IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 13-208V
Filed: August 26, 2015

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HOWARD REDDY and HANAN TARABAY,	*	
as parents and natural guardians of	*	
A.H.R., a minor	*	
Petitioners,	*	Fact Ruling; Statute of
v.	*	Limitations; Onset;
	*	Autism; Encephalopathy;
SECRETARY OF HEALTH	*	Developmental Delay;
AND HUMAN SERVICES,	*	Significant Aggravation.
Respondent.	*	
* *		

Marcus J. Michles, Michles & Booth P.A., Pensacola, FL, for petitioners.
Heather L. Pearlman, U.S. Department of Justice, Washington, DC, for respondent.

DECISION DISMISSING THE PETITION AS UNTIMELY FILED[1]

Vowell, Chief Special Master:

On March 22, 2013, Howard Reddy and Hanan Tarabay ["Mr. Reddy," "Ms. Tarabay," or "petitioners"] filed a petition for compensation on behalf of their minor child, A.H.R., under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] [the "Vaccine Act" or "Program"]. The petition alleged that the diphtheria, tetanus, and acellular pertussis ["DTaP"], haemophilus-influenzae type b ["Hib"], influenza, and varicella vaccinations A.H.R. received on November 3, 2009, caused A.H.R. to suffer from encephalopathy and developmental delays. Petition at 1.

After conducting a fact hearing to ascertain the precise nature of A.H.R.'s symptoms and when they first occurred, I find that A.H.R. first displayed symptoms of

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[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, it will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

developmental delay more than 36 months prior to the filing of this petition. This developmental delay was the first symptom of his autism spectrum disorder [“ASD”]. Although petitioners now claim that the ASD diagnosis is the result of an underlying mitochondrial disorder which first manifested as a developmental regression on March 23, 2010,[3] what led to the ASD diagnosis is not material to the issue of timing. The first symptom of A.H.R.’s developmental delay and encephalopathy (the conditions listed in the petition for which compensation was requested) occurred more than 36 months before the petition was filed. *See* § 300aa-16(a)(2). Accordingly, the petition is dismissed as untimely filed.

I. Procedural History.

Shortly after filing the petition, petitioners filed A.H.R.’s medical records (Pet. Exs. 1-8, 11-14), their affidavits (Pet. Exs. 9, 10, 19), and affidavits from two treating physicians, pediatrician Dr. Randall Reese (Pet. Ex. 15), and geneticist Dr. Dmitriy Niyazov (Pet. Ex. 16).

This case was reassigned to me on June 11, 2013. After petitioners filed some additional medical records, respondent moved to dismiss this case as untimely filed. Rule 4(c) Report and Motion to Dismiss [“Mot. to Dismiss”], filed Oct 31, 2013. An expert report from Dr. (Ph.D.) Judith Miller accompanied the motion. After filings of additional affidavits, petitioners filed a response to the Mot. to Dismiss, which denied that A.H.R. exhibited any symptoms of ASD prior to March 23, 2010. Petitioners’ Response [“Pet. Resp.”] at 1, filed February 19, 2014. Additional evidence from both parties was filed between February and July 2014, including two affidavits from pediatric neurologist Dr. Weldon Mauney (Pet. Exs. 22 and 25), and supplemental affidavits from Dr. Reese (Pet. Ex. 21), Dr. Niyazov (Pet. Exs. 24 and 26) and petitioners (Pet. Ex. 23).[4]

During a status conference on July 23, 2014, petitioners requested that I conduct an onset hearing to resolve the controverted factual issues in this case in order to resolve the motion to dismiss. That hearing was conducted in Pensacola, FL, on November 20-21, 2014.

Based on the record as a whole, I conclude that this case was untimely filed. The reasons for my conclusion are set forth in more detail below but, in summary, the contemporaneous records establish that A.H.R. had speech delay, a symptom of ASD, prior to administration of the allegedly causal vaccinations. This speech delay and behaviors symptomatic of ASD (problems in cognition, self-help, socialization, and play

[3] This date is 36 months prior to the filing of this petition.

[4] The supplemental affidavit of Dr. Reese (Pet. Ex. 21), affidavit of Dr. Mauney (Pet. Ex. 22) and the joint supplemental affidavit of petitioners (Pet. Ex. 23) are each Bates stamped “Petitioners’ Exhibit 21” on the bottom right corner of each page, just above the consecutive page numbers. However, the Notice of Filing accompanying these three affidavits (ECF 29, filed Feb. 19, 2014), properly listed the affidavits as separate exhibits 21-23. Throughout the decision, I refer to the affidavits by the separate exhibit numbers assigned by counsel at the time the Notice of Filing was generated.

skills) were documented in A.H.R.'s medical records as occurring more than 36 months before the petition was filed. His parents expressed concerns to his pediatrician that he might have ASD more than 36 months before the petition was filed. Although something occurred on March 23, 2010 that caused Dr. Reese, A.H.R.'s primary pediatrician, to refer A.H.R. to a neurologist on March 25, 2010, I find that the behaviors A.H.R. displayed on March 23-24, 2010 were symptoms of the ASD petitioners already suspected that A.H.R. had, even though his formal diagnosis was not made until months later. Doctor Mauney's opinion (Pet. Ex. 22 at 106-07) about A.H.R.'s condition before he began treating him in April 2010 is both speculative and inaccurate because A.H.R.'s missing speech milestone was not the only evidence of his ASD prior to March 23, 2010.[5] As Dr. Dmitriy Niyazov, the geneticist who subsequently diagnosed A.H.R. with a mitochondrial disorder, testified (*see* Transcript ["Tr."] at 261-62), the ASD diagnosis was one of the clinical symptoms he relied upon in making the mitochondrial disorder diagnosis. *See also* Pet. Ex. 13, p. 292 (letter from Dr. Niyazov stating that the mitochondrial disease diagnosis "explains his developmental delays and autism"). Thus, the first symptom of ASD would have been a symptom of the purported mitochondrial disorder as well.

II. Summary of Relevant Medical Records.

A. Birth and Early Health and Development.

A.H.R. was born in early August 2008. Pet. Ex. 1. His Apgar scores were 8 and 9, reflecting that he was a healthy newborn.[6] Pet. Ex. 3 at 23. A.H.R.'s growth and development were essentially normal throughout his first year of life. *See generally*, Pet. Ex. 4, pp. 42, 53-54, 58-61. Although he had some minor childhood illnesses, including otitis media, upper respiratory infections, rash, and fever, A.H.R. had no serious illnesses or hospitalizations. *Id.* He received the usual childhood vaccinations during the first year of his life.[7] He achieved developmental milestones on time. Pet. Exs. 3, p. 26; 5, pp. 195-96.

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[5] The affidavit reflects that Dr. Mauney reviewed the records of Drs. Reese and Niyazov, but does not specifically mention the February 2010 well-child visit at which Dr. Reese noted that A.H.R. missed several milestones other than vocabulary. The speech pathology and early intervention records were not listed as records he reviewed. Pet. Ex. 22 at 106. Thus, while I considered Dr. Mauney's affidavit, I did not give it much weight. I did consider carefully his medical records, including the histories therein.

[6] The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"], at 1682; NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S "] at 536-37.

[7] Before his first birthday, A.H.R. received three doses each of hepatitis B, rotavirus, Prevnar, and Pentacel vaccines, as well as an influenza vaccine. Pentacel is the trade name for a combined DTaP, inactivated polio ["IPV"], and Hib vaccine. Shortly after his first birthday, A.H.R. received initial doses of the hepatitis A and measles, mumps, and rubella vaccines, and his fourth dose of the Prevnar vaccine. Pet. Ex. 5, pp. 195-96.

At A.H.R.'s 12 month well-child visit, Dr. Reese found A.H.R.'s growth and development normal. According to the record from this visit, A.H.R. was able to say "mama" or "dada" and one to three words, "[p]oints to desired objects", and "[c]omprehends speech." Pet. Ex. 4, p. 62.

B. Allegedly Causal Vaccinations and Early Indications of Developmental Delay.

At A.H.R.'s 15 month well-child visit on November 3, 2009, he met nearly all of the expected developmental milestones. However, he did not use five to ten words. Pet. Ex. 4, p. 65. Based on this apparent speech delay, Dr. Reese referred A.H.R. to speech therapy. *Id.*, p. 67. In an open diagnoses list found in Dr. Reese's records, speech delay is included, with an onset date of November 3, 2009. *Id.*, p. 99.

At this visit, A.H.R. received the allegedly-causal DTaP, Hib, influenza, and varicella vaccinations. *Id.*, p. 67; Pet. Ex. 5, pp. 195-96. Two weeks later, on November 17, 2009, A.H.R. received an H1N1 influenza vaccination.[8] Pet. Ex. 4, p. 69. He was referred to an audiologist during this visit. *Id.*

C. Evaluations for Developmental Delay

A.H.R. visited the Andrews Institute of Rehabilitation on November 18, 2009, where he was evaluated by speech therapist Kyle C. Lakas, CCC-SLP. Pet. Ex. 6, p. 197. Ms. Lakas recommended an audiology evaluation. She also indicated that A.H.R. should return in two to two and one half months if he failed to develop additional words and sounds. *Id.* The audiologist who conducted A.H.R.'s audiology evaluation found his hearing within normal limits for speech in at least the better ear. *See* Pet. Ex. 7, pp. 199-201. However, she recommended a re-evaluation in six months "to monitor hearing sensitivity and in an attempt to obtain a more complete audiogram." *Id.*, p. 199.

The first documentation of parental concern regarding A.H.R.'s speech was in the December 16, 2009 telephone record from Dr. Reese's practice. Pet. Ex. 28, p. 327. The notation states that "dad would like to speak with you. [Patient] doesn't speak, mom is concerned that [patient] may be autistic." *Id.* Their disquiet was consistent with A.H.R.'s referral to speech therapy for a speech delay diagnosis on January 25, 2010 and Dr. Reese's diagnosis of a speech delay and additional referral to speech therapy on February 1, 2010. *See* Pet. Ex. 4, pp. 72-73, 188-89.

During A.H.R.'s 18 month well-child exam on February 1, 2010, Dr. Reese noted several developmental problems, including A.H.R.'s inability to say six words, combine words, or name body parts. Pet. Ex. 4, p. 72; Tr. at 34. Once again, Dr. Reese diagnosed A.H.R. with a speech delay and recommended speech therapy. *Id.,* p. 73.

[8] In 2009, the H1N1 influenza vaccine was administered separately from the trivalent seasonal influenza vaccine and was not a vaccine included on the Vaccine Injury Table. Thus, petitioners have made no causation claim regarding this vaccination.

On February 3, 2010, Ms. Lakas determined that A.H.R. "require[d] skilled rehabilitative therapy in conjunction with a home exercise program" due to his difficulties with approximating sounds, identifying body parts, and comprehending oral directions. Pet. Ex. 8, p. 202. A.H.R. was babbling but did not have any spontaneous jargon. *Id.* Whether A.H.R. was using any words at all was not addressed in this report, but no "spontaneous jargon" certainly suggests that A.H.R. was not using word approximations spontaneously. *Id.* In one specific area, she noted a decline in A.H.R.'s performance, recording "Decreased Identification of Body Parts."[9] *Id.* The tone of this report contrasts significantly with that of the report Ms. Lakas prepared just three and one-half months earlier. In the November 18, 2009 report, Ms. Lakas commented that she gave the parents tips and ideas to use in helping with speech and sound production and that therapy was not needed. Pet. Ex. 6, p. 197. This evaluation was communicated to Dr. Reese's office on February 11, 2010. *See* Pet. Ex. 4, p. 29.

A.H.R. was evaluated by Early Steps on March 16, 2010, based on a referral dated March 11, 2010.[10] Pet. Ex. 11, pp. 212 (referral), 213-16 (initial information gathering). Based on the testing performed, A.H.R. was formally assessed on April 14, 2010 with delays in cognition, self-help, socialization, and communication of greater than 25%. *Id.*, pp. 217. The individual family support plan ["IFSP"] was dated April 14, 2010. *Id.*, pp. 218-21. A speech and language evaluation took place in the family home on April 14 as well (*id.*, pp. 224-25), resulting in a Treatment Plan of Care signed on April 28, 2010 by Brandi Hook, the speech and language pathologist who conducted the evaluation, and signed on April 29, 2010 by Dr. Reese, A.H.R.'s pediatrician (*id.*, pp. 226-27).

The Early Steps records from the initial information gathering session reflected a number of parental concerns, including A.H.R.'s strange behaviors in playing with toys and whether his lack of vocabulary might be associated with ASD. Pet. Ex. 11, pp. 215-16. Petitioners reported to the evaluator that A.H.R. enjoyed playing with socks. The evaluator noted that "[A.H.R.] will do the same with belts, string and watch them, shake and mom notes he gets stuck with that activity. If he looses [sic] it, he will have a 'hissy fit.'" *Id.*, p. 215. Her evaluation also highlighted some of A.H.R.'s peculiar behaviors, as reported by his parents, including that he "[p]lay[ed] with toys [in a manner] different from other children. He will observe from upside down and will observe how it works and will move on to another activity." *Id.*; *see also* Tr. at 110. In a section of the Early Steps evaluation, entitled "Family's Areas of Concern," the form reflected a notation that "[A.H.R.] has no words, Also is this autism? If on [spectrum], mom feels he will be on the 'other end.'" Pet. Ex. 11, p. 215.

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[9] At A.H.R.'s 15 month well-child visit, he was noted to *point* at body parts appropriately; at the 18 month visit, he failed the milestone of *naming* body parts appropriately. Pet. Ex. 4, pp. 66, 72. When reading the speech evaluation in conjunction with the pediatric records, the problem of whether decreased identification of body parts represents a true loss of skills is unclear, but what is clear is that Ms. Lakas had altered her impression of A.H.R.'s development and now saw real problems.

[10] The referral and initial information gathering took place before the March 24, 2010 sick-child visit. Pet. Ex. 11, pp. 212-16.

