20, 2006, Petitioners wanted to discuss growth hormones for HH with Dr. Karriker. (*Id*., p. 40.)

On August 9, 2006, Mr. Hardy reported to Dr. Cave's staff that HH had been hospitalized for an esophageal perforation caused by swallowing broken glass. (Ex. 7, p. 65; Ex. 14, p. 23.) Dr. Karriker noted this recent history of "esophageal perforation" when he re-examined her on August 14, 2006. (Ex. 14, p. 198.) She had delayed motor development as well as hypotonic reflexes. (*Id*.) Dr. Karriker noted two chronic ailments, developmental delays and microcephaly. (*Id*.) On September 21, 2006, Dr. Karriker examined HH again, noted her developmental delays and the commencement of speech and physical therapy. (Ex. 14, p. 3.)

In a letter to Dr. Karriker dated March 19, 2007, Dr. Superneau stated that HH's symptoms did not suggest a diagnosis of Rett Syndrome. (Ex. 14, pp. 10-11.) A genomic microarray analysis was performed and the results were normal, so no specific genetic syndrome had been identified. (*Id*., p. 11.) He commented that the "microcephaly [abnormally small head size] in [HH] has been present from prior to the immunizations which have been implicated by the mother as potentially complicating [HH's] clinical course." (*Id*.) Dr. Superneau concluded that HH's "physical findings suggested the problems existed from birth, consistent with the majority of problems of this type." (*Id*.)

Six months later, on October 27, 2007, Dr. Superneau sent another letter to Dr. Karriker. (Ex. 14, pp. 12-13.) Dr. Superneau maintained that HH had not demonstrated actual regression, but he noted that HH's mother remained concerned that HH had regressed. (*Id*., p. 12.) He suggested that HH's family seek out a second opinion from another clinical geneticist. (*Id*.)

A multidisciplinary evaluation of HH's educational needs was completed on February 18, 2008, by the Calcasieu Parish School system. (Ex. 22, pp. 1-22.) As part of that process, a psychologist administered the Autism Diagnostic Observation Schedule (ADOS) to HH, and concluded that she fell within the category of "autism" (*i.e.*, Autistic Spectrum Disorder.) (*Id*., pp. 1, 8, 21.)

IV

PROCEDURAL HISTORY

A. The initial Petition

The initial Petition in this case was filed on February 25, 2008. The petition was accompanied by some of HH's medical records and medical literature.[8] The Petition alleged that the DTaP and Prevnar shots of August 26, 2005,[9] either in whole or in part, "caused in

[8] Petitioners filed Exhibits 1, 2, and 5 through 9.

[9] The Petition, at paragraph 23, mistakenly stated that those vaccinations occurred on August 26, 2006.

fact" HH's encephalopathic condition, esotropia of the right eye, fever, seizure disorder, otitis media, and resulting neurodevelopmental delay. (Petition, ¶ 23) The Petition alleged that alternatively, those vaccinations significantly aggravated a pre-existing condition, causing it to worsen. (*Id*., ¶ 21.) The Petition did not contain any allegation that HH suffered from a "Table Injury."

On April 3 and October 23, 2008, the special master then presiding over this case, Special Master Gary Golkiewicz, ordered Petitioners to file certain medical records and affidavits in support of their claim. These items were not filed, but instead on November 18, 2008, Petitioners filed a notification of their intent to remain in the Program and a proposal to transfer the case into the Omnibus Autism Proceeding ("OAP"). On December 16, 2008, the special master issued an order which directed Petitioners to show cause why the case should not be dismissed for failure to prosecute.

Petitioners filed various documents in March 2009.[10] Among those documents, Petitioners included an educational assessment that clearly indicates HH's diagnosis of "autism." (Ex. 22, pp. 1, 21.) On July 6, 2009, Petitioners filed an affidavit by Stephanie Cave, M.D., which supported their claim of vaccine-induced injury. (Ex. 10.) Thereafter, the special master authorized transfer of this case to the OAP. (Order, filed Sept. 10, 2009.) For the next 22 months, there was no docket activity in this case, while litigation in the OAP "test cases" advanced toward completion. (*See* Section II, above.)

B. The Amended Petition

After the conclusion of the autism "test cases," Special Master Golkiewicz issued an order directing the Petitioners in this case to file an Amended Petition that clearly explained their theory of vaccine causation and included all of the documents required by § 300aa-11(c). (Order, filed June 28, 2011.) On July 29, 2011, Petitioners filed an Amended Petition containing the same claims they had alleged in their initial Petition, with only one change. Based on the medical opinion of Dr. Cave, the Amended Petition added a new allegation that HH suffered from a "mitochondrial disorder." (Amended Petition, ¶ 22.)[11]

Attached to the Amended Petition was an undated letter from Dr. Cave addressed "To Whom It May Concern." (Amended Petition, pp.7-8, hereinafter "Dr. Cave's First Letter").[12] In that letter, Dr. Cave stated that

> [HH] experienced seizures two hours after receiving the DTaP, Hepatitis B, IPV, and Prevnar vaccines on August 26, 2005, at six (6) months of age. Her neurological problems progressed to tonic, clonic movements at age (8) months of

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[10] Petitioners filed Exhibits 3, 4, and 11 through 22.

[11] It should be noted that the Amended Petition alleges the existence of a mitochondrial *disorder*, while Petitioners' expert Dr. Cave has repeatedly described an alleged mitochondrial *dysfunction*.

[12] Dr. Cave's First Letter is not designated as an expert report, nor is it identified on the court's electronic docket. The original paper document is marked "Ex. 10(a)." However, that same number was used again to identify a document filed on January 16, 2012; that is, "Expert Report of Dr. Cave, Ex. 10-a." That *latter* document, filed on January 16, 2012, will be cited in this Decision as "Ex. 10-a."

age, to crossed eyes at ten (10) months of age. By eleven (11) months, she was unresponsive without eye contact, and would not cry.

(Dr. Cave's First Letter.) Dr. Cave described HH's various symptoms that appeared during the two years following August 2005, including "gross motor delay, fine motor delay, poor response to sensory stimulation, weak proximal and distal musculature, delayed self care and delayed balance." (*Id.*) She opined that HH's "[l]aboratory abnormalities showed mitochondrial dysfunction, which would explain the hypotonia and muscle weakness, and deficiencies in vitamin B12, B6 and glutathione." (*Id.*) She contended that children with mitochondrial dysfunction "are prone to patterns of regression if they have infections or immunizations." (*Id.*) Dr. Cave concluded that HH "more likely than not became encephalopathic as a result of the August 26, 2005 vaccinations." (*Id.*)

On August 12, 2011, this case was reassigned to the docket of Chief Special Master Patricia Campbell-Smith.

During a status conference held on October 5, 2011, Respondent's counsel indicated that a review of the records did not disclose any support for the allegation that HH had a mitochondrial disorder, or suffered any seizures. (Order, filed Oct. 6, 2011.) Following that discussion, Petitioners were ordered to supplement the record with any test results or other medical evidence that supported their allegations concerning mitochondrial disorder and seizures. (*Id.*) Further, Petitioners were specifically instructed that "any filed expert report would be expected to provide detailed, pinpoint record citations that speak directly to the factual record in this case." (*Id.*) Petitioners' counsel subsequently filed a statement acknowledging that "petitioners are unaware of any additional test results or other medical evidence of HH's mitochondrial disorder or HH's seizures other than the medical records that have previously been filed in this case." (Status Report, filed Nov. 3, 2011.)

On November 30, 2011, Petitioners filed an expert report[13] by Stephanie F. Cave, M.D., a board-certified family physician and one of HH's treating physicians. Dr. Cave's expert opinion is summarized in one sentence: "[HH's] encephalopathic condition, right eye esotropia, fever, seizures, otitis media, and developmental delay is more likely than not caused by the vaccinations she received on August 26, 2005, in particular the Hep B, DTaP and Prevnar vaccines." (Ex. 10, filed Nov. 30, 2011.) Upon review of this report, Special Master Campbell-Smith filed an Order noting that there was "a lack of documentary support for the factual allegations that were made in the expert report." (Order, filed Dec. 12, 2011.) Petitioners were directed to file a supplemental expert report from Dr. Cave that was factually supported by medical records (including exhibit numbers and specific page numbers). (*Id.*) In response, on January 16, 2012, Petitioners filed an amended supplemental report from Dr. Cave, identified as "Ex. 10-a." With a few insignificant changes, this report contained the same statements concerning encephalopathy, mitochondrial dysfunction, and seizures that were presented in Dr. Cave's "First Letter." However, despite the special master's orders, many of the factual allegations in Exhibit 10-a still were not accompanied by any specific citations to the filed medical records.

[13] The filing on November 30, 2011, marked as Exhibit 10 on the paper filing, is identified on the electronic docket as "Expert Report of Dr. Cave." It will be referred to as "Ex. 10."

C. Court orders requiring more evidence from Petitioners

After reviewing the filed medical records and Dr. Cave's expert report, Special Master Campbell-Smith issued a lengthy Order explaining that both the factual record and Dr. Cave's expert report fell short of establishing that the vaccines that HH received on August 26, 2005, caused her alleged encephalopathy and developmental delay. (Order, filed on March 2, 2012, p. 10.) This Order explained that Petitioners' allegations concerning an "encephalopathy" were insufficient to establish a "Table Injury," and further, there was no evidence in the medical record that HH experienced an encephalopathy following her vaccinations. (*Id*., pp. 2-3.) Also, there was "no evidentiary support for petitioners' claim that [HH] has a mitochondrial disorder or suffers from seizures." (*Id*., p. 5.)

In that order, Special Master Campbell-Smith observed that Petitioners' expert witness, Dr. Cave, had not proposed a medical theory of vaccine-related causation, and that the doctor lacked specialized education and training in genetics, neurology, and/or immunology that would give probative weight to her opinions. (Order, filed on March 2, 2012, pp. 4-5.) The Order also discussed evidence in the medical record suggesting a pre-natal origin for HH's condition. (*Id*., pp. 7-8.) Based on these and other shortcomings in Petitioners' claim, the Order concluded that "the reasonableness of moving forward is in question." (*Id*., pp. 9-10.)[14]

In light of these deficiencies in Petitioners' claim, they were ordered to file a response indicating how they intended to proceed. (*See* Order, filed March 2, 2012, p. 10; *see also* Show Cause Order, filed April 10, 2012.) In response, Petitioners filed a Status Report on May 10, 2012, suggesting that they would ask their expert to review the matter. Thereafter, another Order was issued, which again required Petitioners to show cause why the case should not be dismissed, since they "have not addressed the stated inadequacies with their supplemental expert report." (Show Cause Order, filed May 14, 2012.)

On June 27, 2012, Petitioners filed additional medical records and medical articles (Exs. 23-26), and another supplemental expert report (Ex. 10-b), with Dr. Cave's *curriculum vitae* attached. This lengthy "Second Supplemental Report" by Dr. Cave was intended to "address the issues raised by the court." (Ex. 10-b, p. 2) In that report, Dr. Cave discussed a theory of vaccine causation, and her opinions concerning mitochondrial dysfunction and alleged symptoms of encephalopathy. (*Id*., pp. 4-8.) Within the context of this discussion, Dr. Cave argued that "the case could be considered a Vaccine Table Case." (*Id*., p. 14.)

