In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-1498V
(to be published)

CANDACE M. THOMPSON *and* STEPHEN E. POWELL, *parents of* A.H.P., *a minor,*	*	Special Master Corcoran
Petitioners,	*	Filed: May 16, 2017
v.	*	Decision Without Hearing; Dismissal; Diphtheria Tetanus acellular Pertussis ("DTaP") Vaccine; Table Encephalopathy; Autism Spectrum Disorder; Acute and Chronic Encephalopathy.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Phyllis Widman, Widman Law Firm, LLC, Ocean City, NJ, for Petitioners.

Camille Collett, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION GRANTING MOTION TO DISMISS CASE[1]

On December 11, 2015, Candace Thompson and Stephen Powell, on behalf of their son, A.H.P., filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] In it, Petitioners alleged that the Diphtheria Tetanus acellular Pertussis ("DTaP"), haemophilus influenza B ("Hib"), inactivated Polio ("IPV"), pneumococcal

[1] This decision will be posted on the United States Court of Federal Claims website, and later on will be made generally available to the public in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available in its present form. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

conjugate ("PCV"), and rotavirus vaccines A.H.P. received on December 11, 2012, caused him to experience a Table encephalopathy, or (alternatively) that the DTaP vaccine caused A.H.P's encephalopathy as well as his subsequent autism spectrum disorder ("ASD"). Amended Petition at 2-3.

After the medical records and statement of completion were filed, Respondent filed his Rule 4(c) Report, which included a specific motion to dismiss the petition. *See* Respondent's Rule 4(c) Report, filed on October 17, 2016 (ECF No. 27) ("Mot."). I ordered Petitioners to respond, and they did so on December 19, 2016. *See* Response to Respondent's Rule 4 Report, filed on December 19, 2016 (ECF No. 34) ("Opp."). Having completed my review of the evidentiary record and the parties' filings, I hereby **GRANT** Respondent's Motion for a Ruling on the Record Dismissing the Case, and **DISMISS** Petitioners' claim, for the reasons stated below.

I. FACTUAL BACKGROUND

Early Medical History and Vaccination

A.H.P. was born via caesarian section on August 5, 2012, following a normal pregnancy, and was discharged home two days later. Ex. 22 at 2. A.H.P was healthy throughout his first few months of life, although he experienced some gastroesophageal reflux about 12 days after birth. Ex. 4 at 72. He was seen routinely for his well-baby check-ups at Le Bonheur Pediatrics ("LBP") in Memphis, Tennessee,[3] including his two-month visit on October 5, 2012, when Ms. Thompson reported that his prior gastrointestinal issues had improved. At that visit A.H.P. received the DTaP, Hib, IPV, hepatitis B ("Hep B"), PCV, and Rotavirus vaccines. *Id*. at 67.

Two months later, on December 11, 2012, A.H.P was seen for his four-month well-baby exam, where he was noted to be developing normally. A.H.P. now received his second doses of the DTaP, Hib, IPV, PCV, and Rotavirus vaccines. *Id*. at 65. It was the administration of these vaccines that Petitioners allege produced A.H.P.'s subsequent injuries.

Post-Vaccination Medical History

The afternoon of A.H.P.'s December 11, 2012, well-baby visit, Petitioners began to notice that A.H.P. was fussy and irritable; he also ran a temperature which rose to about 102 degrees. Ex. 2 at 3. Petitioners became increasingly concerned that day with A.H.P.'s condition, leading them to call a nurse at LBP, who instructed them to administer Tylenol. *Id.* A.H.P.'s

[3]A.H.P. saw his primary care physician, Leon O. Livingston (or Marybeth Huggins) at LBP for these well-baby visits as well as for routine sicknesses. *See generally* Ex. 4.

symptoms persisted despite the Tylenol, so Petitioners brought him to the emergency room ("ER") at Le Bonheur Children's Hospital ("LBCH") in Memphis, Tennessee on the evening of December 11th, around 9:30 pm. The treating physician at the ER noted A.H.P.'s irritability and fever, as well as the fact that he had displayed no such symptoms prior to receiving his vaccinations. *Id*. While at the ER, A.H.P. underwent cerebral spinal fluid ("CSF") testing, urine analysis, a complete blood count ("CBC"), and CT scan. *Id*. at 7.

Initially, A.H.P.'s differential diagnosis included "fever, viral syndrome, urinary tract infection, sepsis, bacteremia, meningitis, [or] reaction to immunizations." Ex. 2 at 6. The testing results were normal, however, with the exception of a result establishing that A.H.P. was positive for the flu virus, and fullness in the bilateral lateral ventricles and anterior fontanelle of his brain on the CT. *Id*. at 10, 12. By 11:00 p.m. that evening (less than two hours from the time of his arrival at the ER), A.H.P. was noted to be improving. *Id*. at 9. He appeared better, and was noted to be "smiling, happy in dad's lap," and was therefore discharged home at 12:05 am on December 12, 2012, with a diagnosis of an "[a]cute febrile illness, Influenza B, Irritability" and was prescribed Tamiflu.[4] *Id*. at 10-11.

Petitioners were instructed to follow up with A.H.P.'s primary care physician the next day, and they did so on December 13, 2012 at 4:15 p.m. Ex. 4 at 62. At this visit, A.H.P. was still intermittently fussy and running a low grade fever, but he was consolable, and was eating and drinking well. Ex. 4 at 62. The physician specifically noted at the time that A.H.P.'s mother was herself experiencing flu symptoms. *Id*. A handwritten note from the pediatrician on December 14, 2012, stated "child is afebrile/feeding well." Ex. 1 at 14.

