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

No. 08-0308V
Filed: June 1, 2015
Not for Publication

HUSSEIN H. HASHI and SAFIA WEGED, parents of O.H.,	*	
Petitioners,	*	Autism; Fact Ruling; Significant Aggravation; Contemporaneous Records
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Elaine W. Sharp, Esq., Whitfield, Sharp & Sharp, Marblehead, MA, for petitioners.
Traci R. Patton, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

RULING ON FACTS REGARDING SIGNIFICANT AGGRAVATION CLAIM[1]

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. 08-308V, 2013 WL 10487184 (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 16, 2011, at 1. The significant aggravation claim was explicitly raised in the second amended petition filed on September 25, 2013.

The second amended petition asserted that vaccines O.H. received on April 22, 2006, significantly aggravated an underlying mitochondrial disorder.[2] Second Amended

[1]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.

[2] I note that the date of the diphtheria, tetanus, acellular, and pertussis ["DTaP"], measles, mumps, and rubella ["MMR"], and inactivated polio virus ["IPV"] vaccines listed in O.H.'s consultation notes is April 24,

Petition, ¶ 6. As evidence of the significant aggravation, petitioners relied on assertions made by petitioner Hussein Hashi in his affidavit, dated and filed on July 16, 2012. *See* Pet. Ex. 15. 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 O.H.'s condition before and after the April 24, 2006 vaccinations.[3] *Hashi,* 2013 WL 10487184, at *7, n.18.

To resolve the discrepancies between Mr. Hashi's affidavit and the contemporaneous medical records, I conducted a hearing before ruling on the facts regarding O.H.'s condition. *See* Order, issued May 29, 2014. I heard the testimony of Mr. Hashi and Ms. Nimo Hashi, his niece,[4] 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 O.H.'s parents at times closer to the events in question more accurately reflect O.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 O.H.'s condition did not become significantly worse after her April 24, 2006 vaccinations. Given the impact of this factual finding on their significant aggravation claim,[5] 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. 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 O.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 Weged and Hussein Hashi ["Ms. Weged," "Mr. Hashi," or "petitioners"] filed the short-form petition authorized by Autism General Order #1[6] for

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2006, and not, as petitioners allege, April 22, 2006. Petitioners' Exhibit ["Pet. Ex."] 7, pp. 2-3.

[3] These were the only vaccinations she received within the statute of limitations period. *See* Pet. Ex. 7, pp. 2-3.

[4] Ms. Hashi testified that she frequently babysat for O.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 schooling. *See* Tr. at 161-63. When she began college in the fall of 2004, Ms. Hashi continued to visit and babysit on an as-needed basis. Tr. at 163.

[5] *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).

[6] 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).

compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[7] [the "Vaccine Act" or "Program"], on behalf of their minor daughter, O.H. By filing the short-form petition, petitioners joined the Omnibus Autism Program ["OAP"],[8] thereby asserting that O.H. has an autism spectrum disorder ["ASD"][9] and that one or more vaccines listed on the Vaccine Injury Table[10] were causal of her condition. Petitioners did not file any medical records or details regarding O.H.'s injuries with the short-form petition.

On April 28, 2008, the presiding special master[11] ordered petitioners to complete their petition by filing the statutorily required medical documentation[12] and a "Statement Regarding Onset," clearly detailing O.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 23, 2008, petitioners filed 23 exhibits of medical records,[13] 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 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 the MMR vaccine O.H. received on July 1, 2002

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[7] 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 (2006).

[8] 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.

[9] "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).

[10] 42 C.F.R. § 100.3 (2011).

[11] This case was reassigned to me on July 1, 2011.

[12] Section 11(c)(2) of the Vaccine Act and Vaccine Rule 2 require that the petition be accompanied by medical records and affidavits.

[13] Petitioners initially labeled their 23 exhibits A-W. The Guidelines for Practice indicate that petitioners' exhibits should be labeled using Arabic numbers. Accordingly, pursuant to my order of July 20, 2011, petitioners refiled most of these exhibits using numbers as Pet. Exs. 1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, and 3. However, I was unable to locate Petitioners' Exhibit S in the subsequently filed documents, and it continues to be identified as Pet. Ex. S in this ruling.

caused an encephalopathy and sequelae. First Amended Petition, ¶¶ 2-3. The amended petition also alleged that O.H. was later diagnosed with a mitochondrial disorder, specifically a Complex I electron transport chain ["ETC"] deficiency. *Id.,* ¶ 4.

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; *see also* § 16(a)(2). I cautioned petitioners' counsel against obtaining an expert report at that point, 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.[14] Order, issued July 20, 2011; *see also* Order, issued Nov. 1, 2011.

Between August 3, 2011, and October 18, 2011, petitioners filed eight exhibits addressing O.H.'s more recent medical treatment. Shortly thereafter, petitioners' counsel reported that Dr. Katherine Sims, a neurogeneticist, had been retained as an expert to evaluate claims of vaccine causation and an expert report was forthcoming. Petitioners' Status Report, filed Oct. 19, 2011.

In response to petitioners' status report, I reiterated my caution about retaining an expert prior to a determination that this case was timely filed. I emphasized that, given O.H.'s age and ASD diagnosis at the time this petition was filed, a significant issue in this case was an absence of records of O.H.'s routine pediatric care from birth onward. I ordered petitioners to refocus their efforts toward developing a complete medical record. Order, issued Nov. 1, 2011. Additionally, I ordered petitioners to provide medical records identifying the physician or other specialist who diagnosed O.H. with ASD. Order, issued Dec. 2, 2011.