D. Moving forward toward a trial

Petitioners filed a Status Report on June 28, 2012, indicating their desire to proceed to an evidentiary hearing. On July 6, 2012, Special Master Campbell-Smith issued an Order stating that while Petitioners' recent filings were responsive to the recent show cause order, the special master's concerns about various issues still persisted. Nonetheless, in preparation for a hearing,

[14] While it is not relevant to this Decision, I note that Special Master Campbell-Smith issued two Orders clearly questioning whether an award of attorneys' fees and costs for further litigation of this matter might be considered "unreasonable." (Order, filed March 2, 2012, p. 9; Order, filed April 8, 2013, p. 5.)

Respondent was ordered to file a "Rule 4 report" and an expert report. (Order, filed July 6, 2012.) On October 5, 2012, Respondent filed a "Rule 4 report," along with the expert opinion of Dr. Max Wiznitzer, M.D. (Exhibit A.)[15]

On April 3, 2013, counsel for both parties participated in a status conference to discuss how this case would proceed. Special Master Campbell-Smith filed another lengthy Order reiterating that the factual allegations made by Dr. Cave concerning the existence of symptoms of a Table encephalopathy or seizures could not be confirmed by contemporaneous medical records. (Order, filed April 8, 2013, pp. 1-3.) That Order noted that only the retrospective accounts of the parents supported Dr. Cave's recorded history of HH's condition, and the Special Master declined to base her factual determinations on those unsubstantiated claims. (*Id*.) The Order noted that the parties' experts "disagreed entirely" with regard to evidence of mitochondrial dysfunction, and a factual determination could be made only if Petitioners provided a fuller explanation of their theory linking HH's injury to mitochondrial dysfunction and vaccines. (*Id*., p. 3-4.) The Order also noted that Dr. Cave possessed far less of the specialized training needed to offer "an opinion on the neurological aspects of this matter," compared to a pediatric neurologist, such as respondent's witness, Dr. Wiznitzer. (*Id*., p. 5.)

On April 9, 2013, this case was reassigned to my docket.[16]

Petitioners filed a supplemental report from Dr. Cave, on May 29, 2013, acknowledging that Petitioners could not support a finding that HH suffered a Table encephalopathy, or that she had suffered post-vaccination seizures, without relying on the statements of HH's parents. (Ex. 27, p. 1.) Following these concessions, Dr. Cave's supplemental report asserted that HH suffered from a mitochondrial dysfunction, which allegedly made her vulnerable to injury due to the effects of aluminum, a vaccine adjuvant. (*Id*., pp. 4-5.)[17]

Petitioners indicated that they wanted to move forward with an evidentiary hearing. (Status Report, filed June 26, 2013.) During a status conference on July 2, 2013, Petitioners reiterated their intention to proceed to a trial consisting of expert testimony, but stated that it would not be necessary to present their own personal testimony. (Order, filed July 8, 2013.)

Pursuant to instructions from the court, Respondent filed a Pre-Hearing Brief on January 10, 2014, and Petitioners filed a Pre-Hearing Brief on January 14, 2014. An evidentiary hearing featuring testimony only from the expert witnesses (Dr. Cave and Dr. Wiznitzer) occurred on February 7, 2014. The transcript of those proceedings became available on March 11, 2014. (*See* Transcript of Proceedings ("Tr.").) Petitioners filed their Post-Hearing Brief on September 8, 2014; and Respondent filed a Post-Hearing Brief on November 21, 2014. Petitioners had the opportunity to file a reply brief, but did not do so.

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[15] On October 5, 2012, Respondent filed Exhibits A through E, followed by Exhibit F on February 4, 2014. I will refer to these items as Exs. A, B, C, etc.

[16] This reassignment was due to the imminent appointment of Special Master Campbell-Smith as a Judge of this court.

[17] Dr. Cave stated, "The patterns of [HH's] developmental delay may have been determined by genetics or prenatally determined, but it is *possible* that mitochondrial dysfunction did either exacerbate or increase the severity of the delay." (Ex. 27, p. 4, emphasis added.)

V

SUMMARY OF EXPERT WITNESSES' CREDENTIALS AND OPINIONS

At this point, I will briefly summarize both the qualifications and the opinions of the expert witnesses.

A. Petitioners' expert -- Dr. Stephanie F. Cave

Stephanie F. Cave, M.D., graduated from Louisiana State University ("L.S.U.") in 1966, with a B.S. degree in medical technology, then served as a medical technologist at the Ochsner Foundation Hospital. (Ex. 29, pp. 1-2.) From 1972 to 1979, Dr. Cave taught clinical chemistry, medical mycology, and hematology at the Department of Allied Health of L.S.U. (*Id*., p. 2.) She received a M.S. degree in clinical chemistry from L.S.U. in 1978. (*Id*.)

In 1983, Dr. Cave received her medical degree from the L.S.U. School of Medicine. (Ex. 29, p. 1.) Dr. Cave performed her medical internship and residency in family medicine, between 1983 and 1986, at the Earl K. Long Memorial Hospital, where she served as chief resident in 1986. (*Id.*) She served as a preceptor at the L.S.U. Department of Family Medicine from 1986 until 2003. (*Id*.) Dr. Cave was certified by the American Board of Family Practice in 1986, and re-certified repeatedly, most recently in 2011. (*Id*.)

In 1986, Dr. Cave commenced a private practice in "Family Medicine/Integrative Medicine," which she continues to the present. (Ex. 29, p. 2.) That practice specializes in children with developmental delays, and Dr. Cave states that over the past decade, she has participated in treating over 10,000 children with autism. (*Id*., p. 1; Tr. 8, 40.) She currently maintains hospital privileges at Our Lady of the Lake Hospital and Women's Hospital in Baton Rouge. (Tr. 44.)

As part of her specialized practice, Dr. Cave has delivered a multitude of professional presentations concerning autism and immunizations, throughout the United States and internationally. (Ex. 29, pp. 3-6.) She has written or co-authored four articles addressing that topic, and a book entitled *What Your Doctor May Not Tell You About Children's Vaccinations*.[18] (Ex. 29, p. 6; Tr. 8.) She has testified before the U.S. House Committee on Governmental Reform regarding mercury in vaccines, and before a Louisiana state legislative committee regarding the safety of the MMR vaccine. (*Id*.)

Dr. Cave is the mother of Petitioners' counsel, Michael L. Cave. (Tr. 40.)

B. Summary of opinion of Petitioners' expert

On November 30, 2011, Petitioners filed an expert report by Dr. Cave, which contended that "Children with mitochondrial dysfunction are prone to patterns of regression if they have infections or immunizations," and that "[HH] is such a child with mitochondrial dysfunction who experienced a seizure two hours after the vaccine series on August 26, 2005." (Ex. 10, p. 1.) Dr. Cave opined that HH "more likely than not became encephalopathic as a result of the August 26, 2005 vaccines and remains so today." (*Id*.)

[18] *What Your Doctor May Not Tell You About Children's Vaccinations* (Hachette Books 2010).

Petitioners filed a second report of Dr. Cave on January 16, 2012. That report reasserted that HH was afflicted with a "mitochondrial dysfunction," but did not include any references to "seizures." (Ex. 10-a.) Rather, it asserted that, according to reports by her parents, HH suffered a "regression in development" following the vaccinations of August 26, 2005. (Ex. 10-a, p. 2.) Dr. Cave observed that "vaccines could offer environmental triggers that induce inflammation and immune dysfunction in the children with mitochondrial dysfunction." (*Id*.) Dr. Cave concluded that HH "more likely than not became encephalopathic and regressed developmentally" as a result of those vaccines. (*Id*.)

On June 27, 2012, Petitioners filed another, more extensive version of Dr. Cave's opinion, which contended that HH "suffered an acute encephalopathy following the vaccines given on August 26, 2005," and that her case "could be considered a Vaccine Table case." (Ex. 10-b, p. 13.) Dr. Cave contended that, based on parental recollections, HH suffered seizure-like symptoms soon after her vaccinations of August 26, 2005. (*Id*., p. 7.) Dr. Cave also argued that HH had a "mitochondrial dysfunction" that made her likely to suffer regression in response to immunizations. (*Id*., pp. 4-6, 14.) She supported her diagnosis of mitochondrial dysfunction by citing HH's laboratory test results that allegedly showed aberrant levels of various metabolites. (*Id*., pp. 5-6.) Dr. Cave argued that these test results, along with a re-analysis of HH's symptoms, fulfilled or exceeded all of the factors emphasized in a seminal study of mitochondrial disease, published by Morava, et al.[19] (*Id*., pp. 5-6.) Dr. Cave disagreed with notations by HH's treating physicians (Drs. Superneau and Cruse) that the history of HH's rate of head growth indicated onset of HH's condition before she received the vaccinations at issue here. (*Id.*, pp. 7-9.) These treating physicians, she argued, had miscalculated HH's rate of head growth during infancy. (*Id.*)

Thereafter, in response to an order from the court, Dr. Cave prepared a supplemental report, which was filed on May 29, 2014. (Ex. 27.) That report acknowledged that Petitioners could not support a finding that HH suffered from a "Table encephalopathy" based on the medical records, without relying exclusively on the recollections of her parents. (*Id.*, p. 1.) Likewise, Dr. Cave conceded that Petitioners are unable to demonstrate that HH experienced seizures following the vaccinations of August 26, 2005, except by relying entirely on parental statements. (*Id*.)

Instead, Dr. Cave reviewed various laboratory test results and comments recorded in the medical records that allegedly support her contention that HH suffered from mitochondrial dysfunction. (Ex. 27, pp. 1-4.) She also stated that HH possessed two genetic mutations that allegedly decreased her ability to detoxify neurotoxic adjuvants contained in vaccines (such as aluminum), which allegedly increased "oxidative stress" on her central nervous system. (*Id*., p. 5.) Dr. Cave opined that "[t]he patterns of [HH's] developmental delay may have been determined by genetics or prenatally determined, but it is *possible* that the mitochondrial dysfunction did either exacerbate or increase the severity of the delay." (*Id.*, p. 4, emphasis added.)

Finally, Dr. Cave concluded that her "explanation of vaccine contents, the effect of immunization on a child with mitochondrial dysfunction, the deleterious effects of

[19] E. Morava, et al., *Mitochondrial Disease Criteria: Diagnostic Applications in Children*, 67 Neurology 1823-26 (2006), filed as Respondent's Ex. C, on October 5, 2012.

malfunctioning mitochondria in the development of the brain of a child and the showing of a proximate temporal relationship between the vaccination and the injury satisfy the ***Althen*** criteria in this case." (Ex. 27, p. 7.) She concluded by asserting that the "DTaP vaccine" of August 26, 2005, "caused the injury" to HH. (*Id*.)

Dr. Cave's testimony during the evidentiary hearing on February 7, 2014, incorporated some but not all aspects of her four written reports. During the hearing, Dr. Cave relied chiefly upon her understanding that HH suffered a severe adverse event during the 24 hours after her August 2005 vaccinations, and that HH had a mitochondrial dysfunction that made her susceptible to injury by the vaccines.

C. Respondent's expert -- Dr. Max Wiznitzer

Max Wiznitzer, M.D., received his B.S. degree in medical education in 1975, and a medical degree in 1977, both from Northwestern University. (Ex. B, p. 1; Tr. 66-67.) He completed his residency in pediatrics, in 1980, at the Children's Hospital Medical Center in Cincinnati, Ohio. (*Id.*) He completed a one-year fellowship at the Cincinnati Center for Developmental Disorders; a three-year fellowship in pediatric neurology at the Children's Hospital of Philadelphia; and a two-year fellowship at the Albert Einstein College of Medicine in New York, studying higher cortical functions. (Ex. B, pp. 1-2.)