A.H.R. saw Dr. Reese on March 24, 2010. The listed reasons for the visit were a fever, runny nose, and sneezing. Pet. Ex. 4, p. 75. On examination, A.H.R. had a fever of 101° and bilateral bulging and erythematous ear drums. *Id.* Doctor Reese diagnosed him with a URI and bilateral otitis media. *Id.,* pp. 75-76. According to the medical records, A.H.R.'s parents raised concerns about his lack of speech and unspecified "self-stimulating" behaviors. *Id.,* p. 75. Doctor Reese diagnosed A.H.R. with an unspecified developmental disorder. *Id.,* p. 76. The next day, Dr. Reese completed a referral of A.H.R. to a neurologist. The referral type was "routine," but the form contained the notation "very concerned "with devel[opmental] del[ay]." *Id.*, p. 181. It also reflected that A.H.R. was receiving speech therapy. *Id.* Doctor Reese's list of open diagnoses reflects this visit as the date of diagnosis for "Developmental disorder, unspecified." *Id.*, p. 99.

On April 14, 2010, speech and language pathologist Brandi Hook, M.S., CCC-SLP, saw A.H.R. as a part of the Early Steps evaluation.[11] Pet. Ex. 11, pp. 224-25. This assessment was conducted in the family home, with A.H.R. and Mr. Reddy present, as well as the Early Steps service coordinator and a developmental specialist. *Id.*, p. 224. He did not "readily engage" with Ms. Hook, kept his distance from her and the other evaluators, made sporadic eye contact, and was observed to flap his arms. *Id.* Using the Preschool Language Scale, A.H.R.'s auditory comprehension and expressive communication were assessed at the level of a five-month old child. He was "unable to demonstrate appropriate use of toys." *Id.*, p. 225. He did not react to voices or sounds, and had a vocabulary consisting only of "mama." *Id.* Ms. Hook wrote that A.H.R.'s "speech and language characteristics are similar to those with Autism Spectrum Disorders and should be further assessed." *Id.*, p. 225.

On April 23, 2010, pediatric neurologist Weldon A. Mauney, III, M.D., evaluated A.H.R. at the Child Neurology Center of Northwest Florida for his "history of delayed speech as well as suspected autistic behavior." Pet. Ex. 12, p. 236. The patient history form prepared for the initial visit reflected that A.H.R. was being seen by the practice for "delayed speech, hand flapping, question of ASD." *Id.*, p. 286. The patient history recorded by Dr. Mauney at the initial visit reflected Ms. Tarabay's report that "over the last few months," A.H.R. had been saying syllables such as "Di-Di," and over the last three weeks, had been babbling frequently, a new behavior. *Id.* The visit notes reflected that A.H.R. had good eye contact, but would not point to objects, imitate behavior, and only occasionally responded to his name. *Id.* Doctor Mauney noted frequent hand flapping, particularly when A.H.R. was excited, and that A.H.R. frequently rubbed his fingers against his teeth or tongue. *Id.* Although Dr. Mauney's affidavit indicated that A.H.R. presented at this visit with "self-stimulatory facial slapping" (Pet. Ex. 22 at 106) and that his "facial stimulation was exaggerated, constant, and physically violent" (*id.* at 106-07), there is no mention of facial slapping or self-injurious behavior in the record from this initial visit. This includes the parental history, Dr. Mauney's

[11] The evaluation lists April 14, 2010 as the "Date of Consultation." Pet. Ex. 11, p. 224. This was apparently a follow-on to the March 16, 2010 Early Steps evaluation appearing at *id.,* pp. 212-16.

observations, and the physical examination section.[12] Pet. Ex. 12, pp. 236-38. The diagnosis of a developmental speech/language disorder is the only one appearing in Dr. Mauney's records from this visit. Pet. Ex. 12, p. 238.

According to Dr. Mauney, Ms. Tarabay indicated that A.H.R. had frequent tantrums. Pet. Ex. 12, p. 236. He fixated on signs at the park and lines on the football field. *Id.* Doctor Mauney noted that, by history, A.H.R. "has never spoken intelligible words, has never used multiple word phrases." *Id.* His behavior was described as "autistic-like," with poor language function. *Id.,* p. 237. Doctor Mauney recommended Early Steps intervention, speech therapy, and a neuropsychological evaluation to complete the ADOS (Autism Diagnostic Observation Schedule).[13] *Id.,* pp. 238, 288; Pet. Ex. 4, p. 158 (referral for ADOS). He also ordered several tests including a brain MRI, some genetic testing, a thyroid panel, and serum lead levels. *Id.,* p. 238. The test results were reported as normal. *Id.*, p. 239.

On April 28, 2010, Ms. Hook signed a treatment plan of care for A.H.R.that noted he had speech and language characteristics "similar to those with Autism Spectrum Disorders." Pet. Ex. 11, pp. 226-27. Ms. Hook recommended A.H.R. be evaluated by an occupational therapist and attend speech therapy two to three times per week. *Id.* This form was also signed by Dr. Reese on April 29, 2010. *Id.*

On May 12, 2010, occupational therapist Elizabeth Mains conducted an evaluation at Florida Elks Children's Therapy Services. Pet. Ex. 18, pp. 22-23. Ms. Mains found A.H.R. had delays in language, motor, and self-help skills. *Id.,* p. 23. She observed that he "appears to be a sensory seeker – constantly seeking vestibular and oral stimulation which is significantly affecting his daily functional performance." *Id.,* p. 23. She recommended weekly followup visits in order to address his developmental delays, sensory issues, and low muscle tone. *Id.*

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[12] Later records from July-November 2010 continued to describe self-stimulatory behaviors with parental reports that he rubbed his cheek and tongue with his index finger, which occurred more frequently when excited (Pet. Ex. 12, p. 239) and unspecified self-stimulatory behavior at several visits (*id.,* pp. 241, 243, 245). A specific report of "frequent self stimulatory behavior, consisting mainly of almost frequent and constant swiping of the corner of his mouth with his hands and playing with her [sic] saliva. This has caused a significant irritation require [sic] frequent application [of] ointments and creams to the perioral tissue. This behavior has improved significantly after applying soft minced [likely meaning 'mittens'] to the hands" was made in December 2010. *Id.*, p. 246. There is no specific report of self-injurious behavior in any of Dr. Mauney's records. The only indication that Dr. Mauney considered the self-stimulatory behaviors to be serious is the fact that he prescribed various drug therapies to help control them. *See generally* Pet. Ex. 12.

[13] It does not appear that the ADOS was ever administered. *See* Pet. Ex. 12, p. 263 (notes from Dr. (Ph.D.) Karen Hagerott, a psychologist, to Drs. Reese and Mauney). Doctor Hagerott indicated that her clinical impression was "Autism—nonverbal/no language dev[elopment]—severe stereotypies." *Id.* She thought the autism diagnosis was correct and added that she did not think the ADOS would "add diagnostic info or change treatment plan. Therefore we will hold administration unless needed for an agency." *Id.*

D. Subsequent Evaluations and Formal ASD Diagnosis.

A.H.R. had ear tubes placed on June 1, 2010, based on his history of ear infections. Pet. Ex. 4, pp. 145-46, 160. He did well postoperatively. *Id.*, p. 161.

On June 9, 2010, A.H.R. saw Dr. Reese, who spent 40 minutes consulting with the family about A.H.R.'s lack of speech, inability to focus during his speech therapy sessions, the neurology evaluation, and "ASD, and medical management options." Pet. Ex. 4, p. 79. Doctor Reese suggested a neuropsychological evaluation and continued speech therapy. *Id.*, p. 80. His list of open diagnoses for A.H.R. reflects this date for a "Stereotyped repetitive movements" diagnosis. *Id.*, p. 99.

In a followup appointment with neurologist Dr. Mauney on July 14, 2010, Dr. Mauney noted A.H.R.'s continued self-stimulatory behavior and developmental delay. Pet. Ex. 12, pp. 239-40. On July 27, 2010, A.H.R.'s parents completed a "Confidential Child Neuropsychology History," detailing his inability to use real words and his self-stimulatory behavior. Pet. Ex. 14, pp. 402-05. However, they noted his strong eye contact and their impression that he shared an emotional connection with his parents. *Id.,* pp. 402.

During A.H.R.'s two year well-child visit on September 3, 2010, he failed to meet numerous language milestones, including naming one picture, combining words, pointing to four pictures, and using two-word phrases. Pet. Ex. 4, p. 88. He was unable to point to body parts. *Id.* He did not have a 30-50 word vocabulary. *Id.* Delays in social skills were also noted. *Id.* He was again referred to speech therapy. *Id.*, p. 90.

On September 7, 2010, Dr. Mauney noted that A.H.R.'s sleep EEG[14] was normal and that he was no longer taking certain medications, which included Prozac and clonidine. Pet. Ex. 12, pp. 241, 271. During A.H.R.'s October 4, 2010 visit with Dr. Mauney, he noted that A.H.R. had a history of "static encephalopathy with developmental delays." *Id.,* p. 243.

At his speech therapy assessment on September 7, 2010, Ms. Hook commented on A.H.R.'s "excellent attendance and family involvement." Pet. Ex. 11, p. 231. She also noted that, prior to a month long vacation in Ireland, A.H.R. was able to sort some objects, had some understanding of simple cause and effect, and would touch his mother's hand to request her to sing, but had not adjusted back to his previous routine upon return. *Id.* He babbled at times, but "still doesn't have any meaningful words." She described A.H.R. as calming himself with oral stimulation, which involved putting his fingers in his mouth and pushing secretions from side to side. Continued speech therapy was recommended. *Id.*

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[14] An electroencephalogram (EEG) is "a recording of the potentials on the skull generated by the currents emanating spontaneously from nerve cells in the brain. . . . [f]luctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." DORLAND'S at 600.

On September 15-16, 2010, A.H.R. was examined by Debbie Keremer at the Sacred Heart Health System Autism Resource Center. Pet. Ex. 18, pp. 31-36. Ms. Keremer noted her concerns that A.H.R.'s "profound sensory issues" were obstructing his therapy, with specific mention of his continued self-stimulation behavior. *Id.,* p. 31. The history provided at the September 15, 2010 interview with both parents indicated that "[b]y Christmas added stimming – escalating quickly from beginning of 2010 continues to increase." *Id.*

Doctor Mauney noted in November 2010 that A.H.R. had "shown significant improvement with current interventions including occupational therapy, speech therapy, and behavioral development [] therapy." Pet. Ex. 12, p. 245.

In March, 2011, A.H.R. saw Dr. (Ph.D.) Hagerott, a pediatric neuropsychologist, for the first time, although Dr. Reese had made a referral to her in June 2010. Pet. Ex. 14, p. 395 (initial evaluation form); *see also* Pet. Ex. 4, p. 180 (form reflecting the 2010 referral). Her notes from the referral reflect that A.H.R. was non-verbal, had no imitative skills, was intensely sensory seeking, and engaged in self-stimulatory behaviors. Pet. Ex. 14, p. 395. She noted that he had received a thorough neurological workup and indicated that the etiology of his condition would likely remain unknown and that A.H.R.'s parents should pursue therapies, including the addition of ABA therapy, designed to encourage language acquisition. *Id.* She stated that the autism diagnosis was "clear [and] appropriate." *Id.* Her assessment was that A.H.R.'s autism was "severe." *Id.*, p. 396. She encouraged petitioners to continue with treatment by medical "professionals well versed in child neurodev[lopmental] disorders" and to "Avoid [treatments without] empirical data" to support them. *Id.*, p. 396.

A typewritten page apparently prepared by petitioners was a part of Dr. (Ph.D.) Hagerott's records. Pet. Ex. 14, p. 398. The typewritten entries recite some of A.H.R.'s history but another copy of the same page (*id.*, p. 397) also contains clarifying notes by Dr. Hagerott.[15] The history indicates that petitioners "first began noticing sensory issues" when A.H.R. was about "16-18 months" of age, "[s]pecifically [putting his] hand to [his] mouth. This has consistently worsened." Pet. Ex. 14, p. 397. Doctor Hagerott's notes indicated that A.H.R. "stopped progressing" but that there was no regression. *Id.* A.H.R. was 16 months old in early December 2009, and 18 months old in early February 2010. Petitioners also included a paragraph on A.H.R.'s sensory issues. *Id.* Doctor Hagerott's notes indicated that "last year" A.H.R. began putting a sock on his hand and in his mouth and that "6 mos ago" he began doing something undecipherable with saliva and his fingers to make a sound and that "now" he puts his fingers on his lower lip, flaps and watches his fingers, or slaps his face. *Id.* The typewritten entries reflect petitioners' concerns about what "triggered" their son's condition and that they sought Dr. Hagerott's opinion about vaccines and thimerosal, a link between Pitocin and autism, genetic predisposition, gene mutation, and environmental triggers. *Id.*

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[15] Mr. Reddy addressed this document during his testimony, confirming his authorship of portions of the typewritten document, but denying either writing or making any statements similar to the handwritten notations. Tr. at 124-25; Pet. Ex. 14, p. 397.

In July 2011, petitioners consulted Dr. Reese about A.H.R., indicating that they were "not happy" with his pediatric neurologist (presumably Dr. Mauney). Pet. Ex. 4, p. 95. They discussed medications to treat A.H.R.'s self-stimulatory behavior and "meltdowns." *Id.* Doctor Reese's records of open diagnoses reflect an autism diagnosis as of July 13, 2011. *Id.*, p. 99.

At an August 2011 evaluation of A.H.R.'s progress in speech therapy, he was noted to be non-verbal, scored in the first percentile on the Preschool Language Scale, had a vocabulary of three signs ("water, iPad and crackers"), was unable to identify body parts or items of clothing, and poor play skills. Pet. Ex. 11, pp. 232-33. However, he was able to "navigate an iPad in order to find games and videos he enjoys." *Id.*, p. 233. Intense speech therapy three to five times per week was recommended. *Id.*

E. Mitochondria Disorder Evaluation

On October 11, 2011, Dmitriy Niyazov, M.D., evaluated A.H.R. at the Ochsner Clinic Foundation. Pet. Ex. 13, pp. 321-22. Doctor Niyazov noted "a history of regression at 15 months when [A.H.R.] got 5 immunizations." *Id.*, p. 321; *see also id.*, p. 294 (reciting same history). This consultation was at the request of an unidentified individual for the purposes of evaluating "a possible genetic etiology of [A.H.R.'s] developmental delay and autism." *Id.,* p. 321. Doctor Niyazov discussed the possibility that A.H.R. might have a metabolic disorder, noting that "more and more studies now implicate problem[s] with cellular energy metabolism such as mitochondrial dysfunction in autism and developmental delay." *Id.*, p. 322. He ordered multiple tests to evaluate whether A.H.R. suffered from a metabolic or mitochondrial disorder. *Id.,* p. 322.

