



2002, April 9, 2002, July 22, 2002, and September 24, 2002, caused him to develop encephalopathy. Amended (“Am.”) Petition at 2-3 (ECF No. 51).<sup>3</sup>

Under the Program, petitioners may not receive compensation based solely upon their claims, as the petition must be supported by either medical records or by the opinion of a qualified physician to establish a causal relationship. *See* § 13(a)(1). Here, the medical records do not support petitioners’ claims, and the proffered expert opinions fail to provide support for the elements necessary to prove causation. For these reasons, and the reasons discussed below, petitioners have failed to demonstrate that they are entitled to compensation, and thus their petition must be dismissed.

## **II. Overview**

This Decision should be read in concert with the Ruling on Factual Issues (“Ruling”) issued on June 14, 2017. (ECF No. 131). The Ruling covers the procedural history, facts, evidence, and applicable statutory scheme. In it, Special Master Hastings (to whom the case was originally assigned) issued a number of specific factual rulings. I have reviewed all of the exhibits, medical records, expert reports, literature, and all other filings, in accordance with the applicable statutes, and I find the Ruling to be complete, accurate, and soundly reasoned. I agree with it, adopt it, and incorporate it herein by reference as if fully set forth. This Decision begins where the Ruling ends, addressing petitioners’ objections to Special Master Hastings’ Ruling and resolving the issues of causation.

## **III. Procedural History**

This is the last case from the Omnibus Autism Proceeding (“OAP”) remaining in the Office of Special Masters. In his Ruling, Special Master Hastings thoroughly described the procedural history of the case from the date of its filing in 2004 through the fact hearing held on August 1, 2016. *See* Ruling at 7-10. The procedural history following that hearing is set forth below.

After Special Master Hastings issued his Ruling, he ordered petitioners to file a motion for a decision dismissing the petition, or a status report indicating how they planned to proceed. Order dated July 6, 2017 (ECF No. 132). Special Master Hastings issued several orders granting petitioners extensions of time for these filings, including one order in which he reiterated his belief that the claim was unlikely to succeed. Order dated Aug. 23, 2017 (ECF No. 142). On September 12, 2017, in light of Special Master Hastings’ retirement, this case was reassigned to me. Notice of Reassignment dated Sept. 12, 2017 (ECF No. 144). I then gave petitioners 30

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<sup>3</sup> Petitioners initiated this claim by filing a “short-form autism petition,” effectively alleging that C.A.P. had autism and making his case part of the OAP. *See* Petition (ECF No. 1); *Autism General Order #1*, 2002 WL 31696785, at \*4 (Fed. Cl. Spec. Mstr. July 3, 2002). They amended their claim on August 15, 2011, after the OAP test cases found no reliable evidence linking the vaccines in question to autism. *See* Am. Petition; Order dated June 14, 2011 (ECF No. 48). For a thorough discussion of the OAP’s procedural history, please consult pages 4 through 7 of the Ruling.

days in which to file updated medical records or other evidence. Order dated Oct. 27, 2018 (ECF No. 150). In response, petitioners filed additional medical records, along with a memorandum summarizing their position. *See* Petitioners' Exhibits ("Pet. Exs.") 103-11.<sup>4</sup>

On December 13, 2017, respondent filed a Motion for a Ruling on the Record. Mot. for a Ruling on the Record ("Resp. Mot.") dated Dec. 13, 2017 (ECF No. 156). Respondent also filed a supplemental expert report from Dr. Gerald V. Raymond. Ex. U. On February 14, 2018, petitioners filed a letter, in which they sought to amend their petition once again. Amendment dated Feb. 14, 2018 ("2018 Amendment") (ECF No. 166). The request to amend was denied because the 2011 amended petition had already incorporated the requested amendments, and a table encephalopathy claim had already been considered during the fact hearing. Order dated Mar. 14, 2018 (ECF No. 168).

On August 22, 2018, the parties were given 30 days in which to file any additional briefs that they deemed necessary. Order dated Aug. 22, 2018 (ECF No. 169). In response, petitioners filed a status report and motion for an extension of time to file additional evidence, an amended petition, and several other documents. Exs. 113-18. In their amended petition, petitioners alleged that "[e]vidence has been discovered that C.A.P. has a Mitochondrial Metabolism Disorder" that was significantly aggravated by his vaccinations. Ex. 117 at 8-9. Respondent objected to petitioners' attempt to re-open the record, arguing that these filings provided neither new probative evidence nor any reasonable basis to continue to litigate the claims. Resp. Response & Obj. dated Sept. 26, 2018 (ECF 172). Nonetheless, I allowed petitioners an opportunity to file additional evidence by November 26, 2018. Order dated Sept. 26, 2018 (ECF 171).

On November 20, 2018, petitioners filed a motion to change their attorney of record to Curtis R. Webb. Mot. dated Nov. 20, 2018 (ECF No. 173). The Clerk's Office granted the motion pursuant to Rule 83.1(c)(4). Mr. Webb then sought an extension of time to file the results of a mitochondrial DNA test, as well as an expert report on the issue of whether C.A.P. had a mitochondrial disorder. Pet. Mot. dated Nov. 26, 2018 (ECF No. 175). I discussed these issues with the parties during a status conference held on November 29, 2018; I ultimately granted petitioners' motion to file the results of C.A.P.'s mitochondrial DNA testing, but not an expert report. Order dated Dec. 3, 2018 (ECF 176). Mr. Webb filed the test results<sup>5</sup> on February

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<sup>4</sup> On August 18, 2017, petitioners' former counsel, Mr. Clifford Shoemaker, informed the Court of his intent to withdraw from the case. Pet. Motion ("Mot.") dated Aug. 18, 2018 (ECF No. 138). In anticipation of withdrawing, Mr. Shoemaker filed an application for interim attorneys' fees and costs. *See* Pet. Application dated Sept. 29, 2017 (ECF No. 147). On December 5, 2017, the undersigned issued a decision awarding interim fees and costs. Decision dated Dec. 5, 2017 (ECF No. 155). Petitioners' counsel subsequently issued a motion to withdraw as attorney, which was granted on December 19, 2017. Order dated Dec. 19, 2017 (ECF No. 158). Petitioners were given 60 days to retain new counsel, but at that time they chose to proceed *pro se*. *See* Order dated Nov. 29, 2017 (ECF No. 153).

<sup>5</sup> C.A.P.'s mitochondrial DNA genetic testing results did not show any "clinically significant variants" and were interpreted as normal. Ex. 119 at 1.

5, 2019. Ex. 119. I subsequently issued an order stating that the record in the case was closed. Order dated Feb. 7, 2019 (ECF 182).

The case is now ripe for adjudication of respondent's Motion for a Ruling on the Record.

#### **IV. Factual Issues**

Petitioners assert that Special Master Hastings' Ruling was not factually accurate in several respects. Petitioners maintain that C.A.P. suffered from failure to thrive;<sup>6</sup> that his medical records did not accurately document certain symptoms; that he did not have autism; that Special Master Hastings' Ruling was improperly based on a diagnosis of autism; and that the Ruling did not consider certain transcribed medical notes, which petitioners subsequently filed. *See generally* Ex. 103.

A detailed chronology of C.A.P.'s medical records from his birth on December 6, 2001, through approximately 2007 is set forth in the Ruling. The Ruling also includes a summary of additional medical history reported by C.A.P.'s parents, as well as by family friends Nick Chrissikos and Naomi de la Torre. I incorporate by reference all of these facts as set forth in the Ruling.<sup>7</sup>

##### **A. Additional Exhibits Filed After Ruling**

Since the Ruling was issued, petitioners have filed additional exhibits, including a Statement of Position; school evaluations from 2007 through 2017; a supplemental report by Dr. Corbier; transcribed medical notes; a medical history summary; a growth weight chart; a diagnoses chart; general information on autism and learning disabilities; a group of exhibits that were previously filed;<sup>8</sup> and mitochondrial DNA test results. *See* Exs. 103-19. I have reviewed all of the additional exhibits and taken all of these into consideration. Below, I summarize only those portions of the exhibits which are relevant to my Decision.

##### **i. School Evaluations**

Petitioners filed C.A.P.'s school evaluations for 2006 to 2017, chronicling kindergarten through eighth grade. Ex. 104. The earliest evaluation, performed on September 11, 2006, when C.A.P. was 4 years old, assessed whether C.A.P. met the disability requirements for autism. Ex. 28 at 2; Ex. 104 at 19. The results were summarized as follows:

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<sup>6</sup> "Failure to thrive" is defined as "physical and developmental retardation in infants and small children, seen in those with a physical illness or suffering psychosocial effects such as maternal deprivation. Characteristics include lack of physical growth and below normal achievement in fine and gross motor, social-adaptive, and language skills as assessed by psychometric testing." *Dorland's Illustrated Medical Dictionary* 678 (32d ed. 2012).

<sup>7</sup> *See* Ruling at 10-28 (recitation of facts), 43-44 (specific findings of fact).

<sup>8</sup> Exhibit 112 is a group of exhibits previously filed individually as Exhibits 58, 100, 102, and 99, and it does not contain new information.

In July of 2004 Dr. Gordon Bourland evaluated [C.A.P.] and identified him as a child on the Autism Spectrum Disorder. In September of 2006 the Preschool assessment team in Plano ISD conducted an assessment and gave [C.A.P.] an Eligibility of NCEC<sup>9</sup> with a suspicion of Autism. They refrained from making a formal diagnosis at that time due to his young age and because of the scatter of atypical behaviors observed during the assessment.

Ex. 104 at 119. Based on additional school assessments performed on December 5, 2007, including the Gilliam Autism Rating Scale (“GARS”) and the Childhood Autism Rating Scale (“CARS”), evaluators concluded that C.A.P.’s behavior was not consistent with autism. *Id.* at 117. When observed in the classroom, C.A.P. “appeared happy, . . . laughing and smiling with his peers and engaged in verbal interaction with them.” *Id.* at 116. He “made excellent [eye] contact and sustained interaction with his peers and his teacher.” *Id.* C.A.P. had no vision or hearing abnormalities, his behavior was age appropriate, and he was able to dress himself. *Id.* at 113-15. Testing did not reveal a speech impairment. C.A.P. met eligibility requirements for special education services based on a learning disability, but he did not meet criteria for a pervasive developmental disorder (“PDD”)<sup>10</sup> or autism. *Id.* at 120.<sup>11</sup>

An evaluation performed in 2009, when C.A.P. was in second grade, showed he had no significant health issues and no physical conditions that affected his education. Ex. 104 at 97. C.A.P. was described as “a very well behaved child at home,” and although he was “easily distracted” in the classroom, he “responded well to encouragement.” *Id.* at 99, 103, 105. He was assessed with receptive and expressive language deficits. *Id.* at 89. Evaluations performed in the third and sixth grades continued to show deficits with reading comprehension and written expression, but no emotional or behavioral problems. *Id.* at 52-83. The most recent evaluation in eighth grade revealed improvement, but C.A.P. continued to have deficits in reading comprehension. *Id.* at 21. Teachers reported that his emotional and behavioral skills were average or above average. *Id.* at 6. C.A.P. was observed to follow oral and written instruction, interact appropriately with his classmates, and engage with his peers during a small group activity. *Id.* at 13. No significant emotional or behavioral problems at home were documented. *Id.* at 5.