Dr. Wiznitzer has received appointments to practice at several hospitals for various lengths of time, including at the Department of Neurology of Montefiore Medical Center in New York; at the Department of Neurology at Bronx Municipal Hospital Center; and at Rainbow Babies and Children's Hospital in Cleveland. (Ex. B, p. 2.) He has also served as a consultant in pediatrics and neurology at several other hospitals. Dr. Wiznitzer has also maintained a continuous practice as an associate pediatrician and associate neurologist at University Hospitals of Cleveland, since 1986. (*Id*.) He sees approximately 200 to 300 children per month, the vast majority of them exhibiting developmental disorders, and more than 25% of them diagnosed with autism. (Tr. 71.)

At Rainbow Babies and Children's Hospital, in Cleveland, Dr. Wiznitzer served as Co-Director of the Rainbow Autism Center in 1991; as Chief of the Division of Pediatric Neurology from 1992 to 1995; and, concurrently, as the Director of the Rainbow Autism Center, from 1992 through 2010. (Ex. B, p. 3.)

Dr. Wiznitzer is certified by the American Board of Pediatrics. (Ex. B, p. 5; Tr. 67.) He also received certification from the American Board of Psychiatry and Neurology, with a special qualification in Child Neurology. (Ex. B, p. 5.) In 2004, the American Board of Psychiatry and Neurology certified his competence in Neurodevelopmental Disabilities. (*Id*.) He maintains a license to practice medicine in Ohio, Pennsylvania and New York. (*Id*.)

Concurrent with his hospital practice, Dr. Wiznitzer has instructed medical students, residents and attending doctors since 1984, when he was an instructor at the Albert Einstein College of Medicine. (Tr. 67.) Most notably, he has taught pediatrics and neurology since 1986 at the Case Western Reserve University School of Medicine. (Tr. 65-66; Ex. B, pp. 9-11.)

Dr. Wiznitzer has performed medical research funded by grants from the National Institutes of Health, and various university medical programs. (Ex. B, p. 4.) He has been a

reviewer of articles for many medical journals, most notably for Pediatric Neurology, Lancet Neurology, and the Journal of Child Neurology, where he also served on the editorial boards. (*Id*., p. 6.) He currently serves on a multitude of medical advisory groups at the local, state, and national levels. (*Id*., pp. 6-9.) Dr. Wiznitzer has published fifty-eight medical articles, eleven book chapters, and fifty-five abstracts. (*Id*., pp. 13-23.) He has also presented numerous lectures at the invitation of community organizations concerning childhood developmental disorders, primarily on the subject of autism. (*Id*., pp. 23-55.)

D. Summary of opinion of Respondent's expert

The opinion of Respondent's expert was first set forth in Exhibit A, filed on October 5, 2012. Dr. Wiznitzer opined that the first symptoms of HH's neurodevelopmental disorder occurred *prior* to her vaccinations of August 2005. (Ex. A, pp. 12-13.)

Dr. Wiznitzer rejected Petitioners' allegation that HH suffered a "Table Injury encephalopathy," because she did not exhibit symptoms of a "decreased level of consciousness" lasting for more than 24 hours, during the 72 hours following the vaccinations of August 26, 2005. (Ex. A, p. 10.) Further, he noted that HH's contemporaneous medical records make no mention of encephalopathic changes in her level of consciousness after her August vaccinations, but describe only the typical symptoms of upper respiratory infection and otitis media. (*Id*.)

Likewise, Dr. Wiznitzer considered and rejected Petitioners' claims that HH suffered seizures shortly after her August 2005 vaccinations, or in the months thereafter. (Ex. A, p. 13.) He noted that multiple physicians, including pediatric neurologists and a pediatric epileptologist (Dr. Wilfong) examined HH, but none of them diagnosed a seizure disorder or prescribed anticonvulsant medications. (*Id*.)

Dr. Wiznitzer contended that HH has *not* presented the symptoms of a mitochondrial disorder or dysfunction, based on the criteria set forth in the Morava article. (Ex. A, pp. 10-12, referring to the article filed as Ex. C.) He explained that Dr. Cave misinterpreted HH's medical history with regard to many of those criteria, and greatly exceeded the scoring allowed pursuant to the Morava criteria. (*Id.*, p. 12.) While Dr. Cave's method of assigning points produced a score of "14," Dr. Wiznitzer's recalculation of those points produced a score of "1," which he interpreted as "mitochondrial disorder unlikely." (*Id*.)

Dr. Wiznitzer's testimony at the hearing on February 7, 2014, was consistent with, and further explained, the opinions set forth in his written expert report. Based on his own examination of HH's medical record, Dr. Wiznitzer concluded that "the August 26th, 2005, vaccination did not cause or significantly aggravate her present neurologic condition." (Tr. 71.)

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(B) of this Decision), Petitioners and Dr. Cave were not even clear as to *what vaccinations* they allege to have harmed HH. Further, some of the allegations set forth in Petitioners' Amended Petition appear to have been *abandoned* by the Petitioners. For example, Petitioners at one time alleged that HH's esotropia

of the right eye and her otitis media (ear infection) were "caused-in-fact" by her DTaP and Prevnar vaccinations. (Amended Petition, p. 1.) Petitioners' expert, Dr. Cave, initially supported those allegations (Ex. 10), but did not substantiate those particular claims, or even mention them, in her several subsequent expert reports or her trial testimony. Further, the allegations stated by Petitioners in their Post-Hearing Memorandum do not always correspond to Dr. Cave's testimony.

This Decision, accordingly, will be organized according to the two general theories of vaccine causation which *seem* to have been advocated by Petitioners, at the evidentiary hearing and in their Post-Hearing Memorandum. Specifically, the two primary issues to be decided here are: 1) whether HH suffered a "Table Injury encephalopathy;" and 2) whether, as Petitioners alternatively argue, HH's vaccinations of August 26, 2005, played any role in "causing-in-fact" her neurodevelopmental disorder, *either* by "initially causing," or by "significantly aggravating," that disorder.

VII

RESPONDENT'S EXPERT WAS FAR MORE PERSUASIVE IN GENERAL THAN PETITIONERS' EXPERT

For all of the reasons set forth in this section and the sections of this Decision below, I conclude that Petitioners have *failed* to demonstrate that it is "more probable than not" either that HH suffered a "Table Injury encephalopathy," or that HH's vaccinations of August 26, 2005, played *any* role in initially causing, or aggravating, her neurodevelopmental disorder. And the first of the reasons for this conclusion is simply that I found Respondent's expert, Dr. Wiznitzer, to be far more persuasive than the expert upon whom Petitioners relied, Dr. Cave.

A. Qualifications

Dr. Wiznitzer regularly diagnoses and treats children with mitochondrial disorders as part of his everyday clinical practice, in conjunction with mitochondrial and metabolism experts. (Tr. 70.) He received training concerning mitochondrial disorders and neurotoxicology as part of his training for board certifications in both pediatric neurology and neurodevelopmental disorders. (*Id*.)

Dr. Wiznitzer's clinical practice and academic career are focused on children's neurodevelopmental disorders, particularly Autism Spectrum Disorders (ASDs). He devotes approximately 36 hours each week to evaluating and treating children with neurological illnesses such as ASD, seizure disorders, and developmental delay. (Tr. 68.) More than 25% of his regular caseload of 200 to 300 children per month are diagnosed with ASD. (Tr. 71.) Under the auspices of the National Institutes of Health, he has participated in major research projects concerning ASDs. (Ex. B, p. 4.) He has served on the editorial boards of medical journals dedicated to childhood neurological disorders, such as *Pediatric Neurology*, *Lancet Neurology*, and the *Journal of Child Neurology*, and published numerous articles about ASDs in these and other prominent medical journals. (*Id*., p. 6; *see also* Ex. B, pp. 13-17.) He is the author of several medical textbook chapters devoted to ASDs and related disorders. At the Rainbow Babies and Children's Hospital in Cleveland, Dr. Wiznitzer was Director of the Rainbow Autism

Center, from 1992 to 2010. (Ex. B, p. 3.) For all these reasons, he is extremely well qualified to offer an opinion about the matters under consideration here.

In contrast with Dr. Wiznitzer's strong credentials, Dr. Cave lacks strong expert qualifications to opine about the complex issues presented in this case. Beginning with a status conference on October 5, 2011, Petitioners were advised by Special Master Campbell-Smith that Dr. Cave lacked the expertise to be appropriately responsive to Respondent's expert. (Order, filed Oct. 6, 2011.) Five months later, Petitioners were reminded that less evidentiary weight would be afforded to the opinion of an expert such as Dr. Cave, who did not have specialized training as a developmental-behavioral pediatrician, a geneticist, a neurologist, or an immunologist. (Order, filed Mar. 3, 2012, pp. 3-4.) On April 4, 2013, Special Master Campbell-Smith considered Dr. Cave's qualifications as a family practitioner, and commented that - -

> [A] competent medical doctor may be successful in treating the medical needs of children with developmental delays, like [HH], without possessing the expertise to put forward the type of expert opinion that satisfies the *Althen* criteria. Respondent has engaged a pediatric neurologist to opine in this matter, and such witness will most likely bring a more expansive set of skills, education and expertise to bear when offering an opinion on the neurological aspects of this matter.

(Order, filed April 8, 2013, p. 5.) Special Master Campbell-Smith's comparison of the qualifications of the competing experts in this case proved to be quite accurate.[20]

To be sure, Dr. Cave is a physician board-certified in the area of family practice, who, to her credit in this regard, has spent much of her lengthy medical career engaged in treating children with autism spectrum disorders. (*E.g.*, Tr. 8, 40.) However, Dr. Wiznitzer has far superior *academic* credentials and *specialized medical training* qualifications in the area of ASDs and ASD diagnosis.

Thus, in terms of *specialized medical training* relevant to ASDs, Dr. Wiznitzer has the much superior resume.

B. Superior ability of Dr. Wiznitzer to explain his opinion

In addition to the vast gap between Dr. Cave and Respondent's expert in *qualifications*, there was an even greater gap in the experts' *ability to explain* their opinions. The written reports and hearing testimony of Wiznitzer seemed to me to be coherent and logical. In contrast, the written reports of Dr. Cave were not well explained and contained significant factual errors, while her hearing testimony was often poorly explained, self-contradictory, and less than logical.

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[20] In *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. May 21, 2014) the presiding special master (Vowell) issued a warning order very similar to the Orders filed in this case. On February 15, 2012, the petitioners in *Blake* were advised concerning "Dr. Cave's lack of expertise in the relevant specialties of developmental pediatrics, pediatric neurology, or pediatric immunology," *Id*. at *3. Eventually, eligibility to an award was denied in *Blake*, largely due to Dr. Cave's lack of qualifications to opine as petitioners' expert. *Id*. at *15.

In this regard, I note that, as suggested above, both Dr. Cave and Petitioners' counsel never even made it completely clear exactly what they are arguing in this case. For example, they were inconsistent even in stating *which vaccinations* they believe to have harmed HH. In Dr. Cave's first, second, and third written expert reports, she seems to indicate only that the "vaccinations" of August 26, 2005, harmed HH, without specifying *which* of those vaccinations harmed HH. (Ex. 10, Ex. 10-a, Ex. 10-b.) Then, in her fourth written report she pointed only to the "DTaP vaccine" as the alleged agent of harm. (Ex. 27, p. 7.) But in her trial testimony, Dr. Cave merely referred to all of the vaccines received by HH on August 26, 2005, and seemed to imply, without ever clearly stating, that alleged unspecified toxins in those "vaccines" harmed HH. (*E.g.*, Tr. 14-15.)

