

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS**

**No. 08-0307V**

**Filed: June 1, 2015**

**Not for Publication**

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HUSSEIN H. HASHI and SAFIA \*  
WEGED, parents of S.H., \*

Petitioners, \*  
v. \*

Autism; Fact Ruling;  
Significant Aggravation;  
Contemporaneous Records;

SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*

Respondent. \*

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Elaine W. Sharp, Esq., Whitfield, Sharp & Sharp, Marblehead, MA, for petitioners.  
Heather L. Pearlman, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

**RULING ON FACTS REGARDING SIGNIFICANT AGGRAVATION CLAIM<sup>1</sup>**

**Vowell**, Special Master:

On August 26, 2013, I dismissed petitioners' causation in fact claim because it was untimely filed. *Hashi v. Sec'y, HHS*, No. 08-307V, 2013 WL 10543716 (Fed. Cl. Spec. Mstr. Aug. 26, 2013). Petitioners elected to proceed on a significant aggravation claim, a claim not made in their original or first amended petition, but first raised in Petitioners' Status Report, filed December 7, 2011 at 2. The significant aggravation claim was explicitly raised in the second amended petition filed on September 25, 2013. Second Amended Petition, ¶¶13-14.

The second amended petition asserted that vaccines S.H. received January 8, 2007, significantly aggravated an underlying mitochondrial disorder. Second Amended Petition, ¶¶ 11-14. As evidence of the significant aggravation, petitioners relied on assertions made by petitioner Hussein Hashi in his affidavit, dated and filed on July 17,

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<sup>1</sup> This ruling 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, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact 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 redact such material from public access.

2012.<sup>2</sup> See Petitioners' Exhibit 18. In dismissing the causation in fact claim and permitting petitioners to proceed on the significant aggravation claim, I noted that Mr. Hashi's affidavit appeared to contradict the contemporaneous medical records regarding S.H.'s condition before and after the January 8, 2007 vaccinations. *Hashi*, 2013 WL 10543716, at \*8, n.24.

To resolve the discrepancies between Mr. Hashi's affidavit and the contemporaneous medical records, I conducted a hearing before ruling on the facts regarding S.H.'s condition. See Order, issued May 29, 2014. I heard the testimony of Mr. Hashi and Ms. Nimo Hashi, his niece,<sup>3</sup> on September 18, 2014, in a hearing in Boston, MA. Having carefully considered their testimony, I find that the contemporaneous medical records and histories provided by S.H.'s parents at times closer to the events in question more accurately reflect S.H.'s condition than the hearing testimony and affidavits of the two hearing witnesses.

Specific factual findings are set forth below. In summary, I find that S.H.'s condition did not become significantly worse after her January 8, 2007 vaccinations. Given the impact of this factual finding on their significant aggravation claim,<sup>4</sup> petitioners are ordered to provide a copy of this ruling to any expert they consult. **Any expert report must be based on these facts.** Should the retained expert disagree with my factual findings, the expert must identify the source of the information upon which he or she relies, and explain why my factual findings are incorrect. Simply disagreeing with my assessments of the credibility of witnesses is not sufficient. The expert must also explain the effect of relying on the facts I have found on his or her expert opinion. Additionally, any expert report must clearly indicate the expected progression of S.H.'s mitochondrial disorder and how that progression was altered by vaccines received less than 36 months before April 22, 2008, the date of filing of the original petition in this case.

## I. Procedural History.

Petitioners Safia Wedged and Hussein Hashi ["Ms. Wedged," "Mr. Hashi," or "petitioners"] filed the short-form petition authorized by Autism General Order #1<sup>5</sup> for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*<sup>6</sup> [the "Vaccine Act" or "Program"], on behalf of their minor daughter,

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<sup>2</sup> Petitioners filed Mr. Hashi's affidavit as part of their opposition to respondent's motion to dismiss. See Notice of Filing of Petitioners' Exhibit 18, filed July 17, 2012.

<sup>3</sup> Ms. Hashi testified that she frequently babysat for S.H. and her sister starting in October of 2002 (Pet. Ex. 20, ¶ 4) and was often a guest in the Hashi home during her undergraduate and graduate career. See Tr. at 161-163. She babysat for S.H. from around the time of her birth. Tr. at 173. When she began college in the fall of 2004, Ms. Hashi continued to visit and babysit on an as-needed basis. Tr. at 163.

<sup>4</sup> *W.C. v. Sec'y, HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013); *Loving v. Sec'y, HHS*, 86 Fed. Cl. 135, 144 (2009); *Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053 at \*40 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed.Cl. 126 (2010).

<sup>5</sup> The text of Autism General Order #1 can be found at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf>, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002).

<sup>6</sup> 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. §

S.H. By filing the short-form petition, petitioners joined the Omnibus Autism Program [“OAP”],<sup>7</sup> thereby asserting that S.H. has an autism spectrum disorder [“ASD”]<sup>8</sup> and that one or more vaccines listed on the Vaccine Injury Table<sup>9</sup> were causal of her condition. Petitioners did not file any medical records or details regarding S.H.’s injuries with the short-form petition.

On April 28, 2008, the presiding special master ordered petitioners to complete their petition by filing the statutorily required medical documentation<sup>10</sup> and a “Statement Regarding Onset,” clearly detailing S.H.’s first symptom or manifestation of onset or significant aggravation of her injury. Order, issued Apr. 28, 2008. Respondent filed her Rule 4(c) report on May 20, 2008, noting that petitioners had yet to file any evidence and thus, she could not assess the merits of the claim without the medical records. Respondent’s Report at 4. By October 25, 2008, petitioners had filed 17 exhibits of medical records,<sup>11</sup> but did not submit a “Statement Regarding Onset.”

No further activity occurred in this case until after the conclusion of the appeals in the OAP test cases. On January 25, 2011, in view of the test case findings of insufficient evidence linking vaccines and autism, petitioners were ordered to inform the court if they wished to proceed with their claim or if they wished to exit the Vaccine Program. Order, issued Jan. 25, 2011. Petitioners evinced their intent to proceed and filed an amended petition on June 29, 2011, alleging that one or more of the vaccinations S.H. received between birth and four and a half years of age “caused or exacerbated progressive encephalopathy with autistic features” and the sequelae. Amended Petition [“Am. Pet.”] at 2. The amended petition also alleged that S.H. was later diagnosed with a mitochondrial disorder, specifically a Complex I electron transport chain [“ETC”] deficiency. *Id.*

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300aa (2006).

<sup>7</sup> The OAP and the effects of joining it are discussed in detail in *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250, at \*3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). In summary, the OAP created a body of evidence about ASD that could be used to resolve not only the test cases themselves, but all the remaining OAP cases as well. Although the remaining OAP petitioners were not bound by the results in the test cases and remained free to develop and present new evidence and new theories, the OAP evidence could be relied upon by either side in resolving the remaining cases.