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<sup>9</sup> NCEC stands for “non-categorical early childhood,” a term used to describe a variety of learning disabilities, intellectual disabilities, and developmental disorders. *See Non-Categorical Early Childhood, Special Educ. Info. Ctr.*, <https://www.spedtex.org/index.cfm/parent-resources/disabilities/non-categorical-early-childhood/> (last visited Apr. 27, 2019); Ex. 28 at 26.

<sup>10</sup> Pervasive developmental disorder is defined as “a group of disorders characterized by impairment of development in multiple areas, including the acquisition of reciprocal social interaction, verbal and nonverbal communication skills, and imaginative activity, and by stereotyped interests and behaviors.” *Dorland’s* at 552.

<sup>11</sup> This 2007 evaluation and the evaluations done over the next ten years, which clearly show that C.A.P. did not meet the criteria for ASD, call into question whether there was a reasonable basis for petitioners to pursue the claim as part of the OAP after 2007, when they learned that their son did not have an ASD diagnosis.

**ii. Transcribed Medical Notes and Medical History**

In their Statement of Position, petitioners assert that Special Master Hastings' Ruling was "not factually medically accurate," due in part to the unavailability of certain transcribed medical notes. Ex. 103 at 1. Petitioners filed some transcribed medical notes as Exhibit 106, but petitioners do not identify the person who transcribed the notes. The exhibit is not self-authenticated, it is not signed by a notary, and it is not certified by a court reporter or other person. The exhibit does not reference the exhibits or physician's notes it purports to transcribe. Presumably, it was transcribed by petitioners.

These transcribed notes are frequently inconsistent with the medical records. Most notably, Exhibit 106 contains extraneous information not found in the medical records for the relevant dates. For example, the first page of the exhibit includes an entry dated April 30, 2002, referencing a call from C.A.P.'s mother regarding an appointment for C.A.P. later that day. The entry states, "call not found in medical records." Ex. 106 at 1. Additionally, some of the transcribed notes do not accurately reflect the handwritten physician notes. For example, the transcribed note dated July 23, 2002, states, "Very high fever of 102-103," but the original handwritten note from that visit states, "↑ temp 102-103." Compare Ex. 106 at 3, with Ex. 34 at 36. The addition of the words "very high fever" is an inaccurate transcription of the note, which is clear and legible.

Similarly, the transcribed note of July 24, 2002, appears inaccurate. The physical examination is charted as follows:

DATE	1302293	NAME	PROKOPEAS, CHRISTIAN	AGE	17-4	HT					
EXAMINATION											
fever x 2d, shots & #63 7/22/02, not himself, temp high at 103°											
Meds: Tylenol/Motrin NKDA T: 101.4 (R) <i>Dr. Ashley</i>											
<i>no pulse - 2 pers. 8/17</i>											
<i>HEART not R</i>											
<i>Neck supple</i>											
<i>chest clear</i>											
<i>abd clear</i>											
<i>usc - vic</i>											
<i>? dx to start / correct</i>											
<i>NS</i>											
RBC	Hgb	Hct	WBC	Seg	Band	Lymph	Mono	Eos	Plts	Morph	T.
x10 <sup>6</sup> /mm <sup>3</sup>	GM%	%	x10 <sup>3</sup> /mm <sup>3</sup>	%	%	%	%	%	x10 <sup>3</sup> /mm <sup>3</sup>		Sm
4.36	10.7	33.0	5.9	58		35	7		197		ca
Char	Color	pH	Prot	Glu	Keton	Nit	Bld	Wbc	Rbc	Bact	Other
Clear	Yel	5.0-8.0	Neg	Neg	Neg	Neg	Neg	0-9	0-5	Neg	
Strep Screen	T.	BAP	T.	Test	Result	Reference	T.				
N		Neg									

*Id.* at 37. The words to the right of “HEENT” are transcribed as “fast pulse,” but the words, which are difficult to read, could also be “fax” or “f/u” (follow up). *See* Ex. 106 at 3. The transcription also includes a two-paragraph discussion of acute gastroenteritis, which the handwritten note does not contain. *Compare* Ex. 106 at 4, *with* Ex. 34 at 37.

Petitioners assign particular significance to two phrases allegedly documented in the July 24, 2002 note. First, petitioners assert that Dr. Ashley’s note “? Rx to shot” suggests vaccine-related encephalopathy. *See* Ex. 103 at 1-2. Read in the context of the entire note, as well as the note from July 23, 2002,<sup>12</sup> the pediatrician clearly questioned only whether the child’s fever was a reaction to the vaccine. Nothing in the notes suggests that the fever was a symptom of encephalopathy.<sup>13</sup> Dr. Ashley did not diagnose C.A.P. with encephalopathy at that visit, or at any other visit.

Petitioners also assert that Dr. Ashley used the words “weak” or “lethargic” to describe C.A.P. on July 24, 2002. *See* Ex. 103 at 2; Ex. 106 at 3; Ex. 107 at 2. However, I do not see a word that looks like “weak” in the handwritten note, nor do I see the word “lethargic.” *See* Ex. 34 at 37. And even if Dr. Ashley had described C.A.P. as “weak”, weakness is not synonymous with lethargy. Lethargy is defined as “a lowered level of consciousness marked by listlessness, drowsiness, and apathy.” *Dorland’s* at 1025. When C.A.P. presented to the pediatrician for follow-up the next day, the pediatrician described him as “happy,” “playful,” in no acute distress, and “well hydrated.” Ex. 10 at 4. These descriptions are inconsistent with encephalopathy. Thus, due to the discrepancies between the medical notes that were originally filed and the transcribed notes, compounded by the lack of authentication, I find that Exhibit 106 is not a true or accurate transcription of C.A.P.’s medical records.

The same problems apply to the “Medical History” submitted by petitioners as Exhibit 107. Like Exhibit 106, this exhibit appears to include additional history reported by C.A.P.’s parents and family friends. Special Master Hastings’ Ruling has already considered and rejected petitioners’ claims that “C.A.P. showed certain symptoms of an injury that his medical records did not document.” Ex. 103 at 2. The Ruling specifically addressed the additional allegations from family members, friends, and experts, and found C.A.P.’s medical records to be “more reliable than the parental and friend narratives, made later in time, concerning his alleged post-vaccination symptomatology.” Ruling at 32. I concur with Special Master Hastings and will not replot that ground here.

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<sup>12</sup> The patient phone call note from the physician on July 23, 2002, states as follows: “Discussed fevers in general [and] fever control. Also fever as a reaction to the immunization can last 24-36 hours [after] injection.” Ex. 10 at 14.

<sup>13</sup> In the medical community, encephalopathy is typically defined as “any degenerative disease of the brain.” *Dorland’s* at 614; *see also* Ex. 99 at 3. The Vaccine Injury Table, however, defines encephalopathy more narrowly. *See infra* Section VII.B. Dr. Ashley’s note does not suggest signs and symptoms of encephalopathy using either definition.

### iii. Growth Chart

Petitioners assert that C.A.P. failed to gain weight after April 9, 2002, and that his lack of weight gain was a symptom of failure to thrive, which caused a “lasting harmful effect on C.A.P.’s brain development.” Ex. 103 at 2; *see also* Ex. 108.<sup>14</sup> The contemporaneous medical records, however, do not show that C.A.P. had failure to thrive. On February 5, 2002, the date of C.A.P.’s two-month well-child visit and immunizations, his weight was 11 lb., 12 oz. Ex. 34 at 11. Although he had diarrhea and a stuffy nose, C.A.P. was noted to be a well baby, and his developmental screen was normal. Ex. 34 at 15; Ex. 10 at 11. Similarly, on April 9, 2002, at his four-month well-child visit, C.A.P. had a normal developmental screen, and was diagnosed as a “well baby.” Ex. 34 at 15; Ex. 10 at 13. Four-month vaccinations were administered at that time. Ex. 10 at 13. Three weeks later, C.A.P. presented for a sick visit, with a rash, cough, and running nose. Ex. 34 at 35. He was diagnosed with an upper respiratory infection (“URI”) but was noted to be “happy.” *Id.* C.A.P.’s pediatrician documented no concerns regarding his weight.

C.A.P. was next seen by his pediatrician on July 22, 2002, at 7 months, for a well-child visit. He was diagnosed a well child and received his immunizations. Ex. 10 at 14. The next day, C.A.P.’s parents called the pediatrician to advise that C.A.P. had a fever of 102-103° F and that he was fussy, but that he felt better when given Motrin. *Id.* The note specifically addressed intake and noted that C.A.P. was “eating ok.” *Id.* There is no indication that C.A.P. was not eating well or that he had failure to thrive.

Mrs. Prokopeas placed a second call to the pediatrician’s office on July 23, 2002, to again report that C.A.P. had a fever of 102-103° F. Notes from this call stated that C.A.P. “was playful” and had no symptoms other than fever. Ex. 10 at 15. The next day, C.A.P. was seen by the pediatrician, who documented a fever as high as 103° F for two days and noted that C.A.P. was described as “not himself,” but did not express concern about C.A.P.’s weight or mention failure to thrive. Ex. 34 at 37. C.A.P.’s parents took him to another pediatrician, Dr. Porter, on July 25, 2002. They reported that he had diarrhea and “could not keep anything down,” but he was noted to be “happy,” “playful,” and “well hydrated.” Ex. 10 at 4. Dr. Porter diagnosed C.A.P. with viral gastroenteritis, but he did not document anything about failure to thrive. *Id.* Dr. Porter next saw C.A.P. for follow-up on August 14, 2002. Petitioners reported that C.A.P.