To add to the confusion, in both Petitioners' initial Petition (p. 1) and their Amended Petition (p. 1), Petitioners' counsel pointed only to the *DTaP* and *Prevnar* vaccinations as allegedly causing harm. And their Pre-Hearing Memorandum (filed on January 14, 2014) was confused, at one time pointing simply to the "August 26, 2005 vaccines" (p. 7, line 8), but later on the same page pointing only to the DTaP vaccination (p. 7, line 20). Their Post-Hearing Memorandum again was unclear, not specifying at all *what vaccines* allegedly caused injury to HH.

Further, Dr. Cave seemed at times to be *very unsure* of her "causation" conclusion. For example, in her expert report, Dr. Cave stated that "[t]he patterns of [HH's] developmental delay may have been determined by genetics or prenatally determined, but it is *possible* that mitochondrial dysfunction did either exacerbate or increase the severity of the delay." (Ex. 27, p. 4, emphasis added.) Thus, according to Dr. Cave herself, it is only *possible* that a mitochondrial dysfunction contributed to HH's condition. During the hearing Dr. Cave also testified that--

> *[i]t's not really clear* whether or not [HH] had a genetic problem or whether it was something that was caused or exacerbated by an environmental toxin, but the – in the DTaP vaccination that she received on August 26th, 2005, the aluminum that was used as an adjuvant is actually to prolong the immune stimulation for the best result, and this would not be something that would be tolerated by a child with mitochondrial dysfunction, because it increases oxidative stress.

(Tr. 33-34, emphasis added.) Thus, Dr. Cave admitted that "it's not really clear" what caused HH's condition. These ambiguous statements do not constitute a persuasive expert opinion that HH, more likely than not, suffered an injury that was caused by one or more vaccinations. Rather, Dr. Cave's descriptions of her own theory of causation, in the quotations above, acknowledged her *inability* to make a clear attribution of causation, and this acknowledgment was then followed by her speculation about what *might be possible*.

Moreover, as will be detailed below (see section IX(D) of this Decision), while Dr. Cave relied on her (erroneous) belief that HH suffered from a "mitochondrial dysfunction," Dr. Cave made no serious attempt to explain why such a circumstance would therefore tend to show that *vaccinations* either initially caused or aggravated HH's neurodevelopmental disorder. Dr. Cave did not present any *explanation* of her theory that the presence of "mitochondrial dysfunction" would make an infant more susceptible to the unspecified "toxins" in unspecified vaccines. She simply did not explain her theory in this regard in any detail. Dr. Cave merely seemed to *assume* that the presence of "mitochondrial dysfunction" would render an infant more susceptible to

purported vaccine-related damage. But she presented no persuasive reason why I should adopt such an assumption.

C. Dr. Cave's reliance on alleged occurrences <u>not</u> substantiated by the medical records

Another very important difference between Dr. Cave and Dr. Wiznitzer was the huge gap in the two experts' *ability to base* their opinions on HH's *medical records*. The written report and hearing testimony of Dr. Wiznitzer was well grounded in HH's medical records, while Dr. Cave's opinion was *contradicted* by those medical records.

In this regard, I note that Dr. Cave's early reports in this case were *not* based on HH's medical records; rather, they were based on the *parents' retrospective accounts* of events and symptoms that were *not* reported in HH's medical records. As noted above, a prior presiding special master in this case, Special Master Campbell-Smith, ordered Petitioners to file supplementary expert reports with specific citations to the medical records, in order to substantiate Dr. Cave's allegations concerning alleged symptoms of seizures, encephalopathy, and/or "mitochondrial dysfunction," which HH may have experienced. (*See* Orders, filed on Oct. 6, 2011; Dec. 12, 2011; Mar. 2, 2012; Apr. 8, 2013.) Eventually, Dr. Cave acknowledged that she could *not* support the allegations that HH suffered a Table encephalopathy, or that she suffered post-vaccination seizures, without relying *entirely* on the statements of HH's parents. (Ex. 27, p. 1.)

The sequence of events described above is disturbing because Dr. Cave is not new to the Vaccine Program, and she had previously been advised that causation conclusions that are not based on medical records would be in grave danger of rejection for that reason. In *Berge v. HHS*, No. 08-223V, 2010 WL 3431601 (Fed. Cl. Spec. Mstr. Aug. 2, 2010), the presiding special master dismissed the case largely because, "[i]n light of Dr. Cave's report being premised upon information supplied by the parents, without discussing the medical records at all, that opinion is rejected as without factual predicate." *Id*. at *2 (citation omitted). Thus, in 2010 Dr. Cave was made aware of the necessity to substantiate her factual allegations in Vaccine Act cases by citing the medical records, but nevertheless, she failed in this regard in this case. In another case, the presiding special master observed that "[d]ue to 'a lack of documentary support for the factual allegations' in Dr. Cave's report, the special master ordered petitioners to file a supplemental report, referencing the exhibit and page number of records supporting her factual assertions." *Blake v. HHS*, No. 03-031V, 2014 WL 2769979, at *3 (Fed. Cl. Spec. Mstr. May 21, 2014), describing an order issued in that case in 2011.

In the present case, despite the criticisms of Dr. Cave in other cases in 2010 and 2011, described in the paragraph above, Petitioners' counsel filed reports by Dr. Cave containing allegations that HH had suffered seizures, a "Table encephalopathy," and developmental regression, that are *not* supported by the medical records. (*See* Ex. 10-a, filed Jan. 16, 2012.) Special Master Campbell-Smith addressed those deficiencies in detail (s*ee* Orders filed Mar. 3, 2012 and April 8, 2013), but Dr. Cave persisted in relying upon some of the same unsubstantiated factual allegations.

Thus, Dr. Cave's pattern, of repeatedly offering testimony based upon factual allegations that appear contrary to the medical records, gives me another good reason to question her credibility, in general.

More importantly, specifically in this case, Dr. Cave based her opinion, *both* as to the "Table Injury encephalopathy" that HH allegedly suffered, and as to the allegation that HH's vaccinations of August 26, 2005, "caused-in-fact" or aggravated HH's neurodevelopmental disorder, in large part on the following assumption of fact: that HH experienced a "severe adverse event," including "seizures" and a dramatic alteration in her development ("slowness, not grabbing objects, not pushing up on her arms, no attempts to crawl, poor coordination, and [poor] eye contact" - - Tr. 15) *within a day* after her vaccinations of August 26, 2005. (Ex. 10, p. 1; Tr. 15.)

However, HH's medical records *contradict* Dr. Cave's assumption that HH experienced seizures, a "severe adverse event," or a dramatic change in her development within the 24-hour period post-vaccinations. To the contrary, the records indicate that HH was not brought to any health provider until *12 days later*, on September 7, 2005. And at that September 7 visit her mother did *not* report that HH had displayed any seizure-like behaviors, or experienced either a severe adverse event or a sudden behavioral change, either within 24 hours of the vaccinations on August 26, or at any time in the meantime. Instead, HH's mother reported on September 7 only that HH had been experiencing some congestion, a "runny nose," and fever "off and on," for the previous 1½ weeks. (Ex. 2, p. 9.)

I conclude that if HH had *actually* suffered seizures, a "severe adverse event," and/or a dramatic behavioral change in the day following the vaccinations, her parents (1) would have immediately sought medical assistance, and/or (2) would have reported those symptoms to HH's doctor during the visit of September 7, 2005. Therefore, in light of the medical record made on September 7, 2005, combined with the lack of any medical treatment between August 26 and September 7, I conclude that Dr. Cave is relying on a *mistaken* assumption as to HH's symptom history.

To be sure, HH's parents have supplied affidavits, stating that HH suffered "convulsions" two hours after a "Hepatitis B shot," apparently referring to one of the vaccinations of August 26, 2005. (Exs. 3 and 4.) The virtually identical affidavits of the two parents also state that HH "continued to have convulsions on about 7 to 8 occasions later" (although it was not made clear whether "later" meant later that day, or some other time). (*Id*.)[21] However, for the reasons stated in the prior paragraph, I cannot credit those affidavits over the contrary inferences that flow inevitably from the medical record made on September 7, 2005, discussed above.

In this regard, I also note that my own finding is supported by the prior-stated analysis of then-Special Master Campbell-Smith, who noted that HH's medical records do not support the factual assumptions upon which Dr. Cave based her opinions. (See Orders filed Dec. 12, 2011, March 12, 2012, July 6, 2012.)

[21] I also note that Dr. Wiznitzer opined concerning the allegation that HH suffered from "seizures," and concluded that there is no evidence that HH *ever* suffered from seizures. (Ex. A, p. 13.)

VIII

PETITIONERS' "TABLE ENCEPHALOPATHY" CLAIM

Petitioners argue that HH suffered a "Table Injury encephalopathy," and that, therefore, her case "benefits from a statutorily-prescribed, rebuttable presumption of causation." (*See* Pet. Post-Hearing Memorandum ("Pet. Brief"), filed Sept 8, 2014, p. 9.) However, the record as a whole, particularly the contemporaneous medical records, make it clear that HH did *not* suffer a "Table Injury encephalopathy" in temporal proximity to the vaccinations administered on August 26, 2005.

A. The applicable definition of a "Table encephalopathy"

For Vaccine Act petitions, such as this one, filed after the modifications to the Vaccine Injury Table that went into effect on March 24, 1997, "encephalopathy" exists as a Table Injury for DTaP vaccinations. I will set forth the relevant Table Injury definition below.[22]

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, * * * the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the program:

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestion of onset or of significant aggravation after vaccine administration
*	*	*
Vaccines containing whole	A. Anaphylaxis or anaphylactic shock	4 hours 72 hours

[22] 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 the MMR vaccination from the version of the Table contained in the statute. The portion of the revised Table applicable to this case, listing "encephalopathy" as a Table Injury for the DTaP vaccination, appears at 42 C.F.R. § 100.3(a)(III)(B) (2015 edition of C.F.R.).

pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigens (*e.g.* DTP, DTaP, P, DTP-Hib).	B. Encephalopathy (or encephalitis) C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

* * *

(b) *Qualifications and aids to interpretation.*[23] The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

* * *

(2) *Encephalopathy*. For purposes of paragraph (a) of this section a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

* * *

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

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

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

* * *

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination.

42 C.F.R. § 100.3 (2015 edition of C.F.R.).

Thus, to establish their Table Encephalopathy claim, under the regulatory language set forth above, Petitioners must demonstrate that HH manifested an injury encompassed in the definition of an "acute encephalopathy" within 72 hours of her DTaP vaccination, and that a "chronic encephalopathy" was then present for more than 6 months after the acute encephalopathy. 42 C.F.R. § 100.3(b)(2).

For a child younger than 18 months, presenting without an associated seizure event, an acute encephalopathy is, as set forth above, indicated "by a significantly decreased level of consciousness . . . lasting for at least 24 hours." § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is demonstrated by the presence of one of three clinical signs for a period of at least 24 hours: "(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)." § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are not, alone, or in combination, a demonstration of an acute encephalopathy. § 100.3(b)(2)(E).

An acute encephalopathy is an event "that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i).[24]

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination." § 100.3(b)(2)(ii).

The clinical signs and symptoms of an acute encephalopathy were incorporated into the QAI to "clearly distinguish infants and children with brain dysfunction from those with transient 'lethargy.'" Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687. As noted in *Waddell*, by then-Chief Special Master Campbell-Smith,[25] the QAI definition of "significantly decreased level of consciousness" 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.