Between early December 2011 and April 2012, petitioners filed eight more exhibits containing O.H.'s educational and medical records from birth to early childhood. During this time, petitioners submitted a status report indicating that O.H. suffered a pre-existing injury, specifically a mitochondrial disorder, which was exacerbated by repeated vaccinations. Status Report, filed Dec. 16, 2011. However, the report did not identify which specific vaccines were believed to have aggravated O.H.'s disorder.

On May 17, 2012, respondent filed a motion to dismiss petitioners' claim, arguing that the petition was filed approximately two years and four months after the expiration of the statute of limitations.[15] Respondent's Motion to Dismiss, filed May 17, 2012, at 5

[14] 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).

[15] The Vaccine Act provides that "no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." § 16(a)(2).

(noting that the petition should have been filed by December 31, 2005). In response, petitioners filed a joint opposition to respondent's motions to dismiss in both of their children's cases.[16] In their opposition, petitioners assert that the DTaP, MMR, and IPV vaccines administered on April 22, 2006,[17] significantly aggravated O.H.'s pre-existing mitochondrial disorder and that the short-form petition was filed on April 22, 2008, within the statute of limitations period.[18] Petitioners' Joint Opposition to Respondent's Motions to Dismiss at 2, 5.

The filed medical records showed that O.H. received DTaP, MMR, and IPV vaccines on April 24, 2006. However, the records did not include the consultation notes of Dr. Peter Masucci, who served as O.H.'s pediatrician during the time in question. Also missing were the particulars about the vaccinations O.H. received that day, including the lot number and manufacturer. In response to my September 2012 Order to file additional medical records, petitioners filed Dr. Masucci's consultation notes for some of O.H.'s visits occurring between November 2004 and April 2006 as Pet. Ex. 18. They do not appear to be his complete records for treatment of O.H.[19]

On August 26, 2013, I dismissed the causation in fact claim as untimely filed. *Hashi,* 2013 WL 10487184.

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 O.H.'s early growth and development is necessary because evaluation of a significant aggravation claim requires the special master to find the vaccinee's condition before and after the allegedly aggravating vaccine and to determine if any change in the condition constitutes significant aggravation. *W.C.,* 704 F.3d at 1357; *Loving,* 86 Fed. Cl. at 144; *Hennessey,* 2009 WL 1709053, at *40. 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 O.H.'s ASD symptoms or her ASD and mitochondrial disorder diagnoses, at least until the April 24, 2006 vaccinations.

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[16] In addition to this case, petitioners have filed a petition on behalf of their daughter S.H. (No. 08-307V).

[17] The record petitioners cited for this date, Pet. Ex. 7, pp. 2-3, is a visit from June 9, 2007. I note that the vaccination records for the DTaP, MMR, and IPV vaccines now alleged to be causal is listed as April 24, 2006.

[18] This claim differs from petitioners' first amended petition, which identified the July 2002 MMR vaccine as causing O.H.'s encephalopathy and sequelae. First Amended Petition, ¶ 3.

[19] This exhibit contains a vaccine administration record and a few (largely illegible) consultation notes. There are entries in November of 2004, one entry dated in February 2006, and one entry for April 2006.

Thereafter, the testimony and medical records diverge significantly, with virtually all of the symptoms O.H. eventually displayed occurring, according to Mr. Hashi and Ms. Hashi, in close temporal proximity to the April 24, 2006 vaccinations. In contrast, the medical records reflect a significant worsening of O.H.'s ASD symptoms only after November 2007. Additionally, the records demonstrate that some of the symptoms Mr. and Ms. Hashi claimed as occurring for the first time after the April 24, 2006 vaccinations actually occurred prior to the vaccinations.

A. O.H.'s Early Health and Development.

O.H. was born in late June 2001, into a family with a notable family history of developmental delays.[20] Ms. Weged had gestational diabetes and there was moderate meconium in the amniotic fluid, but Dr. Lawrence Stratton, O.H.'s pediatrician, found her to be a well newborn. Pet. Ex. 13, pp. 141-42; *see also* Pet. Ex. 7, p. 55. O.H. received a hepatitis B vaccine prior to her discharge from the hospital and continued to receive routinely-administered childhood vaccinations in her first year of life, without apparent ill effects. *See generally* Pet. Ex. 13. At six months of age, Dr. Stratton described her as having excellent growth. *Id.*, p. 128.

1. Onset of Developmental Delay.

Doctor Stratton first expressed concerns about O.H.'s development on April 9, 2002, at her nine month well child visit. Pet. Ex. 13, pp. 115-20. He referred O.H. to Early Intervention ["EI"] services on May 8, 2002, noting that she had normal development until about nine months of age, but at that point she could not sit independently. *Id*., pp. 111-14.

O.H. received an MMR vaccine two months later at her one year well child visit on July 1, 2002. Pet. Ex. 13, p. 107. She was not seen again until August 29, 2002, when she was diagnosed with a corneal abrasion. No concerns of vaccine reaction were expressed at this visit. *Id*., pp. 101-03.