These test results were within the reference ranges (*id.*, pp. 297-303), except for high plasma lactic and pyruvic acids (*id.*, p. 304) and a slightly low methylbutrylglycine (*id.*, p. 297). The laboratory interpretation noted that the acidemia observed could have several causes, but if a metabolic disorder was suspected, urine organic acid studies should be performed. *Id.* A "slightly low" vitamin D level was also reported. *Id.*, pp. 305 (test results), 313 (interpretation).

During a followup visit on January 3, 2012, Dr. Niyazov reviewed the test results. He noted that A.H.R. had:

> severe developmental delay and low-functioning autism, absence of speech, and no dysmorphic features. His brain MRI was negative and EEG was normal. He had a history of regression from 5 vaccinations and significant repetitive behavior and stimming which is of a great concern to the parents. He had normal oligoarray, karyotype, fragile X and several metabolic studies. He did have high lactate and pyruvate.

Pet. Ex. 13, p. 313.

Doctor Niyazov discussed the possibility of a metabolic disorder with petitioners, and indicated that he would ordinarily suggest testing in a fasting state for metabolic

abnormalities. *Id.*, p. 314. However, because A.H.R. was scheduled for brain auditory response testing under anesthesia on January 24, 2012 (*see id.*, pp. 318, 324-25), he recommended that A.H.R. have a muscle biopsy performed at the same time in order to evaluate him for mitochondrial dysfunction.[16] *Id.*, p. 314. While awaiting the muscle biopsy results, Dr. Niyazov elected to treat A.H.R. empirically for a mitochondrial disorder. *Id.*

A.H.R. had a muscle biopsy at Texas Children's Hospital on January 24, 2012. Pet. Ex. 13, pp. 328-29, 390. The biopsy results did not detect any deficiencies in the mitochondrial electron transport chain, nor were any large deletions in the mitochondrial DNA found. *Id.,* pp. 385-86. A homoplasmic mutation on m.5814T>C (tRNA Cys) was detected, but was considered a provisional rather than a pathogenic mutation.[17] *Id.,* pp. 386-87. The assessment of the physician who signed the final pathology diagnosis was that the changes seen on the muscle biopsy were "mild," but that an underlying mitochondrial dysfunction could not be excluded. *Id.,* p. 308.

During a return visit on May 14, 2012, Dr. Niyazov discussed the muscle biopsy results with A.H.R.'s parents. Pet. Ex. 13, p. 311. He noted improvements in A.H.R.'s sleep cycle, and attributed the progress to his recommended vitamin supplements. *Id.,* p. 310. However, he also noted that A.H.R.'s self-stimulating behaviors persisted. *Id.*

In August 2012, Dr. Niyazov again noted A.H.R.'s persistent self-stimulating behaviors, although there had been some improvement. Pet. Ex. 13, p. 294. He was still nonverbal but babbled more. *Id.* He recorded that A.H.R.'s receptive language had improved, and he was sleeping better and had more energy. *Id.*

In a letter dated October 5, 2012, Dr. Niyazov asserted that A.H.R.'s mitochondrial disease "explains his developmental delays and autism." Pet. Ex. 13, p. 292. According to Dr. Niyazov, "[p]atients with mitochondrial disorders are at risk for regression if too many immunizations are given at once." *Id.* He recommended that

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[16] This test was abbreviated "ABR" in this record. It is sometimes abbreviated as "ABEP" (Auditory Brainstem-Evoked Potentials), and is a test performed on young children or those incapable of communication to determine if the brain is processing sounds. MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th ed. 2010) ["MOSBY'S LABS"] at 562-63.

[17] This mutation has been reported as a pathogenic (disease-causing) mutation, as it has been found in patients with several different mitochondrial disorder syndromes, but it is also found in asymptomatic patients. It has also been reported as a polymorphism. *See* Pet. Ex. 13, p. 386 (laboratory test interpretation). A genetic polymorphism is "the long term occurrence in a population of multiple alternative alleles at a locus, with the rarest ones being at a frequency greater than could be maintained by recurrent mutation alone." DORLAND'S at 1490. Both A.H.R.'s mother and maternal grandmother have the same mutation, but do not have ASD and have not been diagnosed with a mitochondrial disorder. Pet. Exs. 13, p. 311; 24, p. 119. Doctor Niyazov noted that the differences in their presentations could be due to heteroplasmy, which refers to differences in number and type of mitochondria present in cells, tissues, and organs. *Id.*, p. 293; DORLAND'S at 856 (defining heteroplasmy as "the presence of multiple types of mitochondrial . . .DNA within a single cell or individual."); *see also* Pet. Ex. 16 at 412 (Dr. Niyazov's report).

future immunizations be given one at a time, “except for when 2-3 are bound together,” and separated by at least one month between each one. *Id.*

III. Summary of Relevant Hearing Testimony.

In their hearing testimony and affidavits, petitioners acknowledged their concerns about A.H.R.’s language delays began as early as December 16, 2009. Tr. at 73, 103-04, 166; Pet. Exs. 9 at ¶ 10; 10 at ¶ 10. They disagreed that portions of the early intervention records accurately reflected their reports of behavioral symptoms, but when pressed, sometimes acknowledged that the histories might reflect the essence of their reports. Their testimony provided additional examples of A.H.R.’s peculiar and sometimes obsessive behaviors, as well as his significant language delays, prior to what they described as a sudden regression, occurring on a date just inside the 36 months before they filed their petition. They offered explanations that appear to have been carefully calculated to avoid triggering the running of the statute of limitations for nearly every behavioral problem they had reported to therapists or physicians or which are otherwise reflected in medical or treatment records. Throughout their testimony, the parents often provided histories that contradicted contemporaneous medical records, their prior statements, and their own affidavits. They contradicted one another’s testimony on several points.

A. Mr. Reddy’s and Ms. Tarabay’s Testimony.[18]

Mr. Reddy and Ms. Tarabay allege that, while traveling in the family car on March 23, 2010, A.H.R. caught their attention by placing his sock in his mouth and beginning to repeatedly stroke or slap his face and play with his tongue. Tr. at 78-82, 157-59; Pet. Exs. 9 at ¶¶ 12-14; 10 at ¶¶ 13-15. Petitioners claim that the incident on March 23, 2010 represented an instantaneous change in A.H.R.’s behavior, which included his immediate loss of all speech.

Mr. Reddy and Ms. Tarabay met while studying music (opera) at the Curtis Institute of Music in Philadelphia, PA. Tr. at 6, 130. Mr. Reddy had obtained a dual law and business degree in Dublin, Ireland, prior to beginning his music studies. Tr. at 7. The couple married and settled in Ireland, while performing as opera singers throughout Europe. However they traveled to Ms. Tarabay’s hometown, Pensacola, FL, to settle there about a month before A.H.R.’s birth. Tr. at 6, 9, 130.

Mr. Reddy and Ms. Tarabay both described her pregnancy and A.H.R.’s birth as normal.[19] Tr. at 9, 132. Mr. Reddy testified that they first met Dr. Reese, A.H.R.’s

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[18] In response to the motion to dismiss filed by respondent, petitioners filed a joint affidavit (accompanied by video and still photographic depictions of A.H.R.) addressing many points raised by Dr. Miller and commenting on the Early Steps evaluation. *See* Pet. Ex. 23 at 109-17. The matters addressed in this affidavit were also addressed during petitioners’ testimony, and I have thus cited primarily to the testimony.

[19] Ms. Tarabay testified that A.H.R. had a perfect Apgar score. Her recollection was incorrect, as he scored an 8 at one minute and 9 at five minutes, with 10 being the maximum score. Ex. 3, p. 23.

pediatrician, two to three weeks before A.H.R.'s birth in order to discuss homeschooling and other considerations related to the scheduling demands of their musical careers. Tr. at 11-12.

Petitioners also testified that the first year of A.H.R.'s life was quite normal. Tr. at 10, 132. Ms. Tarabay offered A.H.R.'s first birthday party as an example of his normal first year. Tr. at 132-33. However, during A.H.R.'s Early Steps evaluation, Ms. Tarabay had mentioned A.H.R.'s behavior at this party as a concern. Pet. Ex. 11, p. 215; Tr. at 70.

Mr. Reddy testified that the November 3, 2009 well-child visit with Dr. Reese marked the first time he and Ms. Tarabay realized A.H.R. was behind in meeting his speech milestones. Tr. at 15; *see also* Pet. Ex. 4, pp. 66-67. The November 18, 2009 visit with a speech therapist recommended by Dr. Reese temporarily relieved their concern regarding whether A.H.R. had a serious developmental problem. Tr. at 25; *see also* Pet. Ex. 6, p. 197.

However, petitioners filed telephone records from Dr. Reese's practice shortly after the onset hearing. Pet. Ex. 28. A December 16, 2009 record contained the following notation: "dad would like to speak with you. [patient] doesn't speak, mom is concerned that [patient] may be autistic." Pet. Ex. 28, p. 327; *see also* Pet. Exs. 9 at ¶ 10; 10 at ¶ 10. The telephone records reflected that, in response to this concern, Dr. Reese wrote a message to one of his staff members, prescribing "speech therapy" for A.H.R. Pet. Ex. 28, p. 327. He prescribed speech therapy again on January 25, 2010. Pet. Ex. 4, pp. 188-89. Neither Mr. Reddy nor Dr. Reese could recall what prompted the January prescription. Tr. at 106-07, 218. Petitioners' affidavits reflect that, by December 16, 2009, they had specific concerns about whether A.H.R.'s speech delay was a symptom of ASD. Pet. Exs. 9 at ¶ 10; 10 at ¶ 10. At the hearing, Ms. Tarabay testified that she told a co-worker about A.H.R.'s failure to meet a speech milestone, and that the co-worker immediately expressed concern that this meant A.H.R. might be autistic. Tr. at 166; *see also* Tr. at 103-04 (Mr. Reddy's recounting of this concern).

Mr. Reddy testified that the speech evaluation on February 3, 2010, convinced both parents that A.H.R. required speech therapy. Tr. at 35-37. However, they experienced difficulty in scheduling speech therapy because the therapist A.H.R. first saw left the Andrews Institute. Tr. at 37, 109.

Mr. Reddy denied that he or Ms. Tarabay raised the issue of A.H.R.'s fascination with specific objects as a concern during the March 16, 2010 Early Steps evaluation. Tr. at 48. He and Ms. Tarabay also doubted that they said anything to the evaluators that would lead them to believe that A.H.R. had a tendency to become "stuck" or otherwise fixated on such objects. *Id.*; Tr. at 150. Likewise, Mr. Reddy could not recall using the term "repetitive behaviors." Tr. at 68. However, Ms. Tarabay later agreed that it was likely that she and Mr. Reddy expressed concerns to the Early Steps evaluators about A.H.R.'s fascination with specific objects. Tr. at 150.

In explaining the description of A.H.R.'s obsessive behavior in the Early Steps evaluation, Mr. Reddy denied that A.H.R. became "inappropriately fixated" on DVDs. Tr. at 57. Ms. Tarabay initially testified that she and her husband did not characterize A.H.R.'s behaviors as repetitive during the Early Steps evaluation, but she later clarified that she was indeed concerned whether some of A.H.R.'s behaviors were repetitive and likely expressed her concern to the evaluators. Tr. at 150, 156-57.

Mr. Reddy explained that the Early Steps evaluation reflected an interpretation of Mr. Reddy and Ms. Tarabay's dialogue with the evaluators rather than a precise record of their statements. Tr. at 42-43. He denied using the word "hissy-fit" to characterize A.H.R.'s behavior, but acknowledged that A.H.R. had temper tantrums. Tr. at 49. However, Ms. Tarabay confirmed her use of the phrase "hissy-fit." She explained that A.H.R. would enjoy particular activities "a whole lot, that he would just continue playing with those activities and that he would not want to go play with a normal toy," resulting in a tantrum when he was redirected. Tr. at 150-51. Ms. Tarabay's testimony broadly described the type of repetitive and obsessive behaviors recorded in the Early Steps record, despite the conflicting testimony of A.H.R.'s parents. *See* Pet. Ex. 11, p. 215.

The Early Steps evaluator recorded comments that appear to have originated with one or both of petitioners: "[A.H.R.] has no words, Also is this autism? If on [autism] spectrum, mom feels he will be on the 'other end.'" Pet. Ex. 11, p. 215. Although Mr. Reddy testified that neither he nor Ms. Tarabay told the evaluators that A.H.R. "had no words," Ms. Tarabay described the phrase "other end" as an accurate quotation and that she was referring to the higher functioning end of the autism spectrum, such as Asperger syndrome. Tr. at 64, 155. Ms. Tarabay also denied saying that A.H.R. "had no words." Tr. at 153-54. She and Mr. Reddy attempted to explain the inaccuracy of the statement by testifying that A.H.R. used words such as "mama, da-da, ba-ba, d-d." Tr. at 64; *see* Tr. at 168. However, the telephone message left for Dr. Reese in December 2009 also indicated that A.H.R. "doesn't speak." Pet. Ex. 28, p. 327.

Mr. Reddy explained that the question "is this autism?" was based on their concern with "hype in the media," which he described as "Jenny McCarthy" raising the issue of autism on national television programs. Tr. at 65. Mr. Reddy maintained that, although he and Ms. Tarabay were aware of ASD at the time of their interview at the Early Steps evaluation, "we didn't really think there was anything wrong with [A.H.R.], or maybe he was just a bit slow with words and maybe there are some people that are slow to start speaking, but then they end up being fine." Tr. at 67. In his later testimony, Mr. Reddy explained that he and Ms. Tarabay were concerned whether A.H.R.'s lack of speech or delayed speech milestones could be symptomatic of ASD and described that as "an established red flag." Tr. at 73. Again, this testimony is belied by the December telephone message reflecting that "mom is concerned that [A.H.R.] may be autistic." Pet. Ex. 28, p. 327.