<sup>8</sup> “Autism spectrum disorder” is an umbrella term encompassing several neurological disorders manifesting in early childhood with impairments in communication and social interaction, and the display of restricted, repetitive, or stereotypical patterns of behavior, interests, and activities. A more complete description of the disorder is contained in *White v. Sec’y, HHS*, No. 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011).

<sup>9</sup> 42 C.F.R. § 100.3 (2011).

<sup>10</sup> Section 11(c)(2) of the Vaccine Act and Vaccine Rule 2 requires that the petition be accompanied by medical records and affidavits.

<sup>11</sup> The first 17 medical record exhibits were initially filed as Petitioners’ Exhibits 13.1-13.10; 14.1-14.3; 15.1; 16.1-16.2; and 17.1. Petitioners had incorrectly correlated the exhibit numbers with the docket entry number (e.g., the exhibit filed in docket entry 15 was labeled as Exhibit 15.1). Petitioners re-filed these records as Pet. Exs. 1-7 on August 3, 2011.

This case was reassigned to me on July 1, 2011. During a status conference held on July 20, 2011, I advised petitioners' counsel that this claim appeared to have been filed outside the Vaccine Act's 36 month statute of limitations. Order, issued July 20, 2011, at 2. Subsequently, I cautioned petitioners' counsel against obtaining an expert report, in view of the unsettled state of the law regarding the Vaccine Act's statute of limitations and its effect on payment of fees and costs on unsuccessful cases.<sup>12</sup> Order, issued November 8, 2011.

Between October 2011 and April 2012, petitioners filed additional exhibits detailing S.H.'s health from birth through early childhood. On February 27, 2012, respondent was ordered to file a statement indicating whether, based on the available medical records, she believed petitioners' claim should proceed.

On April 11, 2012, in lieu of filing a statement, respondent moved to dismiss petitioners' claim, asserting that the petition was filed after the expiration of the Vaccine Act's statute of limitations. Respondent's Motion to Dismiss at 1, 4-5. Respondent argued that the petition should have been filed no later than November 2, 2007, because the first symptom or manifestation of onset of S.H.'s autism spectrum disorder occurred as early as November 2, 2004. *Id.* at 2-3, 5.

On July 16, 2012, petitioners filed a joint opposition to respondent's motions to dismiss in both of their children's cases.<sup>13</sup> Petitioners asserted that the diphtheria, tetanus, and acellular pertussis ["DTaP"] and inactivated polio virus ["IPV"] vaccines administered on January 8, 2007 significantly aggravated S.H.'s pre-existing mitochondrial disorder and therefore the short-form petition filed on April 22, 2008 was filed well within the statute of limitations period. Petitioners' Response at 2, 5.

On August 26, 2013, I dismissed the causation in fact claim as untimely filed. *Hashi*, 2013 WL 10543716. Only petitioners' significant aggravation claim remains.

## **II. Facts.**

In the factual findings below, I adopt, largely verbatim, the factual findings made in my August 26, 2013 ruling that the causation in fact claim was untimely filed. Incorporating these facts regarding S.H.'s early growth and development is necessary because evaluation of a significant aggravation claim requires the special master to determine the vaccinee's condition before and after the allegedly aggravating vaccine

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<sup>12</sup> At the time of this status conference, interpretation of the Vaccine Act's statute of limitations was under review by the U.S. Court of Appeals for the Federal Circuit. The Federal Circuit, sitting *en banc*, heard oral argument in *Cloer v. Sec'y, HHS*, on May 10, 2011. Because the outcome of that case could affect my determination of timeliness in this case, I opted to wait for the Federal Circuit's decision before ordering petitioners to obtain an expert report. On August 5, 2011, the Federal Circuit reiterated that the first symptom recognized by the medical community at large as a symptom of a disorder triggered the running of the statute of limitations in Vaccine Act cases. *Cloer v. Sec'y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011), *cert. denied*, 132 S. Ct. 1908 (2012).

<sup>13</sup> Petitioners had also filed a petition on behalf of their daughter, O.H. (No. 08-308V).

and to determine if any change in the condition constitutes significant aggravation.<sup>14</sup> *W.C.*, 704 F.3d at 1357; *Loving*, 86 Fed. Cl. at 144; *Hennessey*, 2009 WL 1709053, at \*40, *mot. for rev. denied*, 91 Fed.Cl. 126 (2010). Additionally, in order to distinguish a change for the worse in an underlying condition that is the result of a natural progression of the underlying disorder versus a vaccine-caused change, it is necessary to make findings regarding the onset of the underlying condition and any significant symptoms of that condition. For the most part, the testimony at the fact hearing did not conflict with my earlier findings regarding the onset of S.H.'s ASD symptoms or her ASD and mitochondrial disorder diagnoses, at least until the January 8, 2007 vaccinations.

Thereafter, the testimony and medical records diverge significantly, with virtually all of the symptoms S.H. eventually displayed occurring, according to Mr. Hashi and Ms. Hashi, in close temporal proximity to the January 8, 2007 vaccinations. In contrast, the medical records reflect a significant worsening of S.H.'s ASD symptoms in the fall of 2006, several months before she received the allegedly aggravating vaccinations. Indeed, the records demonstrate that many of the symptoms Mr. and Ms. Hashi claimed as occurring for the first time after the January 8, 2007 vaccinations actually occurred prior to the vaccinations.

#### A. S.H.'s Early Health and Development.

S.H. was born in November 2002 into a family with a notable history of developmental delays.<sup>15</sup> She was delivered full-term without any complications. Her Apgar scores were 9 and 9,<sup>16</sup> reflective of a healthy newborn. Pet. Ex. 1, pp. 1-2. She received a hepatitis B vaccine prior to her discharge from the hospital, *id.*, p. 4, and continued to receive routinely-administered childhood vaccinations in her first three years.<sup>17</sup> Pediatrician Lawrence Stratton's records indicate that S.H. met the appropriate developmental milestones at two and four months of age. Pet. Ex. 4.2,<sup>18</sup> pp. 48-50, 53-

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<sup>14</sup> The Vaccine Act allows petitioners to file claims both in upon showing that they have "sustained or had significantly aggravated" a vaccine-related "illness, disability, or condition." § 300aa-1(c)(1)(C).

<sup>15</sup> S.H.'s older sister, O.H., has also been diagnosed with ASD. Pet. Exs. 4.2, p. 32. Additionally, her paternal uncle did not speak until the age of 7, and one of her paternal cousins is autistic. Pet. Ex. 7, p. 17. Doctor Elizabeth TePas remarked that "[t]here is a strong family history of probable autism spectrum disorder on father's side." Pet. Ex. 11, p. 59.

<sup>16</sup> An 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 between zero and two points awarded in each of the five categories. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1682 (32<sup>nd</sup> ed. 2012).