In the summer of 2002, Dr. Stratton remained concerned about O.H.'s persistent developmental problems. *See, e.g.*, Pet. Ex. 13, p. 108. On December 31, 2002, about five months after O.H. received the July 2002 MMR vaccine, Dr. Stratton noted that she exhibited mild language delays and her motor skills appeared to be worsening. *Id*., p. 94. She was approximately 18 months of age at the time of this visit and was still unable to walk without assistance. *Id*.

At a follow up appointment on April 29, 2003, Dr. Stratton reported that, with the help of intervention services, O.H. had begun walking and spoke a few words, but still exhibited motor delay. Pet. Ex. 13, pp. 80-84. He twice expressed his suspicion that

[20] In the summer of 2007, Dr. Elizabeth TePas of Massachusetts General Hospital noted that there was "a strong family history of autism/developmental delay on the father's side. Apparently, [O.H.]'s paternal uncle did not talk until 7 and his son has autism spectrum disorder and is nonverbal. There is also another sibling who was nonverbal until the age of 12." Pet. Ex, 7, pp. 55.

lack of stimulation or cultural issues were causal. *Id*., pp. 88, 94. While receiving EI services, O.H. gained milestones in both motor and language development. *See, e.g.*, Pet. Ex. 13, p. 84. Doctor Stratton noted that, at 28 months of age, O.H. was walking better and could speak about 15-20 words. *Id*., p. 59.

2. Events Leading to Autism Diagnosis.

In January 2004, at about two and half years of age, O.H. began to lose developmental milestones. Pet. Ex. 13, p. 54. Early Intervention services re-evaluated O.H. and found global delays, noting that she previously put two words together, but no longer spoke many words at all. *Id*. On January 22, 2004, Dr. Stratton noted that O.H. had been examined by a neurologist who indicated that she might have pervasive developmental disorder ["PDD"] or autism.[21] *Id*.

O.H. subsequently underwent a full neurodevelopmental evaluation at the Boston Children's Hospital on October 12, 2004. Pet. Ex. 8, pp. 5-12. According to the report, O.H. had normal language development up until 18 months of age and began regressing at around 20 to 22 months of age. *Id*., pp. 5-6. At the time of the evaluation, all of O.H.'s developmental milestones were delayed. *Id*. Additionally, Dr. Ronald E. Becker at the Children's Hospital found that O.H.'s regression and impaired social development were consistent with the diagnostic criteria for autism. *Id*., p. 12.

On November 4, 2004, Dr. Stratton noted that O.H., then three years of age, had regressed to rare spoken words, such as "mama," "baby," and "hello" (Pet. Ex. 13, p. 8), and by late April 2005, nearing her fourth birthday, she became nonverbal (Pet. Ex. S). On April 27, 2005, Dr. Martha R. Herbert, a neurologist at Massachusetts General Hospital, noted that O.H. had "complete lack of verbal language" in addition to developmental delay. Pet. Ex. S. She also concluded that O.H. met all the criteria for autism disorder. *Id.*

3. Divergence between Testimony and Medical Records.

At this point, Mr. Hashi's recollections begin to differ from the descriptions of O.H.'s development and behavior as presented in the medical records.

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[21] Pervasive developmental disorder, or "PDD," is the umbrella term used in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69, for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder—not otherwise specified ["PDD-NOS"], and Asperger's Disorder. There is possible confusion between "PDD" (the umbrella term referring to the general diagnostic category) and "PDD-NOS," which is a 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 child as having an "autism diagnosis," even though the specific diagnosis is PDD-NOS. In conveying that O.H. may have "PDD/autism," the neurologist, Dr. Krishnamurthy, was likely referring to PDD-NOS and autism as specific diagnoses within the general category of PDD. The current DSM, DSM V, uses the term "Autism Spectrum Disorder" rather than PDD. *See* Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 5th ed. 2013) ["DSM-V"] at 50.

A few weeks after the April 2005 evaluation by Dr. Herbert, Mr. Hashi met with Dr. Becker. O.H. was not present for the appointment. Doctor Becker's consultation notes stated that Mr. Hashi "reports today that [O.H.] is much more regulated than she has been in the past. However, she continues to be nonverbal with intermittent use of language that is usually non-useful for her." Ex. 8, p. 16.

However, at the hearing, Mr. Hashi testified that as late as April of 2006, O.H. still had some vocabulary. Tr. at 84-86. Mr. Hashi insisted that he never informed Dr. Becker that O.H. was nonverbal. Tr. at 86. Instead, he stated that O.H. was shy and thus did not speak during doctor's visits, although, given that O.H. was not present at the appointment when this report was made, her shyness would not account for the report that she was nonverbal at this visit. Tr. at 85-86. Mr. Hashi testified that before the April 2006 vaccinations, O.H. called her parents "mom" and "dad," but that after the vaccinations she "lost her vocabulary…little by little." Tr. at 32-34. Likewise, Ms. Hashi testified that O.H.'s language "gradually disappeared" after the April 2006 vaccinations. Tr. at 132.[22]

The witnesses' accounts of O.H.'s loss of language are contradicted by the histories in O.H.'s medical records as well. In August of 2007, after his initial examination of O.H., Dr. David Dredge[23] noted that O.H. was "completely non-verbal by 3 years and 4 months of age." Pet. Ex. 2.1, p. 20. O.H. would have been three years and four months old in November of 2004. When asked to explain the apparent contradiction during cross examination, Mr. Hashi simply insisted that O.H. did not become nonverbal until 2006. Tr. at 101.