Additionally, the Early Steps evaluation also detailed the parents' concern over peculiar behaviors such as "[A.H.R.] will observe from upside down and will observe how it works and will move on to another activity." Pet. Ex. 11, p. 215. Mr. Reddy

testified that the reference to looking at objects upside down was "in relation to that restroom at Tiger Point Park.[20] "When [A.H.R.] saw the female restroom sign, he went over and looked at it upside down, just kind of tilted his head." Tr. at 51. He stated that "we thought that was a little odd." Tr. at 50. Ms. Tarabay described A.H.R.'s fascination with the park's restroom sign slightly differently, stating that "[A.H.R.] would play down the slide and all this, and out of the corner of his eye on one of the occasions saw the female restroom sign and he went over to it and looked at it." Tr. at 110. She further elaborated that "[A.H.R.] saw that sign on the door, he immediately went over to it, and he did that other times, also." *Id.* She confirmed that A.H.R. repeated this behavior on more than one occasion. Tr. at 111; *see also* Pet. Ex. 12, p. 236 (report at initial visit with Dr. Mauney indicating that A.H.R. was fixated on signs and the lines on the football field). A.H.R. continued to look at things upside, as reflected by typewritten concerns petitioners provided to Dr. (Ph.D.) Hagerott in March 2011. *See* Pet. Ex. 14, p. 398.

The parents provided additional context to the Early Steps evaluation description that "when overwhelmed by lots of folks, he will not tolerate well." Pet. Ex. 11, p. 215. Mr. Reddy described this entry as referring to A.H.R.'s "first birthday party, and we had a surprise birthday. When he came in, he just got overwhelmed with so many different people." Tr. at 70. However, he also claimed that A.H.R. recovered and "he had a great birthday party." Tr. at 72. Ms. Tarabay testified that the birthday party was attended by family from Ireland and other family members who were strangers to A.H.R. She explained: "When [A.H.R.] saw everybody, everybody was right there saying happy birthday when we were walking in, and he got very shy and then clinging on to mommy, so I just thought that was normal, pretty normal." Tr. at 133. They testified that they were not concerned about A.H.R.'s ability to socialize with other people or children. Tr. at 70-71, 151.

The parents' testimony regarding A.H.R. being overwhelmed by people at the birthday party and Ms. Tarabay's comment that she thought A.H.R.'s reaction was "normal" does not fully explain why they mentioned A.H.R. "not tolerat[ing] well" (Pet. Ex. 11, p. 215) large numbers of people as a specific area of concern at the Early Steps evaluation. This remark appears in the section labeled "Family's Areas of Concern," which included the "no words" comment, the question "is this autism?" and "repetitive behaviors" as other concerns. Despite the parents' testimony suggesting that they were not very concerned about A.H.R. becoming overwhelmed by groups, their description of A.H.R.'s visits to the "funplex," a children's facility in Gulf Breeze, FL, indicated that A.H.R.'s lack of social engagement with people other than family members was a problem. Under a section of the evaluation form entitled "Your Family's Routines/Concerns/Priorities/ Resources," the evaluator noted that A.H.R. attended open gym at the funplex, "but there is no social engagement, [he] will watch them but not play with them." Pet. Ex. 11, p. 216. Mr. Reddy testified that this entry was misleading, in that "[t]here was an older gym class of eight- and nine-year-olds and [A.H.R.] was whatever age he was, so there was a massive age gap between him and the others, so….that was heavy play and he was observing." Tr. at 53; 76-77, 113. Mr.

[20] A slightly more detailed explanation from Ms. Tarabay of this behavior is contained in Dr. Mauney's initial visit notes. Pet. Ex. 12, p. 236.

Reddy also testified that A.H.R. did not avoid socialization with similarly aged children, particularly at a park. Tr. at 53.

Mr. Reddy attempted to explain another statement from the evaluation, that "Dad describes him using his hands in repetitive play and will often put in mouth," testifying: "when [A.H.R.] would get excited, he would use his hands moving up towards his face, at this stage, he wouldn't be like -- he wasn't doing what he was doing after the 23rd of March, he wasn't doing any self-injuries or smacking himself, but he'd bring his hands up like this (demonstrating), kind of like excited." Pet. Ex. 11, p. 215; Tr. at 60. He confirmed my description of his gestures, which I described as "You took both hands with your fingers spread and brought them up about six inches from your face and kind of moved them back and forth….[w]aving his hands around his face." Tr. at 60-61. Ms. Tarabay recalled that "[A.H.R.] would get very excited and his hands would out of excitement go to his face and then they would come down, but nothing to the point where I thought that's obsessive behavior." Tr. at 153. Later in his testimony, Mr. Reddy again distinguished A.H.R.'s excitable behavior (the hand waving Mr. Reddy demonstrated) with his behavior "after the regression when [A.H.R.] was slapping his face." Tr. at 112.

However, their typed comments for Dr. Hagerott indicate that A.H.R. was putting his hands in, or at least to, his mouth far earlier than March 23, 2010. These comments reflect that "around 16-18 months old we began noticing sensory issues. Specifically hand to mouth. This has consistently worsened". Pet. Ex. 14, p. 397. According to Doctor Hagerott's notes on this account of the hand to mouth sensory issues, A.H.R. "stopped progressing — ⌀ [a symbol for "no"] regression. *Id*. This comment was likely the result of a follow up question regarding the "consistently worsened" phrase in the typewritten statement and suggests that petitioners did not think A.H.R. had regressed. What is notably absent from the typewritten comments is any report of the sudden and dramatic regression on March 23, 2010 about which they testified.

A.H.R.'s parents both testified at some length about what happened on March 23, 2010. According to their testimony, A.H.R. caught his parents' attention while they were driving near their home. He took his sock off and put it in his mouth, began grinding on it, and then "started violently slapping it and soaking the sock in saliva." Tr. at 79; *see also* Pet. Exs. 9 at ¶¶ 12-14; 10 at ¶¶ 13-15. Ms. Tarabay testified that "[A.H.R.] started slapping his face like crazy and he was trying to make himself throw up . . . .[by] gagging himself." Tr. at 157. She testified that A.H.R. was "sticking his hand down his throat and he was making the gagging sounds and trying very hard to make himself throw up, and at the same time, slapping his face." Tr. at 158.

Once they arrived at their home, they testified that Mr. Reddy called Dr. Reese's office and made an appointment for the next day. Tr. at 79, 159-60. They apparently did not indicate that they needed to talk to someone about A.H.R.'s sudden behavioral change or convey any sense of urgency, as there were no telephone records of a

message.[21] Pet. Ex. 28 at 331-32. Mr. Reddy testified that he and Ms. Tarabay did not discuss taking A.H.R. to an emergency room. Tr. at 81. Although they were both frightened by A.H.R.'s behavior, they were able to use DVDs to calm him down that evening. Tr. at 81, 159.

Mr. Reddy emphasized that the incident on March 23, 2010 represented an instantaneous change in A.H.R.'s behavior, which also resulted in his immediate loss of words. Tr. at 81-82. At one point, Mr. Reddy snapped his fingers to demonstrate that A.H.R. acted as if "he was gone." Tr. at 80. Mr. Reddy described this sudden change "like a light, it was a definite change, sudden change." *Id.* Similarly, Ms. Tarabay testified that "things basically fell off a cliff" in relation to A.H.R.'s development after March 23. Tr. at 164.

Doctor Reese's records from A.H.R.'s sick-child visit on March 24, 2010, reflected that the reason for the visit was A.H.R.'s fever, runny nose, and sneezing, but after the entry "Narrative HPI," parental concerns about "lack of speech and self stimulating behaviors" were listed. Pet. Ex. 4, p. 75. Mr. Reddy testified that although such symptoms were accurate, "that wasn't the reason we went."[22] Tr. at 84-85; *see* Pet. Ex. 4, p. 75. Mr. Reddy thought Dr. Reese was "very concerned" with A.H.R.'s behavior, because he referred A.H.R. to a neurologist. Tr. at 86. Ms. Tarabay testified that A.H.R. was engaged in "[m]ajor flapping" during his March 24, 2010 visit with Dr. Reese. Tr. at 161.

Mr. Reddy and Ms. Tarabay also discussed their visits with Dr. Mauney, a neurologist; Dr. Hagerott, a neuropsychologist; and Dr. Niyazov, a geneticist. Tr. at 89-90, 162. Ms. Tarabay testified that the genetic testing ordered by Dr. Niyazov revealed that A.H.R. has a mitochondrial disorder. Tr. at 163. She and her mother have the same mutation and "if we have a depletion in the mitochondria, our energy levels are out of whack," but that the mitochondrial disorder impacted A.H.R. differently because "[t]he amount of vaccinations that [A.H.R.] was given, his body was not able to cope with that many at one go." Tr. at 163.

B. Dr. Reese's Testimony.

Doctor Reese was A.H.R.'s pediatrician from birth through the time of the hearing. Tr. at 11-12, 134, 211. He typically saw an average of 40-45 patients per day in his practice. Tr. at 182. He described his experiences in working with children with developmental issues, such as ASD and recalled a period around 1999 where "it seemed like [he] was getting a new autistic patient every week for a while." Tr. at 180-

[21] Pet. Ex. 28 contains about 85 pages of telephone records pertaining to A.H.R., but does not include calls for appointments.

[22] This testimony indicates that Mr. Reddy was also present at the March 24, 2010 visit, although the record for the visit indicated that "[p]atient brought by Mother." Pet. Ex. 4, p. 75. This entry does not appear to be a standard or form entry, as some records of other visits do not reflect who accompanied A.H.R. *See, e.g., id.*, pp. 70, 77. At A.H.R.'s 18 month well-child visit, he was accompanied by "[b]oth parents." *Id.*, p. 72.

83. Although he screened children in his practice for ASD at 18-24 months of age, he did not diagnose ASD. Tr. at 225.

Doctor Reese indicated that he had a general recollection of A.H.R. and thought that petitioners were "excellent parents." Tr. at 183-84, 186. In characterizing his relationship with A.H.R.'s parents, he stated that "I have spent a lot of time with them in the office and once in a while I see them at a restaurant and we always speak." Tr. at 184. His tone and demeanor suggested that he had a closer relationship with petitioners than a busy pediatrician might have with most parents of patients. He recalled spending more time on average with A.H.R.'s parents because "they ask appropriate questions, they show up with a list of questions and they're concerned about the feeding and behavior and everything." Tr. at 186, 191. In his testimony, Dr. Reese noted that "it's very interesting to talk to them, they're from a different culture" and added that they were the only professional opera singers in his practice. Tr. at 199.

Doctor Reese did not recall his initial referral of A.H.R. to speech therapy on November 3, 2009. Tr. at 189; Pet. Ex. 4, pp. 66-67. He could not recall why he prescribed a speech therapy evaluation and treatment for a speech delay on January 25, 2010, just a few days prior to A.H.R.'s 18 month well-child exam on February 1, 2010. Tr. at 218; Pet. Ex. 4, pp. 188-89. He could not recall the third speech therapy referral at A.H.R.'s 18 month well-child visit on February 1, 2010. Tr. at 197-98; Pet. Ex. 4, pp. 72-73.

His notation that A.H.R.'s speech was "half understandable" at the 18 month well-child visit on February 1, 2010, meant that "the parents understand half of what [A.H.R.] says." Tr. at 196-97. He also indicated the referral to Ms. Lakas as a speech therapist was based on the parents' insurance. Tr. at 200. Doctor Reese explained that he later referred A.H.R. to Early Steps for speech therapy because Ms. Lakas had left the Andrews Institute.[23] Tr. at 221. He could not recall ever seeing the Early Steps evaluation of A.H.R. Tr. at 222.

However, he specifically recalled A.H.R.'s sick-child visit on March 24, 2010, because he "specifically remember[ed] him acting vastly different from any child." Tr. at 204. He recalled that A.H.R.'s "face was red and he kept messing with his mouth and hitting his face. . . . He was hitting his face and he was putting his hands in his mouth, he just kept touching it." Tr. at 205. Doctor Reese further elaborated that "I remember him still making eye contact and looking at me in my face." Tr. at 205. Doctor Reese could easily recall the visit because as he stated "[t]his was very shocking -- I don't know the right word, this was a very intense visit for me." Tr. at 206.

Doctor Reese noted that, although he had previously treated severely autistic patients who exhibited self-stimulating behaviors, he was shocked by the rapid progression of the symptoms from "essentially normal, little bit of speech delay, to this." Tr. at 205. Doctor Reese recalled that A.H.R. did not exhibit any repetitive behaviors,

[23] *See* Pet. Ex. 11, p. 212. This referral occurred on Mar. 11, 2010, nearly two weeks prior to the sudden and dramatic regression petitioners described.

unusual sounds, or other symptoms of ASD before his March 23, 2010 sick-child visit.[24] Tr. at 203. The sudden change led Dr. Reese to classify A.H.R.'s behavior as a regression, as "even though he had a speech delay prior, now he had no words, he wasn't talking and now he's self-stimming."[25] Tr. at 206.

Doctor Reese testified that the parents' history of the instantaneous change in A.H.R.'s behavior on March 23, 2010 was significant to his decision-making during A.H.R.'s March 24 visit. Tr. at 209. When questioned about the parents' level of concern, Dr. Reese testified that "I remember [A.H.R.'s parents] being concerned to the level of enough to bring him in that day and them being concerned about his behavior." Tr. at 206. However, Dr. Reese's record reflects scant attention to A.H.R.'s dramatic behavioral changes; instead, it focuses almost entirely on the URI symptoms that were listed as the primary reason for the visit. The only mentions of behavioral concerns are the statement: "Parents concerned b/c lack of speech and self stimulating behaviors" listed as one of the reasons for the visit (Pet. Ex. 4, p. 75); the addition of a diagnosis of "Developmental disorder, unspecified" for the first time (*id.*, p. 76); and (under the header "Treatments and instructions given during encounter") "Continue current therapies" "Referral to Neurology" (*id.*). The majority of the record was devoted to A.H.R.'s ear and upper respiratory infections. *See id.*, pp. 75-76.

Doctor Reese testified that, in hindsight, he should have made additional comments in A.H.R.'s medical records, including that "I should have put that he was known to be self-stimming in the office and that he appeared to be agitated, but not to an extreme to where I would want to put him in the hospital." Tr. at 205, 210-11. He also testified that he "did a very poor job of documenting" his observations of A.H.R.'s behavior. Tr. at 222-23, 232.

On cross-examination, Dr. Reese explained that there are three types of referrals he could make to a specialist: "STAT," as in "[r]ight now"; "urgent," meaning "[p]ut it to the top of your list"; and "routine." Tr. at 215-16. He agreed that he characterized A.H.R.'s referral to a neurologist as "routine." Tr. at 223-24. He also explained that the "chief complaint" section of his office notes would reflect the parents' answers to a question about why they were there that day. Tr. at 216.