<sup>17</sup> Between November 2002 and May 2004, S.H. received the following vaccines: hepatitis B (November 3, 2002, December 11, 2002, and May 5, 2003); DTaP (January 9, 2003, March 13, 2003, May 15, 2003, and May 20, 2004); haemophilus influenzae type B ["Hib"] (January 1, 2003, March 13, 2003, May 15, 2003, and May 20, 2004); IPV (January 9, 2003, March 13, 2003, and November 4, 2003); pneumococcal conjugate ["Prevnar"] (January 9, 2003, March 13, 2003, May 15, 2003, and May 20, 2004); measles, mumps, and rubella ["MMR"] (November 4, 2003); and varicella (November 4, 2003). See Pet. Ex. 19.

<sup>18</sup> Petitioners' Exhibit 4 was filed as two separate pdf files: the first (4.1) containing 64 pages and the second (4.2) containing 87 pages. Instead of consecutively numbering the pages from the two files 1 to

### 1. Onset of Developmental Delay.

Doctor Stratton first expressed concerns about S.H.'s development at her six month well child visit on May 15, 2003. Pet. Ex. 4.2, pp. 43, 46. At that visit, he noted "[d]evelopmental delay" and referred S.H. for an early intervention ["EI"] evaluation. *Id.*, p. 46. Later, at S.H.'s nine month well child visit on August 13, 2003, Dr. Stratton noted "mild motor delays." *Id.*, pp. 38, 41.

On April 2, 2004, S.H. was seen by Dr. Stratton to follow up on his concerns regarding her development. Pet. Ex. 4.2, p. 29. Doctor Stratton noted that S.H. was making slow progress, with no loss of milestones, and recommended continuing the EI services. *Id.*, p. 32. At S.H.'s belated 15 month well child visit on May 20, 2004, when she was more than 18 months old, she was still not walking and had a vocabulary of only six to twelve words. *Id.*, p. 18.

On September 7, 2004, when she was about 22 months old, Dr. Stratton formally diagnosed S.H. with developmental delay.<sup>19</sup> Pet. Ex. 4.1, pp. 31, 33. At that time, Dr. Stratton noted that S.H. had not lost any milestones, could speak approximately 20 words, and understood well, though she had not yet begun walking and was "following [the] same pattern as [her] sister." *Id.*

### 2. Autism Diagnosis.

On September 19, 2006, petitioners met with the Everett Public Schools concerning S.H.'s Individualized Education Program ["IEP"]. The IEP form noted her disability as pervasive developmental delay and indicated that she was "on the spectrum of an individual with Autism." Pet. Ex. 15, pp. 2-3. Pervasive developmental disorder, or "PDD," is the umbrella term used in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders ["DSM-IV-TR"], published in 2000, for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder—not otherwise specified ["PDD-NOS"], and Asperger's Disorder.<sup>20</sup> There is possible confusion between "PDD" (a term used to refer to the entire general diagnostic category) and "PDD-NOS," which is a specific diagnosis within the general diagnostic category of PDD. It is not uncommon for parents and even health care providers to use these terms in non-specific ways, such as referring to a

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151, petitioners individually numbered each file. Therefore, this decision refers to Exhibits 4.1 and 4.2 rather than simply Exhibit 4. I note that petitioners' counsel's inconsistent and disorganized numbering of exhibits has led to considerable confusion in this case.

<sup>19</sup> In earlier records, developmental delay was listed in the "Problems" section of the visit note. The record from September 7, 2004 is the first to include developmental delay in the "Diagnosis" section of the note. Within the diagnosis section of the September 7 record, the "recorded start date" for S.H.'s developmental delay is May 15, 2003. That was the date of S.H.'s six month well child visit.

<sup>20</sup> The fifth edition of the DSM ["DSM-V"], released in May 2013, uses the umbrella term "Autism Spectrum Disorder" rather than PDD.

child as having an “autism diagnosis,” even though the specific diagnosis is PDD-NOS. In conveying that S.H. had pervasive developmental delay and was on the autism spectrum, the school official was likely referring to the DSM-IV-TR umbrella category of PDD when describing the nature of S.H.’s disability and reason for the IEP evaluation.

On September 26, 2006, when she was nearly four years old, S.H. was evaluated by Dr. Jean Ashland at the Massachusetts General Hospital’s [“MGH”] Department of Speech, Language, and Swallowing Disorders. She found that S.H. had normal speech and language development in her early childhood, but began regressing after approximately two years of age. Pet. Ex. 11, p. 91. S.H.’s parents reported that when she was two years old, she used two and three word combinations, but that she no longer used more than single words. *Id.* Although the evaluation was focused on S.H.’s expressive and receptive language skills, Dr. Ashland noted that S.H. exhibited decreased eye contact, lack of imaginative play, and general “deficits in social/pragmatic and play skills.” *Id.*, pp. 92. Doctor Ashland was concerned about her speech and language regression, particularly in light of the family history of autism. *Id.*

In October 2006, Dr. Peter Masucci, S.H.’s pediatrician at the time, noted that she had been diagnosed with autistic disorder. Pet. Ex. 11, pp. 17-18. The source for his notation was not specifically identified, but likely was based on two evaluations S.H. underwent in September 2006. In the “problems” section of his records, Dr. Masucci wrote that S.H. had an “unspecified pervasive developmental disorder, current or active state,” with an onset of May 3, 2006. *Id.* at 17.

#### B. S.H. at Ages Four and Five.

S.H.’s IEP for the 2006 to 2007 school year described her as “a limited communicator with a limited verbal vocabulary.” Pet. Ex. 15, p. 5. She required physical prompting in order to successfully use the bathroom. *Id.*, p. 8. Her teachers hoped that she would be able to follow one-step directions 80% of the time by the beginning of the next school year. *Id.*, p. 13. The IEP progress report in January of 2007 did not note any marked regressions in S.H.’s behavior, and, given the nature of these which measure progress toward very specific goals, if such declines had occurred, the IEP progress report would have reflected them.<sup>21</sup> It is reasonable that any steep decline in S.H.’s skills would have been recorded in her IEP progress report.

Doctor Ann Neumeyer, a pediatric neurologist affiliated with MGH’s Learning and Developmental Disabilities Evaluation and Rehabilitation Services [“LADDERS”], examined S.H. on November 15, 2006. Relying on parental reports, Dr. Neumeyer wrote that S.H. began losing her vocabulary after two years of age. Pet. Ex. 7, p. 24. Doctor Neumeyer noted the strong history of developmental regression in S.H.’s family and suggested that S.H. was having a similar developmental regression. *Id.*, p. 26. She also noted that S.H. was very sensitive to sound and bit “everything including non-

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<sup>21</sup> I note that S.H.’s next progress report, detailing her progress for the spring semester of 2007, might have been more helpful, but petitioners did not file it.

edible objects.” *Id.*, p. 25. S.H. returned to LADDERS in December 2006. During this visit, S.H.’s parents were concerned because S.H. “now grinds her teeth together more.” *Id.*, p. 21. Dr. Neumeyer expressed concern that there might be a genetic component to the developmental issues experienced by both S.H. and her older sister, O.H. She encouraged a thorough consideration of possible etiologies. *Id.*, pp. 21-22.