B. Petitioners' failed to demonstrate a "Table Injury encephalopathy" in this case.

Based on my own review of the contemporaneous medical records, it is absolutely clear that HH did not suffer an "acute encephalopathy" that would satisfy the above definition of a "Table encephalopathy." Such contemporaneous records have more evidentiary weight than retrospective accounts recorded months later.[26]

As explained in detail above, HH's parents supplied affidavits indicating that HH suffered "convulsions" about two hours after her vaccination of August 26, 2005. (Exs. 3-4). But, as also explained above, based on the only contemporaneous medical record, the notation recorded on September 7, 2005, I cannot credit those affidavits in that regard. (See the discussion at Section VII(C) of this Decision above.)

Similarly, the medical records offer *no support whatsoever* to the Petitioners' claim that HH suffered an "acute encephalopathy" as described in the regulatory "Table encephalopathy" definition set forth at Section VIII(A) above. The record of September 7, 2005, gives no indication that HH suffered a seizure or a "significantly decreased level of consciousness."

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[24] When the QAI definition was revised, it was noted that the hospitalization requirement was not intended "as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event." Revision of the Vaccine Injury Table, 62 Fed. Reg. 7685, 7687 (Fed. 20, 1997) (preamble to final rule).

[25] On September 19, 2013, Chief Special Master Campbell-Smith was appointed Judge of the U.S. Court of Federal Claims. On October 21, 2013, Judge Campbell-Smith was designated as the Chief Judge of the U.S. Court of Federal Claims.

[26] "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993.)

In this regard, see also the testimony of Dr. Wiznitzer, who similarly concluded that there is nothing in HH's medical records indicating that she suffered an acute encephalopathy within the Table definition. (Tr. 86-87, 133-35.)[27]

To be sure, in the medical record made on September 7, 2005, there is a notation of "sleep↑," indicating that sometime between August 26 and September 7, HH's sleep increased at least to some degree. (Ex. 2, p. 9.) But some increase in sleep certainly does *not* rise to the level of showing the type of "significantly decreased level of consciousness" required by the regulatory definition set forth above. Dr. Wiznitzer so interpreted that record. (Tr. 86-87.) Further, the regulatory definition *itself* states plainly that "sleepiness" does "*not* demonstrate an acute encephalopathy or a significantly change in * * * level of consciousness." 42 C.F.R. § 100(3)(E) (10-1-97 edition of C.F.R.) (emphasis added).

Therefore, I conclude that Petitioners have *failed*, by far, to demonstrate that HH suffered a "Table Injury encephalopathy" within the 72 hours after her DTaP vaccination of August 26, 2005.

IX

PETITIONERS HAVE ALSO FAILED TO DEMONSTRATE THAT VACCINATIONS PLAYED ANY ROLE IN EITHER INITIALLY CAUSING, OR AGGRAVATING, HH's NEURODEVELOPMENTAL DISORDER

Sadly, as noted above, HH has suffered from a severe neurodevelopmental disorder, which has been diagnosed as falling within the category of an Autistic Spectrum Disorder. (*E.g.*, Ex. 22, pp. 1, 8, 21.) However, Petitioners have failed completely to demonstrate that HH's vaccinations of August 26, 2005, played any role in either *initially causing*, or *aggravating*, that neurodevelopmental disorder.

A. Dr. Cave's causation opinion was based upon the assumption of alleged occurrences not substantiated by the medical records.

As explained in detail above, Dr. Cave based her opinion as to "actual causation," just like her opinion that HH suffered a "Table Injury encephalopathy, on the assumption that HH experienced a "severe adverse event," including "seizures" and a dramatic alteration in her development, within 24 hours of her vaccinations of August 26, 2005. But as explained above, I have rejected Dr. Cave's factual assumption in that regard as *plainly wrong*, so that her causation conclusions must be rejected for that reason alone. (See Section VII(C) above.)

[27] In their Post-Hearing Memorandum, Petitioners rely upon a written report concerning HH's alleged reaction to the vaccinations of August 26, 2005, which they filed into the "VAERS"--Vaccine Adverse Event Reporting System. (Post-Hearing memo, p. 9.) However, the VAERS report submitted by Petitioners was not dated until February 11, 2006. (Ex. 11, p. 2.) I find the *actual medical* record made on September 7, 2005 (Ex. 2, p. 9) to be a *more accurate* report of what symptoms HH did or did not display in the days immediately after the August 2005 vaccinations then a report submitted nearly six months later, after HH's developmental delay had become apparent.

B. *Dr. Cave erroneously discounted the fact that HH was suffering from her neurodevelopmental disorder <u>prior</u> to the vaccinations of August 26, 2005.*

On March 2, 2012, the then-presiding Special Master Campbell-Smith filed an order in this case stating that "the evidence suggests that [HH's] neurodevelopmental injury was already underway prior to the administration of the vaccines at issue here." (Order, filed Mar. 2, 2012, pp. 5-6.) This suggestion was based on a series of head circumference measurements performed during HH's infancy, which were later analyzed by a treating pediatric neurologist of HH, Dr. Robert Cruse. On June 26, 2006, Dr. Cruse recorded the following assessment of HH:

> Of concern is that her head circumference has decreased over time and crossed percentile lines; it was initially at the 50th percentile *up to about 3 months of life* * * *.

(Ex. 14, p. 9, emphasis added). Therefore, Dr. Cruse's opinion was that a significant brain abnormality in HH became evident soon after age *three months,* and thus likely before the vaccinations here in question. Similarly, on March 19, 2007, Dr. Duane Superneau, a treating geneticist of HH, opined that the "microcephaly [abnormally small head and brain size] in [HH] has been present from prior to the immunizations which have been implicated by the mother as potentially complicating [HH's] clinical course." (Ex. 14, p. 11.) Dr. Superneau concluded that HH's "physical findings suggested the problems existed from birth, consistent with the majority of problems of this type." (*Id*.)

Dr. Cave contended that both of these treating medical specialists, Drs. Superneau and Cruse, misinterpreted the available data concerning HH's head growth. (Ex. 10-b, p. 9.) During the trial, Dr. Cave testified that she had re-analyzed the various head measurements in the medical records, and concluded that HH's head size was roughly at the 5th percentile at birth, and her rate of head growth thereafter was about the 5th to the 7th percentile. (Tr. 11.) "She's small, and she has a small head." (*Id*.) Dr. Cave concluded that "the evidence *does not* suggest that [HH's] developmental injury was already underway prior to the administration of the vaccines at issue here." (Ex. 10-b, p. 10, emphasis in original.)

Respondent's expert Dr. Wiznitzer, however, testified that HH was microcephalic, meaning a significantly abnormally small head size, a sign of an abnormal brain development. (Tr. 85.) Moreover, he performed an analysis of HH's medical records and concluded that she had an abnormal head circumference *prior* to the vaccinations in question. (Ex. A, pp. 9, 12-13.) Dr. Wiznitzer concluded that HH displayed "a slowing of head circumference growth [that] reflects a slowing of brain growth that predated the 8/26/05 vaccinations." (Ex. A, p. 12.) Dr. Wiznitzer reiterated this analysis at the trial. (Tr. 79-85).

In analyzing this issue, I have studied the contemporaneous medical notations, the experts' opinions, and the various growth charts submitted in evidence by both parties. I note that two different treating doctors of HH--one pediatric neurologist (Dr. Cruse) and one geneticist (Dr. Superneau)--have opined that onset of HH's microcephaly *pre-dated her* vaccinations of August 26, 2005, and probably contributed to her subsequent neurodevelopmental problems. (Ex. 14, pp. 9, 11.) Respondent's well-qualified medical expert, Dr. Wiznitzer, also a pediatric neurologist, reached the same conclusion. To be sure, Dr. Cave, a family practitioner, opined that all three of those specialists were not correct. However, I find

that the persuasive weight of the opinions of those three highly qualified doctors is supported by multiple growth charts showing that HH's head size (and therefore brain size), in comparison to other infants, was abnormally small well before the vaccinations of August 26, 2005.

Dr. Cave argued that HH's head circumference measurements "started out in the 5th percentile at birth and two years later ended up at the 5th percentile." (Ex. 27, p. 5.) During the trial she re-stated this argument. (Tr. 11.) When I reviewed the medical records as Dr. Cave suggested, I found that HH had a head circumference notation of 12½ inches (31.75 cm) at birth (see Ex. 1, p. 8), which appears to register on the pediatric growth charts as the 5th percentile or less, as alleged by Dr. Cave. However, I also noted Dr. Wiznitzer's opinion that a head measurement taken immediately after birth is often distorted by compression of the infant's skull during the birthing process, and that measurements taken at two weeks of age are considered more accurate.[28] (Tr. 80.) Measurements were, in fact, recorded at two weeks of age and regularly thereafter, by Dr. Chatters, HH's first pediatrician. (Ex. 2, pp. 47-50.) Using either of the standard growth charts submitted in this case,[29] none of Dr. Chatters' head circumference measurements (Ex. A) is close to the 5th percentile, as Dr. Cave alleged.

Apparently, Dr. Cave's assessment of the first few months of HH's life excluded all of the head measurements performed by HH's first pediatrician, Dr. Chatters, and emphasized only the measurement of 31.75 cm at birth. (S*ee* Ex. 1, p. 8; Tr. 84). This maneuver by Dr. Cave concealed the significant deceleration of HH's head growth rate during infancy, which was described by both the treating pediatric neurologist, Dr. Cruse (Ex. 14, p. 9), and Respondent's expert witness, Dr. Wiznitzer (Ex. A, p. 12). Both of these pediatric neurologists diagnosed "microcephaly" (abnormally small head size) with an onset that *preceded* HH's vaccinations of August 26, 2005. Dr. Cave's testimony did nothing to persuade me otherwise.

Dr. Wiznitzer also pointed out more evidence in HH's medical records, *in addition* to the head circumference data, indicating that HH was likely developmentally delayed *prior* to the vaccinations in question. (See Tr. 72-74, 75-77.)

Accordingly, in this case I find further reason to conclude that the vaccinations of August 26, 2005, did not initially cause HH's neurodevelopmental problems, because the evidence concerning HH's microcephaly shows that her "neurodevelopmental injury was already underway prior to the administration of the vaccines at issue here," (*quoting* the Order of Special Master Campbell-Smith, filed on Mar. 2, 2012). Further, Dr. Cave's misanalysis of HH's pre-existing microcephaly and other evidence of HH's pre-existing delay adds additional reason to doubt the credibility of Dr. Cave's *overall causation theory* in this case.

[28] At birth, HH's head circumference measured 12½ inches (31.75 cm); while at two weeks of age, her head measured 35 cm. (Ex. 1, p. 8; Ex. 2, p. 47.) Thus, in the first two weeks of her life, HH's head circumference apparently "grew" a total of 3.25 cm. This large amount of "growth" seems unlikely. Dr. Wiznitzer's explanation that HH's initial birth measurement was actually reduced by compression during birthing seems more likely.

[29] The growth charts referenced in this discussion are located at Ex. 2, p. 43, and Ex. A, pp. 16, 17.

C. "Mitochondrial dysfunction" and the Morava Criteria

In this regard, I note that Dr. Cave's theory that HH's vaccines either "initially caused," or "significantly aggravated," HH's neurodevelopmental disorder rests on the argument that HH suffered from a "mitochondrial dysfunction" that allegedly made her more vulnerable to neurologic injury by toxins contained in vaccines, particularly aluminum. (Ex. 27, p. 4; Tr. 19; 46-47.) Consequently, there was extensive discussion in the parties' expert reports and hearing testimony concerning whether HH suffered from "mitochondrial disorder" and/or "mitochondrial dysfunction," based on certain criteria elaborated by Morava, et al.[30] ("Morava article") (*See* Ex. 10-b, pp. 6-7; Ex. 27, pp. 1-7; Ex. A, pp. 11-13; *see also* Tr. 23-33; Tr. 90-95.) The Morava article, in turn, acknowledged its reliance on the consensus mitochondrial disease criteria scoring system proposed by Wolf and Smeitink[31] ("Wolf article"), with particular emphasis on the "General Criteria" found in an attachment to that article.[32]

To summarize, my analysis of this issue shows that Dr. Cave's analysis was fatally flawed in yet *another* respect, and was far inferior to that of Dr. Wiznitzer.