In questioning Dr. Reese, I indicated that I thought he was trying to answer questions accurately and honestly, but that I had concerns about the dichotomy between his testimony about what he observed and what his records reflected and the actions he took at the time. I expressed my concern about how he reported handling a report of a sudden regression in behavior, and in particular one presenting in a child with a fever, an ear infection, and an acute neurological problem. Tr. at 232. I asked Dr. Reese to explain why "if a child standing in your office is hitting himself in the face

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[24] The previous visit was a little more than seven weeks earlier.

[25] The term "stimming" was misspelled in the transcript as "stemming." In quoting from the transcript, I substitute the correct spelling. "Stimming" refers to the many and varied self-stimulatory behaviors displayed by many individuals with ASD.

while with his mother, would you write down 'no apparent distress'…. you would not do an immediate referral for some concern of an acute encephalopathic event?" Tr. at 232-33. Doctor Reese defended his position by testifying that he did refer A.H.R. to a neurologist but that some mistake was made in the urgency of the referral. Tr. at 233. However he also admitted that, under the circumstances, "I should have sent him immediately to a neurologist or I should have called one." Tr. at 234. He never adequately explained why his records documented A.H.R.'s illness, but not the behavior problems he observed.

I had similar concerns about Dr. Reese's affidavit dated February 18, 2014 (Pet. Ex. 21). He stated that he personally observed A.H.R. use three words ("mama," "dada," and "baba") "on multiple occasions and with purpose . . .to specifically identify individuals." *Id.* at ¶ 4a. At best, Dr. Reese had four opportunities to observe this use: at A.H.R.'s 12 month well-child visit (Pet. Ex. 4, pp. 62-64, when he reported the use of "mama" and "dada," with "baba" perhaps making up the third word of the "1-3 words" he recorded at that visit); at the 15 month well-child visit (Pet. Ex. 4, pp. 65-67, when he referred A.H.R. to speech therapy), a sick child visit in January 2010 (Pet. Ex. 4, pp. 70-71, at which there were no notations about developmental milestones); and at the 18 month well-child visit (Pet. Ex. 4, pp. 72-74, when he recorded several unmet speech milestones).

This specific recollection contrasts with his testimony that he did not recall his initial referral of A.H.R. to speech therapy in November 2009 (Tr. at 189), or why he prescribed speech therapy and treatment in January 2010 (Tr. at 218), or the referral to speech therapy in early February 2010 (Tr. at 197-98). It contrasts with the telephone message in December that A.H.R. was "not speaking" (Pet. Ex. 28, p. 327).

Doctor Reese's affidavit also stated that if A.H.R. "[h]ad [] presented with the repetitive behaviors he manifested following his regression, as well as the obvious facial redness and swelling due to repeated slaps to the face, it would have been documented in my records." Pet. Ex. 21 at ¶ 7. However, Dr. Reese *did not document* A.H.R.'s presentation in the records of the March 24, 2010 visit, and did not record that A.H.R. had a diagnosis of stereotyped repetitive movements until June 2010 (*see* Pet. Ex. 4, p. 79), in spite of another patient encounter with A.H.R. in May 2010 (*id.*, pp. 77-78). Although this was a sick-child visit, the notes reflect that the parents were seeking a referral to a neuropsychologist ("neuropsy"), suggesting that A.H.R.'s developmental problems were discussed during the visit. *Id.*, p. 77. There were no comments in the records from either the May or June visits documenting any specific repetitive or self-injurious behaviors. I thus conclude that Dr. Reese's assertions regarding what he would have done are relatively meaningless, because he did not record them at the March 24 visit when he claimed he was confronted with such behaviors.

It may be that Dr. Reese truly did see behaviors on March 24, 2010, that concerned him and that were different from those he had previously observed, as he made a referral to a neurologist. That does not mean that the behaviors he observed had occurred suddenly the prior day. I note that Dr. Reese had not seen A.H.R. for

about seven weeks—since the 18 month checkup that had resulted in the Early Steps referral. I also note that Ms. Hook, the speech pathologist who observed A.H.R. at the mid-April speech evaluation, did not note any of the severe types of behavior about which the parents and Dr. Reese testified as having occurred on March 23-24, 2010.

C. Geneticist's Testimony.

Doctor Niyazov is a medical geneticist at Ochsner Clinic Foundation, which he described as "the largest healthcare system in Louisiana and Southern Mississippi." Tr. at 245. He performed his residency and fellowship at Emory University School of Medicine in Atlanta, GA, and is board certified in medical genetics. Tr. at 245; Pet. Ex. 16 at ¶¶ 2-3. He explained medical genetics as based on "the science of genes and DNA." Tr. at 246. Medical geneticists differ from basic geneticists in their interactions with patients, as well as in using sophisticated testing to craft treatments for genetic problems. Tr. at 246.

His primary work is focused on mitochondrial disease and autism and the genetics of autism. Tr. at 245-46. He provides patients with the "genetic diagnosis that can cause or can predispose [a patient] to autism," but he does not diagnose autism or ASD. Tr. at 247, 271. He stated that "[i]t's up to the developmental pediatrician or psychologist's testing" to determine whether A.H.R.'s speech delay was a symptom of ASD. Tr. at 271. He does diagnose and treat mitochondrial disease. Tr. at 247.

In testifying, Dr. Niyazov was in the difficult position of having to impeach medical records that he created at the same time he was relying on what petitioners told him about A.H.R.'s medical history for his opinions on diagnosis and causation.

1. Doctor Niyazov's Records.

Doctor Niyazov's testimony about the reliability of his records pertaining to A.H.R. was somewhat inconsistent. The record of A.H.R.'s initial consultation on October 11, 2011 reflected a "History of Present Illness" that stated:

> Andrew's prenatal history was uncomplicated. His development has been delayed especially in language and cognition. He started walking at 16 months of age, but he is currently averbal. His hearing is reportedly normal. There's a history of regression at 15 months when he got 5 immunizations. He's been diagnosed with autism. He had significant repetitive behavior and stimming which is of great concern to the parents. He's in speech and ABA therapy. His EEG and MRI were normal. Previous karyotype and fragile X were negative.

Pet. Ex. 13, p. 321.

The past medical history reflected symptoms of hypotonia and drooling, and that A.H.R. had been seen by a "DAN doctor."[26] Pet. Ex. 13, p. 321. On the physical examination section, Dr. Niyazov wrote: "[A.H.R.] was averbal. He has not maintained good eye contact and did not interact well with me. He frequently stimmed with his hands." *Id.*

Doctor Niyazov offered several different explanations for what he characterized as incorrect entries in this record. The entries he identified as incorrect were: (1) the timing of A.H.R.'s regression; (2) the age at which A.H.R. began to walk; and (3) the information pertaining to treatment by a "DAN doctor." Tr. at 249-50. His explanations for the incorrect entries included a computer error, mistakes in his recollection, and a failure to record the correct information.

In testifying about the computer error, he appeared to cast doubt on the entire record, saying that the information in the "Past Medical History" section of the record at Pet. Ex. 13, p. 321, did not belong to A.H.R. and involved another child.[27] Tr. at 248-49. He then temporized, indicating that it was possible he "misworded himself" and "mixed up" a particular milestone, specifically, that A.H.R. did not walk until he was 16 months old. Tr. at 250. He also explained that notes from an office visit might not be dictated immediately, permitting recollection errors to creep into the records. *Id.* at 250.

He focused on the notation that A.H.R. regressed at 15 months of age, testifying that this was incorrect in that A.H.R. did not regress until March 2010, as the "parents have been telling me all along and that's the time line that I was following." Tr. at 250. However, in his June 22, 2014 affidavit (Pet. Ex. 26), he dated A.H.R.'s developmental regression as occurring "after November 3, 2009" not in March 2010.

When cross-examined about whether any of the medical records from the Ochsner Clinic Foundation reflect that A.H.R. experienced a regression in March 2010, Dr. Niyazov asserted that the error would have been corrected and that "those later notes would reflect the regression in March 2010." Tr. at 279. During the hearing, Dr. Niyazov reviewed more recent (and, as of the hearing date, unfiled) records on his computer and acknowledged that the more recent records repeated the same reference to a regression at 15 months. Tr. at 284.

After the hearing, petitioners filed the more recent records from the Ochsner Clinic Foundation, which contained a history of A.H.R.'s present illness that was nearly identical to the one found in the earlier records. Pet. Ex. 27, pp. 206-07. The most recent record, from June 26, 2013, specified the precise vaccinations administered to

[26] Defeat Autism Now! ["DAN!"] physicians subscribe to treatment protocols developed by the Autism Research Institute. These treatments may include chelation and other therapies not vetted as efficacious by controlled clinical studies. *Dwyer*, 2010 WL 892250, at *20, 178. Other than Dr. Niyazov's record, there is no evidence that A.H.R. was ever treated by a DAN! doctor.

[27] He attributed the errors to a change in the electronic medical records software, and "some of these records did not quite transfer from one system to the other, so this is something that should not belong there." Tr. at 249.

A.H.R. "(Hib, Varicella, DTaP, flu)"[28] that A.H.R.'s vaccination records show as administered on November 3, 2009. *Id.,* p. 206; Pet. Ex. 5, pp.195-96. Similarly, this record repeated the history that A.H.R. walked at 16 months of age, which is relatively consistent with his pediatric records, which show that he walked alone at 15 months of age. Tr. at 249; Pet. Exs. 27, p. 206; 4, pp. 66-67. The other similarities between A.H.R.'s pediatric records and Dr. Niyazov's records likely indicate that Dr. Niyazov was mistaken in claiming that the records filed as A.H.R.'s belong to another child, even though there may have some errors in the history.[29]

2. Mitochondrial Disorder Diagnosis and Opinions on Onset.

Doctor Niyazov testified that the speech delay noted at the 15 month well-child visit was not related to A.H.R.'s subsequent developmental delay, and was thus not relevant to his mitochondrial disorder diagnosis. He frequently saw patients with speech delay but in "much more" than 50% of his patients, the delay is only temporary. Tr. at 253-54. He noted that mild speech delays were common in boys and thought that the November 2009 delay was likely attributable to a problem with hearing caused by ear infections, rather than being an early symptom of ASD. Tr. 252-53, 255-58. He disagreed that the audiogram performed in December, 2009 (*see* Pet. Ex. 7, p. 199) showed normal hearing.[30] Tr. at 253-57.

In opining that the speech delay in November 2009 was unrelated to the March 2010 regression, Dr. Niyazov admitted that he could not predict whether A.H.R. would have overcome his initial speech delay, but for the regression. Tr. at 260-61. He simply thought that hearing loss was a more likely explanation for speech delay than either autism or mitochondrial disease. Tr. at 286. He declined to offer an opinion regarding whether the speech delay noted at A.H.R.'s 18 month well-child visit was symptomatic

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[28] A.H.R. received only these four vaccinations in November 2009, although the text preceding the parenthetical listing of the vaccinations stated that he received "five immunizations." Pet. Ex. 27, p. 206. It is possible that the H1N1 influenza vaccination administered two weeks later in November 2009 was counted in reaching the total of five immunizations at 15 months of age.

[29] Data consistent with A.H.R.'s pediatric and other records include the uncomplicated prenatal history, the delays in language and cognition, being averbal, the diagnosis of autism, the presence of significant repetitive behavior and stimming being of "great concern" to the parents, the therapies mentioned, and the other diagnostic testing performed (EEG, MRI, karyotype and fragile X tests). A.H.R. did not have a formal diagnosis of hypotonia nor was he noted to drool as set forth in the past medical history portion of Pet. Ex. 27, p. 206, but he had been assessed with low muscle tone (*see, e.g.*, Pet. Ex. 18, p. 23) and his records and the testimony established that he had a problem with saliva and oral-hand and finger contact (*see, e.g., id.*, p. 28; Pet. Ex. 14, p. 397).

[30] The audiologist who performed the test read the audiogram as normal, but did recommend a repeat audiogram in six months "to monitor hearing sensitivity and in an attempt to obtain a more complete audiogram." Pet. Ex. 7, p. 199. Doctor Niyazov testified that the "gold standard" in determining hearing loss was an auditory brain stem response test, "which was not done." Tr. at 286. That assertion was correct regarding the hearing testing performed in December, 2009. See Pet. Ex. 7, pp. 199-201. However, by the time he reached his mitochondrial disorder diagnosis, A.H.R.'s hearing was confirmed as normal by an auditory brain stem response test performed at the same time as A.H.R.'s muscle biopsy, along with a pre-operative audiogram. *See* Pet. Ex. 13, pp. 324-25, 328-30, 390. Both demonstrated that A.H.R. had normal hearing. *Id.*

of his ASD. Tr. at 268-71; *see* Pet. Ex. 4, pp. 72-73. To some degree, Dr. Niyazov's testimony that 50% or more of children with speech delay catch up to their peers (Tr. at 254) was more focused on the specificity of speech delay in diagnosis rather than whether it was recognized by the medical community at large as an early symptom of ASD. He indicated that he did not read the Early Steps evaluation performed on A.H.R. prior to the events of March 24, 2010, indicating that it was "not my prerogative to judge that" because he did not diagnose autism or developmental delays. Tr. at 272-73.

Doctor Niyazov established, at least for the purposes of this hearing, that A.H.R. has a mitochondrial disorder.[31] *See* Tr. at 273 (testifying that the mitochondrial disorder diagnosis was "a fact."). He explained that he diagnosed A.H.R. with this disorder after receiving the results of a muscle biopsy that showed a mitochondrial DNA mutation. Tr. at 262. He explained that he typically used the "Nijmegen criteria" in general and in diagnosing A.H.R.[32] Tr. at 288-89. He agreed that A.H.R.'s autism diagnosis was one of the criteria he used in making the mitochondrial disorder diagnosis, and agreed with my observation that it accounted for one point, in the category of central nervous system dysfunction, on the score. Tr. at 288-89. He testified that A.H.R.'s "clinical phenotype of regression and developmental delay in autism," along with "abnormal metabolic findings" and the muscle biopsy, all indicated that A.H.R. has mitochondrial disease. Tr. at 262.