At S.H.’s four year well child visit on January 8, 2007, Dr. Masucci noted that she had unspecified pervasive developmental disorder with “up and down” progression. Pet. Ex. 11, pp. 9-10. He also noted that Ms. Wedeg was concerned about S.H. gritting her teeth. *Id.*, p. 9. S.H. received the allegedly aggravating DTaP and IPV vaccines at this visit. She did not return to her pediatrician until late March 2007.

On January 23, 2007, approximately two weeks after the allegedly aggravating vaccinations, S.H. was evaluated at Children’s Hospital of Boston’s Developmental Medicine Center by Dr. Ronald Becker, a behavioral and developmental pediatrician, and Dr. Rachel Hundley, a staff psychologist. Pet. Exs. 3, pp. 2-13; 11, pp. 71-78. This appears to have been S.H.’s first visit with these physicians. Their consultation notes are based on the oral history recounted by Ms. Wedeg and on their observations of S.H. S.H.’s communication skills were clustered at a 12 to 18 month level, her socialization skills around the 13 month level, and her self-care and domestic skills at the late one-year to early-two-year level, although she did have some emerging skills at higher levels. Pet. Ex. 3, p. 8. S.H.’s motor skills were clustered around the two year, seven month level, with her gross motor skills more developed than her fine motor skills. *Id.*

At this visit, Ms. Wedeg was concerned about behavioral difficulties, as S.H. had “been frustrated and biting people.” Pet. Ex. 3, p. 2. She expressed concern that “there has been loss of some language skills associated with the increase in tooth grinding and biting others in frustration,” but the doctors noted that a “dental visit 3 months ago did not identify a dental reason for the tooth grinding.” *Id.*<sup>22</sup> When S.H. was between 36 and 42 months of age, she may have experienced language regression. “At that time language was fully lost, but some improvements have been made again since that time.” *Id.*, p. 3. S.H. spoke primarily in “I want” statements when prompted by the clinician. *Id.*, p. 5. She also made word-like vocalizations. *Id.* Her verbal skills were described as “extremely limited in comparison to age expectation.” *Id.*, p. 6.

Doctors Becker and Hundley also concluded that S.H.’s behavioral development was delayed. They noted that her “eye contact was poorly modulated and she did not generally direct her facial expressions toward others.” Pet. Ex. 3, p. 7. She held her hands over her ears. *Id.* S.H. had been toilet trained at the age of two, but still required some assistance and wore diapers at night. No concerns regarding toilet training or elimination problems were raised by Ms. Wedeg during the visit. *Id.*, p. 3. Based on various tests, observations, and the history provided,<sup>23</sup> Drs. Becker and Hundley

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<sup>22</sup> This indicates that S.H.’s tooth grinding had become problematic before her visit with Drs. Becker and Hundley.

<sup>23</sup> The tests included the Stanford-Binet Intelligence Scales, Bayley Scales of Infant and Toddler Development—Third Edition, Autism Diagnostic Observation Schedule, and the Vineland Adaptive



concluded that S.H. met the diagnostic criteria for autistic disorder. She was also diagnosed with mental retardation, severity unspecified. *Id.*, p. 10. There were no notations of concern about any steep decline in S.H.'s development or behavior in the prior two weeks.

At the end of January 2007, S.H.'s teachers reported on the minimal progress she had made during the semester. S.H. had "been sick for the last two months and ha[d] had many aggressive behaviors that are now being addressed in a Behavior Plan." Pet. Ex. 15, p. 13. Using the new behavior plan, S.H. was once more working toward meeting her goals. *Id.* S.H.'s teachers also remarked that she had had "some difficulty in completing the toileting routine" over the last two months. *Id.*, p. 14. Although S.H. was noted to be "reluctant to speak," she did use one to two word phrases. *Id.*, p. 18. Her IEP semester evaluation did not indicate any marked regression in skills, development, or behavior; rather, she had made some progress or remained at the same level.

On March 23, 2007, nearly three months after the administration of the allegedly aggravating vaccines, S.H. returned to her pediatrician. Pet. Ex. 11, pp. 7-9. She was feverish, but not tired. *Id.*, p. 7. She was diagnosed with sinusitis. *Id.*, p. 8. Her parents did not express any concerns about a vaccine reaction, regression, or behavioral changes at this visit.

Four days later, S.H. saw Dr. Neumeyer, who remarked that S.H. was "now losing her vocabulary," although "[r]eview of systems is otherwise unchanged." Pet. Ex. 7, p. 19. Doctor Neumeyer's notation is the only remark in the records indicating that S.H. was becoming less verbal in the early months of 2007.<sup>24</sup> Doctor Neumeyer described herself as "still perplexed as to the etiology of [S.H.]'s and her sister's developmental regression." Pet. Ex. 7, p. 20. She did not note any concerns about dramatically deteriorating health and behavior at this visit.

The next day, S.H.'s parents brought her to the Emergency Department at Whidden Hospital with complaints of a persistent cough. The attending physician, Dr. Ralph Epstein, described her as "essentially nonverbal." Pet. Ex. 11, p. 64. A chest X-ray showed her lungs were clear, but her doctor noted a "large amount of gas" in her colon. *Id.* He recommended an over-the-counter laxative. *Id.*, p. 65.

Shortly thereafter, on April 2, 2007, S.H. returned to Dr. Masucci and was diagnosed with possible viral gastroenteritis or an upset stomach, likely caused by the antibiotics she was prescribed for her sinusitis. Pet. Ex. 11, p. 7. Again, no concerns of a regression in behavior or a loss of skills were recorded.

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Behavior Scales. Pet. Ex. 11, p. 73.

<sup>24</sup> In fact, S.H.'s IEP progress report, dated at the end of January 2007, stated that S.H. was making "some nice progress" with speech. Her teachers said that she usually spoke one or two words at a time and that she was "using her language more and more every day." Pet. Ex. 15, pp. 18-19.