A.H.P's next visit to the pediatrician was on January 29, 2013, over a month after receipt of the vaccines in question, due to a cough, congestion, and fussiness. Ex. 4 at 61. His past medical history was noted to be unchanged since his last visit, and he otherwise appeared healthy. *Id*. He was diagnosed with otitis media and an upper respiratory infection and was prescribed amoxicillin. *Id*. at 62. A.H.P continued to experience coughing and wheezing, however, and was seen two days later by his pediatrician. *Id*.at 58. He was diagnosed with bronchiolitis and was treated with Albuterol Sulfate[5] and was prescribed an inhaler to use as needed for coughing and wheezing. *Id*.

Close to two months later (and three months from the December 11, 2012 vaccinations), A.H.P was seen for his six month well-baby exam on March 19, 2013. Ex. 4 at 55. The record characterized the exam as a normal, routine visit, and A.H.P. was described as a well-developed

[4] Tamiflu is the trademark for oseltamivir phosphate, which is an inhibitor of viral neuraminidase used to treat the flu. *Dorland's Medical Dictionary* 1342 (32nd ed. 2012) (hereinafter "*Dorland's*").

[5] Albuterol is administered by inhalation as a bronchodilator for the treatment and prophylaxis of bronchospasm associated with bronchitis. *Dorland's* at 45.

baby who babbled, made vowel sounds, enjoyed vocal turn-taking, rolling over, and passing objects between his hands. *Id*. at 56. He received his third dose of the PCV and Rotavirus vaccines, and at the request of his mom to split vaccine administration due to his purported previous reaction he was scheduled to receive the DTaP and Hib vaccines in two weeks, followed two weeks later by the IPV and Hep B vaccines. *Id*. at 56.

A.H.P. returned to LBP on April 8-9, 2013 for complaints of vomiting, congestion, cough, high fever, and fussiness. Ex. 4 at 51. At the exam, A.H.P. was irritable, and both of his tympanic membranes were erythematous, leading to a diagnosis of otitis media. *Id*. at 51-52. The next day, Petitioners returned with A.H.P. reporting that his ears had improved overnight. *Id*. at 49.

First Record Evidence of Developmental Regression

A.H.P. did not return to LBP for the remainder of the spring or summer of 2013. His next medical visit occurred on September 18, 2013, for his 12-month well-baby exam (now eight months after the vaccinations in question). Ex. 4 at 47. In the review of systems section of the medical records from this visit, Ms. Thompson is noted to have reported that A.H.P. had no problems in the various identified physiologic fields.[6] *Id*. The pediatrician, Dr. Leon Livingston, stated that A.H.P. was meeting "normal 9-month milestones drinks from cups, feeds self with finger, and waves bye-bye. Does not say Mama or Dada specifically. Walks holding on to furniture."[7] *Id*. at 48. A.H.P now received his third doses of the DTaP and IPV vaccines, as well as the first dose of Hepatitis B. *Id*. Dr. Livingston instructed Petitioners to return for A.H.P.'s 15 month well-baby exam, and to "consider hearing screen if speech does not improve." *Id*. Although the basis for this comment is not explicitly set forth in this particular record, it most likely was in response to the reports of A.H.P.'s parents regarding his inability to say mama or dada.

About three months later, on December 13, 2013, A.H.P. returned to LBP for his 15-month well-baby visit. Ex. 4 at 45. The examining pediatrician noted that A.H.P. did not have a vocabulary of three to six words, although his motor skills (with respect to handling a bottle) seemed normal, and he displayed other indicia of normal development (*i.e.*, would bring and show toys, scribbled, *etc.*). *Id*. at 46. A.H.P. received the fourth dose of the DTaP vaccine, varicella, and influenza vaccines. *Id*. The visit was generally characterized as a "normal routine history and physical well-baby," but the treating doctor added that there was a "concern for speech delay," and that a hearing test would therefore be scheduled. *Id*.

[6] The areas covered in the review of systems was, systemic, otolaryngeal, cardiovascular, pulmonary, gastrointestinal, genitourinary, musculoskeletal, and skin system. Ex. 4 at 47.

[7] Although this visit occurred when A.H.P was thirteen months old, the records reference nine month milestones. Notably, however, A.H.P. appears to have not had a nine-month well-baby exam.

A.H.P. was seen for his 18-month well-baby exam on March 14, 2014. Ex. 4 at 42. Again, Dr. Livingston noted concerns about speech delay, stating that A.H.P. lacked the expected vocabulary of a child of his age. *Id*. at 43. In the "development" section of this record, Dr. Livingston specifically stated that A.H.P. "was normal for 18 mnth [sic] milestones except scored a zero in communication. MCHAT [Modified Checklist for Autism in Toddlers] score: failed screening." *Id*. At this visit A.H.P. was also screened for lead, chemical, and heavy metal poisoning. *Id*. Likely, because of growing concern about A.H.P's speech delay, Dr. Livingston proposed moving A.H.P.'s audiology appointment to an earlier date. *Id*. As scheduled, however, A.H.P. also received the Hib and Hep A vaccines. *Id*.

Thereafter, from April to December 2014, A.H.P. was seen several times by Dr. Livingston for minor, common childhood illnesses. Ex. 4 at 21-41. It was noted at each of those visits that A.H.P. had a speech delay. *Id.* at 21, 23-24, 26, 29, 31, 33, 35-36, and 38. On July 7, 2014, Ms. Thompson herself reported that although A.H.P. walked, ran, and climbed like other toddlers, she had concerns that he was not talking. *Id*. at 36.