However, he went further in tying the two diagnoses together, testifying that developmental delay and autism could be symptoms of a mitochondrial disorder (Tr. at 273-74) and that there was an association between ASD and mitochondrial disorders, although he stopped short of saying that the mitochondrial disorder actually caused A.H.R.'s ASD. Tr. at 273. He identified A.H.R.'s lack of language, "association interaction" and stimming behaviors were a part of his mitochondrial disorder diagnosis and a part of "developmental delay in autism." Tr. at 274. He reluctantly agreed that if A.H.R. had these symptoms prior to the "regression," they could be symptoms of A.H.R.'s mitochondrial disorder. Tr. at 274-75. In his June 22, 2014 affidavit, he clearly described A.H.R.'s behavior after the regression as "classic autistic behavior." Pet. Ex. 26 at 205.

Based on what the parents told him, Dr. Niyazov thought A.H.R. experienced a developmental regression in March 2010. Pet. Ex. 16 at ¶ 8; *but see* Pet. Ex. 26, p. 205 (placing the regression after November 3, 2009, the date of the allegedly causal vaccinations). He also indicated that "there were no other 'stressor' events during this

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[31] Given the procedural posture of this case and the limited purpose for the hearing, respondent did not directly challenge the mitochondrial disorder diagnosis by producing an expert report or testimony from a mitochondrial disease specialist. Indeed, in view of Dr. Niyazov's assertions that A.H.R.'s ASD diagnosis resulted from his mitochondrial disorder, it was unnecessary for respondent to challenge the diagnosis at this hearing.

[32] He did not explain which of the Nijmegen criteria he thought A.H.R. met. For purposes of this decision, I will accept Dr. Niyazov's testimony that A.H.R. has a mitochondrial disorder as accurate and correct.

time period [referring to the period between the November vaccinations and the March 23 regression] that would cause such a regression."[33] Pet. Ex. 16 at ¶ 8.

Ultimately, Dr. Niyazov's contributions to the issue of onset of A.H.R.'s condition, and thus to the issue of whether the petition was timely filed, were not particularly helpful to petitioners in that he directly linked the mitochondrial disorder diagnosis to the developmental delay and autism diagnoses. Although he waffled at one point, saying that "the issues he had before [the regression] doesn't [sic] necessarily have anything to do with what happened after regression" (Tr. at 275-76), taken as a whole, Dr. Niyazov's testimony and his June 22, 2014 affidavit (Pet. Ex. 26) were a concession that developmental delay and ASD were connected to A.H.R.'s mitochondrial disorder.

D. Psychologist's Testimony.

Doctor Miller received her Ph.D. in Clinical Child and Family Psychology from the University of Utah. Res. Ex. B at 1. She currently serves as an assistant professor of psychology in the psychiatry department at the Pearlman School of Medicine at the University of Pennsylvania. Tr. at 292. She lectures on ASD and has approximately 40 publications on ASD. *Id.,* pp. 293-94. Doctor Miller also serves as the Autism Director of an interdisciplinary and training clinic affiliated with the national Leadership, Education and Neurodevelopmental Disabilities Program. Tr. at 295.

As part of her clinical practice, Dr. Miller has diagnosed individuals with ASD since 1993. Such diagnoses have included cases involving developmental regression. Tr. at 296. Doctor Miller testified that an ASD diagnosis is generally provided by a licensed psychologist, a developmental pediatrician, or a neurologist. Tr. at 376. In making a diagnosis, clinicians rely on the criteria provided in the Diagnostic and Statistical Manual ["DSM"].[34] Tr. at 299. An ASD diagnosis requires that a patient have a number of characteristic symptoms but the DSM does not require that a patient have all of the impairments listed in order in order to reach the diagnosis. Tr. at 301. ASD manifests with impairments in social communication and restricted or repetitive behaviors. Tr. at 297. Speech delay is not diagnostic of ASD, but remains a recognized symptom and one commonly reported by parents and caregivers. Tr. at 301; *see also* R. Landa, *Diagnosis of autism spectrum disorders in the first 3 years of*

[33] In attributing the March regression to the vaccinations received the prior November, Dr. Niyazov referenced the mitochondrial mutation shared by A.H.R.'s asymptomatic mother and grandmother and asserted that the "104 antigens injected straight to [A.H.R.'s] blood stream provoked an immune response" causing A.H.R.'s regression. Tr. at 263. I note that no vaccine is injected into the blood stream; most are administered into muscle and some are administered orally or subcutaneously.

[34] The previous version of the DSM, DSM-IV-TR, was replaced in 2013 by the DSM-V. The symptoms recognized by the medical community at large as those of an ASD did not change as a result. The diagnostic criteria have been refined, and the distinctions drawn in the DSM-IV among the diagnoses of autistic disorder, PDD-NOS, and Asperger's disorder have been eliminated. *See* American Psychiatric Association, Autism Spectrum Disorder Fact Sheet, available at http://www.dsm5.org/Documents/changes%20from%20dsm-iv-tr%20to%20dsm-5.pdf (last visited August 21, 2015) (highlighting the differences between DSM-IV and DSM-V).

life, Nature Clinical Practice Neurol., 4(3): 138-47 (2008), filed as Res. Ex. D ["Landa, Res. Ex. D"], at 139 (Table 1).

Doctor Miller testified that she reviewed the video evidence, medical records, and statements from Drs. Reese, Mauney, and Niyazov in arriving at her opinions in this case. Tr. at 306. She was the only expert witness to testify about the video evidence, although Dr. Mauney's one page affidavit (Pet. Ex. 25) reflected that he reviewed the videos from December 25, 2008 through November 27, 2009, and that he did "not appreciate any signs or symptoms of Autism or a developmental regression in A.H.R." and believed "they depict a normally developing child." *Id.*

Doctor Niyazov's June 22, 2014 affidavit (Pet. Ex. 26) regarding the video evidence is unhelpful for two reasons. First, it reflected that the "regression" happened "after November 3, 2009" (*id.*), and thus does not differentiate between problem behaviors that occurred after that date and those that occurred after the purported March 23, 2010 regression. Second, Dr. Niyazov testified that he did not diagnose ASD and would defer to someone who did. Tr. at 271-72. Petitioners primarily commented on the videos in their joint affidavit, Pet. Ex. 23.

Although Dr. Miller heard the testimony of petitioners and Drs. Reese and Niyazov, she resolved the conflicts between their testimony and the "multiple evaluations that chart this steady identification [of ASD symptoms] over time" in favor of the records. Tr. at 349.

1. Video Evidence.[35]

Doctor Miller testified that the speech delay identified at A.H.R.'s 15 month well-child checkup was the first symptom of ASD in the medical records, but found concerning behaviors in video records of A.H.R. when even younger.

In her review of the video evidence, Dr. Miller noted that A.H.R. had "an unusual squeal, and that stood out because there's really an absence of a lot of other babbling or other purposeful vocalizations." Tr. at 307; Res. Ex. E at 2-3 (referring to videos from the first year of A.H.R.'s life). Likewise, she observed that "[h]e made some sounds that were potentially repetitive, the a-a-a-a-a while he was shaking ribbons at his birthday party." Tr. at 307.

Doctor Miller observed that A.H.R.'s "facial expressions seemed flat to me and he didn't use his body and face to communicate to other people." *Id.,* p. 308; Res. Ex. E at 3. She elaborated that A.H.R. demonstrated a deficient amount of communication for

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[35] Petitioners initially filed some video segments as exhibits attached to Pet. Ex. 23, the joint affidavit petitioners filed in response to the motion to dismiss. *See* Notice of Intent to File CD filed February 20, 2014. They explained the significance of these video records in their joint affidavit. Pet. Ex. 23. Pursuant to my order to file any additional video of A.H.R. from his birth through age two, (Order filed March 11, 2014), additional video footage was filed as Pet. Ex. 25. Doctor Miller discussed the filed videos in her supplemental expert report, filed as Res. Ex. E.

a toddler his age in the videos and also “some body twisting and some mild flapping when he was excited.” Tr. at 308.

Doctor Miller also observed that videos of A.H.R. at around 15 months of age demonstrated a continuation of his previous behaviors. He displayed challenges in interacting with others. Tr. at 308; Res. Ex. E at 2-3. She testified that “he was smiling at other people, but he didn't do things to keep the interaction going.” Tr. at 308. For instance, Dr. Miller observed that “his dad tries to play with him. His grandma tries to talk to him and somebody tries to play itsy-bitsy spider and it's very short, he's not doing things to kind of keep that going.” *Id.*

Doctor Miller noted some additional behaviors of concern such as the lack of “sustained play with objects. He kind of moves quickly from toy to toy and he does things with toys that are a little bit unusual.” Tr. at 308-09; Res. Ex. E at 3. He shook his hands in circles while he was squealing. Tr. at 309; Res. Ex. E at 3. Doctor Miller also noticed that when eating, A.H.R. “had a routine where he would sort of bang his spoon on the highchair before he would put it in his mouth, and he did that each time before he put a spoon in his mouth.” Tr. at 309.

2. Medical Records.

Doctor Miller acknowledged that she approached the medical record review with the benefit of hindsight, because an observer armed with the diagnosis can more easily interpret earlier behaviors as abnormal or otherwise supportive of the ASD diagnosis. Tr. at 307, 324-25. According to Dr. Miller, A.H.R.’s first symptom of ASD was the missed speech milestone at his 15 month well-child visit with Dr. Reese. Tr. at 324. However, on cross-examination, Dr. Miller conceded that at 15 months of age, the differences between a child with ASD and a typically developing child would be narrow. Tr. at 331.

Doctor Miller also testified that A.H.R. displayed many other symptoms of ASD between the 15 month checkup and mid-March, 2010. A.H.R.’s inability to meet several language milestones at his 18 month visit (after failing to meet one milestone at the 15 month visit (Pet. Ex. 4, pp. 65-67)) “suggest[ed] a plateau” in his language development. Tr. at 310. At 18 months of age, a child “should have at least six really good words, you should be combining some words, and he's not doing that.” Tr. at 310. Expectations for a typically developing child would include acquiring additional words and the ability to label objects. *Id.*

She pointed to the February 2010 speech therapy evaluation, noting that it contained information about other ASD symptoms, in addition to the concern about the extent of A.H.R.’s vocabulary. The observation that “there's no jargon”[36] indicated

[36] She explained “jargon” as a term “used to describe repetitive sounds that are not meaningful but they have a very repetitive quality or they might be a child's word approximations of -- it's like the beginning of echolalia sometimes where it's a repetitive sound.” Tr. at 384. In contrast, she described atypical jargoning as “repetitive vocalizations that have a repetitive and patterned intonation.” Tr. at 379. Doctor

"there's not sounds that sound like conversation or sound like a sentence….he's having difficulty approximating sounds." Tr. at 312; Pet. Ex. 8, p. 202. These records also indicated that A.H.R. had trouble with speech comprehension, knowledge of body parts, and compliance with simple oral instructions. *Id.*

According to Dr. Miller, the purpose of the Early Steps evaluation was to gather the family's concerns and ideas about their goals for their child in order to guide the intervention team's response. Tr. at 318. She zeroed in on the narrative of the interview on March 16, 2010, as the primary basis for her conclusion that A.H.R. had many symptoms of ASD before March 23, 2010. Res. Ex. A. at 3-4, 6; Tr. at 313; Pet. Ex. 11, pp. 213-16.[37] These symptoms included repetitive actions, lack of social engagement, obsessive behaviors, and abnormal behaviors with toys and objects. Res. Ex. A. at 3, 6; Tr. at 313-19; Pet. Ex. 11, pp. 213-16.

She observed that petitioners expressed concerns about whether A.H.R.'s behaviors were reflective of autism, which suggested that, despite their testimony at the hearing, they thought his repetitive behaviors and lack of speech were matters of concern. Tr. at 319; Pet. Ex. 11, p. 215.

In reference to the Early Steps comments about A.H.R.'s behavior at the funplex, Dr. Miller found the lack of social engagement to be a significant symptom, in that, "at the open gym, [A.H.R.] is watching the other kids but not playing with them." Tr. at 319; Pet. Ex. 11, p. 216.

Doctor Miller also concluded that A.H.R.'s reported fixation with socks, belts, and strings represented behaviors symptomatic of ASD because "while children play with everyday objects, they often don't engage in repetitive play with any objects for very long." Tr. at 314. She distinguished A.H.R.'s unusual play and obsessive behaviors with toys and objects from normal children, noting that "[m]ost children, once they figure out a toy quickly, they use it as a toy rather than studying how the mechanics are." Tr. at 315. Her opinion was also influenced by A.H.R.'s fixation on signs and lines on the football field while visiting the park (Tr. at 323), as referenced by Ms. Tarabay at the initial consultation with Dr. Mauney (Pet. Ex. 12, p. 236).

Miller explained that some of what Mr. Reddy called babbling, such as "d-d-d," might be best classified as atypical jargoning or repetitive vocalization with a patterned intonation. Tr. at 379; *see also* Tr. at 29, 64, 168 (the parents describing A.H.R.'s words).

[37] The Early Steps IFSP (individual family support plan) date of "04/14/10" appears in the header of Pet. Ex. 11, pp. 212-23. However, the parent interviews took place on March 16, 2010. Pet. Ex. 11, pp. 212-16 (date information gathered listed at the top of pp. 213, 215). A separate Early Steps speech and language evaluation does not have a header (*id.*, pp. 224-25), but the first page of the actual evaluation has a "Date of Consultation" of April 14, 2010 (*id.*, p. 224). The treatment plan was signed by the speech pathologist on April 28, 2010, and by Dr. Reese on April 29, 2010. *Id.*, p. 227. The speech and language evaluation was conducted in petitioners' home, with Mr. Reddy as the only parent present. *Id.*, p. 224. Both parents participated in the parent interviews on March 16, 2010, as they both testified about discrepancies between what was written down and what they told the evaluators. *See, infra*, Section III.A.

With regard to the Early Steps evaluation and petitioners' testimony, Dr. Miller expressed skepticism about their host of "clarifications…that most of those observations sprinkled throughout the [Early Steps evaluation] report or notes were not what the parents meant." Tr. at 352; *see also* Tr. at 349.

Doctor Miller did not believe that A.H.R. experienced a developmental regression on March 23, 2010, because the contemporaneous medical records did not reflect one. Tr. at 320, 324; Pet. Ex. 4, pp. 75-76. The April 23, 2010 neurology consultation also lacked any comment about a recent regression, although A.H.R. was clearly displaying signs of an ASD, with Dr. Miller noting that "he's not pointing to things, he does not imitate, and he only occasionally seems to respond to his name." Tr. at 322; Pet. Ex. 12, p. 236.