In mid-May, S.H.'s parents brought her back to Dr. Masucci with complaints of a runny nose and cough. Pet. Ex. 11, pp. 3-5. Dr. Masucci reviewed her problem history and remarked that it remained the same as in September of 2006. S.H. was diagnosed with acute bronchitis. *Id.*, p. 5. Less than a month later, on June 9, 2007, Dr. Masucci diagnosed her with an acute upper respiratory infection. *Id.*, pp. 2-3. He noted that S.H. was "a little more interactive and cooperative than usual" during the examination. *Id.*

During the summer of 2007, Dr. Neumeyer reported that S.H. had made significant progress since her last visit to LADDERS on March 27, 2007. Pet. Ex. 7, p. 17. She was using single words and occasionally used full and scripted sentences. *Id.* Doctor Neumeyer also noted that what S.H.'s physicians had previously described as a large regression was in fact more behavioral, and that S.H. "has not really lost much language at all since birth." *Id.*

In late 2007, Mr. Hashi and Ms. Wedged brought their daughter to a new pediatric practice. S.H. saw Dr. Marc Rosenthal at Burlington Pediatrics for a five year well child appointment in November 2007. Doctor Rosenthal reviewed her medical records and spoke with her neurologist. Pet. Ex. 10, p. 9. He questioned whether S.H. had experienced a true regression of skills, indicating that she probably exhibited "slow increase and variability of development" and "continues to gain new skills [ ]but others seem to fall away." *Id.*, p. 10. Doctor Rosenthal twice noted that S.H.'s mother was "a poor historian." *Id.*, pp. 9, 11. S.H. returned to the pediatrician early in 2008 and was diagnosed with a probable upper respiratory infection. *Id.*, p. 7.

#### C. Divergence between Medical Records and Testimony.

Mr. Hashi and his niece's affidavits and testimony concerning S.H.'s behavior and symptoms paint a picture of a child whose already profound health and behavioral problems dramatically deteriorated within a month of receiving the January 2007 vaccinations. Their memories, however, do not align with the facts recounted in S.H.'s medical and school records. Ms. Hashi testified that she saw S.H. approximately two weeks before she received the January 2007 vaccinations, though she conceded that she is "not good with dates." Tr. at 174. She could not recall the first time she saw S.H. after she had received the allegedly aggravating vaccinations. Tr. at 175.

Mr. Hashi believed that his daughter was "born normal" and that "[a]fter the vaccine...something hit [her] and get all these problems." Tr. at 75. He said that although S.H. does have a "genetic mitochondrial disease," receiving the vaccines "hit her and damaged her and threw her over the cliff." Tr. at 75. Mr. Hashi testified that his wife also has the same mitochondrial disease and is "normal" because she never received childhood vaccines. Tr. at 76-77. He conceded that S.H. was not "normal" even before the allegedly aggravating vaccines, but insisted that her previously mild problems became far worse after she received these vaccines in January 2007. Tr. at 77-78. During the hearing, he testified that about two weeks after the vaccinations, he informed Dr. Becker about S.H.'s recent deterioration, and that Dr. Becker told him to

speak with S.H.'s pediatrician. Tr. at 117-118. Mr. Hashi reported that S.H.'s pediatrician, Dr. Masucci, told him to take her to a specialist, and "[t]hat is when we make the appointment with Doctor Sims." Tr. at 118. Records reflect that S.H. first saw Dr. Sims in August of 2007. See Pet. Ex. 11, p. 53. Mr. Hashi stated that he also told Dr. Neumeyer about S.H.'s worsening health and behavior. Tr. at 120.

The alarming symptoms described by Mr. and Ms. Hashi began, by their accounts, very shortly after S.H. received her January 8, 2007 vaccinations. Mr. Hashi testified that S.H. developed a fever about an hour after receiving them. Tr. at 49-50, 106. He could not recall how high the fever was. Tr. at 106. He said that he and his wife phoned Dr. Masucci, who advised them to give S.H. Tylenol. Tr. at 107. No record of such a call has been filed. See Pet. Ex. 11.<sup>25</sup> Mr. Hashi recalled S.H.'s fever as lasting for three or four days. Tr. at 107.

Both Mr. Hashi and Ms. Hashi spoke about S.H.'s tendency to grind her teeth. Although she couldn't recall whether S.H. ground her teeth before January of 2007 (Tr. at 175), Ms. Hashi said that after the vaccinations, her cousin would grind her teeth so loudly that it could be heard in the next room, and that she did this constantly. Tr. at 150; see *also* Tr. at 60 (similar testimony from Mr. Hashi). Mr. Hashi also testified that S.H.'s tooth grinding worsened after the January 2007 vaccinations. Tr. at 49. On direct examination, he said that the grinding increased about a week after she received the January 2007 vaccinations (Tr. at 49), although during cross examination he said that it started the same day and became worse a few days later (Tr. at 108). He agreed that she had developed this habit before receiving the vaccinations in question, but said that after January of 2007, the tooth grinding became "[c]onstant, uncontrollable, very loud." Tr. at 53. When asked about a record from Dr. Neumeyer indicating that S.H. had been grinding her teeth together more in December of 2006, Mr. Hashi said that in January 2007, "it went uncontrollable." Tr. at 59-60.

During cross examination, respondent's counsel asked Mr. Hashi about a consultation note from Dr. Becker, dated January 23, 2007 (Pet. Ex. 3, p. 2), indicating that Ms. Wedged had become concerned about S.H.'s loss of language skills associated with an increase in tooth grinding and biting others. Dr. Becker had remarked that "[a] dental visit three months ago did not identify a dental reason for this tooth grinding." Pet. Ex. 3, p. 2. Mr. Hashi could not remember the dentist visit, which likely occurred in October of 2006. Tr. at 108-09.

Mr. Hashi testified that the same day she received her January 2007 vaccinations, S.H.'s eyes became "unfocused" and "glassy" and she began staring into the distance. Tr. at 50, 109, 113. During those times, she did not seem to understand her parents. Tr. at 54. Mr. Hashi said that S.H. had made good eye contact before the

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<sup>25</sup> It appears that Dr. Masucci's office kept fairly detailed phone logs. For instance, in the summer of 2007, Ms. Wedged called and asked the office to write her a letter excusing her from jury duty because of her autistic children. See Pet. Ex. 11, p. 50. Given that the telephone logs recorded much more mundane concerns, it is unlikely that the pediatric practice would have failed to memorialize a phone call from either Mr. Hashi or Ms. Wedged regarding a fever a few hours after S.H. received a vaccination.

vaccines in question, but that she had none after them. Tr. at 50, 110. Ms. Hashi reported that S.H. stared into space after the January 2007 vaccinations. Tr. at 154-55.

Mr. Hashi testified that the same day she received the vaccine, S.H. began crying. Tr. at 51, 111. He said that she also wept as she ground her teeth. Tr. at 51. Although he conceded that S.H. would occasionally cry before the vaccinations, he explained that she did not do so “inconsolably.” Tr. at 111.