However, references to O.H.'s lack of language before 2006 are found in other records as well. A record from Everett Public Schools dated June 23, 2005, reflected that "[O.H.]'s parents are extremely concerned with their daughter's inability to communicate." Pet. Ex. 11 at 24.[24]

Based on the records filed, there is little doubt that O.H. was unable to speak long before she received the April 2006 vaccinations. Given that Dr. Herbert, Dr. Becker, Dr. Dredge, and several other physicians had noted O.H.'s lack of words,[25] and

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[22] In Ms. Hashi's affidavit, drafted ten days before the hearing, she said that O.H. became nonverbal immediately after the April 2006 vaccinations. Pet. Ex. 20 at 3-4.

[23] Dr. Dredge saw O.H. for this appointment. The attending physician who signed off on Dr. Dredge's notes was Dr. Katherine Sims.

[24] Records from Everett Public Schools also indicate that by the age of four, O.H. was able to communicate by signing, though her signs were only approximations. Pet. Ex. 11 at 24.

[25] For instance, Dr. Peter Masucci remarked that "[a]t around a year-and-a-half of age [O.H.] started losing words and became completely non-verbal by age three." Pet. Ex. 7, p. 46. In a May 2005 letter from Kimberly Dunn, a certified nurse practitioner, to Dr. Masucci, she wrote that O.H. "continues to be nonverbal with intermittent use of language that is usually non-useful for her." Pet. Ex. 1.1, p. 1. Ms. Dunn went on to discuss O.H.'s attempts to learn sign language and communicate using a picture system, indications that O.H. was unable to communicate verbally. *Id*. Following a December 2006 visit to Learning and Developmental Disabilities Evaluation and Rehabilitation Services [LADDERS], Dr. Ann

that Dr. Herbert's and Dr. Becker's medical records were created contemporaneously, I credit Dr. Herbert's and Dr. Becker's conclusions, supported by Dr. Dredge and other physicians, that O.H. had lost the ability to communicate verbally, at the very latest, by the spring of 2005. Thus, as I did in my earlier fact ruling, I find that O.H. was nonverbal at least one year prior to the administration of the allegedly aggravating vaccinations.

B. O.H.'s Behavior and Symptoms within a Month after April 2006 Vaccinations.

The witnesses' affidavits and testimony concerning O.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 April 2006 vaccinations. Their memories, however, do not align with the facts recounted in O.H.'s medical and school records.

1. General Health Prior to and After April 2006 Vaccinations.

Doctor Masucci served as O.H.'s primary care physician beginning in late 2004. *See generally*, Pet. Ex. 7. Between November 2004 and February 2006, O.H. saw him on at least 16 separate occasions for a number of infections, including otitis media, acute sinusitis, and unspecified viral infections. *Id*., pp. 15-16. In October of 2005, O.H. presented with abdominal pain and constipation. *Id.*, p. 14. At a visit in February of 2006, Dr. Masucci diagnosed O.H. with anorexia. *Id.*

O.H. received DTaP, MMR, and IPV vaccines at her five year well child visit on April 24, 2006. Pet. Ex. 18, p. 1; *see also* Pet. Ex. 7, p. 14. Doctor Masucci noted her history of autism and indicated that she appeared well at the visit. Pet. Ex. 18, p. 2. O.H. next saw him about a month later, on May 30, 2006, when Dr. Masucci diagnosed her with an acute upper respiratory infection ["URI"]. Pet. Ex. 7, p. 14.

According to Dr. Masucci's records, O.H. continued to suffer from a number of infections from June 2006 through June 2007. Pet. Ex. 7, pp. 9-15. She was prescribed multiple antibiotics during that year for various infections, including otitis media, pharyngitis, URI, sinusitis, and streptococcal sore throat. *Id*., pp. 9-14, 21.

During this time, O.H. made some gains in communication skills. Her school records indicate that by late June of 2006, O.H. was able to communicate using gestures and a book with 80% accuracy. Pet. Ex. 11, pp. 2-3. Despite her progress, O.H. remained "unable to put sounds together to make words." *Id*., p. 3.

Neumeyer stated that O.H. "began regressing at about 18 months of age, where she lost her words," and described O.H. as "remain[ing] nonverbal." Pet. Ex. 3, p. 1; *see also id.*, p. 23. Further, at O.H.'s first visit with Dr. Marc Rosenthal in October of 2007, he noted that she had been nonverbal "since 3yrs [and] 4 months when she stopped talking." Pet. Ex. 6, p. 19. Dr. Martin Häusler, the child neurologist O.H. visited in Germany, commented that although O.H. developed normally until she was 18 months old, "[f]rom then she showed no more speech development and even a loss of speech functions." Pet. Ex. 14, p. 1. The records demonstrate that the only references to O.H. being able to communicate verbally after she was approximately three and a half years old are found in the testimony and affidavits of Mr. Hashi and Ms. Hashi.

The day of the allegedly aggravating vaccinations, Mr. Hashi testified that O.H. experienced a fever of about 100 or 102 degrees Fahrenheit, vomiting, and crying. Tr. at 13-16, 88-90. O.H.'s eyes became unfocused the day of the vaccination. Tr. at 91. Mr. Hashi stated that he called Dr. Masucci's office and was advised to give O.H. Tylenol. Tr. at 14, 88. According to Mr. Hashi, O.H. began vomiting and crying inconsolably shortly thereafter. Tr. at 88.