A.H.P. received a formal developmental evaluation at the Boling Center for the Developmental Disabilities ("BCDD"), in Memphis, Tennessee on November 20, 2014. *See generally,* Ex. 15. He was referred for this evaluation by Dr. Livingston to "rule out an autism spectrum disorder and possible speech delay." Ex. 15 at 1. The report indicated that while A.H.P. began babbling near 14 months of age, he had not by that date said his first word, nor was he able to follow basic instructions. *Id*. The evaluation determined that A.H.P. had auditory comprehension at a ten-month level, total language ability at an 11-month level, receptive language of six months, and expressive language of seven months. *Id*. at 2. His scores indicated that he had a "severe mixed receptive and expressive language delay relative to his chronological age." *Id*.

Further Evaluation for Autism and Mitochondrial Dysfunction

On January 14, 2015, A.H.P. returned to LBP for treatment of a cough and congestion. Ex. 4 at 18. Mr. Powell informed the treaters about A.H.P.'s developmental evaluation at BCDD, but that he had received no additional information regarding next steps. *Id*. at 19. Dr. Livingston thus began a discussion with the Petitioners about having A.H.P. evaluated through chromosomal analysis if an ASD was confirmed to be the diagnosis. *Id*. In the meantime, Petitioners told Dr. Livingston that A.H.P. would begin speech therapy with Tennessee Early Intervention ("TEI"). *Id*.

A.H.P. was next seen at Le Bonheur Early Intervention and Development ("LBEID") for a behavior early intervention observation and interview on February 5, 2015. *See generally* Ex. 9. The records from the visit reference a prior initial development test conducted by TEI, which

concluded that A.H.P. was 25 percent delayed in social emotional skills, and 40 percent delayed in motor skills, cognition, communication, and self-help skills.[8] *Id*. at 1. The evaluators at LBEID determined through the Screening Tool for Autism in Toddler and Young Children that A.H.P. scored the minimum score to be considered at risk for autism. *Id*. at 5.

Shortly thereafter, on February 11, 2015, A.H.P. was referred by BCDD for a psychological evaluation at the University of Tennessee Health Science Center in Memphis. *See generally* Ex. 11. It was noted that A.H.P. had a maternal family history of schizophrenia, anxiety, depression, and paternal family history of bipolar disorder and behavioral problems. *Id*. at 1. Petitioners now reported that their concerns about A.H.P. had only begun when he was 18 months old (a year after his December 2012 vaccinations), as evidenced by his delayed language development. *Id*. at 2. After evaluation, it was determined that A.H.P. met the criteria for an ASD, a global development disorder, and a language disorder. *Id*. at 8.

Dr. Livingston subsequently referred A.H.P. to Kathleen Jalandoni, M.D., a neurologist, for further evaluation and for consideration of the significance of a recent "staring spell." *See generally* Ex. 7. Dr. Jalandoni performed a full exam on March 26, 2015, noting that Petitioners reported A.H.P.'s behavior had been present for the past three to six months (meaning that it did not begin before the fall of 2014). *Id*. at 1. The diagnosis section of the report listed otitis media, asthma, head injury,[9] "head trauma-CT normal since April 2014," multiple ear infections, and reaction to immunizations at four months old. *Id*. at 2-3. Dr. Jalandoni ordered and electrocardiogram, fragile X, cytogenomic microarray analysis ("CMA"), chromosomal analysis, and an MRI of A.H.P.'s brain.[10] *Id.* at 4. The CMA showed interstitial deletion that involved two exons of the NRXN1 gene, which the report stated "ha[s] been associated with autism, intellectual disability, and schizophrenia." Ex. 8 at 3. Both the chromosomal analysis and the fragile X testing came back showing no significant abnormalities. *Id*. at 1.

On April 1, 2015, A.H.P. was seen at Mid-South Ear, Nose and Throat, in Memphis, Tennessee, for multiple ear infections (four in the past year). Ex. 24 at 1. The treating doctor

[8] Although this visit at TEI is mentioned in multiple records, it does not appear that the record of this prior visit was filed in this case.

[9] It is unclear what the head injury was. When A.H.P. was six weeks old he fell out of a hammock. Ex. 11 at 2. Other evaluations have also documented self-injurious behavior, which could also account for this notation. *Id*.

[10] Fragile X testing examines the X chromosome to determine if there is a fragile site, indicating that a patient has a fragile X syndrome, which is characterized by mental retardation and enlarged facial features. *Dorland's* at 1830. CMA is a "novel diagnostic tool for individuals with unexplained developmental delay, autism spectrum disease, and mental retardation." *Insights: Testing for Developmental Diseases,* Mayo Clinic (Sept. 5, 2014) https://news.mayomedicallaboratories.com/2014/09/05/testing-for-developmental-diseases/ (last visited March 30, 2017). Chromosomal analysis also called karyotyping analyzes the karyotypes of an individual's chromosomes looking for abnormalities. *Dorland's* at 977. MRI stands for Magnetic Resonance Imaging. *Id*. at 1184.

determined that a myringotomy and tubes were necessary, placement of which would be scheduled. *Id*. at 8. It was also noted that "patient is at increased risk of speech, language, or learning problems from otitis media due to baseline factors." *Id*. The procedure to insert the Sheehy Activent Tubes was on April 30, 2015 and was well tolerated by A.H.P. with no complications. *Id*. at 10. He was subsequently seen at two follow-up visits (on June 17, 2015 and December 16, 2015), which noted that his ears looked good and he should follow-up every six months. *Id*. at 13, 16.