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<sup>14</sup> Exhibit 108 appears to be the weight portion of C.A.P.’s growth chart for birth through 12 months. However, growth charts should also include length-for-age and head circumference-for-age data. Clinical Growth Charts, *Nat’l Ctr. for Health Statistics*, [www.cdc.gov/growthcharts/clinical\\_charts.htm](http://www.cdc.gov/growthcharts/clinical_charts.htm) (last visited Apr. 16, 2019). Infants (birth to 24 months) must be measured for length, and the data documented on the sex-appropriate length-for-age chart. *Id.* “Growth charts are not intended to be used as a sole diagnostic instrument. Instead, growth charts are tools that contribute to forming an overall clinical impression of the child being measured.” CDC Growth Charts: United States, *Nat’l Ctr. for Health Statistics*, [www.cdc.gov/growthcharts/background.htm](http://www.cdc.gov/growthcharts/background.htm) (last visited Apr. 16, 2019).

had a cough for three days and diarrhea for seven days. *Id.* Dr. Porter diagnosed C.A.P. with thrush<sup>15</sup> and feeding issues, prescribed gentian violet for thrush, and encouraged solid food. *Id.*

C.A.P. was next seen for his nine-month well-child visit. He was noted to be crawling and standing with assistance. Ex. 10 at 3. Dr. Porter diagnosed C.A.P. as a well child, making no reference to failure to thrive, and administered a Hep B vaccination. *Id.* Approximately one week later, on September 30, 2002, C.A.P. presented with congestion, runny nose, and vomiting. *Id.* He was noted to be teething, but his appetite was normal (“app ok”). *Id.* Physical examination revealed that C.A.P. was alert and cooperative. *Id.* Dr. Porter diagnosed C.A.P. with a viral URI and a feeding problem, but he did not diagnose him with failure to thrive. *Id.*

On October 13, 2002, C.A.P. was taken to the ER with vomiting and diarrhea. Ex. 35 at 16-19. His weight at the time was 8.35 kg, or approximately 18.4 lb. *Id.*; Ex. 108. C.A.P. was diagnosed with gastroenteritis, but not failure to thrive.<sup>16</sup> Ex. 35 at 19. After this ER visit, there are no medical records for approximately one year. Once medical care resumes in 2003, however, the records still do not reflect failure to thrive.

Based on the growth chart provided by petitioners, C.A.P.’s weight gain slowed in September 2002. Ex. 108 at 1. This plateau, however, was short lived. *Id.* By October 13, 2002, C.A.P. had gained a pound. *Id.* Subsequently, C.A.P.’s weight continued to increase. *Id.* He weighed 21.7 lb. on June 5, 2003; 26 lb. on January 6, 2004; and 30 lb. on May 14, 2005. *Id.* By June 5, 2012, his weight placed him in the 80th percentile as reported by the CDC. *Id.* The last measurement reported by petitioners for C.A.P., taken when he was nearly 16 years old, is 170 lb., placing him in the 90th percentile. *Id.*

In short, no treating physician noted or suggested that C.A.P. had failure to thrive, and no physician documented any concerns about his weight. I thus find no basis to conclude that Special Master Hastings’ Ruling was inaccurate based on petitioners’ argument about weight loss or failure to thrive.

#### **iv. MITOswab Test and Mitochondrial DNA Test Results**

On September 20, 2018, petitioners filed C.A.P.’s MITOswab test results from December 2017. Ex. 115. The report does not appear to be signed or dated by any physician or laboratory director. The results purport to show that the “overall content of mitochondria is in the normal range” but that there are significant deficiencies in the activity of respiratory chain complex I and IV. *Id.* at 1-2. Notably, the report includes a caveat that “the buccal mitochondrial enzyme testing approach is still a work in continued improvisations. While the published data supports the evidence for the representation of skeletal muscle . . . RC enzymes activities by buccal tissue . . . , more work is needed to be undertaken to have a more conclusive statement.” *Id.* at 2. The

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<sup>15</sup> Thrush is defined as “candidiasis of the oral mucosa, usually the buccal mucosa and tongue, and sometimes the palate, gingivae, and floor of the mouth.” *Dorland’s* at 1924.

<sup>16</sup> Gastroenteritis is defined as “inflammation of the lining of the stomach and intestines, characterized by anorexia, nausea, diarrhea, abdominal pain, and weakness.” *Dorland’s* at 764.

report also contains a disclaimer: “Please note that this MITOswab test is a lab developed test . . . and not yet approved by FDA.” *Id.* After filing this study, petitioners requested “additional time to investigate the question of what role mitochondrial dysfunction may have played in the cause of [C.A.P.’s] disabilities.” Pet. Response to Mot. for Ruling on the Record (“Pet. Response”) (ECF No. 174) at 3. According to petitioners, their experts recommended that C.A.P. have a “mitochondrial DNA test” to determine whether he had a mitochondrial disorder. *Id.* at 4.

C.A.P.’s mitochondrial DNA test was performed and returned a normal result. Ex. 119 at 1. The report states as follows:

Mitochondrial DNA sequencing and deletion analysis did not identify any clinically significant variants. . . . This test result may be called “normal” or “negative” because a genetic change that may explain [C.A.P.’s] medical and/or developmental history was not found. All sequence variants reviewed were classified based on the American College of Medical Genetics (ACMG) standards and guidelines.

*Id.* The report was electronically signed by Peter L. Nagy, M.D., Ph.D., Laboratory Director, and the methodology used is described in detail. *Id.* at 4. The report also contains the caveat that the test has not been “cleared or approved” by the FDA, although the laboratory that performed the test is certified under the Clinical Laboratory Improvement Amendments (“CLIA”).<sup>17</sup> *Id.*

Petitioners sought mitochondrial DNA testing to determine whether C.A.P. had a mitochondrial disorder, asserting that the test would be “highly relevant . . . in understanding the symptoms which accompanied the high fever that [C.A.P.] suffered after his July 22, 2002 vaccinations . . . .” Pet. Response at 4-5. They described the DNA test as “the best available evidence” on the issue of whether C.A.P. had a mitochondrial disorder. *Id.* at 5. The results, however, do not provide evidence of a mitochondrial disorder. Therefore, I find no factual basis to allow petitioners to continue pursuing this theory, through additional expert review or otherwise.

#### **v. Other Exhibits**

The balance of petitioners’ exhibits includes a summary of C.A.P.’s various diagnoses (Exhibit 109);<sup>18</sup> an overview of autism (Exhibit 110); an overview of “Specific Learning

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<sup>17</sup> The Clinical Laboratory Improvement Amendments of 1988 are regulations which “include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.” Clinical Laboratory Improvement Amendments (CLIA), *Ctrs. for Disease Control & Prevention*, <https://wwwn.cdc.gov/clia/About.aspx> (last visited Apr. 29, 2019).

<sup>18</sup> The summary of diagnoses refers to exhibits previously filed as Exhibits 5 through 90, and is a demonstrative exhibit. While it summarizes prior information, it does not provide new evidence.

Disabilities” (Exhibit 111); a group of exhibits previously filed (Exhibit 112); and written testimony by Mrs. Prokopeas (Exhibit 118).<sup>19</sup>

The overview regarding learning disabilities provides general information and definitions. *See generally* Ex. 111. Based on this information, and C.A.P.’s school records, C.A.P. meets the criteria for a learning disability. However, the information provided does not explain the etiology or causes of C.A.P.’s specific learning disability. The records do not refer to C.A.P.’s learning disability as an encephalopathy, nor do they describe any association between C.A.P.’s learning disability and encephalopathy. Moreover, this exhibit does not reference vaccines or associate vaccines with C.A.P.’s learning disability.

**B. Request for Reconsideration of Special Master Hastings’ Ruling on the Basis that C.A.P.’s Diagnosis is Encephalopathy Rather Than Autism**

In their Statement of Position, petitioners assert that Special Master Hastings’ ruling was based on a “‘causation-in-fact’ connection between vaccines and autism,” and that C.A.P. does not have autism. Ex. 103 at 2-3. Petitioners, however, misinterpret Special Master Hastings’ Ruling. Throughout the Ruling, Special Master Hastings clearly states that “[p]etitioners allege that C.A.P. suffered from an encephalopathy that was ‘caused-in-fact’ by the cumulative effects of [his] vaccinations.” Ruling at 1; *see also* Ruling at 8 (“Petitioners filed an Amended Petition . . . alleging that C.A.P. ‘developed encephalopathy from repeated exposures to mercury and other vaccine ingredients.”); Ruling at 30-31 (summarizing Dr. Corbier’s opinion that C.A.P. had a brain disorder described as static encephalopathy or chronic encephalopathy); Ruling at 45 n.40 (finding that C.A.P. did not suffer encephalopathy, a Table injury).

Special Master Hastings does refer to the fact that C.A.P. had been diagnosed with autism, but petitioners concede this in Exhibit 109, in which they provide a chart with a “History of Diagnoses for C.A.P. from birth to present.” *See* Ex. 109. Included in that list is the diagnosis of PDD-NOS<sup>20</sup> given by Dr. Bourland on July 22, 2004, which is an Autism Spectrum Disorder. *Id.* Dr. Bourland’s records show that in November 2003, C.A.P.’s parents noted a substantial change in his behavior. Ex. 9 at 1. After assessment, Dr. Bourland diagnosed C.A.P. with PDD-NOS. *Id.* at 4. The diagnosis of Autism-PDD also appears in the medical records of Dr. Hamel on July 19, 2004. Ex. 18 at 7. Later records indicate that C.A.P. no longer had the diagnosis of autism, and his updated diagnosis was learning disability coupled with speech and language delay. Ex. 47 at 22; Ex. 48 at 27 (“Past Diagnosis: Autism/PDD, Today’s Diagnosis: LD – Learning Disability”); Ex. 56 at 45 (recommending in 2007 that C.A.P.’s school district “consider eligibility of autism [to] be removed,” but also recommending “an eligibility of a specific learning disability in the area of oral expression”). However, the records clearly indicate that C.A.P. *did* have the diagnosis of autism and received special education services for that

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<sup>19</sup> Exhibit 118, entitled “Testimony from Ellena Prokopeas, July 30, 2014,” is a two-page document that does not offer any new evidence.

<sup>20</sup> PDD-NOS is Pervasive Developmental Disorder Not Otherwise Specified, an Autism Spectrum Disorder (“ASD”). *See* Ruling at 4 n.2.

diagnosis for a period of time. Thus, it was accurate for Special Master Hastings to refer to C.A.P.'s autism diagnosis in his Ruling.