In analyzing this issue, I note first that the parties' experts both claim that they relied on the Morava article to assess HH's condition, yet they reached completely opposite conclusions. Second, I note that Petitioners' expert, Dr. Cave, declined to utilize the terminology employed by these articles (*i.e.*, "mitochondrial disorder") in her reports and testimony, and chose instead to generally use the expression "mitochondrial dysfunction." (*E.g.*, Ex. 10, p. 1; Ex. 10-a, p. 2; Ex. 10-b, p. 5; Ex. 27, pp. 1-3; Tr. 17-18, 38, 61.) In my analysis, I will generally employ the term used in the defining articles, that is, "mitochondrial disorder."

1. Dr. Cave's understanding of mitochondrial disorders and the Morava criteria seemed highly questionable.

Dr. Cave contended that Respondent's expert, Dr. Wiznitzer, does not understand "how to interpret laboratory tests that are pertinent to the [Morava] criteria." (Ex. 27, p. 1.)[33] Rather, she argued that this is her own "field of expertise," because she possesses a "Master of Science Degree in Clinical Chemistry." (*Id*.)

I found, however, that in her testimony, it was *Dr. Cave* who often demonstrated a lack of knowledge about that subject matter. For example, she explained that "I've done quite a bit of

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[30] E. Morava, et al., *Mitochondrial Disease Criteria: Diagnostic Applications in Children*, 67 Neurology 1823-26 (2006), filed as Respondent's Ex. C, on October 5, 2012. Petitioners filed an abstract of this article twice: as an attachment to Ex. 10-a (pp. 15-17) on Jan. 16, 2012; and as Ex. 25, on June 27, 2012. Eighteen months later, on January 14, 2014, Petitioners filed a copy of the original Morava article, identified as Exhibit 28.

[31] Nicole I. Wolf and Jan A.M. Smeitink, *Mitochondrial Disorders: A Proposal for Consensus Diagnostic Criteria in Infants and Children*, 59 Neurology 1402-05 (2002), filed by Respondent as Ex. D, on Oct. 5, 2012.

[32] Nicole I. Wolf and Jan A.M. Smeitink, *Mitochondrial Disorders: The Mitochondrial Disease Criteria – General Criteria*, an attachment to the above-cited article, filed by Respondent as Ex. E, on Oct. 5, 2012.

[33] According to Dr. Cave, Respondent's expert "did not bring to this case a working knowledge of how to interpret Laboratory tests, which are necessary to define the mitochondrial dysfunction." (Ex. 27, p. 6.)

CME [continuing medical education] activity in the field of toxicology and heavy metal toxicology" (Tr. 9), and, when explaining that her theory of causation implicates aluminum as an injurious component of vaccines, she asserted that "aluminum itself is a heavy metal and it's destructive" (Tr. 19; *see also* Tr. 51). However, when Dr. Wiznitzer was asked whether aluminum was a heavy metal, he replied that it was not, "it's actually light." (Tr. 88.) In this matter, as in many others, I found Dr. Wiznitzer's opinion to be more informed. That is, "heavy metal" means "one with a high specific gravity, usually defined as being above 5.0." *Dorland's Illustrated Medical Dictionary* (31st ed. 2007), p. 1161. Aluminum has a specific gravity of 2.699 (*id*., p. 56), placing it outside, contrary to Dr. Cave's assumption, the category of "heavy metals."

Moreover, Dr. Cave also seemed to misunderstand the Morava article and the Morava criteria, as I will demonstrate in detail in the next section of this Decision.

2. Dr. Wiznitzer's application of the Morava criteria to HH's case was much more persuasive than that of Dr. Cave.

It is important to examine the specific content of the Morava article as it pertains to the contrasting opinions of Drs. Cave and Wiznitzer. The Morava article sets forth a diagnostic scoring system to identify mitochondrial disorders. (Ex. C, see also the Wolf article, Ex. D.) According to the authors of the Morava article, the Morava criteria can and should be applied in clinical situations where mitochondrial disease is suspected but not yet confirmed by a muscle biopsy. (Ex. C, p. 1; Ex. D, p. 3.) No muscle biopsy was performed on HH, so the criteria appear to apply directly to this case.

The system set forth in these articles requires assessment in three major diagnostic Sections: I – clinical signs and symptoms; II – metabolic/imaging studies; and III – morphology/histopathology. (Ex. C, pp. 1-2; Ex. D, pp. 1-2; *see also* Tr. 91-92.) In devising this system, the authors allotted points for each symptom exhibited by a patient, but capped the total amount of scoring in *each* of these three Sections at four points, resulting in a maximum possible score of twelve (12) points when the three sections are combined. (Ex. D, p. 1.) This explicit limitation was meant to avoid giving unreasonable diagnostic weight to multiple symptoms that may present together within a particular section. (Ex. D, pp. 1-2.)[34] It is notable that the criteria included within Section III (morphology/histopathology) are used only when the results of a muscle biopsy are available. (Ex. C, p. 2.) No muscle biopsy was performed on HH. Thus, without results from a muscle biopsy test, the *total maximum score* would amount only to eight points. These diagnostic scoring limitations are carefully reiterated in the Morava article (Ex. C, pp. 2-3), and in the table appended to the Wolf article (Ex. E).

The first major Section (I--Clinical signs and symptoms) is further divided into three categories with specific point limitations: A – Muscular presentation (2 points); B – Central nervous system presentation (2 points); Multisystem disease (3 points). (Ex. C, pp. 1-2; Ex. F,

[34] "In order to avoid disproportionate contribution from a multitude of single clinical, metabolic, imaging, or morphologic criteria to the scoring for a given patient, we capped the number of points that could be achieved for each section. Thus clinical presentation, metabolic investigations and imaging, and histopathology can each contribute a maximum of four points." (Ex. D, pp. 2-3.)

pp. 2-5; *see also* Ex. 25, pp. 3-4; Tr. 91-92.) Thus, the points assigned to categories A, B, and C could reach a possible total of seven points, when considered *separately*, but when combined *together* in Section I, the authors deliberately restrict the total to only four points. (Ex. C, pp. 2-3.) Likewise, in Section II (Metabolic/imaging studies), there are various individual components that may be assigned one or two points, which would result in a potential total of 17 points if all of them were present; however, the authors will allow a total score of only four points, no matter how many of the individual laboratory test results are present. (*Id*.)

Dr. Cave discussed application of the Morava criteria in her supplemental expert reports. (*See* Ex. 10-a, p. 2; Ex. 10-b, pp. 4-6.) In the first supplemental report, she calculated that HH exceeded "the highest score on Morava's 2006 Criteria for Mitochondrial Disorder – above 12." (Ex. 10-a, p. 2.) In the second supplemental report, she calculated a total score of 14 points. (Ex. 10-b, p. 6.) During the hearing, Dr. Cave revised her calculations to reach a total of 9 or 10 points. (Tr. 31-32.) It is notable that for each of these estimates, points were not included for category III, because there were no muscle biopsy results. Thus, the points allowed for Sections I and II under the Morava criteria without a muscle biopsy, by the very definition set forth in the Morava article itself, could reach a *maximum* total of only 8 points. Yet all of Dr. Cave's various calculations, incongruously, *exceeded the maximum* allowed by the Morava criteria.

This is not surprising. Dr. Cave's diagnosis of a mitochondrial "dysfunction" is achieved by tabulating all the points available in the major Sections identified in the Morava and Wolf articles (regarding mitochondrial *disorders*), but without applying any of the limitations *required* by the articles. (See Tr. 90.) Respondent's witness, Dr. Wiznitzer, observed that Dr. Cave's total score of 14 was "impossible, because there's defined rules for how many points you can apply per section of the criteria … [a]nd unfortunately, it appears that … the specific instructions were not followed to achieve [Dr. Cave's] score of 14." (*Id*.) The same criticism can be applied to all of Dr. Cave's assessments totaling between 9 and 14 points, allegedly based on the Morava criteria. Dr. Cave has simply not adhered to the methods described in the Morava and Wolf articles.

The Morava article presents the *consensus* mitochondrial disease criteria, a methodology that imposes strict limitations on scoring relevant symptoms for the purpose of making a diagnosis. The authors wanted an analytical methodology that was not impeded by "the lack of agreement on optimal biochemical assays and cut-off values" related to diagnosing mitochondrial disorders. (Ex. C, p. 1.) This goal is stated explicitly in the first sentence of the article. Yet, in Dr. Cave's expert reports and in her trial testimony, there are many pages of discussion concerning optimal biochemical assays and cut-off values. This is precisely what the authors stated that they wished to *avoid* when making this type of diagnosis. Dr. Cave asserted that she relied on this article, but she refused to accept the underlying premises articulated by the authors.

Dr. Cave appears to have attempted to obscure her refusal to accept the Morava article's underlying premises, by her insistence that HH suffers from a mitochondrial "dysfunction," rather than a mitochondrial "disorder" (Ex. 10-b, p. 5),[35] which, she seemed to assert, allows her

[35] "The first thing that I want to clear up is that I did not use the term 'mitochondrial disorder' in my report. I found evidence *** that [HH] had significant mitochondrial dysfunction." (Ex. 10-b, p. 5.)

to select only those aspects of the Morava article that are useful to her argument. In her final expert report, she spoke exclusively of HH's mitochondrial "dysfunction." (Ex. 27, pp. 1, 4, 6.) In her testimony, she also insisted that mitochondrial "dysfunction" is the appropriate diagnosis, but acknowledged that her diagnosis in this case has never been confirmed by a mitochondrial disease specialist.[36] However, when discussing the final "score" that Dr. Cave presented at trial (that is, "9"), she argued that her calculations meant that HH had "a definite mitochondrial disorder." (Tr. pp. 32-33.) When questioned about this, Dr. Cave reiterated: "I don't think there's a chance [HH] doesn't have a mitochondrial disorder, and I think by the criteria we use, it's a definite. I don't think – I don't think that's even a question." (Tr. 62.) This assertion of a mitochondrial "disorder" in HH seems to be a contradiction of Dr. Cave's previous characterization of mitochondrial "dysfunction." Moreover, this late assertion that HH suffered from a mitochondrial "disorder" demonstrates that Dr. Cave was mistaken in failing to utilize the actual methodology used by Morava and Wolf in their articles published in the distinguished medical journal, *Neurology*. Dr. Cave's analytical method clearly contradicts the premises of those articles. Thus, I find that her opinion that HH suffered either a mitochondrial "disorder" or a "dysfunction" is *not* reliable.