Due to Petitioners' increasing concern for A.H.P.'s development, they sought an evaluation at Janna Hacker and Associates, speech and language pathologists, in Germantown, Tennessee, on November 4, 2015. *See generally* Ex. 3. Dr. Janna Hacker noted that A.H.P's medical history was remarkable for "encephalopathy, dairy allergy, encephalitis, RSV, high fevers, anxiety, apraxia, ADD/ADHD, PDD/Autism, chronic colds, reflux, frequent ear infections, and PE tubes." *Id*. at 1. This record does not elaborate on the basis for her statement that A.H.P. had in fact experienced an encephalopathy, however. She performed a comprehensive speech and language evaluation and concluded that A.H.P. "demonstrates a severe receptive-expressive language disorder, pragmatic disorder, and feeding disorder." *Id.* at 4.

On December 17, 2015, A.H.P. was seen for a consultation with Dr. Jill Dickerson at Vibrant Kids Pediatrics, in Newnan, Georgia. *See generally* Ex. 17. The concerns expressed at the visit included speech delay, mood swings (anger and rage), attacking violently (including himself), picky eater, obsessive/compulsive behaviors, and sensory issues. *Id*. at 31. Dr. Dickerson also listed several ongoing issues including purported chronic Lyme disease, coughing fits-choking, knot behind left shoulder.[11] *Id.* at 33. The record also noted "encephalopathy after reaction to vaccines?" without explanation for that conclusion or proposition. *Id*. On January 28, 2016, Dr. Dickerson wrote a letter medically exempting A.H.P. from future vaccinations stating "[i]t is now being shown in Vaccine Court that children with mutation in the MTHFR gene have more adverse reactions to vaccines. In light of this knowledge, [A.H.P.] will receive no further vaccines. He is medically exempted." Ex. 6 at 1.

Beginning in February 2016, A.H.P. received therapy at the Germantown Speech Language and Learning Clinic, in Germantown, Tennessee. *See generally* Ex. 25. The records from these therapy sessions are brief entries describing what occurred on each particular visit. At one such visit on February 15, 2016, Mr. Powell "questioned if behavior is all Lyme's Disease - not sure Autism is an appropriate diagnosis." *Id*. at 8. In June 2016, Ms. Thompson indicated a concern about plastic in the house and her efforts to remove all plastic. *Id*. at 6. In addition, she

[11] This is the first record evidence of Lyme disease. Later in the record it purports that "mom thinks she may have Lyme." Ex. 17 at 33.

noted that she "met Wakefield and further discussion regarding infant shots as "cause" of Autism diagnosis."[12] *Id.*

II. PROCEDURAL HISTORY

As noted above, this action was initiated in December 2015. Petition at 1. From that date to March 8, 2016, Petitioners filed medical records, designated as Exhibits 1 through 9. On March 9, 2016, Respondent indicated that there were still outstanding medical records, which (after conferring with Petitioners) he anticipated could be filed in 90 days. Petitioners filed Exhibits 10-27 and an amended petition by July 27, 2016, and subsequently filed a status report indicating that the record was complete. *See* Joint Status Report, filed on July 29, 2016 (ECF No. 23).

Respondent filed his Rule 4(c) Report in October 2016 recommending that compensation be denied and the Petition be dismissed. *See generally* Mot. I subsequently held a status conference on November 4, 2016, where I discussed how the case should move forward in light of the arguments made by Respondent in his Motion. In particular, I raised concerns about the apparent weaknesses in the case, and the fact that the claim seemed little different from numerous other similar claims alleging that a vaccine precipitated a developmental problem in a child. *See* Scheduling Order, filed on November 4, 2016 (ECF No. 28), at 1-2. I allowed Petitioners time to respond to the motion, specifically instructing them to attempt to identify proof of developmental issues in close proximity to his four-month vaccination, in order to distinguish their case from those that were unsuccessfully litigated in the Omnibus Autism Proceeding ("OAP") as well as thereafter.

Petitioners undertook to produce such evidence and file their brief, which was due on December 5, 2016. On that date, Petitioners requested an extension of time in order to obtain testing information from a mitochondrial specialist and from Dr. Dickerson. *See* Unopposed Motion for an Extension of Time, filed on Dec. 5, 2016 (ECF No. 32). I denied this motion on the grounds that it lacked sufficient reasoning as to why Petitioners could not comply with my previously-scheduled order, and instead ordered Petitioners to file their overdue brief on or before December 19, 2016, but allowed them to explain how mitochondrial testing would possibly assist them in their claim. *See* Order Denying Motion for an Extension of Time, filed on

[12] Although the record does not specify, "Wakefield" is presumably a reference to Dr. Andrew Wakefield. Dr. Wakefield is known for creating, with the help of some of is colleagues, "the hypothesis that the receipt of the MMR vaccine results in the development of autism spectrum disorders and gastrointestinal problems in certain children." The techniques used by Dr. Wakefield and his colleagues to implicate the measles vaccine in the development of inflammatory bowel disease were criticized as flawed. Eventually, Dr. Wakefield's hypothesis was dismissed by the scientific community following the publication of a series of methodologically sound studies by a number of groups in the late 1990s unable to replicate the alleged findings of Dr. Wakefield." *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 n.70 (Fed. Cl. Spec. Mstr. March 12, 2010).