There is no record that Mr. Hashi or Ms. Weged contacted O.H.'s pediatrician with complaints of a fever, unfocused gaze, vomiting, or uncontrollable crying shortly after her April 2006 vaccinations. They did not bring O.H. back to her pediatrician until she developed an upper respiratory infection more than a month later, and did not mention these post-vaccination symptoms at this visit. *See* Pet. Ex. 7, p. 14.

I note that Dr. Masucci's practice kept fairly detailed records of telephone calls from O.H.'s parents. Had Mr. Hashi or Ms. Weged called Dr. Masucci to report that their daughter had a fever shortly after her vaccinations, such a call would likely have been memorialized, given the records of calls involving much more mundane problems. *See* Pet. Ex. 7, pp. 39-41 (noting multiple phone calls from O.H.'s parents detailing the need for referrals, prescriptions, advice about their children's diets, complaints of illnesses, etc.). Moreover, there is also no indication in Dr. Masucci's records that Mr. Hashi or Ms. Weged expressed concern to him about a profound decline in O.H.'s health and behavior in the weeks following the allegedly aggravating vaccinations.

According to Mr. Hashi, O.H. also began having problems with her mouth shortly after the vaccinations. He recalled that, within a day or two of the vaccinations, O.H. began grinding her teeth. Tr. at 16. Ms. Hashi also remembered O.H. grinding her teeth shortly after her vaccinations. Tr. at 129-30, 166. Mr. Hashi testified that the behavior continued for months or "even couple of years." Tr. at 17-18, 90-91. Although Mr. Hashi said that he called Dr. Masucci "a day later after she started grinding her teeth" (Tr. at 99), there is no record of such a phone call (*see* Pet. Ex. 7).

In addition to the tooth grinding, Mr. Hashi also testified that O.H. developed a biting problem after the April 2006 vaccinations, although he seemed somewhat unsure of precisely when this behavior started. Tr. at 22-23, 94. He explained that O.H. did not have a previous history of biting people and objects. Tr. at 94.

Mr. Hashi recalled O.H. engaging in more self-stimulating behavior after receiving the April 2006 vaccines. He remembered that O.H. ran in circles around the family's table far more frequently (Tr. at 18, 37), a behavior that Ms. Hashi also witnessed (Tr. at 134-35, 171). According to Mr. Hashi, this behavior became "worse and worse" and continued through 2007. Tr. at 37-38.

According to the medical records, however, O.H. had had this problem for quite some time. At a visit on August 15, 2007, Dr. Dredge noted that "[o]ver the *last couple of years*, [O.H.] has developed a lot of repetitive behavior such as circling the table." Pet. Ex. 7, p. 48 (emphasis added).

Mr. Hashi and Ms. Hashi recounted other similar behaviors. Ms. Hashi recalled that, beginning a few weeks after the vaccinations, her cousin would tremble almost as if she were "having a seizure." Tr. at 130-31, 168-70. Ms. Hashi did not call the doctor after any of these incidents. Tr. at 169-70. O.H. also rocked back and forth. Tr. at 136.

Ms. Hashi also described a marked change in O.H.'s play routine after the April 2006 vaccinations. She testified that O.H. stopped role-playing and became obsessively focused on one toy in particular. When the toy became soiled and needed to be removed, O.H. would become "very aggressive" and make loud noises. Tr. at 137-39.

Mr. Hashi also testified that O.H. began making loud vocalizations after the April 2006 vaccinations. Tr. at 19. However, based on the medical records, it appears that O.H. had been making the noises in question for quite some time. In the summer of 2007, Dr. Dredge remarked that "[o]ver the *last couple of years*, she has developed a lot of repetitive behavior such as…frequent vocalizations." Pet. Ex. 7, p. 48 (emphasis added). On cross examination, Mr. Hashi agreed that O.H. made loud sounds a "[l]ittle bit" before the vaccinations, but that they were "[n]ot as bad and not the same tone, not the same way." Tr. at 93. Ms. Hashi did not remember whether O.H. made these vocalizations before April 2006, but after the vaccinations, she remembered O.H. making "loud noises" that were not words. Tr. at 134-35.

Both witnesses testified that O.H. was always a shy child and not prone to socialization. Mr. Hashi testified that after the vaccines, her anxiety around strangers dramatically increased and she became afraid even of relatives, as if she had forgotten who they were. Tr. at 23-24. Within a week, she began hiding behind her mother when people came to her home. Tr. at 94-95. She also stopped having eye contact with people. Tr. at 34. Ms. Hashi agreed that O.H. stopped having eye contact and seemed less interactive after the April 2006 vaccinations. Tr. at 127-29. She described her cousin as becoming "withdrawn from her environment" (Tr. at 136) and exhibiting "excessive fear" (Tr. at 139-40). O.H. also stopped wanting to be touched. Tr. at 131.

According to Mr. Hashi, O.H. began sleeping irregularly after the April 2006 vaccinations. Tr. at 20- 22. She became lethargic about a week after the vaccinations. Tr. at 93. He said that she gradually lost interest in things she had previously enjoyed, like television. Tr. at 34.