3. Dr. Wiznitzer's testimony concerning mitochondrial disorders and the Morava criteria was logical and persuasive.

In contrast to the vagueness, ambivalence, self-contradiction, and illogic of Dr. Cave's testimony, the testimony of Dr. Wiznitzer was coherent, consistent, and logical throughout. He reviewed the totality of the medical records, not just selected parts, and reached a diagnosis of microcephaly predating the vaccinations (Tr. 79-85), in concurrence with the treating pediatric neurologist, Dr. Cruse. Further, Dr. Wiznitzer considered each of Dr. Cave's allegations concerning application of the Morava criteria to the facts of this case, regarding: exercise intolerance, muscle weakness, eye problems, developmental regression, possible seizures, constipation, and multiple laboratory test results. (Ex. A, pp. 10-12.) He concluded that Dr. Cave had used unreliable information and/or misapplied the medical standards in all but one of her allegations about HH's symptoms, in relation to the Morava criteria. (*Id.*) That is, Dr. Wiznitzer agreed with Dr. Cave on one issue, that HH suffered from developmental delay, and that solitary positive criterion registered only one point on the consensus mitochondrial disease criteria advocated by the Morava and Wolf articles. Thus, Dr. Wiznitzer, in contrast to Dr. Cave, found that HH actually should be scored as a total of only "1" on the Morava criteria, which would put her in the "mitochondrial disorder unlikely" category. (Ex. A, p. 12.)

Further, Dr. Wiznitzer noted that HH's *medical records* do not support a diagnosis of mitochondrial "dysfunction," either. (*Id.*) The medical records do not indicate that HH was ever even sent to a mitochondrial specialist[37] for evaluation of *possible* mitochondrial problems, as Dr. Cave herself was forced to admit. (Tr. 61.)

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[36] "Q. Have any of – have your – has your diagnosis of a mitochondrial disorder been verified by a specialist in mitochondrial disorders?
A. I'm saying mitochondrial dysfunction. I have not sent her to a mitochondrial specialist, no." (Tr. p. 61.)

[37] Dr. Wiznitzer explained that if he had a patient whom he suspected might have a mitochondrial disorder, he would "definitely" send such patient to a mitochondrial specialist. (Tr. 120.)

I find that HH did not have a mitochondrial "disorder" or "dysfunction" that predisposed her to injury by the vaccinations she received on August 26, 2005.

D. Dr. Cave simply never presented a logical or coherent case concerning "causation-in-fact," while Dr. Wiznitzer's presentation was far more persuasive.

As noted above, Petitioners' entire presentation concerning "causation-in-fact" has been generally vague, unclear, often self-contradictory, and far from persuasive. As set forth above in Section IX (A) of this Decision, Dr. Cave has relied completely upon a *misassumption* of fact. As set forth in Section IX (B), she misanalyzed the evidence that shows that HH had a serious neurodevelopmental problem *prior* to the vaccinations in question. As set forth in Section IX (C), while Dr. Cave based her causation theory on the proposition that HH suffered from a "mitochondrial dysfunction" or "mitochondrial disorder," she in fact seriously misanalyzed the evidence in that regard too, so that there is no good reason to believe that HH *even had* any type of mitochondrial dysfunction or disorder.

Finally, I note again that even if one were to assume for the sake of argument, that HH *did* suffer from some kind of mitochondrial dysfunction or disorder, Dr. Cave made no serious attempt to explain *why* such a circumstance would therefore tend to show that *vaccinations* either initially caused or aggravated HH's neurodevelopmental disorder. Dr. Cave did not present any explanation of her theory that the presence of "mitochondrial dysfunction" would make an infant more susceptible to the unspecified "toxins" in unspecified vaccines. She simply did not explain her theory in this regard in any detail. Dr. Cave merely seemed to *assume* that the presence of "mitochondrial dysfunction" would render an infant more susceptible to purported vaccine-related damage. But she presented no persuasive reason why I should adopt such an assumption.[38] (And Dr. Wiznitzer testified to the contrary. Tr. 132.)

E. Summary concerning "causation-in-fact" allegations

To be sure, I do *not* have any reason to doubt that Dr. Cave is a competent clinical practitioner in her field. My conclusion is simply that, in general, the presentation of Dr. Wiznitzer in this case was *far more persuasive* than that of Dr. Cave, as to all points. I thus conclude, for all the reasons set forth above, that Petitioners have *failed* to demonstrate that it is "more likely than not" that the vaccinations of August 26, 2005, *either* initially caused, or aggravated, HH's tragic neurodevelopmental disorder.[39]

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[38] I am aware of the recent opinion *Paluck v. HHS*, 786 F.3d 1373 (Fed. Cir. 2015), in which the Federal Circuit Court of Appeals concluded that a child's pre-existing mitochondrial disorder was significantly aggravated by his receipt of the MMR, varicella, and pneumococcal vaccines. However, the facts of that case, as well as the vaccines involved, were quite different from the circumstances here. HH did *not* have a mitochondrial disorder diagnosis, nor did HH manifest any exacerbation of her condition within a proximate temporal relationship to the vaccinations.

[39] Dr. Cave also asserted very briefly that HH may have suffered from two "genetic mutations," suggesting that such mutations may have "compromised" HH's ability to clear the aluminum adjuvant in the vaccine from her system. (Ex. 27, p. 5; Tr. 18-19.) But Dr. Cave never explained in any detail why she believes that the existence of these mutations might have any relevance to Dr. Cave's overall causation theory. Dr. Wiznitzer, on the other hand, persuasively explained why there is no evidence that such genetic mutations had any effect on HH's neurodevelopmental disorder. (Tr. 120-27.)

Dr. Cave also briefly mentioned an article by Poling, et al., suggesting that the article "discusses the possible links between the developmentally disabled and mitochondrial dysfunction." (Ex. 10-b, p. 6; Ex. 27, pp. 3-

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PETITIONERS' CASE FAILS THE TESTS REQUIRED BY *ALTHEN* AND *LOVING*

In this part of my Decision, I will explain how this case fits specifically within the interpretive standards set forth in the *Althen* and *Loving* decisions. The short answer is that I find that Petitioners' case clearly does *not* satisfy the standards presented in either *Althen* or *Loving*.

In this regard, as previously noted, Petitioners' presentation in this case has been so jumbled and poorly explained that it is not even clear whether they are ultimately contending (1) that the vaccinations of August 2005 *initially caused* HH's neurodevelopmental disorder, or (2) that those vaccinations *significantly aggravated* a preexisting neurodevelopmental disorder. That does not matter to the outcome of this case, since it is clear that Petitioners have clearly failed to show *either*. But, in this Section of my Decision, I will, therefore, analyze Petitioners' case first under *Althen*, assuming that they are raising an "initial causation" argument. Then I will analyze Petitioners' case under the six-part *Loving/Althen* test, assuming that they are advancing a "significant aggravation" claim.

A. Applying the Althen standard to Petitioners' "initial causation" claim

First, I will analyze the Petitioners' "initial causation" claim, utilizing the *Althen* standard.

The U.S. Court of Appeals for the Federal Circuit declared in *Althen* that it is a petitioner's burden:

> 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 vaccination and injury.

Althen, 418 F.3d at 1278 (citations omitted). 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 or aggravating 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).) In the pages above, of course, I have already set forth *in detail* my analysis in rejecting Petitioners' "actual causation" theory, including their "initial causation" portion of that 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

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4; Tr. 33.) However, Dr. Cave did not discuss the article in detail, in any of her reports at the hearing. In their Post-Hearing Memorandum, at p. 16, Petitioners did cite the article--Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child With Autism*, 21(2) J. Child Neurology 170 (2006). But the article offers no support for Dr. Cave's theory in this case, because, as explained above (Section IX(C)), the evidence in this case does *not* show that HH suffered from any mitochondrial dysfunction or disorder.

sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners "initial causation" claim in this case clearly does *not* satisfy the *Althen* test.

1. 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 HH received on August 26, 2005, contributed to the causation of her tragic neurodevelopmental disorder.

2. 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 in this case seems to be that HH's vaccinations of August 26, 2005, in the context of an alleged "mitochondrial dysfunction" in HH, *initially caused* HH's neurodevelopmental disorder. However, as described above in Section IX, Dr. Cave has *not* demonstrated that any type of vaccination *can* cause a neurodevelopmental disorder. Thus Petitioners' claim clearly fails under *Althen* Prong 1.

3. 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 HH's vaccination of August 26, 2005, *did* initially cause HH's *own* condition. But this they have also failed to do, for all of the reasons detailed above in Sections IX of this Decision.

4. 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, as discussed above (Section IX(B)), the evidence clearly shows that HH was suffering from a neurodevelopmental disorder *prior* to the vaccinations in question, so that clearly those vaccinations did not *initially cause* her developmental disorder.

B. Applying the Loving/Althen standard to Petitioners' "significant aggravation" claim

If Petitioners' arguments in fact raise an alternative "significant aggravation" claim, that claim, too, must be rejected.

1. *Analysis of a "significant aggravation" issue is guided by the ruling in Loving.*

The Vaccine Act states that "[t]the term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4).

The elements of an off-Table significant aggravation case were set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). The United States Court of Appeals for the Federal Circuit acknowledged that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims," in *W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Thus, the Federal Circuit Court of Appeals, which sets binding precedent for decisions by the Office of Special Masters, endorsed the use of a six-part test for significant aggravation, which was first elaborated in *Loving*. A petitioner must prove by preponderant evidence that a vaccination caused significant aggravation by showing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant

> aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

W.C. v. HHS, 704 F.3d at 1357 (Fed. Cir. 2013).

The standard elaborated in *Loving*, and endorsed in *W.C. v. HHS*, combines elements from previous Federal Circuit decisions. *W.C. v. HHS*, 704 F.3d at 1537 ("The *Loving* test combines the first three *Whitecotton* factors, which establish significant aggravation, with the *Althen* factors, which establish causation.") Since the last three elements of the *Loving* test include the entirety of the *Althen* test, with insignificant wording modifications, the analysis of those three elements would be the same using either standard.

2. Analysis of this case, under the six-part Loving/Althen test

In this Section, I will discuss whether Petitioners have satisfied the six-part *Loving* test to establish the existence of vaccine-related *significant aggravation* of a preexisting condition.

1. What was HH's condition prior to the administration of the vaccinations in question?

On August 26, 2005, during HH's well baby exam at six months of age, her pediatrician recorded that she had no significant illnesses or ongoing diagnoses. (Ex. 2, p. 6.) However, with the benefit of *hindsight* the evidence indicates that HH already had an abnormally small head circumference, indicating that a serious brain problem existed *prior* to that date. (See discussion at Section IX(B), above.)

2. What was HH's condition soon after the vaccinations in question, and what is her current condition?

Petitioners and Dr. Cave based their causation theories in this case on the factual assertion that HH suffered a "severe adverse event," including seizures and a dramatic alteration in her development, within a day after her vaccinations of August 26, 2005. However, for the reasons detailed above, I have rejected that factual assertion as mistaken. (See Section VII(C), above.) Therefore, I find that HH's condition *soon after* the vaccinations was, contrary to Petitioners' factual allegation, *substantially unchanged* from her pre-vaccination condition.

However, on December 21, 2005, four months after the vaccinations, HH's pediatrician expressed concern that she was not yet scooting or crawling, and indicated that her development should be monitored carefully. (Ex. 2, p. 13.) Tragically, since then HH has proved to have a very significant neurodevelopmental disorder, which has been classified as an Autism Spectrum Disorder--that is her "current condition."

3. HH's <u>current condition</u> legally constitutes a "significant aggravation" of her prior condition.

As explained in the prior paragraph, I must *reject* Petitioners' allegation that HH suffered an aggravation of her condition *soon after* the vaccinations in question. However, in the *Loving/Althen* formulation set forth in *W.C.* and quoted above, *one* question posed is whether the vaccinee's *current condition* constitutes a "significant aggravation" of the vaccinee's condition prior to vaccination. *W.C.*, 704 F.3d at 1357. As to *that* question, my conclusion is that HH's "current condition" *is* "significantly worse" than her condition appeared immediately prior to the vaccinations in question. Therefore, following the standard set forth in *Loving* and *W.C.*, HH's "current condition*" does* amount to a "significant aggravation" of her neurodevelopmental disorder (though the worsening has definitely *not* been shown to have been related to her *vaccinations*).