Dec. 5, 2016 (ECF No. 33) at 2. Petitioners filed their response on December 19, 2016, and the next day Respondent indicated in a status report that he did not intend to file a reply. *See* Status Report, filed on Dec. 20, 2016 (ECF No. 35).

III. PARTIES' RESPECTIVE ARGUMENTS

Petitioners allege that A.H.P. suffered a table encephalopathy following his receipt of the DTaP vaccine in December 2012. Alternatively, they maintain that A.H.P.'s vaccinations caused an acute and chronic encephalopathy and subsequent ASD. Respondent's Motion, however, contends that dismissal is appropriate due to a lack of evidence in support of either claim – deficiencies that are self-evident at this stage in the case and that cannot be remedied later. Mot at 8-12.

First, Respondent asserts that A.H.P. did not suffer a Table encephalopathy, which (in accordance with the "qualifications and aids to interpretation" ("QAI") promulgated by the regulations governing the Table) requires a decreased level of consciousness lasting for at least 24 hours, and occurring within 72 hours of vaccination. Mot. at 8-9, *citing* 42 C.F.R. § 100.3(b)(2). The medical records, however, indicate that although A.H.P. was seen at the ER the same day as vaccination on December 11, 2012, there was no change in his consciousness lasting 24 hours, noting that A.H.P. was "awake, smiling, and happy" not long after being brought in, and that he was discharged from the ER a few hours after he was admitted. *Id*. at 9.

Petitioners' opposition brief contests the above, pointing to purported evidence of A.H.P.'s regression that was close in time to the vaccination – mainly statements by the Petitioners about their observations of A.H.P. rather than contemporaneous proof. *See generally* Opp. at 1-8. Although Petitioners concede that the "first documentation [in the medical records] was eight months" after vaccination, they argue that their case is nevertheless factually similar to those Table encephalopathy cases that have been successful, such as *Wright v. Sec'y of Health and Human Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). Opp. at 10. They further argue that the medical records do not accurately reflect the concerns expressed by Petitioners about A.H.P.'s development to treaters at the time, and therefore that there is evidence of an earlier reaction sufficient to meet the Table definition. *Id*. at 1-2.

Second, Respondent's motion argues that Petitioners have not established a logical sequence of cause and effect between vaccination and injury, as they are required to do when attempting to establish a causation claim. Mot. at 10. Petitioners have also not established an appropriate medical timeframe between vaccine and injury, given that the records reflect no concerns about A.H.P.'s development until eight months after vaccination—a timeframe too attenuated for vaccine causation. *Id*. In addition, Respondent asserts that Petitioners' claim

ignores other, more likely causes for A.H.P.'s regression, such as his underlying chromosomal deletion and genetic mutations, both of which are commonly associated with ASD. *Id*. at 10-11.

In response, Petitioners argue that the "medical record is clear evidence of the temporal relationship between the vaccine administration and A.H.P's reaction," despite their own admission that the first documented sign of developmental issues was in fact *eight months* after vaccination. Opp. at 9. They also assert that they are still exploring potential diagnoses or causes, such as a possible underlying mitochondrial disorder, and therefore their claim should not be dismissed until they are permitted time to flesh out such possible explanations for A.H.P.'s injury, or before expert opinions have been offered in support. *Id*.

IV. APPLICABLE LEGAL STANDARDS

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[13]

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human*

[13] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

1. *Table Claim Elements*

Petitioners in this case argue that A.H.P suffered a Table encephalopathy. According to the QAI applied to vaccine Table claims, a vaccinee is considered to have suffered a Table encephalopathy if he or she manifests an injury encompassed in the definition of an "acute" encephalopathy within the appropriate time period, and then a "chronic" encephalopathy is present for more than six months after the immunization. 42 C.F.R. § 100.3(b)(2) (emphasis added). In accordance with the QAI, an acute encephalopathy must be sufficiently serve to require hospitalization (regardless of whether the vaccinee is actually hospitalized). 42 C.F.R. § 100.3(b)(2)(i). Children less than 18 months of age presenting after a seizure are considered to have an acute encephalopathy if they have experienced a "significantly decreased level of consciousness" that persists beyond 24 hours and cannot be attributed to the seizure or medication. *Id.* The referenced phrase "significant decreased level of consciousness" must be evidenced by the presence of at least one of the following clinical signs for at least a 24-hour period: "(1) [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things)." 42 C.F.R. § 100.3(b)(2)(i)(D).

The acute encephalopathy must also be followed by a chronic encephalopathy (as defined by the QAIs) in order to succeed on a table claim of encephalopathy. 42 C.F.R. § 100.3(b)(2). A chronic encephalopathy exists if the change in mental state that began with the acute encephalopathy persists for at least six months. 42 C.F.R. § 100.3(d)(1)(i). However, there is the express caveat that;

> Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis. 42 C.F.R. § 100.3(d)(1)(ii).