Mr. Hashi and Ms. Hashi described considerable changes in S.H.’s ability to communicate during the winter of 2007. According to both Mr. Hashi and his niece, before the January 2007 vaccinations, S.H. was able to communicate verbally. Tr. at 51, 148. After the vaccinations, Mr. Hashi said that “she totally shut down.” Tr. at 51. He said that while at age three and a half S.H. “had words,” after the vaccinations “[s]he was not like talking.” Tr. at 61. Ms. Hashi testified that S.H.’s vocabulary decreased after she received the vaccinations (Tr. at 149), though she could not recall when this started. Tr. at 175.

Mr. Hashi and Ms. Hashi also reported marked changes in S.H.’s speaking voice. Mr. Hashi said that “her tongue seemed thick” and that she “sounded like a machine, like a robot.” Tr. at 54; see also Tr. at 114. She had difficulty getting words out. Tr. at 55. Likewise, Ms. Hashi stated that S.H.’s words became “[s]lurred” (Tr. at 149) and she began speaking gibberish. Tr. at 152. When confronted with a record from Dr. Neumeyer’s office indicating that in July of 2007 (Pet. Ex. 7, p. 17), S.H. spoke single words and occasionally used full sentences, Mr. Hashi insisted that “[t]he doctor is wrong on that.” Tr. at 65. He said her speech was more like mumbling, and S.H.’s parents interpreted on behalf of their daughter. Tr. at 65-66. Rather than speaking in sentences, Mr. Hashi said that S.H. echoed or parroted things she heard others say. Tr. at 66. He was then shown a record from Dr. Rosenthal, dated in November of 2007 (Pet. Ex. 10, pp. 9-11), indicating that S.H. was able to put several words together and gave many single-word responses. Tr. at 66-67. Mr. Hashi said that S.H.’s speech was still difficult to understand and that she “lost some of the words that she knew, but whatever comes to her head, her mind she will say like a machine and not complete.” Tr. at 67. She spoke softly (low in volume). Tr. at 69. During cross examination, respondent’s counsel asked Mr. Hashi about a speech and language evaluation S.H. underwent in the fall of 2006 (Pet. Ex. 11, pp. 91-96), during which her examiners noted that she had a flat affect. Mr. Hashi said he did not remember the visit. Tr. at 116.

In July of 2008, Dr. Neumeyer noted that S.H. had made progress and was using words to communicate. Pet. Ex. 7, pp. 10-11. Mr. Hashi stated that when S.H. responded to questions, it was just because she had memorized the answers, and that she had no understanding of what was being asked of her. Tr. at 71-72. This was, according to him, in marked contrast to S.H.’s communication abilities prior to the January 2007 vaccinations, when she was able to answer questions. Tr. at 72. Mr. Hashi said that before the January 2007 vaccinations, S.H. asked questions spontaneously and was curious. Tr. at 68. In November of 2007, Dr. Rosenthal remarked that S.H. had “no overt questioning.” Pet. Ex. 10, p. 10.

According to Mr. Hashi and his niece, S.H.'s behavior deteriorated in the winter of 2007. Mr. Hashi testified that after she received the January 2007 vaccinations, S.H. began to bite "everything," including furniture. Tr. at 51. When confronted with notes from Dr. Neumeyer indicating that S.H. had begun biting non-edible objects in the fall of 2006 (Pet. Ex. 7 p. 24), Mr. Hashi said that her biting became "much, much worse." Tr. at 59. Though she occasionally bit before, after the January 2007 vaccinations she began to bite furniture and people, "anything she can get hold of. Even she will sometimes bite herself." Tr. at 59.

Ms. Hashi also testified that S.H. became aggressive. She began to scratch people and became "agitated" and would "charge" at people "like a bull." Tr. at 155. She could not recall when this began. Tr. at 179.

S.H. also kept her mouth open constantly and "would drool a lot." Tr. at 154. Ms. Hashi testified that this began a few weeks after the vaccinations. Tr. at 178-79. Ms. Hashi described her cousin's tongue as "thick" and "heavy," making it difficult to understand what she was saying. Tr. at 154. S.H. also "breath[ed] through her mouth heavily." Tr. at 160.

Mr. Hashi testified that after the 2007 vaccinations, S.H. became clumsy. Tr. at 52. Within a day or two of receiving the vaccines, she began walking in circles, a behavior that continued for months. Tr. at 53, 114. She rocked back and forth "non-stop," a behavior which started about a week after she received the vaccines. Tr. at 56, 117, 151-52. During cross examination, Ms. Hashi stated that she could not recall when the rocking began. Tr. at 178. Ms. Hashi also reported that S.H. "banged her head on the dining table." Tr. at 153.

During direct examination, Ms. Hashi described how she used to play with S.H. She said that S.H. enjoyed making adults chase after her for toys. Tr. at 148. Mr. Hashi stated that after the January 2007 vaccines, S.H.'s interest in toys became decreased (Tr. at 57-58), and that she no longer engaged in creative play (Tr. at 58). When asked why Dr. Masucci said that S.H. was more interactive and cooperative than usual at her June 2007 appointment (Pet. Ex. 11, p. 2), Mr. Hashi said that sometimes she had good days. Tr. at 63-64. Before the January 2007 vaccination, S.H. was "social and playful," but afterward she became afraid and stayed away from other children. Tr. at 67. Her demeanor in public also changed; S.H. began making loud noises and "invad[ing] other's space." Tr. at 156. She also began removing her clothing in public. Tr. at 157. Ms. Hashi testified that she noticed an improvement in S.H.'s behavior after she began taking the mitochondrial cocktail and receiving ABA therapy. Tr. at 158-59. S.H. began taking the mitochondrial cocktail and receiving ABA therapy in the spring of 2008. See Pet. Ex. 7, p. 10.

Mr. Hashi testified that after receiving the January 2007 vaccinations, S.H. became very sensitive to noise and would hold her ears, just as her older sister did. Tr. at 56. Although Dr. Neumeyer's notes indicate that S.H. had become overly sensitive to noise by the fall of 2006, Mr. Hashi stated that "[i]n 2007 the degree of sensitivity went

so high and she would hold her ears and even small, small little things would really sound like a train going by or a jet engine.” Tr. at 58-59. Ms. Hashi testified that S.H. “held her ears so tight always.” Tr. at 153.

Mr. Hashi and his niece agreed that S.H. was toilet trained before January of 2007. Tr. at 61, 150. Mr. Hashi said that beginning about a week after she received the January 2007 vaccinations, she stopped asking for the bathroom and began to soil herself. Tr. at 61-63. Ms. Hashi also recalled her cousin wetting herself. Tr. at 151. Her toileting issues became worse over time. Tr. at 63. When asked why, on January 23, 2007, Drs. Becker and Hundsley said she was toilet trained, Mr. Hashi said that he simply didn’t see S.H. “wetting her pants, all that, because he is not with her all the time.” Tr. at 62-63. Mr. Hashi reported that her problems persisted for years, but eventually subsided. Tr. at 73.