Even assuming a regression occurred on March 23, 2010, Dr. Miller maintained that the earliest symptom of ASD was documented at the 15 month well-child visit on November 3, 2009. Tr. at 367. Other symptoms of ASD before the purported regression were the repetitive and stereotypic behaviors and speech delay documented in the Early Steps evaluation. Tr. at 347. Having symptoms of autism prior to regression is not uncommon in ASD. Tr. at 349; *see also* Landa, Res. Ex. D, at 141 (regression may follow earlier abnormal development in those with ASD).

In discussing the speech and language pathologist's direct observations of A.H.R., Dr. Miller noted that "that [A.H.R.] was seen at home where he would be most comfortable . . . [but] he didn't really engage with the clinician." Tr. 320-21; Pet. Ex. 11, pp. 224-25. A.H.R. "kept his distance from the evaluator and he engaged in some repetitive [behaviors] or some flapping [of] his arms while he vocalized." Tr. at 321; Pet. Ex. 11, p. 224. Similarly, she noted that A.H.R. "also didn't speak well and he didn't have much output. It says they couldn't assess his articulation because he had such limited output and that he should be producing more constant sounds than he was." Tr. at 321.

IV. Untimely Filing.

A. Legal Standards Regarding Application of the Statute of Limitations.

The Vaccine Act's statute of limitations provides in pertinent part that, in the case of:

> a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury."

§ 300aa-16(a)(2). The date of occurrence "is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Cloer v. Sec'y, HHS*, 654 F.3d 1322, 1339 (Fed. Cir. 2011) (en banc). Additionally, the date "does not depend on the knowledge of a petitioner as to the cause of an injury." *Id.* at 1338. When drafting the Vaccine Act, Congress rejected a discovery rule-based statute of limitations, in favor of one that does not consider knowledge and runs solely from the date of the first symptom or manifestation of onset. *Id.* at 1338-39.

Because petitioners filed their petition on behalf of A.H.R. on March 22, 2013, the first symptom or manifestation of onset of his ASD must have occurred after March 22, 2010, in order for the petition to be considered timely. *See Markovich v. Sec'y, HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007) (holding that "either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer,* 654 F.3d at 1335 (holding that the "analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset.").

B. Symptoms of Autism Spectrum Disorders.[38]

The diagnostic criteria for ASD are set forth in Diagnostic and Statistical Manual of Mental Disorders ["DSM"]. "Landa, Res. Ex. D" at 138. Speech delays are often the first symptom of ASD that parents report to their child's pediatrician. *Id*. at 139. Other early symptoms of ASD recognized by parents include exploring toys in unusual ways, poor motor skills, or regulatory problems related to attention, eating and sleep. *Id.,* at 139-40. As Dr. Miller testified, the focus in the DSM is on deficits in social communication and restrictive and repetitive patterns of behavior. Tr. at 297. Additionally, self-injurious behaviors, such as A.H.R.'s repetitive face slapping, are also commonly seen in ASD. *See* Res. Ex. E at 4: Res. Ex. F, N. Minshawi, et al., *The association between self-injurious behaviors and autism spectrum disorders*, PSYCHOLOGY RESEARCH AND BEHAVIOR MANAGEMENT, 7: 125-36 (2014) at 127.

There does not appear to be any dispute concerning whether these symptoms are ones that the medical community at large would recognize as symptoms of ASD. *See Cloer*, 654 at 40 (holding that "[t]he statute of limitations begins to run on a specific statutory date: the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large." *See also Markovich,* 477 F.3d at 1360 (holding that "the first symptom or manifestation of onset … is the first event objectively recognizable as a sign of a vaccine injury by the

[38] I have previously described the symptoms of ASD at length in *White v. Sec'y, HHS*, 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011). There does not appear to be any material dispute regarding what constitutes a symptom of an ASD in this case, but rather when the symptoms first presented. Although Dr. Niyazov offered an alternative explanation for the earliest speech delay symptoms, he did not assert that speech delay was not a symptom of ASD, and he appeared to concede that speech delay could be such a symptom. Tr. at 270-71.

medical profession at large.") (internal citation and quotation omitted). Neither Dr. Niyazov's testimony[39] nor that of Dr. Reese contradicted Dr. Miller's testimony and the other evidence regarding ASD symptomatology. Doctor Mauney possessed the requisite qualifications to opine whether a specific behavior or missed milestone would be a symptom of ASD recognized by the medical community at large. However his affidavit did not exclude speech delay as a symptom of ASD; he merely opined that missing one milestone with regard to speech would not be a sign or symptom of ASD. Pet. Ex. 22 at 107.[40]

To the extent Dr. Mauney's affidavit conflicts with Dr. Miller's reports and testimony regarding what constitutes a symptom of ASD, I relied more heavily on Dr. Miller's testimony and reports. I note that, in spite of language delay and other ASD symptoms appearing in Dr. Mauney's records, the filed records never indicated that he diagnosed A.H.R. with ASD. Rather, he repeatedly diagnosed a speech and language developmental delay and at least twice recommended that A.H.R. be tested for ASD using the ADOS. *See, e.g.*, Pet. Ex. 12, pp. 239-40; 246, 288.

C. Determining Onset of A.H.R.'s Symptoms.

In determining onset of A.H.R.'s ASD symptoms, I relied primarily on the testimony of Dr. Miller, rather than that of Drs. Reese and Niyazov, given her greater expertise. Both Drs. Reese and Niyazov testified that they did not diagnose ASD.

The primary areas of controversy are whether A.H.R.'s November 2009 speech delay was a symptom of ASD; whether to credit petitioners' testimony over the contemporaneous medical records regarding A.H.R.'s behavioral symptoms before the events of March 23, 2010; and whether A.H.R. experienced a developmental regression on March 23, 2010. For purposes of resolving the motion to dismiss based on untimely filing, it is unnecessary to resolve the issue of whether a developmental regression occurred, as I find that there is ample evidence that A.H.R. experienced developmental delay and symptoms of autism more than 36 months prior to the filing of this petition.

The legal standards applicable to resolving factual conflicts are set forth below, followed by my factual findings and the reasons therefor.

1. Legal Standards.

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[39] *See* Tr. at 271 (Dr. Niyazov's testimony that determining whether speech delay was a part of A.H.R.'s ASD was not his call, and that this decision should be made by a developmental pediatrician or based on a psychologist's testing).

[40] Doctor Mauney did opine that, based on his "review of the aforementioned records, there was no indication, sign, or symptom prior to March 24, 2010 that [A.H.R.] was suffering from an autism spectrum disorder." Pet. Ex. 22 at ¶ 9. The problem with this opinion is that either Dr. Mauney did not receive a copy of A.H.R.'s 18 month evaluation by Dr. Reese, which contained evidence of more than one missed milestone, or he did not read the record carefully. Furthermore, the Early Steps evaluation was not listed as one of the documents he received. *Id.* at ¶5. Thus, his opinion that there was no indication that A.H.R. exhibited any of the behaviors he saw in April 2010 prior to March 24, 2010, and that there was no evidence he suffered from an ASD prior to March 24, 2010 was not a fully informed one.

Special masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991) *aff'd,* 968 F.2d 1226 (Fed.Cir.1992), *cert. denied,* 506 U.S. 974 (1992) (citation omitted). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *See Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by "clear, cogent, and consistent testimony" explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990).

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

2. Experts and Qualifications to Opine.

Expert qualifications play a significant role in the weight given to expert opinions, particularly when the opinions expressed are otherwise inadequately supported by reliable evidence. *See Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1325 (Fed. Cir. 2010) ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.") (citations omitted).

A.H.R.'s treating physician, Dr. Reese, testified that he has experience working with pediatric patients afflicted by behavioral developmental issues, such as ASD. Tr. at 180-83. His affidavit claims that "[p]rior to joining Pensacola Pediatrics, I spent time in a developmental clinic treating children with learning disorders or developmental delays who were referred to the practice by their treating doctors." Pet. Ex. 15 at ¶ 2 (citing Pet. Ex. A. "C.V. of Dr. Reese," which was apparently never filed).

Petitioners' second expert, Dr. Niyazov, is a medical geneticist at Ochsner Clinic Foundation, where his primary practice focuses on the issues of mitochondrial disease, genetics, and autism.[41] Tr. at 245; Pet. Ex. 16 at ¶¶ 1, 3. He testified that in determining whether A.H.R.'s speech delay during his 15 month well-child visit was related to A.H.R.'s ASD, "[i]t's up to the developmental pediatrician or psychologist's

[41] During his later testimony, Dr. Niyazov clarified that his autism expertise was in trying to identify the cause of autism and regression. Tr. at 273. He testified that deciding what symptoms constituted a part of an autism spectrum disorder was "up to the developmental pediatrician or psychologist's testing. *I do not diagnose autism*." Tr. at 271 (emphasis added); *see also* Tr. at 272-73.

testing. I do not diagnose autism." Tr. at 271, 274. He neither purported to be an expert in diagnosing symptoms of ASD nor was he willing to opine on A.H.R.'s early developmental delay.

Doctor Reese's inability to recall his multiple referrals of A.H.R. to speech therapy, on November 3, 2009, January 25, 2010, and February 1, 2010, caused me to question either his ability to recall or his credibility. Tr. at 189, 197-98, 218; Pet. Ex. 4, pp. 66-67, 72-73, 188-89. When the telephone records from December 16, 2009 were filed, in which A.H.R.'s inability to speak was documented, my concerns about the reliability of his testimony were made even more acute. Pet. Ex. 28, p. 327.

Doctor Reese testified that A.H.R. did not exhibit any repetitive behaviors, unusual sounds, or other symptoms of ASD before his March 23, 2010 sick-child visit. Tr. at 203. He also testified that he had no recollection of reviewing the Early Steps evaluation (Tr. at 222), but I note that his signature appeared on the speech and language treatment plan prepared as a part of the Early Steps assessment (Pet. Ex. 11, p. 227). Doctor Reese explained that he referred A.H.R. to Early Steps for speech therapy instead of the Andrews Institute because of Ms. Lakas's departure from the Andrews Institute. Tr. at 221. It is true that Ms. Lakas departed the Andrews Institute, but the specific timing of her departure is unclear. I think it more likely that he made the referral to Early Steps rather than just to another speech therapist because of the parents' concerns about their child having ASD. *See* Pet. Exs. 28, p. 327; 11, p. 215; Tr. at 64, 73, 104.

In contrast, respondent's expert, Dr. Miller, holds a Ph.D. in Clinical Child and Family Psychology and has 20 years of experience in research and clinical care for individuals with ASD. Res. Exs. A at 1; B at 1. Doctor Miller serves as an assistant professor of psychology in the psychiatry department at the Pearlman School of Medicine at the University of Pennsylvania. Tr. at 292. She continues to lecture on ASD and has produced around 40 publications on the subject, mostly related to the early diagnosis and classification of ASD. *Id.* at 293-94; Res. Ex. B at 4-11. Doctor Miller also serves as the Autism Director and Clinical Training Director for the Center for Autism Research at the Children's Hospital of Philadelphia. Tr. at 295; Res. Exs. A at 1; B at 1. As part of her work at the Children's Hospital of Philadelphia, she oversees a psychology training program for developing experts in ASD diagnostics. Res. Ex. B at 1.

Doctor Miller's observations of the video evidence of A.H.R. were particularly informative. Tr. at 307-09. She noted additional instances of A.H.R.'s behaviors, such as his repetitive and obsessive behaviors and his impairments in social communication, which were consistent with the reports in the Early Steps evaluation. *Id.*; Pet. Ex. 11, pp. 213-15.

Doctor Miller's interpretation of the Early Steps evaluation was a coherent narrative that complements and reinforces information contained in A.H.R.'s other medical records. Tr. at 318-20; *see* Pet. Exs. 4, pp. 66-67; 11, pp. 215-16; 13, p. 321;

28, p. 327. Doctor Miller refused to accept much of the testimony from petitioners and their witnesses at face value, as accepting it would require her to "disregard the multiple evaluations that chart this steady identification of autism over time." Tr. at 349. Doctor Miller's opinions are rational and are well-supported by A.H.R.'s medical records. Most critically, even if I were to find that the alleged developmental regression occurred just as petitioners and Dr. Reese testified, Dr. Miller's conclusion remained unwavering because a regression would not be inconsistent with A.H.R.'s displaying symptoms of ASD at an earlier date. Tr. at 347.

While I appreciate Dr. Reese's role as A.H.R.'s treating physician and his first-hand observations of A.H.R.'s development and the concerning behaviors he displayed on March 23, 2010, Dr. Miller has superior knowledge about the symptoms and diagnosis of ASD and, in particular, in identifying the early symptoms of ASD. Based on their respective medical backgrounds, I placed a greater weight on the expert opinion of Dr. Miller regarding the onset of A.H.R.'s ASD symptoms than the opinions of Drs. Reese and Niyazov.

My concerns about Dr. Mauney's affidavit about what he observed at the initial visit with A.H.R. are addressed elsewhere. I cannot accept his opinions on the signs and symptoms of ASD and whether and when they were present in A.H.R., as it appears that he was presented with medical records for review that were less than complete. An expert's opinion is only worth as much as the facts upon which it is based. *Dobrydnev v. Sec'y, HHS*, 566 Fed.Appx. 976, 982-83 (Fed. Cir. 2014) (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)); *Fehrs v. United States*, 620 F.2d 255, 265 (Ct. Cl.1980).

3. Factual Findings.

In general, I placed more reliance on the contemporaneous medical records and videos, and histories provided when petitioners were seeking medical treatment or therapies for A.H.R. than on evidence prepared or presented after litigation commenced. I find that the parents' statements contained within A.H.R.'s medical records, made contemporaneously with his treatment, retain appreciably higher indicia of reliability than their inconsistent, convoluted, and sometimes disingenuous hearing testimony.

Instead of providing clear, cogent, and consistent testimony explaining the discrepancies between their affidavits and testimony and the contemporaneous records and histories provided before they filed their claim, Mr. Reddy and Ms. Tarabay's testimony repeated the refrain that they were misunderstood, misquoted, or their reports were taken out of context regarding A.H.R.'s gradual development of ASD. This might happen with one health care provider or in one record, but not in every record in which symptoms were recorded that placed their claim outside the statute of limitations.

a. First symptoms of ASD/Developmental Delay.