2. *Non-Table Claim Elements*

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed

as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "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." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained

in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd, Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Determination to Resolve Case Without Hearing

I have opted to decide entitlement in this case based on written submissions and evidentiary filings filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 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 hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.,* 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy*

v. Sec'y of Health & Human Servs., No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioners Cannot Meet Their Evidentiary Burden Given the Facts of this Case

After careful review of the medical records, and the arguments of both sides, I conclude that Petitioners will not be able to establish preponderant evidence in favor of their claim, and therefore the matter should not proceed, even if expert reports have not yet been obtained. My decision is rooted in both the facts of this case as well as applicable decisions in previously-litigated matters involving causation theories highly similar to the present, and which have been exhaustively litigated since resolution of the OAP test cases.[14]

A. The Petitioners Cannot Establish a Table Encephalopathy

First, the record evidence does not support Petitioners' principal allegation: that A.H.P. experienced a table encephalopathy after his December 2012 vaccinations. In analyzing this component of Petitioners' claim, I apply the "very restrictive" definition of encephalopathy utilized in Table cases, where causation is presumed only after relevant factual predicates are

[14] Several years ago, more than 5,400 cases were initially filed under short form petition in the OAP, where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit, unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines

established). *Dixon v. Sec'y of Health & Human Servs*., No. 01-605V, 2003 WL 23218020, at *4 (Fed. Cl. Spec. Mstr. Nov. 25, 2003), *mot. for review den'd*, 61 Fed. Cl. 1 (2004).

Petitioners cannot meet their evidentiary burden under that definition based on the medical records. As Respondent points out, A.H.P. never experienced any significant change in consciousness or the hospitalization required by the QAI to constitute an "acute" encephalopathy. A.H.P. was seen at the hospital the night he received his vaccination, but the records indicate that within three hours, he was noted to be "smiling, happy in dad's lap" and was discharged home with a diagnosis of an "Acute febrile illness, Influenza B, Irritability." Ex. 2 at 10. What is more, there is no record evidence suggesting a subsequent "chronic" encephalopathy extending for more than six months from vaccination. Indeed – the first evidence of any developmental problems at all in the records does not occur until the fall of 2013, with no intervening incidents that could help flesh out Petitioners' claim of an ongoing encephalopathy after the December 11th vaccinations.

B. The Petitioners' Non-Table Claim Cannot Succeed Given the Record Facts

Second, Petitioners' non-table causation-in-fact claim is not supported by the record evidence, which fails to establish that A.H.P. suffered an encephalopathic event after vaccination later resulting in autism and/or developmental problems. At best, and as Petitioners concede, the first recorded evidence of a developmental problem is eight months after vaccination at A.H.P.'s 12-month well-baby exam. Ex. 4 at 48. That temporal gap is problematic for Petitioners, as it is far too distant from the date of vaccination to possibly evidence an encephalopathic occurrence. *See Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063, 2016 WL 3034047, at *35 (Fed. Cl. Spec. Mstr. April 25, 2016). To prove the existence of an encephalopathy, Petitioners would need some evidence closer in time to the vaccinations of neurologic injury – yet even when I specifically instructed the Petitioners to point to all record evidence of regression or other harm, this remains the best evidence they can muster.

Petitioners maintain that their own testimony can help remedy this evidentiary gap, maintaining that their concerns about A.H.P. were voiced to treaters but not set down in the medical records. As a general matter, however, contemporaneously-recorded medical records are generally found to be deserving of greater evidentiary weight than after-the-fact oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947). The assertion that medical records consistently failed to include parental developmental concerns are not well-founded or persuasive, and are not otherwise corroborated by any other evidence that would bulwark

caused autism. The OAP proceedings concluded in 2010.

Petitioners' own assertions about A.H.P.'s medical status in this time period. The record suggests more strongly the opposite conclusion: A.H.P. did not experience an encephalopathy after his December 2012 vaccinations.

C. This Case is Similar to Other Unsuccessful Cases Alleging Vaccine- Caused Autism

Dismissal of this case is also warranted given its high similarity to the many other dismissed non-Table claims alleging that a vaccine caused an autism or ASD-like developmental injury. As I have noted in other similar cases, in the wake of the OAP petitioners seeking to establish an autism injury after vaccination face a very high bar – for to date, no such claims have succeeded. *See Wolf v. Sec'y of Health & Human Servs.*, No. 14-342V, 2016 WL 6518581, n. 13 (Fed. Cl. Spec. Mstr. Sept. 15, 2016). Indeed, more recent efforts by petitioners to cast their claim as autism indirectly caused by a vaccine-induced encephalopathy (as the Petitioners argue herein) have been noted by the Court of Federal Claims to reflect attempts to evade the long line of cases casting considerable doubt on theories involving autism and vaccines. *Cunningham v. Sec'y of Health & Human Servs.,* No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Aug. 1, 2016) *aff'd*, 2017 WL 1174448 (Fed. Cl. March 22, 2017) (disregarding "petitioner's attempt to differentiate this case from other autism cases by creating this second step"—that post-vaccination developmental regressions can be attributed to a vaccine-induced encephalopathy even if there is no evidence of an encephalopathic reaction). While the outcome herein is not determined by these numerous prior decisions, which do not control my decision from a precedential standpoint, they persuasively suggest that this case should be resolved in similar fashion.

Because of the foregoing, I ordered Petitioners to explain what made this case different – factually or otherwise – from those that have gone before it. In response, Petitioners have referenced *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466v, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. Apr. 10, 2008) and *Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). *See* Opp. at 10. They argued that, like the petitioners in those purportedly-successful cases, A.H.P.'s ER visit the night of his vaccination showed "clear causation, demonstrating the extreme factual circumstances reflecting an encephalopathy." Opp. at 10. It is instructive to consider the particular facts of those two cases – for each is readily distinguishable, as I have explained before in other decisions.