Both Mr. Hashi and his niece referenced S.H.’s problems with constipation. Mr. Hashi testified that S.H. was given a laxative for her constipation. Tr. at 70. He said that she sometimes had better days. He also stated that the combination of laxatives and the mitochondrial cocktail prescribed by Dr. Sims caused S.H. to improve, though she was still “not like a normal child.” Tr. at 71. Ms. Hashi stated that S.H.’s constipation problems worsened after the vaccinations. Tr. at 179.

#### D. Exploration of Possible Mitochondrial Disorder.

S.H. and her older sister, O.H., had an appointment at MGH’s Mitochondrial Clinic on August 15, 2007, about seven months after S.H. received the allegedly aggravating vaccinations. They were evaluated by pediatric neurology resident Dr. David Dredge and attending physician Dr. Katherine Sims. Mr. Hashi and Ms. Wedge reported that their concerns with S.H. started when she was approximately two years old, and that they felt she had a significant decline in language skills around 24 to 30 months of age. Pet. Ex. 11, p. 53. Given her past abnormal laboratory results, Drs. Dredge and Sims suggested that S.H. might have an “underlying disorder of cellular metabolism contributing to her [autistic] symptoms.” *Id.*, p. 54. Because of the marked similarities in the symptoms experienced by both Hashi sisters, petitioners elected to initially only perform genetic tests on O.H., the elder sister. Depending on the results, testing might be conducted on S.H. *Id.*, p. 55.

The July 3, 2008 consultation note from LADDERS indicated that although S.H. had not undergone a muscle biopsy, based on the results of O.H.’s biopsy, which found a Complex I ETC deficiency, S.H. had begun to take a mitochondrial cocktail.<sup>26</sup> Pet. Ex. 7, p. 10. Since starting the cocktail in the spring of 2008, S.H. had made progress in her language and communication skills. However, because this improvement coincided with an improvement in the school program she was attending, Dr. Neumeyer noted the

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<sup>26</sup> The cocktail consisted of thiamine, riboflavin, vitamin C, vitamin E, carnitine, alpha-lipoic acid, coenzyme Q10, and creatine monohydrate. Pet. Ex. 7, p. 11.

cause for her progress could not be conclusively identified. However, she recommended that S.H. continue taking the mitochondrial cocktail. *Id.*, p. 11.

On December 29, 2009, S.H. returned to Dr. Becker's office. Pet. Ex. 3, p. 20. Mr. Hashi and Ms. Wedged informed him that S.H. shook her head, whispered robotically, required prompting in order to speak, was sensitive to noise, and ground her teeth at night. Doctor Becker noted that S.H. had been diagnosed with a mitochondrial disorder. He described S.H.'s "pattern of neurodevelopmental progress" as "some loss of skills followed by a gain and then a loss again." Pet. Ex. 3, p. 20.

On January 22, 2010, S.H. was examined by Dr. Daniel Doody. She was referred to him because her parents were considering having her undergo muscle and skin biopsies. Doctor Doody recorded that S.H. began to develop signs of developmental regression at four years of age. Pet. Ex. 9, p. 21-22. However, during the pre-anesthesia telephone consultation a week later, her language regression reportedly began when she was three years old. *Id.*, p. 23. The three-year point is more consistent with the contemporaneous records. See, e.g., Pet. Ex. 11, p. 91.

S.H. underwent a muscle and skin biopsy on February 3, 2010. Pet. Ex. 9, pp. 151, 178-185. The electron microscopy analysis of the muscle tissue revealed "small subsarcolemmal clusters of mitochondrial with pleomorphic shapes and increased internal complexity." *Id.*, p. 186. Pathologist Dr. Anat Stemmer-Rachamimov indicated that those findings are "non-specific, but may be seen in mitochondrial disorders." The skin biopsy uncovered "no definitive evidence of mitochondrial abnormality." *Id.*, p. 187.

The Baylor College of Medicine's Medical Genetics Laboratory reported the results of their mtDNA Complex I subunits sequencing of S.H.'s sample on May 24, 2010. The analysis detected "an apparently homoplasmic familial m.5194C>T (p.P242L, ND2) variant." Pet. Ex. 3, p. 17. The report noted that the laboratory was requested to evaluate the sample for the found variant, which had previously been found in both S.H.'s mother and her older sister. Other regions of the mitochondrial genome were not sequenced. *Id.* The ND2 gene variant observed was listed in MitoMap as a polymorphism, but at the time of the report was not listed in mdDB. Pet. Ex. 3, p. 17, referencing <http://www.mitomap.org> and <http://www.genpat.uu.se/mtDB>. The polymorphism was not identified as causal of S.H.'s condition; it was not noted to be a variant associated with disease or dysfunction. Pet. Ex. 9, p. 129.

S.H. had a follow-up visit at MGH's Mitochondrial Clinic on October 6, 2010. Doctor Sims reported that since her April 2010 clinic visit, S.H. had been making progress at school. Ms. Wedged expressed frustration about the pace of S.H.'s progress, but agreed that there had been no regression in skills. Pet. Ex. 9, p. 129. In reviewing the biopsy results, Dr. Sims noted that the observed "mtDNA change is of unclear significance." *Id.*, p. 130.

On June 2, 2011, S.H. had saw Dr. Neumeyer at LADDERS.<sup>27</sup> The past medical history section of the consultation note indicates that S.H.'s evaluation at the Cleveland

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<sup>27</sup> This is the most recent relevant medical record filed. The most recent record filed is from July 11,

Clinic did not confirm or uncover a mitochondrial disorder. Pet. Ex. 9, p. 113. No date was given for the evaluation and records from this evaluation were not filed. Doctor Neumeyer did note that S.H. carried an mtDNA variant. *Id.* She remarked that the “etiology of [S.H.]’s autism is still unknown but presumed metabolic/genetic with a possible mitochondrial disorder.” *Id.*, p. 114.

#### E. Resolving Conflicts between Testimony and Records.

The testimony reflected a dramatic and steep regression in nearly every aspect of S.H.’s behavior within a month after receiving the January 2007 vaccinations. The medical records, however, present a very different picture of events. After the allegedly aggravating vaccines, S.H. did not return to her pediatrician for more than three months. There are no records of phone calls to her pediatrician describing any of the alarming symptoms presented in the Hashis’ testimony. And, at her March 2007 pediatrician’s appointment, S.H.’s parents did not recount any of the concerning behavioral changes described in the testimony. See Pet. Ex. 11, pp. 7-9.

The conflicts between the hearing testimony and the medical records are profound. Although Mr. and Ms. Hashi appeared sincere about the nature and timing of a deterioration in S.H.’s behavior and other symptoms as occurring shortly after the vaccination, I cannot accept their detailed and interlocking testimony about substantial changes that would have occurred more than seven years earlier, in the absence of any contemporaneous reports reporting those changes. Where there were reports of similar or even less dramatic changes in the existing medical records, the events described occurred or were reported to have occurred at times preceding the vaccinations in question by several months.