To the extent that petitioners request reconsideration of Special Master Hastings' Ruling based on his reference to C.A.P.'s autism diagnosis, that request is denied.

## V. Expert Opinions

In support of their claim, petitioners offer the expert reports of Dr. Jean-Ronel Corbier, Dr. Joseph Bellanti, and Dr. Brett Abrahams.<sup>21</sup> *See* Exs. 87, 89, 96, 98, 99, 105, 116.

Respondent submits expert reports by Dr. Gerald Raymond and Dr. Judith Miller. *See* Exs. A, H, L, T.

### A. Petitioners' Expert, Dr. Joseph Bellanti, M.D.<sup>22</sup>

Dr. Bellanti opined that C.A.P. had repeated allergic reactions to some component in the vaccines that he received in 2002, causing him to be diagnosed with "static encephalopathy" two years later in 2004.<sup>23</sup> Ex. 87 at 3. As explained by Special Master Hastings, the factual predicates upon which Dr. Bellanti based his expert opinions, taken in part from petitioners' joint affidavit and from the medical history documented by Dr. Kotsanis (which was, in turn, taken from the parents), are inconsistent with the facts set forth in C.A.P.'s contemporaneous medical records. Ruling at 44; *see also* Ex. 87. For all the reasons discussed in the Ruling, I agree with Special Master Hastings, who rejected the parents' affidavit testimony, written and oral statements, and testimony regarding C.A.P.'s post-vaccination symptoms. I also reject the medical history documented by Dr. Kotsanis for the same reasons – that it was not based on the contemporaneous records of C.A.P.'s pediatrician. *See* Ex. 5 at 2-3.

As for causal theories, Dr. Bellanti initially hypothesized that C.A.P. might have an abnormal *de novo* genetic mutation of chromosome 21, which made him susceptible to autism.<sup>24</sup>

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<sup>21</sup> Much of the medical literature cited in petitioners' expert reports was not filed. *See, e.g.*, Ex. 89 at 3; Ex. 96 at 4-5; Ex. 105 at 5; Ex. 116 at 2. On April 25, 2019, the undersigned ordered petitioners to file all outstanding medical literature by May 16, 2019. Order dated Apr. 25, 2019 (ECF No. 183). Petitioners did not comply.

<sup>22</sup> Dr. Bellanti's qualifications are described in Special Master Hastings' Ruling and will not be restated here. *See* Ruling at 28-29.

<sup>23</sup> Dr. Bellanti references several different diagnoses in his expert reports, including ASD, static encephalopathy, injury of the nervous system, and mental retardation. *See* Ex. 87 at 3; Ex. 89 at 3.

<sup>24</sup> Dr. Bellanti's reference is to genetic studies conducted on July 12, 2007, and filed on May 19, 2009, which showed "[a]bnormal hybridization pattern for 21q subtelomere probe." *See* Ex. 25 at 8.

Ex. 89 at 2. Citing an article by Molloy,<sup>25</sup> Dr. Bellanti questioned whether C.A.P. had a genetic risk factor, and if so, the significance of such a risk factor. Ex. 87 at 3. However, in his supplemental report, Dr. Bellanti concludes that the significance of the defect in C.A.P.'s chromosome 21 was "not entirely clear." Ex. 89 at 2. He also observes that a follow-up study to Molloy, published by Parr, et al., did not confirm Molloy's findings. *See id.* at 1. Thus, Dr. Bellanti is unable to determine the significance of C.A.P.'s chromosomal abnormality, other than to say that it has been associated with "various forms of mental retardation and could have contributed to the injury caused by the vaccines." *Id.* at 2.

As another "medical theory of causation," Dr. Bellanti asserts that "there is a documented literature supporting a relation between vaccines and immunologically-mediated injury of the nervous system and mental retardation." Ex. 89 at 3. Dr. Bellanti does not explain what he means by "immunologically-mediated injury." He does not describe the mechanism, nor does he offer any explanation of how it caused injury. He references four articles,<sup>26</sup> but they all relate to the abnormality in chromosome 21 and its association with developmental regression and/or mental retardation. They do not appear to explore potential associations between vaccines and injury of the nervous system, vaccines and mental retardation, or vaccines and encephalopathy or static encephalopathy.

In a similarly conclusory fashion, Dr. Bellanti asserts that there was a "logical sequence of cause and effect" due to the "striking history of a well child then sustaining fever, high pitched cry and developmental abnormalities." Ex. 89 at 3. Dr. Bellanti does not state any facts from C.A.P.'s contemporaneous medical records in support of this conclusion. Again, this conclusion is based upon Dr. Bellanti's misassumption of facts which I have specifically rejected and found, as did Special Master Hastings, to be clearly erroneous. *See Ruling at 44-45.*

As for *Althen* Prong Three, Dr. Bellanti asserts that the "onset of serious developmental abnormalities in timing with the receipt of the vaccines supports a temporal relationship." Ex. 89 at 3. Dr. Bellanti did not explain what temporal relationship would be expected given his proposed theory of immunologically-mediated injury. Specifically, he did not explain how or why the temporal association was appropriate when the records showed that the vaccinations at issue were administered in 2002, but C.A.P. was not diagnosed with encephalopathy until 2004.<sup>27</sup>

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<sup>25</sup> In Molloy, the authors reported that genetic elements in certain regions of chromosomes 21 and 7 "are likely to confer susceptibility to autism or modify the disease presentation in a subgroup of children characterized by a history of developmental regression." Ex. 87 at 4.

<sup>26</sup> Specifically, Dr. Bellanti references articles from Molloy, et al. ("Evidence for linkage on 21q and 7q in a subset of autism characterized by developmental regression"); Parr, et al. ("Response to paper by Molloy et al.: linkage on 21q and 7q in autism subset with regression"); Ozkinay, et al. ("Prenatal diagnosis of de novo unbalanced translocation 8p;21q using subtelomeric probes"); and Kok, et al. ("Application of a comprehensive subtelomere array in clinical diagnosis of mental retardation"). *See Ex. 89 at 3.*

<sup>27</sup> The first time that C.A.P. was suspected to have encephalopathy was November 8, 2004, when Dr. Tardo suggested that he suffered from "static encephalopathy." *See Ex. 75 at 3; Ex. 109 at 1.*

With regard to diagnosis, Dr. Bellanti refers to C.A.P.'s injury as autism spectrum disorder and static encephalopathy. Ex. 87 at 2-3. Dr. Bellanti defines autism in his second report as "a pervasive development disorder with a genetic component." Ex. 89 at 1. He also describes C.A.P. as having "neurological and developmental abnormalities" and "mental retardation." *Id.* at 2-3.

**B. Petitioners' Expert, Dr. Jean-Ronel Corbier, M.D.<sup>28</sup>**

Dr. Corbier filed four expert reports, with inconsistent diagnoses and differing medical theories. *See* Exs. 98, 99, 105, 116. Dr. Corbier's reports are somewhat difficult to follow, but he appears to propose six causal mechanisms.

In his first report, Dr. Corbier states: "For the purpose of this report, I would like to specifically mention *possible* triggers that relate to [C.A.P.]" Ex. 98 at 1 (emphasis added). He then maintains that "[i]t is well known that environmental triggers play an important role in the development of neurological disorders." *Id.* He asserts that vaccines are among these environmental factors, and that "the strong association of immunization and neurological regression has been undeniable for many clinicians and families." *Id.* However, Dr. Corbier does not explain how these possible environmental triggers cause injury that manifests as a learning disorder or encephalopathy. *See id.*

Next, Dr. Corbier seems to propose a theory based on preservatives and/or adjuvants in the vaccines at issue. Ex. 105 at 5. He alleges that immunological changes occurred "perhaps" due to adjuvants in the DTaP vaccine. *Id.* Dr. Corbier mentions ASIA (autoimmune/inflammatory syndrome induced by adjuvants), or Shoenfeld's syndrome, but he does not describe how the syndrome applies in this case. *Id.* He also briefly references "immune activation," presumably in the context of adjuvants. *Id.* Dr. Corbier offers no analysis or evidence to support these references.

Dr. Corbier's third theory focuses on the pertussis portion of the DTaP vaccine. He opines that the DTaP vaccine administered to C.A.P. on July 22, 2002, caused a Table encephalopathy "within a day of his vaccinations."<sup>29</sup> Ex. 99 at 4-5. He bases this opinion on allegations that C.A.P. was "lethargic, lifeless and febrile within 72 hours" of the vaccination. *Id.* at 5. Dr. Corbier further opines that C.A.P. had "chronic encephalopathy" characterized by "dysfunction in his cognitive and social skills." *Id.* Dr. Corbier does not explain how the DTaP vaccine caused this injury.

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Dr. Usman later diagnosed C.A.P. with "toxic encephalopathy" on December 13, 2004. *See* Ex. 23 at 2; Ex. 109 at 1.

<sup>28</sup> Dr. Corbier's qualifications are described in Special Master Hastings' Ruling and will not be restated here. *See* Ruling at 30.

<sup>29</sup> Dr. Corbier's theory that C.A.P. had a Table encephalopathy is discussed in more detail below, in Section VII.C.

The next theory is very similar to the third theory. Dr. Corbier states that “after multiple vaccines on 2/5/2002, 4/9/2002, 7/22/2002 and 9/24/2002, [C.A.P.] developed symptoms of Vaccine Induced Encephalitis,<sup>30</sup> an inflammation of the brain caused by vaccines.” Ex. 98 at 3. This theory is not well developed, but it appears to be a variation on Dr. Corbier’s opinion that C.A.P. had a Table encephalopathy. *See id.*

Dr. Corbier’s fifth theory relates to mitochondrial dysfunction<sup>31</sup> and its association with neurological disorders. Ex. 98 at 2; Ex. 116. However, C.A.P. has not been diagnosed with a mitochondrial disorder or dysfunction, and no references in the medical records suggest that he was ever so diagnosed. C.A.P.’s mitochondrial DNA genetic testing returned normal results and therefore provides no support for Dr. Corbier’s theory.