I find that A.H.R. displayed symptoms of speech delay before the allegedly causal vaccinations were administered; specifically, he did not use five to ten words at his 15 month checkup. As there was no evidence of a sudden loss of language when Dr. Reese reviewed A.H.R.'s developmental milestones at this November 3, 2009 visit, the delay in language existed before the vaccinations were administered. Additionally, the video evidence reviewed by Dr. Miller suggested problems in language development, social communication (facial expression and body language), and some mild hand flapping in videos taken before the November 2009 vaccinations were administered.

I find that, notwithstanding Dr. Mauney's assertions that missing one language milestone is not a symptom of ASD, Dr. Miller's testimony that language delay is indeed a symptom of ASD recognized by the medical community at large as symptomatic, but not diagnostic of, ASD is correct. I note that Dr. Miller's testimony was well-supported by Landa, Res. Ex. D, Table 1. Table 1 reflects that delayed receptive and expressive language and low diversity in consonants produced communicatively are both symptoms commonly reported in children at 9-14 months of age who were later diagnosed with ASD. The article also reflects that about 80% of parents of children with ASD had noticed abnormalities in their child by 24 months of age, and that these abnormalities "usually involve delays in speech and language development." Landa, Res. Ex. D, at 139. Petitioners acknowledged his low production of sounds, specifically referring to the "di, di, di" sound, and the very few words he spoke at 15 months of age.

b. Parental Concern about ASD Predating the Alleged Regression.

Assuming, *arguendo*, that Dr. Mauney was correct in asserting that the missed milestone at 15 months of age did not constitute an early symptom of ASD or that Dr. Niyazov was correct in attributing the missed milestone to a hearing problem, I find that the next symptom of ASD was the parental concern about lack of speech and possible autism expressed in the December 16, 2009 telephone record from Dr. Reese's practice. This record, when read in concert with the history they provided in September 2010 to the evaluator at the Sacred Heart Health System Autism Resource Center (mentioning the onset of A.H.R.'s self-stimulatory behaviors at around Christmastime 2009 (*see* Pet. Ex. 18, p. 31)) and their expressed concern about autism, likely encompassed more than A.H.R.'s lack of speech.[42] The December 16, 2009 record contradicts petitioners' claim that "[A.H.R.] did not manifest any symptom of his vaccine-related injury prior to his sudden regression on March 23, 2010." Pet. Resp. at 1. I also note that Dr. Reese referred A.H.R. to speech therapy on at least three occasions before March 23, 2010, and only one of these could have been prompted by the departure of the initial speech therapist at the Andrews Institute. Thus, the problem with A.H.R.'s language development at 15 months of age persisted in the following months.

[42] The December 16, 2009 telephone record was not addressed by Mr. Reddy, Ms. Tarabay, or Dr. Reese at the hearing because it had not been filed. The telephone records (Pet. Ex. 28) were filed shortly after the two-day onset hearing in Pensacola, FL.

c. Other ASD Symptoms with Onset Prior to the Alleged Regression.

Assuming, *arguendo*, that Dr. Niyazov was correct in attributing the delay in expressive language at 15 months of age to a hearing loss and that the speech delay resulted from the hearing loss was the sole prompter for the December telephone call about A.H.R. not speaking, the first symptoms of ASD were documented in the Early Steps records from the evaluation ordered on March 11, 2010, and conducted on March 16, 2010.

In making this finding, I accept that medical records may not always be complete or accurate and that a parent may report one thing while the evaluator writes down another. However, I find these records to be accurate in documenting A.H.R.'s behavior at the time (mid-March 2010) that they were made. Specifically, I find reliable evidence in the Early Steps record that A.H.R. had significant delays in social communication, cognition, and self-help skills. He displayed abnormal play skills and he engaged in repetitive and stereotypic activities. He had unusual fascinations with socks, belts, and string, and became over-focused or "stuck" on activities. I find that A.H.R. used his hands in repetitive motions and placed them in his mouth with sufficient frequency that Mr. Reddy mentioned this habit to the evaluators. I also find that petitioners expressed concern about autism as an explanation for A.H.R.'s behavior at this visit—the same concern they had expressed in December 2009 to Dr. Reese's staff.[43]

I carefully considered Ms. Tarabay's and Mr. Reddy's testimony and their joint affidavit addressing onset of A.H.R.'s distressing behaviors. I am confident that they believed what they said at the hearing and in the affidavit, but their attempts to explain away virtually every behavioral manifestation of ASD reflected in the Early Steps records were unavailing. Either petitioners volunteered the information that appears in the fairly detailed Early Steps evaluation records based on a growing concern about whether A.H.R.'s behaviors were abnormal, or something in the referral or what the parents said prompted the evaluators to ask searching and detailed questions about specific areas of behavior. I conclude that petitioners' question about autism triggered the depth of the inquiry reflected and petitioners answered the questions in the manner the exhibit reflects.

In support of my decision to credit the contemporaneous medical records over the parents' testimony, I note that virtually every behavior described at the Early Steps

[43] Ms. Tarabay and Mr. Reddy's question during the March 16, 2010 Early Steps evaluation as to whether A.H.R.'s lack of speech and other behaviors were symptomatic of ASD also documented their concern about his development. This was one of the few statements attributed to them during the evaluation that both parents did not attempt to "explain away" at the hearing. This question is essentially the same one Mr. Reddy communicated to Dr. Reese's staff as reflected in the telephone message on December 16, 2009. *See* Pet. Ex. 11, p. 215; Pet. Ex. 28, p. 327; *See also* Pet. Ex. 12, p. 236 (parents indicating to Dr. Mauney that A.H.R. "has *never* spoken intelligible words.") (emphasis added). While a co-worker's concern may have triggered the parents' initial inquiry to Dr. Reese in December, the concern persisted and was repeated three months later. This reflects more than a causal inquiry based on a co-worker's comment.

evaluation also appeared as an area of concern later. These later incidences of the same behaviors documented in the Early Steps evaluations completely undercut petitioners' attempts to discredit the Early Steps records. I accept that A.H.R.'s behaviors worsened over time, a progression not uncommon in ASD, but I find no reliable evidence that A.H.R. lost skills that he once displayed.

Moreover, petitioners' testimony regarding A.H.R.'s March 16, 2010 Early Steps evaluation contains inconsistencies and contradictions. At times Ms. Tarabay even contradicted herself. *See* Tr. at 156-57. Perhaps the most serious of these conflicts is their denial that they told the Early Steps evaluators in mid-March that A.H.R. "has no words," particularly in view of the December 16, 2009 telephone record from Dr. Reese which indicated that "[Patient] doesn't speak, mom is concerned that [patient] may be autistic." *Compare* Tr. at 64, 67, 153-55, 168, *with* Pet. Ex. 28, p. 327 *and* Tr. at 73.

(1) Speech Problems.

The record as a whole demonstrates that A.H.R.'s early speech problems at 15-18 months of age became a consistent concern prior to March 23, 2010. The speech therapy records from February reflected five specific areas of concern, which included both expressive and receptive language issues, as well as a possible loss of a skill previously demonstrated—the ability to point to body parts upon request. At the March 16 Early Steps evaluation, he was reported to have "no words," virtually the same report Mr. Reddy made ("doesn't speak" (Pet. Ex. 28, p. 327)) in December 2009. He scored poorly on the speech evaluation conducted on April 14, 2010. His parents described his speech to Dr. Mauney on April 23, 2010 as never including intelligible words; he was nonverbal during Dr. Mauney's examination. A.H.R.'s speech delay persisted, and by the time he was seen by Dr. Hagarott, he was nonverbal. Thus, the "no words" comment in the Early Steps records correctly reflects the state of A.H.R.'s expressive language. As the initial audiology examination showing normal hearing was later confirmed by an auditory brain stem response test performed at the same time as A.H.R.'s muscle biopsy, along with a pre-operative audiogram, it is unlikely that A.H.R.'s speech problems ever reflected a hearing loss.

(2) Abnormal Fixations, Fascinations, and Play Behaviors.

Petitioners' own descriptions of A.H.R.'s actions on March 23, 2010, reflect a fixation on a sock, the same item described in the Early Steps evaluation as a play item that he looked at and the loss of which would cause a temper tantrum ("hissy fit") when he lost track of it or it was removed.

The Early Steps evaluation completed on March 16, 2010, described A.H.R. as "moving his hands in repetitive play" and "often" putting them in his mouth. This is very similar to the descriptions petitioners provided to Dr. Mauney about A.H.R.'s self-stimulatory behaviors on April 24, 2010, and with the arm flapping Ms. Hooks observed at the mid-April speech and language evaluation.

Thus, regardless of what the parents observed on March 23, 2010, A.H.R. displayed abnormal play and fixations on objects prior to the events of that day, and at a time that placed onset of these ASD characteristics outside the statute of limitations.

(3) Eye Contact.

The Early Steps evaluation completed on April 14, 2010 described the presence of "some eye contact." This is consistent with what Ms. Hooks observed at the Early Steps speech and language evaluation of "sporadic eye contact" in mid-April 2010. At Dr. Mauney's initial visit later in April 2010, A.H.R. had good eye contact. I conclude that A.H.R.'s eye contact was not entirely normal in April 2010, but cannot conclude that his diminished eye contact began at a period outside the statute of limitations.

d. Regression on March 23, 2010.

In view of the clear symptoms of ASD present prior to March 23, 2010, it is not necessary to determine if A.H.R. actually experienced a loss of skills once reliably demonstrated (the definition of a regression used by Dr. Reese in his affidavit (Pet. Ex. 21 at ¶ 5)). Although both Drs. Reese and Mauney described self-injurious behaviors occurring at their first visits with A.H.R. after March 23, 2010, their medical records do not reflect them. Doctor Mauney's record merely reflects a parental report of rubbing a finger on face and tongue, not slapping or hitting. Petitioners' testimony describing A.H.R.'s slapping himself on March 23 was similar to the testimony of Dr. Reese describing what he observed on March 24. *Compare* Tr. at 79, 83, 157-158 *with* Tr. at 205. However, Mr. Reddy testified that A.H.R.'s behavior on March 24 was more muted, explaining that the new environment of the doctor's office calmed him and A.H.R. "definitely presented [the previous day] as a totally different child than Dr. Reese would have seen." Tr. at 84.

Dr. Reese's classification of A.H.R.'s behavior on March 24, 2010 as a regression because "even though he had a speech delay prior, now he had no words, he wasn't talking and now he's self-stimming," (Tr. at 206) is inconsistent with his own records, which reflected that A.H.R. was not talking in December. I do not give much weight to Dr. Reese's affidavit describing the words that A.H.R. spoke prior to March 24, 2010 (*see* Pet. Ex. 21, ¶ 4), given that these words were not recorded in the medical records, Dr. Reese saw approximately 40 patients per day, he had received the February speech and language evaluation reflecting significant speech problems, and that his affidavit was prepared nearly four years later after the events in question.

If A.H.R. was truly behaving in a manner "vastly different from any child," at the March 24, 2010 visit, I would expect that visit's records to indicate something other than the routine visit recorded. Tr. at 204, 232; Pet. Ex. 4, pp. 75-76 181. I would expect that the neurology referral would have reflected a sense of urgency. Instead, it was a routine referral. Pet. Ex. 4, p. 181. While physicians and their staffs are not immune to mistakes, the entirety of what Dr. Reese recorded and did at the March 24, 2010 visit does not reflect the acute concern about which he testified and wrote in his affidavits. I

also note that he did not include a diagnosis of repetitive and stereotypic disorder until June 2010, whereas his other diagnoses on the list of open diagnoses were recorded when he observed them. At the March 24 visit, the diagnosis he recorded was "Developmental disorder, unspecified." *Id.*, p. 104.

Doctor Niyazov's reliance on vaccines being the only possible explanation for a mitochondrial regression occurring on March 23, 2010, may well be misplaced. On that date, A.H.R. was acutely ill with an upper respiratory and ear infection and presented with a fever.

Assuming, *arguendo,* that this event, occurring more than four months after the allegedly causal November 2009 vaccination, did constitute the manifestation of a mitochondrial disorder, the claim is still untimely. Petitioners are seeking compensation for a developmental delay. Pet. at ¶ 16. This delay first manifested before March 23, 2010. The loss of language (characterized by petitioners in their December 2009 telephone message to Dr. Reese as "not speaking") first occurred before March 23, 2010. Symptoms of ASD, including stereotypic behavior, dysfunctional play skills, fascination with particular objects, and language delays, first occurred before March 23, 2010. Doctor Niyazov used A.H.R.'s diagnosis and symptoms as part of the diagnostic criteria for the mitochondrial disorder diagnosis, thus identifying a causal relationship between the two disorders. As the mitochondrial disorder diagnosis was partially based on the ASD symptoms, then the first ASD symptoms were the first symptoms of the mitochondrial disorder as well.

VI. Conclusion.

Autism spectrum disorders cannot be diagnosed by any single abnormal behavior; they are diagnosed based on an accumulation of symptomatic behaviors. However, the existence of any one behavioral abnormality associated with autism is sufficient to trigger the running of the statute of limitations. *Carson v. Sec'y, HHS,* 727 F.3d 1365, 1369 (Fed. Cir. 2013) ("[I]t is the first symptom or manifestation of an alleged vaccine injury, not the first date when diagnosis would be possible, that triggers the statute of limitations under § 300aa-16(a)(2).").

Although much of the hearing testimony concerned what actually happened on March 23, 2010, ultimately the events of that day have little relevance to the statute of limitations issue that necessitated the onset hearing. The symptoms of A.H.R.'s developmental delay and ASD, ones commonly recognized as such by the relevant medical community, occurred over the fall and winter of 2009-10, and by the time of the Early Steps interview in mid-March 2010, A.H.R. was displaying many such symptoms. They clearly worsened over time, a common pattern in ASD, and contributed to the mitochondrial disorder diagnosis made by Dr. Niyazov.

The developmental delays and behavioral problems A.H.R. has are profound and life-altering for both him and his family, and I have the greatest of sympathy for their suffering. Nevertheless, there is preponderant reliable evidence that the first symptoms

of his condition occurred more than 36 months before the petition was filed on his behalf, and thus was untimely filed.

The petition is dismissed as untimely filed.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Chief Special Master