4. Petitioners have failed to establish Prong 4 of <u>Loving</u>/Prong 1 of <u>Althen</u>.

As discussed above, Prongs 4, 5 and 6 of the *Loving* test are, in effect, the same as Prongs 1, 2, and 3 of the *Althen* standard. Under Prong 4 of *Loving* and Prong 1 of *Althen*, a petitioner must provide a medical theory demonstrating that the *type* of vaccinee in question can cause a significant worsening of the *type* of preexisting condition of the vaccinee. In this case, however, for the reasons stated above, the Petitioners have *failed* to show that the vaccinations in question *can* aggravate the type of neurodevelopmental disorder from which HH suffers. Further, the Petitioners have *failed* to show that HH was afflicted with a preexisting mitochondrial disorder, or that the vaccinations in question *can* aggravate a preexisting mitochondrial disorder, or any type of neurological disorder.

Specifically, in this case the Petitioners' theory seems to be that toxic substances contained in some of HH's vaccinations, especially aluminum adjuvants in the context of a mitochondrial dysfunction/disorder, significantly aggravated HH's neurodevelopmental disorder. However, in this case I have already explained in detail the numerous deficiencies in Dr. Cave's theory in that regard. Petitioners, thus, have wholly failed to show that, whether in the context of a mitochondrial dysfunction/disorder or in other circumstances, the *types of* vaccinations that HH received *can cause* an aggravation of a neurodevelopmental disorder.

Accordingly, it is quite evident that Petitioners have wholly *failed* to establish Prong 4 of *Loving*/Prong 1 of *Althen* in this case.

5. Petitioners have failed to establish Prong 5 of Loving/Prong 2 of Althen in this case.

Under Prong 5 of *Loving*/Prong 2 of *Althen*, the Petitioners need to show that it is "more probable than not" that HH's vaccinations of August 26, 2005, *did* aggravate the specific neurodevelopmental disorder of *HH herself*. But they have failed to do so. As discussed at Section VII(C), above, Dr. Cave based her aggravation theory regarding HH on a misassumption of fact. Further, as shown in Section IX(C), Dr. Cave's theory about the cause of HH's neurodevelopmental delays was based upon the premise that HH suffered from a mitochondrial dysfunction/disorder, but there is no good evidence that she did suffer from any mitochondrial

abnormality. Moreover, as discussed in Section IX(D) above, Dr. Cave's theory as to how components of HH's vaccinations might have allegedly worsened the effects of a pre-existing mitochondrial dysfunction/disorder lacks any evidentiary support.

Accordingly, Petitioners have failed to establish Prong 5 of *Loving*/Prong 2 of *Althen* in this case.

6. Petitioners have failed to establish Prong 6 of Loving/Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen* (4th and 5th prongs of *Loving*), I need not discuss why Petitioners' case also fails to satisfy the Prong 3 of *Althen/*Prong 6 of *Loving*. However, in the interest of completeness, I will analyze whether there was "a showing of a proximate temporal relationship" between the vaccinations and the alleged significant aggravation of HH's neurodevelopmental disorder.

As to an alleged significant aggravation of HH's neurodevelopmental disorder soon after the vaccinations, I note that the report of symptoms of HH's developmental delay was not made until December 21, 2005, *four months* after the vaccinations in question, when her pediatrician recorded his concern that she was not scooting or crawling. (Ex. 2, p. 13.) During those four months, there are no entries in the medical records linking HH's vaccinations temporally to any adverse reactions or the loss of any previously acquired skills. Thus, Petitioners have not shown a proximate temporal relationship between the vaccination and the alleged significant aggravation. They have failed establish Prong 6 of *Loving*/Prong 3 of *Althen* in this case.

C. This <u>not</u> a close case.

As noted above, in *Althen*, the Federal Circuit indicated that the Vaccine Act involves "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280. Accordingly, I note here that this case is ultimately *not* a close call. For all the reasons set forth above, I find that Dr. Cave's causation theory, either as to "initial causation" or "significant aggravation," was *not at all* persuasive, while Respondent's expert was *far* more persuasive.[40]

XI

NOTATIONS CONCERNING VIABILITY OF DR. CAVE, AND THE "MITOCHONDRIAL DISORDER" THEORY IN GENERAL

A. Dr. Cave

[40] It should be noted that in this case the Petitioners never came close to carrying their burden of making a "*prima facie*" case showing that HH suffered a vaccine-caused or vaccine-aggravated injury. Therefore, the burden *never shifted* to Respondent to demonstrate that HH's condition was "due to factors unrelated to the administration of the vaccine." §300aa-13(a)(1)(B).

As I have stressed above, I found that Dr. Cave, despite her apparent sincerity, to be a *very unpersuasive* witness in this case. As explained, Dr. Cave, in general, presented a muddled, often illogical, and sometimes self-contradictory theory of causation. Dr. Cave based her theory of vaccine-causation in this case on an assertion that a child with a mitochondrial "dysfunction" would be more susceptible to vaccine-causation of a neurodevelopmental disorder, than a child without mitochondrial disease, without any coherent explanation of *why* that might be the case. (See Section IX(D), above.) Further, she insisted that HH suffered from a mitochondrial "dysfunction," even though she seemed to be poorly informed about the diagnosis of mitochondrial disease, and grossly misapplied the accepted set of medical criteria for diagnosing mitochondrial disorders. (See Section IX(C) above.)

Further, Dr. Cave insisted upon relying upon a factual assumption concerning HH's symptom history that was *flatly contradicted* by HH's medical records, even after being warned on a number of occasions by Special Master Campbell-Smith that Dr. Cave's factual assumption was untenable in light of the medical records. (See Section VII(C) above.)

Moreover, Dr. Cave's totally unpersuasive presentation in this case appears to be the *norm* for her. For example, as detailed above at p. 22, Dr. Cave was warned in the *Berge* and *Blake* cases, in 2010 and 2011, that her causal opinions would be rejected when contradicted by the medical records in the case. In addition, special masters have often commented negatively upon the quality of Dr. Cave's presentations as an expert witness. In *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. May 21, 2014), Special Master Vowell observed that "I do not attribute great weight to Dr. Cave's opinion as she lacks expertise in the specialties relevant to the issues in this case," particularly in the fields of developmental pediatrics, pediatric neurology and pediatric immunology. *Id*. at *15. In *Nilson v. HHS*, No. 98-797V, 2005 WL 6122524 (Fed. Cl. Spec. Mstr. Aug. 31, 2005), Special Master Sweeney (now Judge Sweeney) compared the expert reports and testimony of both Dr. Cave and Dr. Wiznitzer regarding several disputed issues, and found that Dr. Wiznitzer's opinion on each was more credible. *Id*. at *17-*20. The special master concluded that "[i]n this case, Dr. Cave's theories of causation were effectively rebutted by a highly-credentialed pediatric neurologist, Dr. Wiznitzer, whose testimony was far more credible and compelling." *Id*. at *20. In *Mooney v. HHS*, No. 05-266V, 2014 WL 7715158 (Fed. Cl. Spec. Mstr. Dec. 29, 2014), Special Master Vowell declined to award costs for the production of Dr. Cave's expert opinion, awarding only a small amount for consultation services, adding that "I am unlikely to authorize Dr. Cave's consultant fees for hearing preparation in any similar cases filed by Mr. Cave." *Id*. at *14.

Finally, in *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. August 18, 2015), Special Master Vowell, like Special Master Sweeney in *Nilson*, specifically compared the qualifications and testimony of Dr. Cave and Dr. Wiznitzer, and found Dr. Cave's testimony to be far inferior in quality and credibility. 2015 WL 5456093 at *11-12, *26-29, *34-35, *41-43. Special Master Vowell specifically found that Dr. Cave's attempts to use the Morava criteria, the same criteria at issue in this case, showed a "lack of understanding" of those criteria. *Id*. at *29.

Therefore, even in this case, whether it was reasonable for Mr. Cave to proceed to hearing with Dr. Cave as his sole expert is quite questionable. But certainly, I hereby put Vaccine Act attorneys (and *pro se* litigants) on notice that if Dr. Cave's opinion, relying on the same discredited theories and approaches, is offered in *other* Vaccine Act cases, I will *not* be

likely to compensate such a petitioner for any work by Dr. Cave performed after the publication date of this Decision.

B. Experts alleging vaccine-causation of ASDs in conjunction with an alleged mitochondrial disorder

In addition, in a number of cases recently, each involving a child with an ASD, expert witnesses for petitioners have based their causation theories on an allegation that the child suffers from a *mitochondrial* dysfunction or disorder. But in many of those cases, as in this case, there has been a lack of any persuasive evidence that the child even has any type of mitochondrial disorder. *See, e.g., Coombs v. HHS*, supra; *Brook v. HHS, supra*; *Miller v. HHS, supra; Allen v. HHS, supra; R.K. v. HHS, supra.*

In all those cases, there also has been a lack of persuasive evidence that even *genuine* mitochondrial disorders are of any relevance--*i.e.*, as in this case, a lack of any persuasive evidence that the existence of a true mitochondrial disorder can make a child more susceptible to *the causation or aggravation of an ASD by vaccination*.

In this regard, I am aware that in *Paluck v. HHS*, 786 F.3d 1373 (Fed. Cir. 2015), the Court of Appeals affirmed a ruling that a particular child's mitochondrial disorder was significantly aggravated by receipt of MMR, varicella, and pneumococcal vaccines, thereby affecting the course of the child's neurodevelopmental disorder. I have also reviewed the medical article by Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child with Autism,* 21(2) J. Child Neurology 170 (2006). However, the facts in *Paluck* were quite different from the circumstances in any of the cases cited above. Moreover, in no case presented to me, nor in any of the cases cited above, has there been presented any persuasive evidence that even in a child with an actual mitochondrial disorder, *vaccines* can cause or aggravate that child's *ASD*.

Therefore, I strongly advise counsel in Vaccine Act cases to carefully *scrutinize*, for *credibility*, any cases in which an expert witness asserts that the existence of a *mitochondrial disorder* caused the child to be susceptible to causation or aggravation of an ASD by vaccines. If, as in this case, and in the cases cited at Section 11(A) above, there is no credible evidence that the child even suffers from a mitochondrial disorder, *I will be unlikely to find that the use of such expert was reasonable*, and thus compensable. Further, even in the context of an actual mitochondrial disorder, the expert must be able to supply *credible evidence* that a mitochondrial disorder can make a child susceptible to *causation or aggravation of an ASD* by vaccines, or else I may, again, be disinclined to compensate the attorney for presenting such expert.

XII

CONCLUSION

The record of this case demonstrates plainly that HH and her family have been through a tragic ordeal. The great dedication of HH's family to her welfare is readily apparent to me.

Nor do I doubt that HH's parents are sincere in their belief that HH's vaccinations played a role in initially causing or aggravating HH's neurodevelopmental disorder. HH's parents have heard the opinion of Dr. Cave, who professes to believe in a causal connection between vaccines and neurodevelopmental disorders. After studying the extensive evidence in this case, I am convinced that the opinion provided by Petitioners' expert in this case, advising the Hardy family that there is a connection between the vaccinations in question, and the causation or aggravation of HH's neurodevelopmental disorder, was *quite wrong*. Nevertheless, I can understand why HH'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 Hardy 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* children with ASDs or similar disorders, 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 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 individuals whose injuries or deaths can be linked causally, either by Table Injury or presumption or by 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 HH's behalf.[41]

IT IS SO ORDERED.

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

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