As for Dr. Corbier’s sixth theory, he alleges an association between autistic regression and an underlying mitochondrial disorder, suggesting that C.A.P. had “an abnormal immune activation with a high fever leading to increased oxidative stress and a regressive encephalopathy.” Ex. 116 at 2. Dr. Corbier opines that “C.A.P. got sick immediately after 7-22-02 vaccination then regressed. The regressive encephalopathy, among other things are characterized by C.A.P.’s acquired speech impairment and learning disability.” *Id.* These conclusions, however, are based on facts specifically rejected by Special Master Hastings in his Ruling:

I reject the Petitioners’ allegation that shortly after his vaccinations of July 22, 2002, C.A.P. had uncontrollable screaming and crying, and failed to nurse. I reject that C.A.P.’s sleeping difficulties began soon after his vaccinations of July 22, 2002. I also reject Petitioners’ allegations that C.A.P.’s lack of eye contact began in the time period immediately after his vaccinations of July 22, 2002. Further, I credit the notation in the record of the second phone call of July 23, 2002, that C.A.P. was “playful,” and that he had no additional symptoms at that time other than his fever.

Ruling at 43 (emphasis omitted). Additionally, Special Master Hasting ruled that Dr. Corbier relied on misassumptions of fact in concluding that “soon after his vaccinations of July 22, 2002, C.A.P. became ‘lifeless’ and ‘lethargic,’ and was ‘crying inconsolably.’” Ruling at 45. I concur.

Dr. Corbier also asserts that C.A.P. had “failure to thrive,” but it is not clear whether this constitutes a separate theory of causation. *See* Ex. 105 at 3. Regardless, he failed to cite to any medical records demonstrating that C.A.P. was ever given that diagnosis. *See id.* To the extent that failure to thrive is a theory of causation, Dr. Corbier failed to describe any mechanism or

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<sup>30</sup> Encephalitis is defined as “inflammation of the brain.” *Dorland’s* at 612.

<sup>31</sup> Dr. Corbier references Dr. Richard Frye’s association of mitochondrial dysfunction and neurological disorders. Ex. 98 at 2. Other special masters have thoroughly documented their concerns with Dr. Frye’s theories. *See, e.g., Bast v. Sec’y of Health & Human Servs.*, No. 01-565V, 2012 WL 6858040, at \*28 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (“Dr. Frye’s proposed theory of causation is not supported by sound and reliance science.”), *mot. for rev. denied*, 117 Fed. Cl. 104 (2014).

theory as to how vaccines cause failure to thrive or how vaccine-induced failure to thrive causes encephalopathy. Moreover, I find no evidence in the medical records to support the notion that C.A.P. had failure to thrive.

With regard to diagnosis, Dr. Corbier denies that C.A.P. was autistic. Ex. 105 at 2. Instead, he alternatively opines that C.A.P. suffered from “regressive symptoms,” “hypotonia,” “failure to thrive,” “encephalitis,” “static encephalopathy,” “chronic encephalopathy,” “Table encephalopathy,” “regressive encephalopathy,” and “parenchymal brain disease.” See Exs. 98, 105, 116. Dr. Corbier defines encephalitis as “inflammation of the brain,” and he defines static encephalopathy as “permanent or unchanging brain damage” due to “injury, damage, defect, or illness” that interferes with “normal function, development, or learning.” Ex. 98 at 4; Ex. 99 at 3. He does not provide any further explanation of these diagnoses, nor does he describe the relevant signs and symptoms, diagnostic studies, clinical course, or prognosis for these conditions. He asserts that symptoms of static encephalopathy may be varied and unique, depending on the severity of the injury and the area of brain affected. Ex. 99 at 4. Dr. Corbier explains that if the damage “is in the part of the brain that controls speech and language, [the] child might be delayed in learning to talk or to understand” what is said to him. *Id.* If, however, the damage is more diffuse and widespread, the child may have cerebral palsy, learning problems, mental retardation, or seizures. *Id.*

### **C. Petitioners’ Expert, Dr. Brett Abrahams, Ph.D.**

Dr. Abrahams earned his Ph.D. in neuroscience from the University of British Columbia and completed a postdoctoral fellowship at UCLA, where he received a postdoctoral scholar award from the UCLA Brain Research Institute. Ex. 97 at 3. Over the course of his career, he has authored or coauthored twenty-eight peer-reviewed articles and six book chapters/review articles. *Id.* at 5-6. He now serves as director of the Laboratory of Autism Genetics and as an assistant professor in the Departments of Neuroscience and Genetics at the Albert Einstein College of Medicine. *Id.* at 2. Dr. Abrahams also actively consults on biotechnology matters, such as the launch of a commercial test for the assessment of autism risk. *Id.* at 1-3.

In his expert report, Dr. Abrahams focuses on the DNA variation at 15q11.2, the initial genetic mutation found in C.A.P., and its association with an increased risk for autism. See *generally* Ex. 96. Dr. Abrahams concluded that there was no strong support for the notion that duplication of genetic material associated with this genetic variation increases the risk of autism. *Id.* at 3.<sup>32</sup>

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<sup>32</sup> C.A.P. was twice screened for chromosomal abnormalities. In 2004, chromosomal microarray analysis revealed a duplication of two clones on chromosome 15q. Ex. 75 at 12. Later, in 2007, tests showed a duplication of the subtelomere probe for chromosome 21q. Ex. 25 at 8. None of parties’ experts consider these abnormalities dispositive. Although Dr. Bellanti notes that “major defects in chromosome 21 have been associated with severe forms of mental retardation,” he emphasized that studies of potential links between such chromosomal abnormalities and autism had been inconclusive. Ex. 89 at 1-2 (concluding that “the significance of the chromosomal abnormality is not entirely clear”). Dr. Raymond observes that “[t]here are limits to definitive statements regarding the magnitude of the respective alterations since neither one [has been]

**D. Respondent's Expert, Dr. Gerald V. Raymond, M.D.**

Dr. Raymond, a neurologist and clinical geneticist, received his M.D. from the University of Connecticut and served as a resident in neurology at Massachusetts General Hospital. Ex. T at 1-2. Subsequently, he completed a fellowship in developmental neuropathology at the Universite Catholique de Louvain (Brussels, Belgium), and a fellowship in genetics and teratology at Massachusetts General Hospital. *Id.* Dr. Raymond has authored or coauthored over one-hundred peer-reviewed articles. *Id.* at 3-10. He has also authored and coauthored a variety of other publications, including book chapters and editorials. *Id.* at 12-14. Currently, he serves as a professor of pediatrics and neurology at the Penn State College of Medicine and as an adjunct professor of neurology at the University of Minnesota. *Id.* at 1. His *curriculum vitae* also documents his considerable experience in classroom and clinical instruction. *Id.* at 14-15. Dr. Raymond is certified by the American Board of Medical Genetics and the American Board of Psychiatry and Neurology, with special competency in child neurology. *Id.* at 16.

Dr. Raymond rejects Dr. Corbier's references to the causal theory of ASIA, or vaccine adjuvant-induced injury, as these mechanisms are controversial and C.A.P. did not demonstrate any "immunologic changes" attributable to these conditions or theories. Ex. U at 2. Dr. Raymond similarly disagrees with Dr. Corbier that C.A.P. had an altered mental status, signs and symptoms of encephalopathy, neurological regression, encephalitis, or brain inflammation at any time following vaccination. Ex. L at 3. Specifically, Dr. Raymond disputes Dr. Corbier's conclusion that C.A.P. was irritable and lethargic, since these signs and symptoms were absent from the contemporaneous medical records. *Id.* In summary, Dr. Raymond opined that there was "no evidence of an adverse reaction to any of the immunizations received and definitely no findings of an acute encephalopathy or injury to the brain from [C.A.P.'s] vaccinations." Ex. U at 3.

Dr. Raymond also disagrees that C.A.P. had a mitochondrial disease or disorder. He notes that the alleged association between mitochondrial dysfunction and autism is controversial, supported by "little evidence" of causation. Ex. L at 2. Regardless, Dr. Raymond opines that there is no evidence that C.A.P. has a mitochondrial disorder. *Id.* Dr. Raymond also rejects the notion that C.A.P. had "failure to thrive" associated with vaccines. Ex. U at 2. Dr. Raymond agrees that a child's weight can reflect feeding problems, but he disagrees that feeding problems suggest encephalopathy. *Id.*

With regard to diagnosis, Dr. Raymond provides a thorough summary of C.A.P.'s medical history and concludes that C.A.P. was diagnosed with "intellectual disability [and] receptive and expressive language issues," coupled with social and behavioral problems in early life which "placed him on the autistic spectrum." Ex. A at 3. Raymond further opines that no

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adequately evaluated," but also states that "[t]here is no evidence that the chromosomal abnormalities found in this child makes him susceptible to a vaccine-related event." Ex. A at 6-7; *see also* Ex. L at 2. And Dr. Abrahams opines that the "assertion that increased gene dosage across this specific portion of Chromosome 15 increases risk of autism in any meaningful way" is "untenable." Ex. 96 at 1. Thus, these abnormalities do not factor into my causation analysis. Note also that these tests are distinct from the test results filed on February 5, 2019, which involved mitochondrial DNA sequencing and deletion analysis. *See* Ex. 119.

“contemporaneous adverse events” were associated with C.A.P.’s childhood vaccinations, and in fact, that the medical records consistently describe him as a “happy, awake, and alert baby.” *Id.* With respect to petitioners’ allegations of encephalopathy, Dr. Raymond opines that C.A.P.’s medical records contain no reports of any such adverse effects following his two-month and four-month vaccinations. *Id.* Dr. Raymond thus concludes that C.A.P. never had acute encephalopathy. *Id.*

#### **E. Respondent’s Expert, Dr. Judith Miller, Ph.D., Licensed Psychologist**

Dr. Miller earned her Ph.D. in clinical child and family psychology from the University of Utah. Ex. I at 1. She subsequently served as a psychology fellow at the Primary Children’s Medical Center at the University of Utah School of Medicine, and as a postdoctoral fellow at the Emory Autism Resource Center at the Emory School of Medicine. *Id.* She has coauthored thirty-seven peer-reviewed publications, as well as a number of reviews, editorials, and book chapters. *Id.* at 6-12. Over the course of her career, Dr. Miller has taken on substantial academic and teaching responsibilities at a number of institutions, including the University of Utah and the University of Pennsylvania. *Id.* at 3-4. She now serves as a senior scientist, among other roles, at the Center for Autism Research at the Children’s Hospital of Philadelphia. *Id.* at 1.