In *Poling*, the child in question (who was later diagnosed with a mitochondrial disease that allegedly made her susceptible to adverse effects of vaccination) had received several vaccinations, and then within 48 hours developed a high fever that became low-grade over the next several days, along with inconsolable crying, sleeplessness, and significant, noticeable motor problems that worsened over the next several days. Respondent settled that case before a trial was held, and thus there was no adjudication in favor of the claimant. Thus, *Poling* not only

says nothing about the strength of *this* case (since there is no holding that can provide me with guidance), but it also facially involves facts more extreme than the present circumstances (given that A.H.P. has not been shown to have experienced immediate and/or dramatic changes in behavior, consciousness, or otherwise after the December 11, 2012 vaccinations). A.H.P. did not continue to have a low-grade fever, nor did he begin to show decreased motor function after his ER visit the day of his vaccination, but instead experienced a rapid and immediate recovery. Ex. 4 at 61. The medical records would tell a completely different story if an encephalopathic reaction had occurred.

In *Wright*, Petitioners met the Table criteria for an "acute encephalopathy" following vaccination by establishing with preponderant evidence that the vaccinated child had experienced a seizure followed by loss of consciousness shortly after receipt of pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with resulting demonstrable significant changes in behavior. No such facts are evident here. Moreover, *Wright* provides little guidance in determining the outcome of a non-Table claim involving an alleged encephalopathy resulting in autism – for as the special master responsible for that decision (former Chief Special Master Vowell) explicitly noted in her decision, the petitioners' expert presented a causation opinion that she found "absurd and biologically impossible." *Wright*, 2015 WL 6665600, at *2.

Given the above, it is evident that Petitioners have not established that this case is anything like the very rare instances in which a vaccine has been held to be related to a child's developmental injury – while also failing to rebut the claim's high similarity to the vast majority of cases that have found such a theory wanting.

D. Petitioners Cannot Satisfy the Three *Althen* Prongs

Give the above, it is evident that Petitioners have not met their burden under the analysis set forth in *Althen* for proving a causation-in-fact claim.

Prong One: Petitioners cannot present a reliable medical or scientific theory explaining how the DTaP vaccine could cause a table encephalopathy, or (alternatively) cause an acute and chronic encephalopathy leading to an ASD. Even if I were to allow Petitioners time to hire experts and develop a theory, it is highly unlikely to be distinguishable from those that have been repeatedly advanced but rejected in the Program. And in any event, my determination that under the facts of *this* case A.H.P. did not experience an encephalopathy, and did not manifest developmental problems in a medically-recognized and appropriate timeframe from his December 2012 vaccinations, moots any possible successful showing Petitioners might make with respect to theory. *Combs v. Sec'y of Health & Human Servs.,* No. 08-0818 , 2014 WL 1677584, at n. 12 (Fed. Cl. Spec. Mstr. April 8, 2014).

Prong Two: Petitioners' obligation under the second *Althen* prong was to demonstrate a logical sequence of cause and effect connecting the particular facts of their case to their medical theory. *See, e.g., Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529, at *18 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (prong two requires a fact-based inquiry into whether the vaccine in question *did* cause the particular injury). But the medical record is bereft of reliable evidence that any reaction A.H.P. experienced the day of vaccination rose to the level of an encephalopathy – or that this alleged encephalopathy subsequently lasted for several months until the time that A.H.P. actually manifested developmental problems. Without such evidence, Petitioners cannot succeed on a claim that A.H.P. suffered a table or non-table encephalopathy leading to an ASD.

Prong Three: Even if I had accepted Petitioners' theory that A.H.P. experienced an encephalopathy, his ASD or developmental symptoms have not been shown to have occurred within a medically appropriate timeframe from the date of the December 2012 vaccinations. The Petitioners themselves admit that the medical records do not show developmental issues until eight months after vaccination. Although they urge me to rely on their affidavits (that would identify the symptoms beginning sooner) rather than the medical records, to do so would be at odds with the established practice of the Program of giving greater weight to contemporaneous medical evidence. *Murphy*, 23 Cl. Ct. 726, 733 (1991)(citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight."). Here, the temporal gap between receipt of the vaccines at issue and the documented beginning of A.H.P.'s developmental problems is demonstrably too great to suggest a causal relationship.

II. Dismissal of the Claim is Appropriate at this Early Stage

A hearing provides a petitioner with the opportunity to put on 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 a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon or illuminate points already set forth in paper filings, or respond to unanticipated questions raised in the matter – but again, only where necessary to reach a decision.

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 400-01 (citing Rule

3(b)). But that rule also includes the obligation of creation of 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 his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing.

In this case, live witness testimony was not required in order for me to reach a reasoned decision. The medical record itself was expansive and contained sufficient evidence upon which to base my decision. The flaws in Petitioners' theory and factual arguments were self-evident from review of the medical records. Petitioners' witness statements were uncorroborated by, or contrary to, the contemporaneous medical record. Such evidentiary deficiencies did not require oral testimony to be understood for purposes of deciding the case. On the contrary: the congruence between the theory espoused herein and numerous, previously-rejected variations on the same theme counseled against expending the time and effort necessary for a hearing.[15]

In seeking to avoid dismissal, Petitioners also argue that they should have the opportunity to explore further diagnoses and expert opinions. Opp. at 8-11. But the basis for my decision is rooted in the undisputed facts - the lack of recorded medical evidence documenting regression shortly after vaccination, as well as the absence of evidence that A.H.P. suffered a sufficiently severe neurologic injury that could have precipitated developmental issues.