Both witnesses testified that O.H.'s behavior regarding food changed after the April 2006 vaccinations. Her father stated that until April of 2006, O.H. was able to ask for foods that she wanted; though she was a picky eater and unskilled with utensils, she did manage to eat. Tr. at 28. After the vaccinations, however, Mr. Hashi stated that O.H. refused to eat foods she had previously enjoyed. She no longer asked for food; instead, her parents used pictures of food as a way to communicate with her. O.H. also lost the ability to use utensils at all. Tr. at 26-30. Ms. Hashi said that O.H. refused to eat, going so far as to pull any food in her mouth out and throw it away. Tr. at 132-33, 146-47. When O.H.'s parents became concerned, Dr. Stratton instructed them to force-

feed her. Mr. Hashi testified that he and his wife started to feed their daughter using a large syringe filled with mashed up food "about a week" after the vaccinations. Tr. at 29-30. This lasted for about a month, at which point O.H. began eating French fries and chips. Tr. at 26-30, 95-98. There is no evidence in the medical or telephone records that force-feeding was discussed or recommended.

In her capacity as babysitter, Ms. Hashi had firsthand experience with O.H.'s toileting problems. Although O.H. had never been toilet trained, after April 2006, she began smearing feces "on the walls or herself, the bed sheets, her face," sometimes "eat[ing] it or lick[ing] her fingers." Tr. at 140-41. Ms. Hashi was unsure of when exactly this behavior began, but said that "about a month or so [after the vaccinations] the feces became troublesome." Tr. at 172.

During direct examination, Mr. Hashi recalled that while O.H. experienced constipation before the April 2006 vaccinations, her problems increased about ten days after the shots. Tr. at 31-32. On cross examination, however, he testified that he did not notice O.H.'s constipation problems had worsened until three weeks to a month after the April 2006 vaccinations. Tr. at 98. In addition to being constipated, Mr. Hashi stated that O.H. grabbed her feces and smeared them on herself and the walls. He recalled that this behavior started about ten days after the April 2006 vaccinations and continued for about two years. Tr. at 31-32, 102-03.

When confronted with a consultation note from Dr. Dredge,[26] written in August of 2007,[27] stating that O.H. had begun playing with her feces only six to eight months earlier, Mr. Hashi insisted that this behavior started ten days after the vaccine and continued for a year. Tr. at 100-04. I note that on March 27, 2007, approximately eleven months after the allegedly aggravating vaccines, Dr. Neumeyer remarked that "[O.H.] has now began fecal smearing and has no attempts any more to communicate." Pet. Ex. 3, p. 37. O.H.'s IEP school records from November 2004 to June 2006 were filed as Petitioners' Exhibit 11. They do not contain any references to her smearing, eating, or licking her own feces, though her toileting habits are discussed throughout the school records. *See* Pet. Ex. 11.

Mr. Hashi stated that after the April 2006 vaccines, O.H.'s sensitivity to noise and light dramatically increased, and that she often covered her ears. Tr. at 19-20. Although O.H. had exhibited this behavior as early as 2004 (*see* Pet. Ex. 8, p. 6), Mr. Hashi said that the intensity of her reactions to noise changed after she received the April 2006 vaccines (Tr. at 92). Mr. Hashi also said that O.H.'s sensitivity to light began between ten and fourteen days after the April 2006 vaccination. Tr. at 23-26, 95. Ms. Hashi explained that O.H. became very sensitive to light and was prone to hiding herself

[26] This note was also signed by Dr. Sims, the attending physician.

[27] The transcript reflects that respondent's counsel referred to petitioners' Exhibit 21. This is an error. Petitioners' Exhibit 21 is a photograph of O.H. Instead, respondent's counsel was referring to petitioners' Exhibit 2.1. Petitioners' counsel's inconsistent and disorganized labeling of exhibits in this case has led to considerable confusion.

in dark places. Tr. at 136-37, 167-68. When O.H heard loud noises, she would hold her ears and run away. Tr. at 143-44. She also recalled that O.H. became more sensitive to water temperatures. Tr. at 141-42.

Mr. Hashi testified that after the vaccinations, O.H.'s jaw became misaligned. Tr. at 43-46. He and his wife first noticed the change "about a month" after she received the vaccine. Tr. at 104. He took O.H. to a dentist, who said she had TMJ.[28] Tr. at 105. He could not recall how much time passed between when he noticed her jaw had shifted and when O.H. went to the dentist. *Id.* This report is contradicted by other medical records.[29] In January 2008, nearly two years after the vaccinations in question, O.H. had not yet seen a dentist, according to information her parents provided to Dr. Neumeyer.[30]

Considered as a whole, the testimony indicated that within a month after receiving the April 2006 vaccinations, O.H.'s development had profoundly deteriorated. The medical records, however, present a very different picture of events. After the allegedly aggravating vaccines, O.H. did not return to her physician until more than a month had passed. There are no records of phone calls to her pediatrician describing any of the alarming symptoms presented in the Hashis' testimony. And, at the May 2006 appointment, O.H.'s parents did not recount any of the remarkable behavioral changes described in the testimony. *See* Pet. Ex. 7, p. 14.

O.H.'s school progress report from June of 2006 indicated that she had improved skills in recent months. *See* Pet. Ex. 11, p. 15. Her teachers did not report the dramatic behavioral and health changes that her father and cousin recounted. *See generally* Pet. Ex. 11.

When the symptoms described in the testimony appear in O.H.'s medical or school records (including running in circles around the table, smearing feces on herself and other surfaces, and refusing to eat), the time periods when they arose conflict with the testimony provided at the fact hearing. When the records are silent about symptoms, the symptoms described in the testimony are of a nature or severity (extreme and sudden sensitivity to light) that parents who took their child to her pediatrician for respiratory infections, sore throats, and eye redness likely would have mentioned such dramatic changes. Instead, there were no reports of these significant changes in behavior and onset of new symptoms at any of the health care visits after the vaccinations.