Dr. Miller’s opinions generally pertain to the onset of C.A.P.’s autism-related diagnoses. She reviewed C.A.P.’s medical and educational records and notes that “the first documented signs of an autism spectrum disorder” occurred when he was 22 months old, when his parents shared their concerns with Dr. Kotsanis. Ex. H at 7. Unfortunately, she observes, no medical records between the ages of approximately 10 to 22 months of age were provided. *Id.* Dr. Miller notes that the lack of records from this time period “suggests that family did not seek clinical care for any particular concerns.” *Id.* at 8. She contrasts the paucity of medical records before the age of 22 months to the many records evidencing the frequent treatment petitioners sought for C.A.P. after the age of 22 months. *Id.* Based on this change in parental behavior, she believes that that his parents’ concerns “crystallized” when C.A.P. was 22 months old. *Id.* Thus, she concludes that C.A.P. had an ASD in October 2003, when he was seen by Dr. Kotsanis. *Id.* While Dr. Miller agrees that it is “possible that early, nonspecific signs of [C.A.P.’s] autism” may have been present earlier, she does not believe that they had “risen to a level of concern . . . due to wide variations in early childhood development and limited understanding of early signs of autism during the years [C.A.P.] was a toddler.” *Id.* at 9.

#### **VI. Issues**

The parties dispute the following causation issues:

- Whether the DTaP vaccine administered to C.A.P. on July 22, 2002, caused him to suffer an encephalopathy as defined by the Vaccine Injury Table, 42 C.F.R. § 100.3(b)(2) (2004). *See* Ex. 103 at 3.
- Whether any of the vaccines C.A.P. received in 2002 resulted in encephalopathy based on a causation-in-fact theory.

- Whether the “vaccinations C.A.P. received on July 22, 2002, significantly aggravated an underlying mitochondrial disorder, which . . . manifested as a regressive encephalopathy with features of a learning disability.” *See* Ex. 117 at 13.

## VII. Discussion

### A. Resolution of Case Without Hearing

I opted to determine entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on papers rather than via evidentiary hearing, when (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. § 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec’y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at \*21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of a hearing). A hearing is not required in every matter, regardless of the parties’ preferences. *See Hovey v. Sec’y of Health & Human Servs.*, 38 Fed. Cl. 397, 400-01 (1997) (determining that the special master acted within his discretion in denying evidentiary hearing), *appeal dismissed*, 135 F.3d 773 (Fed. Cir. 1997); *Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec’y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at \*2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991), *mot. for rev. denied*, 23 Cl. Ct. 726 (1991), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992).

A hearing provides a petitioner with the opportunity to present live testimony, which aids the special master most in cases where witness credibility is at issue, or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g., Hooker*, 2016 WL 3456435, at \*21 (discussing the factors that weigh against holding a hearing); *Murphy*, 1991 WL 71500, at \*2 (finding no justification for a hearing where “the claim is fully developed in the written record and the special master sees no need to observe the fact witnesses personally for the purpose of assessing credibility). Prior decisions have recognized that a special master’s discretion in deciding whether to conduct an evidentiary hearing “is tempered by Vaccine Rule 3(b),” or the duty to afford each party “a full and fair opportunity to present its case.” *Hovey*, 38 Fed. Cl. at 401. But that rule also includes the obligation to create a record “sufficient to allow review of the special master’s decision.” *Id.* Thus, the fact that a claim is legitimately disputed, such that the special master must exercise her intellectual faculties in order to decide a matter, is not itself grounds for a trial. Special masters are expressly empowered to resolve fact disputes without a hearing, and they may do so if the record at issue has been sufficiently developed to determine that each side’s “full and fair” opportunity has not been abridged.

In this case, live witness testimony was not required in order for me to reach a reasoned decision on entitlement. Thanks in part to the fact hearing held by Special Master Hastings in August 2016, the record itself was expansive and contained sufficient evidence upon which to base this decision. The flaws in petitioners’ theory and factual arguments were self-evident from review of the medical records and the expert reports submitted, which relied heavily on

speculative assertions and statements unsupported by the contemporaneous medical record or by reliable scientific evidence. I simply do not require additional oral testimony to decide the case. Ultimately, the most significant issue in deciding whether to hold a hearing is whether the refusal to do so will deprive the claimants of the fair opportunity to prosecute their case. Petitioners have received such an opportunity here. Therefore, these circumstances counsel in favor of resolving the matter on the papers.

## **B. Applicable Legal Standards**

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” *Rooks v. Sec’y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3 (1986), *as reprinted in* 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation under the Program, petitioners must prove either: (1) that C.A.P. suffered a “Table injury” — i.e., an injury listed on the Vaccine Injury Table — corresponding to a vaccine that he received, or (2) that C.A.P. suffered an injury that was actually caused by the vaccines he received. *See* §§ 11(c)(1), 13(a)(1)(A); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

The Vaccine Injury Table<sup>33</sup> includes an injury of encephalopathy occurring within 72 hours of a vaccine containing certain pertussis bacteria or antigens. The Qualifications and Aids to Interpretation (“QAI”) section of the Table provides that “a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, . . . an acute encephalopathy, and then a chronic encephalopathy . . . for more than 6 months beyond the date of vaccination.”<sup>34</sup> 42 C.F.R. § 100.3(b)(2). For children 18 months of age or younger, acute encephalopathy requires a “significantly decreased level of consciousness<sup>35</sup> lasting for at least 24 hours.” *Id.* § 100.3(b)(2)(i)(A).

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<sup>33</sup> Citations are to the version of the Table in effect on November 29, 2004, when this petition was filed. *See* 42 C.F.R. § 100.3 (2004); Revisions and Additions to the Vaccine Injury Table, 67 Fed. Reg. 48,558 (July 25, 2002) (to be codified at 42 C.F.R. pt. 100.3). Although revisions to the Table in 2017 made minor alterations to the definition of encephalopathy, and added a definition of encephalitis, these amendments do not impact this case. *See* Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6,294 (Jan. 19, 2017) (to be codified at 42 C.F.R. pt. 100.3) (noting that changes to the Table “apply only to petitions for compensation under the VICP filed after this final rule becomes effective”).

<sup>34</sup> A chronic encephalopathy exists if the change in mental status that began with the acute encephalopathy persists for at least six months. 42 C.F.R. § 100.3(b)(2)(ii).

<sup>35</sup> A “significantly decreased level of consciousness” is indicated by the presence of one or more of the following signs: “(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

In the wake of the OAP proceedings, some petitioners continued to pursue their cases by characterizing their children’s injuries as “encephalopathy” accompanied by developmental delay rather than autism. *See Fester v. Sec’y of Health & Human Servs.*, No. 10-243V, 2013 WL 5367670, at \*1 n.5 (Fed. Cl. Spec. Mstr. Aug. 27, 2013). Such petitioners often chose to amend their theories “based on a belief that claims alleging autism [would] not be compensated, but that claims alleging these other conditions may be compensated.” *Id.* However, “recharacterizing a condition as an ‘encephalopathy’ — a term that can encompass conditions ranging from intoxication to a coma — when another diagnosis is more specific and appropriate does little to advance a vaccine injury claim.” *Id.*; *see also* Ruling at 7 n.4 (discussing two cases where vaccinees who suffered from autism also alleged Table injuries and differentiating those claims from petitioners’ claim).

### C. Alleged Table Injuries

Petitioners ask that C.A.P.’s claim be considered a Table injury, alleging that the DTaP vaccine administered to C.A.P. on July 22, 2002, caused encephalopathy. Am. Petition at 2-3. Petitioners also assert that DTaP vaccines given February 5, 2002, and April 9, 2002, mark the initial starting point of C.A.P.’s developmental delay, and that his failure to thrive, speech impairment, and learning disability are manifestations of his Table encephalopathy. *Id.* Petitioners identify four reasons that the evidence supports a finding of Table encephalopathy: C.A.P.’s symptoms following vaccination; petitioners’ efforts to address C.A.P.’s symptoms; the response by C.A.P.’s pediatrician; and petitioners’ expert reports. Ex. 103 at 1-2; 2018 Amendment at 19.

Although this claim was initially based on the diagnosis of autism, petitioners’ 2011 amended petition reframed their claim based on the diagnosis of encephalopathy. Dr. Corbier affirmatively opines that C.A.P. does not have autism, but his most recent report seems to conflate autism with speech impairment and learning disability. *See* Ex. 116 at 2. For instance, Dr. Corbier suggests that C.A.P. has an “underlying susceptibility” caused by “impairment of mitochondrial function,” which caused “regressive encephalopathy.” *Id.* at 1-2. He does not define “regressive encephalopathy,” but uses the phrase in the context of the Shoffner study on “autistic regression” and the Poling study on “Developmental Regression . . . in a child with Autism.”<sup>36</sup> *Id.* at 2. These references to autism seem misplaced, since petitioners deny that C.A.P. has or ever had autism, and Dr. Corbier fails to explain how autism relates to C.A.P.’s speech impairment and learning disability.

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upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).” 42 C.F.R. § 100.3(b)(2)(i)(D).

<sup>36</sup> The author of the Poling case study was also the father of the study’s subject, and the Poling family had a pending claim in this Program. This history was more fully addressed by former Chief Special Master Vowell in a ruling on a motion for discovery in another matter. *See R.K. v. Sec’y of Health & Human Servs.*, No. 03-632V, 2015 WL 10911950, at \*15-17 (Fed. Cl. Spec. Mstr. May 23, 2016), *mot. for rev. denied*, 125 Fed. Cl. 57 (2016). Neither the familial relationship nor the pending claim for compensation had been disclosed. *Id.* at 16.