Conflicts between contemporaneous records and testimony given several years later at a hearing are common in Vaccine Act cases, and this case is no exception. Two general legal principles guide the resolution of conflicts between contemporaneous records and later-adduced evidence. The first is that the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame. See, e.g., *Murphy v. Sec’y, HHS*, 23 Cl. Ct. 726, 733 (199), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992) (“[T]he absence of a reference to a condition or circumstances is much less significant than a reference which negates the existence of the condition or circumstance” (citation omitted)).

The second principle addresses the degree of reliance commonly accorded to contemporaneous records. 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*, 23 Cl. Ct. at 733 (citation omitted); see also *Cucuras v. Sec’y, HHS*,

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2011, when S.H. was seen for a swollen bug bite on her cheek. There was no evidence of infection, and petitioners were instructed to observe the area. Pet. Ex. 9, p. 110.



993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *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 discrepancies. *Stevens v. Sec’y, HHS*, No. 90-221V, 1990 WL 608693, at \*3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990).

In general, I found the contemporaneous medical records to be more reliable than the testimony of Mr. and Ms. Hashi. Ms. Hashi seemed unsure of when precisely her cousin experienced changes in her development. Mr. Hashi merely insisted that all of the medical records that conflicted with his testimony were inaccurate and that, although S.H.’s problems began before she received the vaccinations in question, they worsened immediately thereafter. His assertions are not supported anywhere in the medical records.

One such example is the issue of toilet training. At the hearing, Mr. Hashi testified that S.H. began soiling herself about a week after she received the allegedly aggravating vaccinations. Tr. at 61-63. Approximately two weeks after receiving the allegedly aggravating vaccinations, S.H. was evaluated for the first time by Drs. Becker and Hundsley. Their thorough consultation notes do not include any reference to a regression in S.H.’s toilet training skills. In making their determinations about S.H.’s development, they considered Ms. Wedeg’s account of S.H.’s development and deterioration. I find it difficult to believe that they would have failed to include information about S.H. experiencing a dramatic toilet training regression in the prior two weeks. Further, given the detail recounted in their consultation notes, I also cannot believe that Ms. Wedeg would not have told Drs. Becker and Hundsley if S.H. had recently experienced a marked change in her toilet training habits.

The best summary of S.H.’s development was provided by Dr. Becker several years later, when S.H. was approximately seven years old. In late 2009, Dr. Becker described S.H.’s “pattern of neurodevelopmental progress” as “some loss of skills followed by a gain and then a loss again.” Pet. Ex. 3, p. 20. I concur with Dr. Becker’s assessment—S.H.’s development has been marked by periods of brief improvement followed by regression.

Under these circumstances, I find that S.H.’s behavior and health did not significantly decline after she received the January 2007 vaccinations. In the months following the allegedly aggravating vaccines, S.H.’s health remained much the same as it had been for the previous several months—she spoke few words, ground her teeth, displayed sensitivity to noise, and was profoundly developmentally delayed. Therefore, I find that S.H. did not experience a significant deterioration in her behavior or health between the months immediately following her January 2007 vaccinations.

### III. Applying the Facts to the Law.

#### A. Untimely Filing.

I adopt my August 26, 2013 ruling that the vaccine causation claim found in the first amended petition was untimely filed. Nothing in the testimony or Ms. Hashi's affidavit persuades me that my earlier factual findings were incorrect.

#### B. Significant Aggravation.

To recover under a significant aggravation theory, petitioners must demonstrate that the vaccination caused a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4); *Hennessey*, 2009 WL 1709053, at \*1, *mot. for rev. denied*, 91 Fed. Cl. 126 (2010). In *Loving*, 86 Fed. Cl. at 144, the Court of Federal Claims created a six-factor test for significant aggravation, requiring a petitioner to establish by preponderant evidence: (1) the vaccinee's condition prior to administration of the vaccine; (2) the vaccinee's current condition or condition following the vaccine; (3) whether the comparison of the two conditions constitutes a significant aggravation of the person's condition; (4) a medical theory causally connecting a significantly worsened condition to the vaccine; (5) a logical sequence of cause and effect demonstrating that the vaccine was the reason for the significant aggravation; and (6) a proximate temporal relationship between the vaccine and the significant aggravation. This test has been cited with approval by the Federal Circuit. *W.C.*, 704 F.3d at 1357.

S.H. was diagnosed with autism in September 2006 and had been suffering from developmental problems since she was six months old, long before she received the January 2007 vaccinations. See, e.g., Pet. Ex. 4.2, pp. 43, 46. Following her January 2007 vaccines, S.H.'s parents did not seek medical care for her until more than three months later, when she was seen for sinusitis. Contemporaneous records indicated that S.H.'s parents had become concerned about her loss of vocabulary, tooth grinding, and propensity to bite in the fall of 2006, at least four months prior to the January 2007 vaccinations.

Many of the claimed deteriorations were behavioral in nature. During the three months following the January 2007 vaccinations, S.H. saw Drs. Becker and Hundsley at Children's Hospital Developmental Center and Sr. Neumeyer at LADDERS. These doctors were developmental specialists. None of the doctors' consultation notes indicated that Ms. Wedge or Mr. Hashi had noticed a recent and dramatic deterioration in S.H.'s behavioral or development in the winter of 2007.

Thus, based on my factual findings above, petitioners have failed to demonstrate that S.H.'s symptoms and behavior worsened within 18 months of the January 2007 vaccinations.

### III. Conclusion.

Petitioners' only remaining claim is the significant aggravation claim set forth in the second amended petition. Based on these factual findings, it appears unlikely that any reputable expert can opine that S.H.'s condition was significantly aggravated by the vaccinations administered in January 2007. It may, therefore, be unreasonable for petitioners to continue to pursue this case.

Nevertheless, I will permit petitioners 60 days to file a status report identifying an expert. Any expert identified must be provided a complete copy of this fact ruling, and the expert identified shall state either (1) that he or she can offer an opinion, based on the facts set forth herein, that the January 2007 vaccinations significantly aggravated S.H.'s condition, or (2) provide reasons, grounded in something other than the credibility of the testifying witnesses, that one or more specific factual findings are incorrect, and that based on the correct facts, that he or she can opine favorably that the vaccines significantly aggravated S.H.'s condition. **Petitioners must submit their status report identifying an expert witness by no later than Friday, July 31, 2015. No extensions to this deadline will be granted.**

If no expert can be identified, petitioners shall file a status report so stating, and request a ruling on the record. Alternatively, petitioners may file a motion to dismiss.

If an expert is identified, petitioners shall propose a date, within 60 days of the filing of the status report, by which the expert's report will be filed.

**IT IS SO ORDERED.**

**s/Denise K. Vowell**

Denise K. Vowell  
Special Master