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[28] TMJ is a disorder involving the temporomandibular joint (the jaw). *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32d ed. 2012) at 1932-33.

[29] No dental records have been filed in this case.

[30] During a January 2008 LADDERS visit, Dr. Neumeyer noted that O.H. "has not been to a dentist yet." Pet. Ex. 3, p. 7. At the time, O.H. was six and a half years old, and a year and a half would have passed since Mr. Hashi said he noticed changes in O.H.'s jaw. In October of 2008, Dr. Neumeyer remarked that O.H. "[w]as at dentist 3 months ago and that went well," Pet. Ex. 3, p. 14 (indicating that O.H. did not have her first dental appointment until July of 2008, around her seventh birthday, and more than two years after the April 2006 vaccinations).

2. January 2007 Hospitalization.

O.H. was seen by Dr. William E. Butler at the Massachusetts General Hospital on January 4, 2007, to discuss the results of her December 29, 2006 magnetic resonance imaging ["MRI"] scan, which had revealed the appearance of an arachnoid cyst compressing the superior vermis of her cerebellum. Pet. Ex. 2.2, p. 2. Doctor Butler concluded that the cyst might be contributing to her gross motor imbalance.

On January 29, 2007, O.H. underwent surgery to decompress the cyst. Pet. Ex. 2.3, p. 5. Shortly thereafter, on February 5, 2007, her physical therapist noted that O.H.'s motor skills were improving. Pet. Ex. 2.2, p. 18.

C. O.H.'s More Recent Medical History.

1. Primary Care Visits.

Doctor Marc A. Rosenthal served as O.H.'s primary care physician beginning in October 2007 until about March 2008. *See generally*, Pet. Ex. 6. At O.H.'s second visit, which occurred on November 12, 2007, he expressed concerns about what Ms. Weged reported as O.H.'s "severe regression," noting that O.H. had no verbal language and did not follow general directions. *Id*., pp. 17-18. He was not convinced that autism was the most accurate diagnosis, but agreed that it defined her profile. *Id*., p. 18.

Mr. Hashi testified that he and his wife questioned whether the deterioration in O.H.'s behavior was related to the removal of the cyst. He reported that Dr. Rosenthal told him that the cyst removal had nothing to do with her behavior. Tr. at 38-39.

O.H. was seen by Dr. Rosenthal again on January 18, 2008 for behavioral changes. Petitioners reported that recently O.H. had become impulsively aggressive and appeared more irritated without apparent cause. Pet. Ex. 6, p. 11; *see also* Pet. Ex. 3, p. 7. Doctor Rosenthal remarked that Ms. Weged felt that O.H.'s aggression problems subsided after her cyst removal surgery, only to reemerge a few months later and had significantly increased in the "last few weeks." Pet. Ex. 6, p. 12.

During the evaluation, Dr. Rosenthal noted that O.H. exhibited self-injurious behavior, hand flapping, an inability or refusal to follow commands, and lacked "social regard." Pet. Ex. 6, p. 12. He also noted that O.H. had no history of current illness and attributed her behavioral changes to the "evolution of her developmental disorder/autism" and not to "a specific NEW cause." *Id*. (emphasis original). When Ms. Weged asked about having O.H. tested for heavy metals, Dr. Rosenthal refused to give her any names or numbers "given lack of [evidence] and potential for harm." *Id.* Presumably, he was referring to the lack of evidence of heavy metal poisoning, but an alternate reading suggests that he meant lack of evidence that treatment for "heavy metals" such as chelation therapy was effective in improving ASD symptoms.

2. Events Leading to Mitochondrial Disorder Diagnosis.

On December 13, 2006, before her cyst removal surgery, O.H. was evaluated at LADDERS. Pet. Ex. 3, pp. 1-2. Doctor Neumeyer noted that O.H. had continued to regress after the initial onset of regression at 18 months of age, and currently exhibited possible myopathy and proximal muscle weakness. She also discussed the strong possibility of a genetic and metabolic disorder underlying O.H.'s developmental problems. *Id*.

O.H. was subsequently evaluated at the Massachusetts General Hospital's Mitochondrial Disorders Clinic on August 15, 2007 by pediatric neurology resident Dr. Dredge and attending physician Dr. Sims. Pet. Ex. 2.1, pp. 20-22. They noted that O.H. had developed repetitive behaviors and stereotyped hand movements over the last few years and her parents were concerned that she was regressing. *Id*., p. 20. However, they indicated that O.H. had no history of frequent illnesses and, apart from O.H.'s initial regression, which is a common occurrence among autistic children, O.H. had not exhibited any "clear regression or loss of skills in the last couple of years." *Id*., p. 22.

Doctor Neumeyer authored a letter, dated October 25, 2007, indicating that O.H. had a notable family history of autism in that her paternal cousin and paternal uncle both had autism spectrum disorder. Pet. Ex. 3, p. 5. She also stated that O.H.'s muscle biopsy revealed "some nonspecific features with complex mitochondrial cristae and some subsarcolemmal clusters with enlarged mitochondria." *Id*.