None of the above would be ameliorated by an expert opinion. In the Vaccine Program, an expert opinion must rely on the correct facts if it is to have evidentiary value. *Davis v. Sec'y of Health & Human Servs.*, 20 Cl. Ct. 168, 173 (1990) (expert's conclusions are only as sound as their factual predicate); *Loesch v. United States*, 645 F.2d 905, 915 (1981), *citing State of Washington v. United States*, 214 F.2d 33, 43 (9th Cir.), *cert denied*, 348 U.S. 862 (1954); *Fehrs v. United States*, 620 F.2d 255, 265 (1980). Given that the facts of this case neither suggest that A.H.P. suffered an encephalopathy nor a developmental problem sufficiently associated temporally with his December 2012 vaccinations to meet the preponderant tests for a causation claim, the mere *ipse dixit* of an expert willing to say the contrary would not change the outcome of this case.

Petitioners similarly request additional time to explore whether A.H.P. suffered from a mitochondrial disease[16] or disorder that could have interacted with the December 11, 2012

[15] The decision not to hold a hearing because the claim reflected a frequently-litigated theory is not something that would only ever negatively impact a petitioner. The opposite circumstances – where a petitioner asserted a claim that has repeatedly *succeeded* in the past (for example, the allegation that the flu vaccine can cause Guillain-Barré syndrome) – would motivate me to act in the same manner, and propose to Respondent that either the case be settled or that it be resolved on the papers.

[16] A mitochondrial disease or disorder is a maternally inherited, multi-systemic disorder, caused by mutations in the mitochondrial DNA. *Dorland's* at 539. As noted below, Program petitioners have frequently alleged that a child's

vaccines and produced his autism/developmental problems. Opp. at 8. At the outset, I note than no such testing has been forthcoming despite Petitioners' representations; their brief purported that A.H.P. was scheduled to have such testing performed at the end of March 2017, but no records have been produced from that visit indicating the findings (let alone corroborating the claim that A.H.P. has some form of mitochondrial dysfunction).

More fundamentally, however, the very claim that an underlying mitochondrial disease is a component in a child's vaccine-induced autism has (like the theory that encephalopathy inherently precedes autism) been repeatedly tested in the Vaccine Program - without success. Many special masters have analyzed the medical literature on the proposed link between vaccination and cause of an ASD due to aggravation of an existing mitochondrial disorder, but found that persuasive evidence of such a relationship does not exist. *See e.g., R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *25 (Fed. Cl. Spec. Mstr. Feb. 19, 2016) *citing Hardy v. Sec'y of Health & Human Servs.,* No. 08-108V, 2015 WL 7732603, at *35 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) ("in no case presented to me…has there been presented any persuasive evidence that even in a child with an actual mitochondrial disorder, vaccines can cause or aggravate that child's ASD"); *Myers v. Sec'y of Health & Human Servs.,* No. 13-885V, 2016 WL 7665435, at *13 (Fed. Cl. Spec. Mstr. Nov. 17, 2016); *Miller v. Sec'y of Health & Human Servs.*, No. 02–235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015).[17] I myself have addressed the issue on more than one occasion. *See, e.g., R.V.,* 2016 WL 3882519, at *25. And I have also been previously asked to permit a claimant to look for expert support for mitochondrial dysfunction, even though the record provides no corroboration for the conclusion that the child in question *might* have such a condition. *Murphy v. Sec'y of Health & Human Servs.*, No. 05-1063, 2016 WL 3034047, at *37 (Fed. Cl. Spec. Mstr. April 25, 2016). There is no more reason here for allowing the case to telescope out in a fruitless search for such evidence than there has been in similar situations in the past.

Given all of the above, I cannot conclude that Petitioners' claim should proceed further, due to the lack of success of cases with factually similar circumstances. The theory that the

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preexisting mitochondrial dysfunction or disease could cause the child to experience a negative reaction to a vaccine, thereafter resulting in sufficient neurologic injury to produce a developmental condition like autism.

[17] The only exception to the above is *Paluck v. Sec'y of Health & Human Servs.,* 786 F.3d 1373 (Fed. Cir. 2015). There, the Federal Circuit affirmed a Court of Federal Claims's determination that a special master erred in denying compensation to petitioners claiming (in a non-Table case) that the MMR, varicella, and pneumococcal vaccines significantly aggravated their child's mitochondrial disease, resulting in severe neurodegeneration with developmental effects. However, that case is readily distinguishable – both because the record evidence established far more conclusively an obvious immediate reaction (that, significantly, was classified as "neurodegenerative," rather than as an ASD), and also because the child's underlying mitochondrial dysfunction was largely not in dispute. *Id.* The result in *Paluck* is thus *sui generis*, and also underscores the kind of significant and persuasive showing a claimant must make in these circumstances.

vaccines A.H.P. received could have caused an encephalopathy sufficient to manifest as autism or other developmental problems, remains unreliable and lacks critical scientific support, especially given the weak facts of this case. Under such circumstances, allowing the matter to continue on does a disservice to the Petitioners, while misallocating judicial resources away from cases in which factual and legal disputes warrant more attention.

CONCLUSION

The factual record does not support the Petitioners' contention that A.H.P. suffered from a table encephalopathy, nor does his clinical progression support a causal relationship necessary for a non-table claim. Petitioners have similarly not established that the vaccines *could* cause autism or something resembling it. Thus, Petitioners have not established entitlement to a damages award I must **DISMISS** their claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[18]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[18] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.