Ultimately, I do not accept petitioners' allegation that C.A.P. suffered a Table encephalopathy. As former Chief Special Master Campbell-Smith noted in *Waddell v. Sec'y of Health & Human Servs.*, the symptoms of a Table encephalopathy are "neither subtle nor insidious." No. 10-316V, 2012 WL 4829291, at \*6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012). Petitioners assert that Dr. Porter's records demonstrate that the onset of C.A.P.'s acute encephalopathy was July 24, 2002, two days after the DTaP vaccine administered on July 22, 2002. *See* Ex. 103 at 2; Ex. 105. However, neither Dr. Porter's notes, nor Dr. Corbier's report, provide any foundation for such a finding. C.A.P.'s post-vaccination medical records, documented by two different pediatricians, show the following:

<b>Date</b>	<b>Event</b>	<b>Citation</b>
July 22, 2002	Physical Exam by Pediatrician <ul style="list-style-type: none"> <li>• Normal neurological exam (mental status, development, language)</li> <li>• Diagnosis: well child</li> </ul>	Ex. 34 at 36
July 23, 2002	Phone Call from Chris Prokopeas <ul style="list-style-type: none"> <li>• Temperature of 102-103° F</li> <li>• Reported that C.A.P. was fussy, but felt better with Motrin</li> </ul>	Ex. 34 at 36
July 23, 2002	Phone Call from Ellena Prokopeas <ul style="list-style-type: none"> <li>• Temperature of 102-103° F</li> <li>• Reported that C.A.P. was playful, with no other symptoms</li> </ul>	Ex. 34 at 37
July 24, 2002	Physical Exam by Pediatrician <ul style="list-style-type: none"> <li>• Temperature of 103° F</li> <li>• "[N]ot himself"</li> <li>• Neck supple</li> <li>• Chest clear</li> </ul>	Ex. 34 at 37
July 25, 2002	Physical Exam by Pediatrician <ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Decreased appetite; "[c]an't keep anything down"</li> <li>• Fussy</li> <li>• Happy, playful, no acute distress</li> </ul>	Ex. 10 at 4

While C.A.P. may have had a febrile reaction to the vaccines administered on July 22, these daily observations of his mental status show a baby who is alternately described as fussy but happy and playful, and in no acute distress. Nothing in C.A.P.'s July 2002 records indicates that he had a "significantly decreased level of consciousness" lasting 24 hours, as required for Table encephalopathy.

Dr. Corbier frequently seems to disregard these medical realities in his efforts to establish that C.A.P. suffered from a Table encephalopathy. For instance, Dr. Corbier's conclusory assertion that C.A.P. had "clear regressive symptoms and became encephalopathic" ignores the pediatrician's descriptions of C.A.P.'s mental state. *See* Ex. 98 at 4. In subsequent reports, Dr. Corbier again concludes that C.A.P.'s "irritability, high fever and lethargic state" were evidence of acute encephalopathy, but the contemporaneous medical records do not contain the words "irritable" or "lethargic." *See* Ex. 99 at 3. Dr. Corbier asserts that a fever persisting for two days, coupled with the observation that C.A.P. was "not himself," indicates altered mental status and lethargy. Ex. 105 at 2. However, neither altered mental status<sup>37</sup> nor lethargy are used to describe C.A.P. in his medical records.<sup>38</sup> Lastly, Dr. Corbier states that on July 24, 2002, the pediatrician documented that C.A.P. was "weak." *Id.* A physical examination was documented, but the record of it is partly illegible. Regardless, I do not see the word "weak." Dr. Corbier's conclusions of altered mental status and lethargy are erroneous.

In contrast to Dr. Corbier, Dr. Raymond firmly grounds his opinion in the symptoms documented by C.A.P.'s medical records. He notes, for example, that after C.A.P.'s vaccinations on July 22, 2002, he had "a few days of fever, but . . . 'felt better with Motrin and was eating.'" Ex. L at 2. Dr. Raymond observes that on July 24, C.A.P. had a normal examination, and on July 25, he was noted to be happy and playful. *Id.* (citing Ex. 10 at 4). Furthermore, Dr. Raymond opines that the records from September 2002 show no evidence of altered mental status. *Id.* He thus concludes, as I have, that there "is no indication that [C.A.P.] had altered mental status, was acutely encephalopathic, or was manifesting any degree of neurologic regression." *Id.* at 3.

Based on my review of the medical records and expert reports, I find Dr. Raymond's opinions much more accurate and persuasive than those of Dr. Corbier. I find that C.A.P. did not sustain acute encephalopathy or encephalitis after the vaccination administered to him on July 22, 2002. I also find that C.A.P. did not have onset of acute encephalopathy or encephalitis within 72 hours of vaccination. I reject petitioners' assertions that C.A.P.'s symptoms following vaccination; the family's efforts to address C.A.P.'s symptoms; the response by C.A.P.'s pediatrician; or petitioners' expert reports provide preponderant evidence of a Table injury. Therefore, I find that petitioners have failed to show by preponderant evidence that C.A.P. suffered a Table injury.

#### **D. Causation in Fact**

Because petitioners have not proven that C.A.P. suffered a "Table injury," they must show that he sustained an injury that was actually caused by the vaccines he received. To do so,

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<sup>37</sup> Examples of altered mental status include confusion, delirium, or psychosis. *See* 42 C.F.R. § 100.3(b)(2)(i)(B)(1).

<sup>38</sup> Similarly, Dr. Porter's recommendation on July 25 to "call for ↑ listlessness, ↑ vomiting, fever > 48 [hours] or more" should not be read as an implication that C.A.P. was lethargic. *See* Ex. 10 at 4. As Dr. Raymond explains, the pediatrician had simply "provided guidance on warning symptoms which would require return." Ex. U at 2.

they must establish, by preponderant evidence: (1) a medical theory causally connecting a vaccine and C.A.P.’s injury (“*Althen* Prong One”); (2) a logical sequence of cause and effect showing that a vaccine was the reason for his injury (“*Althen* Prong Two”); and (3) a proximate temporal relationship between a vaccine and his injury (“*Althen* Prong Three”). *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); § 13(a)(1) (requiring proof by a preponderance of the evidence). For the reasons set forth below, I find that petitioners have failed to satisfy the *Althen* test and are therefore not entitled to compensation.

## **E. Causation Analysis**

### **i. C.A.P. Did Not Have a Post-Vaccination Encephalopathy.**

Although the term “encephalopathy” is less strictly defined in the context of a non-Table claim, it nevertheless is not so broad as to include any possible type of brain injury, no matter the degree. *See Murphy v. Sec’y of Health & Human Servs.*, No. 05-1063V, 2016 WL 3034047, at \*25-26 (Fed. Cl. Spec. Mstr. Apr. 25, 2016), *mot. for rev. denied*, 128 Fed. Cl. 248 (2016); *Wright v. Sec’y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600, at \*6 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). Thus, even though a petitioner with a non-Table causation-in-fact claim might be able to evade some of the Table’s requirements for establishing an encephalopathy (such as the distinction between “acute” and “chronic” as defined by the Table’s QAI), a non-Table petitioner will still need to point to reliable evidence from the record establishing that the injured party’s symptoms were sufficiently evident and severe enough to constitute an encephalopathy. The decisions of other special masters in non-Table cases have identified the specific kinds of symptoms that would suggest an individual had experienced an encephalopathy, including strange forms of crying, anorexia, insomnia, fever, or irritability. *See Cook v. Sec’y of Health & Human Servs.*, No. 00-331V, 2005 WL 2659086, at \*14 (Fed. Cl. Spec. Mstr. Sept. 21, 2005); *Noel v. Sec’y of Health & Human Servs.*, No. 99-538V, 2004 WL 3049764, at \*16 (Fed. Cl. Spec. Mstr. Dec. 14, 2004) (non-Table encephalopathy characterized by “high-pitched and bizarre, gurgly, cat-like crying, fever, difficulty breathing, unresponsiveness, and staring off”).

Petitioners’ claim depends on a finding that C.A.P. suffered from an encephalopathy after vaccination – making this a threshold matter for resolution. *See Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (noting that when an injury or diagnosis is disputed, and “the proposed injuries differ significantly in their pathology,” the special master may “first find which of [the] diagnoses was best supported by the evidence presented in the record before applying the *Althen* test”). The medical records, however, do not support the conclusion that C.A.P. experienced any kind of encephalopathic reaction after his vaccinations.

### **ii. *Althen* Prong One: Lack of a Reliable Medical Theory**

Petitioners must set forth a medical theory explaining how C.A.P.’s vaccines could have caused his alleged encephalopathy. *See Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Although petitioners need not identify the exact mechanism involved, their theory of causation must be informed by a “sound and reliable medical or scientific explanation.”

*Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994); *see also Veryzer v. Sec’y of Health & Human Servs.*, 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). If petitioners rely upon medical opinions to support their theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford that opinion. *See Broekelschen*, 618 F.3d at 1347 (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); *Perreira v. Sec’y of Health & Human Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (“[An] expert opinion is no better than the soundness of the reasons supporting it.”) (citing *Fehrs v. United States*, 620 F.2d 255, 265 (Ct. Cl. 1980)).

Petitioners have failed to provide preponderant evidence of *Althen* Prong One for four reasons. First, the expert reports contain erroneous and misleading information. Second, the experts’ opinions as to causal mechanisms are conclusory and lack evidentiary support. Third, some of the proffered opinions are merely speculative. Fourth, the evidence reflects that C.A.P. does not have a mitochondrial disorder or dysfunction, invalidating petitioners’ most recently proffered theory.

### 1. Erroneous and Misleading Information

“[S]pecial masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.” *Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011). Erroneous or misleading claims may profoundly undermine an expert’s credibility. As my fellow special masters have indicated in past cases, I cannot accept “dubious tactics” such as relying on studies with serious methodological flaws or quoting medical literature in an inaccurate manner. *See, e.g., Rogero v. Sec’y of Health & Human Servs.*, No. 11-770V, 2017 U.S. Claims LEXIS 1200, at \*135-40 (Fed. Cl. Spec. Mstr. Sept. 1, 2017).

Both Dr. Bellanti and Dr. Corbier proffer erroneous and misleading information, which undermine the persuasiveness of their opinions. For example, Dr. Bellanti’s second report misquotes medical literature and asserts that “there is a documented literature supporting a relation between vaccines and immunologically-mediated injury of the nervous system and mental retardation.” Ex. 89 at 3. The referenced literature, however, appears to relate solely to chromosomal abnormalities and mental retardation. There is absolutely no mention of vaccines in the article. Moreover, C.A.P.’s medical records do not identify or reference his condition as mental retardation. Dr. Corbier also offers a very misleading causal theory based on mitochondrial dysfunction or disorder. *See* Ex. 98 at 2; Ex. 116. This proffered theory is irrelevant because C.A.P. was never diagnosed with a mitochondrial disorder. Dr. Corbier’s opinion based on his assertions that C.A.P. had an altered mental status and was lethargic and weak on July 24, 2002, is similarly misleading. *See* Ex. 105 at 2. As discussed above, there is no evidence to support those assertions.

By including clearly erroneous and misleading information, the experts undermine the veracity of their opinions as a whole.