On January 23, 2008, petitioners related their concerns of behavioral changes in O.H. to Dr. Neumeyer. Pet. Ex. 3, pp. 7-8. Petitioners were worried that O.H.'s language skills were worsening and felt that her behavior was similar to what was seen prior to the cyst removal. However, Dr. Neumeyer noted that Dr. Rosenthal had found no etiology for O.H.'s behavioral changes and there was no current basis for concluding that it was related to a re-accumulation of the cyst. *Id*.

On February 6, 2008, Dr. Sims discussed the results of O.H.'s earlier muscle biopsy with Ms. Weged, indicating that O.H. had a probable mitochondrial complex I enzyme deficiency and some abnormal cellular membrane findings as well as some enlarged mitochondria on the muscle biopsy. She also had a low selenium level. Pet. Ex. 2.1, pp. 17-18; Tr. at 39-42. Doctor Sims also noted that the Complex I deficiency was "an unusual phenotype for that as she has not episodic events and no real multiorgan system problems." Pet. Ex. 2.1, p. 18.

O.H. was treated with a "mitochondrial cocktail," which seemed to help with her behavioral problems. Tr. at 41-43. At a follow up visit on April 2, 2008, Dr. Sims noted that, in addition to a Complex I ETC deficiency, O.H. also had "clinical features including autism-like global developmental delay, developmental regression, behavioral disorder and GI dysmotility." Pet. Ex. 2.1, p. 13. Furthermore, she believed that O.H.'s selenium deficiency might be the cause of her myopathy. *Id*.

3. Most Recent Medical Records.

On July 9, 2008, shortly after O.H.'s seventh birthday, Dr. Sims reported that O.H. was in good health and showed "excellent and improving pre-language skills." Pet. Ex. 2.1, p. 10. By late January 2009, O.H. had made great strides in learning sign language. *Id*., p. 6. Later that year, petitioners took their daughter to Germany for a neurological evaluation. Tr. at 46-48. The neurologist told them that O.H. had seizures during REM sleep and prescribed medication that seemed to help. *See* Pet. Ex. 14; Tr. at 47-48.

On September 13, 2010, Dr. Timothy Buie wrote a letter to Dr. Stephen Nishiyama detailing a recent visit with O.H. Doctor Buie wrote that "there is a large cluster of Somalian families followed in the United States to have a significant history of mitochondrial dysfunction and autism that may well be related to environmental toxicity or an alternate sensitivity of this group of children." Pet. Ex. 5, p. 19. Doctor Buie believed that O.H. also had gastroesophageal reflux and constipation. *Id.*

As of November 2012, the date of the most recent record, O.H. remained nonverbal, and exhibited stereotyped vocal responses, sensitivity to noise, and difficulty in attending to environmental cues. Pet. Ex. 9, pp. 2, 6.

D. Analysis of Conflicting Evidence and Factual Findings.

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,* 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 (Cl. Ct. Spec. Mstr. Dec. 21, 1990).

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 O.H.'s behavior and other symptoms as occurring shortly after the vaccinations, I cannot accept their detailed and interlocking testimony about substantial changes that would have occurred more than eight years earlier in the absence of any contemporaneous reports supporting their testimony, and in the presence of conflicting statements in the existing contemporaneous records. Where there were reports of such changes in the existing medical records, the events described occurred or were reported to have occurred at times either preceding the vaccinations in question or months or years later than the witnesses described.

Under these circumstances, I find that O.H.'s behavior and health did not significantly decline after she received the April 2006 vaccinations. In the months following the allegedly aggravating vaccines, O.H.'s health remained much the same as it had been for the previous year—she was nonverbal, prone to stereotyped behaviors, and profoundly developmentally delayed. It was not until the fall of 2007, approximately a year and a half later, that O.H.'s parents and physicians became concerned about another regression. Therefore, I find that O.H. did not experience a significant deterioration in her behavior or health between the time she received the allegedly aggravating vaccinations and the fall of 2007.

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 any of my prior factual rulings 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, ***aff'd***, 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.

O.H. was diagnosed with autism in October 2004 and had been suffering from developmental problems long before she received the April 2006 vaccinations. *See* Pet. Ex. 8, pp. 5-12. Following her April 2006 vaccinations, she next sought medical care over a month later when she was seen for a URI. She was seen for a number of infections in the following year, received surgery for a brain cyst, and made gains in motor skills subsequent to the surgery. The first contemporaneous medical record to note regression was at a primary care visit in November 2007, 19 months after the April 2006 vaccinations. In a non-contemporaneous history recorded in January 2008, petitioners dated O.H.'s regression to a few months after the January 2007 surgery, placing onset of the regression about one year after the April 2006 vaccinations. I accept the contemporaneous account's conclusion that O.H. regressed again approximately a year and a half after the April 2006 vaccinations. Additionally, both Dr. Rosenthal and Dr. Neumeyer considered the progression of O.H.'s developmental problems as consistent with her autism diagnosis. *See* Pet. Exs. 6, p. 12; 2.1, p. 22.

Thus, based on my factual findings above, petitioners have failed to demonstrate that O.H.'s symptoms and behavior worsened within 18 months of the April 2006 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 O.H's condition was significantly aggravated by the vaccinations administered in April 2006. 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 proffer an opinion, based on the facts set forth herein, that the April 2006 vaccinations significantly aggravated O.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 based on the correct facts, that he or she can opine favorably that the vaccines significantly aggravated O.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
Chief Special Master