## 2. Conclusory Expert Opinions

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject “conclusory expert statements that are not themselves backed up with reliable scientific support.” *Kreizenbeck v. Sec’y of Health & Human Servs.*, No. 08-209V, 2018 WL 3679843, at \*32 n.44 (Fed. Cl. Spec. Mstr. June 22, 2018). The undersigned will not rely on “opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Moberly v. Sec’y of Health & Human Servs.*, 85 Fed. Cl. 571, 596 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)), *aff’d*, 592 F.3d 1315 (Fed. Cir. 2010). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. *See id.*

Dr. Bellanti’s reports offer textbook illustrations of conclusory opinions. In his first report, for instance, he makes the following assertion: “It is my opinion that the injury to [C.A.P.’s] brain was caused by his repeated allergic (immune mediated) reactions to his vaccines.” Ex. 87 at 3. Dr. Bellanti does not explain how an allergic reaction can cause ASD, encephalopathy, or any kind of brain injury. In his second report, Dr. Bellanti offers a one-sentence conclusion as a theory:

A medical theory of causation. As described previously there is a documented literature supporting a relation between vaccines and immunologically-mediated injury of the nervous system and mental retardation.

Ex. 89 at 3. Again, Dr. Bellanti fails to explain how vaccines cause an immune-mediated injury such as mental retardation. In a similar manner, Dr. Corbier offers theories which are simply assertions without any explanation. *See, e.g.*, Ex. 98 at 3 (stating, without support from the medical records, that C.A.P. had “clear regressive symptoms and became encephalopathic”).

## 3. Speculative Theories

Possible theories or mechanisms are insufficient to establish causation by a preponderance of evidence. “Expert medical testimony which merely expresses the possibility – not the probability – of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.” *LaCour v. Sec’y of Health & Human Servs.*, No. 90-316V, 1991 WL 66579, at \*5 (Fed. Cl. Spec. Mstr. Apr. 15, 1991); *accord Burns v. Sec’y of Health & Human Servs.*, No. 90-953V, 1992 WL 365410, at \*6 (Fed. Cl. Spec. Mstr. Nov. 6, 1992), *aff’d*, 3 F.3d 415 (Fed. Cir. 1993). The Federal Circuit has likewise made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. *Moberly*, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); *Waterman v. Sec’y of Health & Human Servs.*, 123 Fed. Cl. 564, 573-74 (2015) (denying petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. *Id.*; *see also De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008).

Dr. Corbier presents his theory that vaccines are environmental triggers as merely a possible mechanism. Although he opines that “environmental triggers [such as vaccines] play an important role in the development of neurological disorders,” he does not explain how these triggers cause injuries such as encephalopathy, learning disabilities, or autism. *See* Ex. 98 at 1. At most, he asserts that “the strong association of immunization and neurological regression has been undeniable for many clinicians and families.” *Id.* As such, this opinion is legally insufficient.

#### 4. Mitochondrial Disorder Theory

Petitioners’ newest theory of causation is based on an alleged underlying illness – a mitochondrial disorder that allegedly resulted in regressive encephalopathy after C.A.P.’s vaccination. However, mitochondrial DNA testing has been conducted, and the results reflect no mitochondrial disorder or dysfunction. *See* Ex. 119. Based on my review of all of the medical records, the testing results, and the expert reports, I find that the evidence is insufficient to establish that C.A.P. had a mitochondrial illness.

In conclusion, I note that I am certainly not the first special master to reject medical theories like those proffered by petitioners’ experts. Many decisions following from the OAP have addressed causation issues related to autism, encephalopathy, and mitochondrial disease or dysfunction. In each of these post-OAP cases, petitioners have failed to demonstrate that any vaccination caused or contributed to the vaccinee’s injury. Additionally, those decisions that have been challenged have been upheld upon review at the Court of Federal Claims and on appeal to the U.S. Court of Appeals for the Federal Circuit.<sup>39</sup>

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<sup>39</sup> *See, e.g., R.K. v. Sec’y of Health & Human Servs.*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Sept. 28, 2015), *mot. for rev. denied*, 125 Fed. Cl. 57 (2016), *aff’d*, 671 F. App’x 792 (Fed. Cir. 2016) (mem.); *R.V. v. Sec’y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for rev. denied*, 127 Fed. Cl. 136 (2016); *Anderson v. Sec’y of Health & Human Servs.*, No. 02-1314V, 2016 WL 8256278 (Fed. Cl. Spec. Mstr. Nov. 1, 2016), *mot. for rev. denied*, 131 Fed. Cl. 735 (2017), *aff’d*, 717 F. App’x 1009 (Fed. Cir. 2018) (mem.); *Holt v. Sec’y of Health & Human Servs.*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. June 24, 2015); *Coombs v. Sec’y of Health & Human Servs.*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Apr. 8, 2014); *Brook v. Sec’y of Health & Human Servs.*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. May 14, 2015); *Bushnell v. Sec’y of Health & Human Servs.*, No. 02-1648V, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. June 12, 2015); *Miller v. Sec’y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015); *Hardy v. Sec’y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Nov. 3, 2015); *Hooker v. Sec’y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435 (Fed. Cl. Spec. Mstr. May 19, 2016); *Dempsey v. Sec’y of Health & Human Servs.*, No. 04-394V, 2017 WL 1058480 (Fed. Cl. Spec. Mstr. Feb. 23, 2017); *Pope v. Sec’y of Health & Human Servs.*, No. 14-78V, 2017 WL 2460503 (Fed. Cl. Spec. Mstr. May 1, 2017); *Kreizenbeck*, 2018 WL 3679843.

For these reasons, the undersigned finds that petitioners have failed to provide preponderant evidence that the vaccines C.A.P. received could have caused encephalopathy through the mechanisms set forth by petitioners' experts.

**iii. *Althen* Prong Two: Lack of a Logical Sequence of Cause and Effect**

*Althen* Prong Two requires petitioners to show, by preponderant evidence, a logical sequence of cause and effect demonstrating how the vaccines at issue caused C.A.P. to develop encephalopathy. This logical sequence should 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 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). As explained above, the medical records in this matter are devoid of any evidence that C.A.P. ever developed encephalopathy. Moreover, petitioners' experts do not set forth any facts or other evidence to support a logical sequence of cause and effect between these alleged injuries and C.A.P.'s vaccinations.

As thoroughly discussed by Special Master Hastings, petitioners' experts rely upon medical presumptions which are not supported C.A.P.'s medical records. For example, Dr. Bellanti opines that “repeated, allergic (immune mediated) reactions” to vaccines administered in 2002 caused C.A.P.'s encephalopathy, which was diagnosed in 2004. Ex. 87 at 3. The medical records from 2002 or 2003 do not indicate that C.A.P. suffered from encephalopathy, and C.A.P.'s treating physicians did not consider the diagnosis during those years. The assertion that C.A.P. suffered from an encephalopathy that went undetected and untreated for over one year is not supported by the record.

Furthermore, Dr. Bellanti failed to cite any laboratory results, diagnostic reports, or any facts from the contemporaneous medical records to suggest that C.A.P. had an allergic reaction or immune-mediated reaction to the vaccines he received in 2002. In fact, Dr. Bellanti does not describe or define allergic or “immune-mediation” reactions, nor does he describe the clinical course of these reactions. As defined by *Dorland's*, “allergic reaction” is a phrase used to describe a hypersensitivity reaction, specifically, type I hypersensitivity. *Dorland's* at 1598. Hypersensitivity is defined as “a state of altered reactivity in which the body reacts with an exaggerated or inappropriate immune response to what is perceived to be a foreign substance.” *Id.* at 896. There are four classifications of hypersensitivity, and type I “occurs rapidly (within several minutes) upon re-exposure to an antigen.” *Id.* C.A.P.'s contemporaneous medical records from 2002 do not show that he was diagnosed with such an allergic reaction, hypersensitivity, or immune reactions to his vaccines. Dr. Corbier and Dr. Bellanti offer no facts from C.A.P.'s contemporaneous records to suggest otherwise. Similarly, Dr. Corbier fails to set forth facts from C.A.P.'s medical records to support his theory of vaccine injury based on vaccine preservatives and adjuvants.

For all of these reasons, petitioners have failed to provide preponderant evidence of a logical sequence of cause and effect, as required by *Althen* Prong Two.

**iv. *Althen* Prong Three: Lack of a Medically Appropriate Temporal Relationship**

Under *Althen* Prong Three, petitioners must provide “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan*, 539 F.3d at 1352. The acceptable temporal association will vary according to the particular medical theory advanced in the case. *See Pafford*, 451 F.3d at 1358. However, “a temporal relationship alone will not demonstrate the requisite causal link.” *Veryzer v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011). As explained above, petitioners’ experts did not offer sufficient evidence to show that the vaccines at issue *can* cause encephalopathy, much less that C.A.P. *did* develop encephalopathy from the vaccines. It follows, then, that petitioner cannot prove Prong Three of *Althen*.

In his expert report, Dr. Bellanti asserts that “[t]he onset of serious developmental abnormalities in timing with the receipt of the vaccines supports a temporal relationship.” Ex. 89 at 3. But the medical records do not demonstrate any developmental abnormality until C.A.P. was seen by Dr. Kotsanis on October 23, 2003. *See* Ex. 67 at 3. In the note from that visit, Dr. Kotsanis documented that C.A.P. fell and sustained a head injury on September 20, 2003. *Id.* Dr. Kotsanis noted that C.A.P. was irritable, and that he appeared to “drift slightly to the right side.” *Id.* Dr. Kotsanis diagnosed C.A.P. with “post-concussion syndrome” and referred C.A.P. for hearing and speech evaluations. *Id.*

C.A.P. received his third set of vaccines on July 22, 2002 (DTaP, Hib, Hep B, and Prevnar). Ex. 34 at 36. His last vaccination in 2002 was Hep B, administered September 24, 2002. Ex. 10 at 3. No contemporaneous medical records suggest that C.A.P. had any developmental problems after any of his vaccinations in 2002 or 2003, until the note from Dr. Kotsanis in October 2003. Petitioners’ experts failed to explain why an onset of greater than one year after vaccination would be appropriate under any of the proposed mechanisms.

Apart from the assertions of petitioners’ experts, based on misassumptions of facts related to the onset of the alleged encephalopathy, no facts in the contemporaneous medical records demonstrate a temporal association between C.A.P.’s vaccinations and the alleged injuries. Therefore, petitioners have failed to prove *Althen* Prong Three.

**VIII. Conclusion**

Over the nearly fifteen years since they filed their petition, petitioners have demonstrated remarkable patience and dedication. While I commend their commitment to their son’s well-being, the evidentiary requirements of the Vaccine Act do not allow me to award them compensation. Thus, because petitioners have not established entitlement to compensation, their petition must be dismissed for insufficient proof. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**  
Nora Beth Dorsey  
Chief Special Master