

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-1753V

Filed: December 1, 2009

TIM HOKKANEN and NANCY HOKKANEN,	)	
as parents and natural guardians,	)	
on behalf of their minor son,	)	TO BE PUBLISHED
ANDREW HOKKANEN	)	
	)	Statute of limitations; <u>Markovich</u> ;
Petitioners,	)	Autism Spectrum Disorder
	)	
v.	)	
	)	
SECRETARY OF THE DEPARTMENT	)	
OF HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	

Sheila A. Bjorklund, Minneapolis, MN, for Petitioners.

Voris E. Johnson, United States Department of Justice, Washington, D.C., for Respondent

## DECISION<sup>1</sup>

Lord, Special Master.

### I. INTRODUCTION AND SUMMARY

Mr. and Mrs. Hokkanen allege that their minor child, Andrew, developed an autism spectrum disorder as a result of certain childhood vaccines.<sup>2</sup> The issue presented is whether the

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<sup>1</sup> As provided by Vaccine Rule 18(b), each party has fourteen days within which to request the redaction “of any information furnished by that party (1) that is trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of timely objection, the entire document will be made publicly available.

<sup>2</sup> Petitioners characterize Andrew’s condition as “PDDNOS/autism.” See, e.g., Petitioners’ Response to Respondent’s Motion to Dismiss at 1. PDDNOS signifies Pervasive Developmental

Hokkanens' Petition was filed more than 36 months after the first symptom of Andrew's autism disorder. Petitioners assert that Andrew's vaccine injury was not "manifest" until "sometime after his three-year-old well child examination on or about April 13, 2001" and that the "first evidence of concern by any professional working with Andrew" was "in the fall of 2001," when his pre-school teachers were concerned about his behavior in class. Response at 6-7. Petitioners note that Andrew was not given the diagnosis of PDDNOS until early 2002. Id.

Andrew's medical records show that Andrew experienced a number of developmental problems in infancy and early childhood. By around 15 months, in July 1999, he was noted in treating physician records to be slow to speak. The medical records also noted delays by the age of 14 months in Andrew's motor skills. During this time period, three different treating physicians noted that Andrew suffered from language deficits, motor delays, and eating problems, including difficulty with food textures. Although Andrew was reported to have made progress in his development, the documented delays persisted, according to the records of treating professionals, through the time of his diagnosis.

Andrew's early symptoms, including his speech delay, appropriately commence the limitations period. The record contains medical literature as well as testimony admitted in the Omnibus Autism Proceeding (OAP) showing that speech delay is one symptom -- if not, indeed, the most prominent symptom -- of autism in children between the ages of one and three. The abundance and consistency of the expert evidence leave no doubt that the medical community would recognize speech delay as an early symptom of a subsequently diagnosed autistic disorder.

The expert evidence submitted by Petitioners, on the other hand, does not negate the significance of speech delay as an early symptom of autism but simply highlights the fact, which is indisputable, that a definitive diagnosis of autism is not possible based on speech delay alone. Clear and binding precedent instructs, however, that the symptoms necessary to support a diagnosis of autism need not be present to trigger the statute of limitations. Instead, we are to focus on the symptoms recognized by the medical community as first symptoms of autism in an individual who is later diagnosed. The expert evidence submitted by Petitioners does not contradict the fact that speech delay is among those symptoms.

At a status conference held on September 29, 2009, counsel for both parties agreed that the issue is ripe for decision and that no hearing concerning application of the statute of limitations is required. See Order, dated October 27, 2009. For the reasons stated below, the Petition is dismissed as untimely based on Andrew's medical history, the reliable expert evidence that speech delay is a recognized early symptom of autistic disorders, and the binding precedent regarding application of the statute of limitations in Vaccine Act proceedings.

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Disorder Not Otherwise Specified. See Nelson's Textbook of Pediatrics 133-35 (Robert Kliegman, M.D., et al. eds., 18th ed. 2007). For ease of reference, we use the terms "PDDNOS," "autism" and "autistic spectrum disorder" interchangeably.

## II. FACTUAL AND PROCEDURAL BACKGROUND

### A. The Petition

On July 22, 2003, Tim and Nancy Hokkanen (“Petitioners”) filed a Short-Form Autism Petition (hereinafter “Petition”) for Vaccine Compensation under the National Childhood Vaccine Injury Act (hereinafter “Vaccine Act” or the “Act”) pursuant to Autism General Order #1, which adopted the Master Autism Petition for Vaccine Compensation. Short-Form Autism Petition for Vaccine Compensation (hereinafter Pet.) at 1.<sup>3</sup> Petitioners alleged that Andrew developed autism “on or about April 13, 2001,” as a result of certain childhood vaccinations. Petitioner’s Response to Respondent’s Motion to Dismiss at 7, filed March 5, 2008 (“Response”).

### B. Pertinent Medical Background

We review the medical records in some detail to place the facts regarding the early symptoms of Andrew’s autistic disorder in appropriate perspective. We note at the outset, for the assistance of the reader, that medical evidence of Andrew’s condition through July 22, 2000, 36 months before the Petition was filed, is directly pertinent to the question of timeliness. Evidence that Andrew manifested symptoms of autism before July 22, 2000, indicates that the Petition was filed too late.

#### Medical evidence for 1998

Andrew was born on March 30, 1998. Pet’r Ex. 3 at 29. He was delivered by a cesarean section because labor “failed to progress.” *Id.* at 46. During delivery, Andrew’s “skull reportedly

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<sup>3</sup> The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §300aa of the Vaccine Act.

By electing to file a Short-Form Autism Petition for Vaccine Compensation Petitioners alleged that

[a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the “thimerosal” ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two.

Autism General Order #1 filed July 3, 2002, Exhibit A, Master Autism Petition for Vaccine Compensation at 2.

became wedged,” Pet’r ex. 6 at 4, and Andrew required resuscitation at birth, id. His APGAR scores were three at one minute and eight at five minutes. Pet’r Ex. 3 at 29.<sup>4</sup>

In a later evaluation based in part on a diagnostic interview with Andrew’s parents, Jeannie Gilfix, a licensed social worker, reported that:

Ms. Hokkanen was put on bed rest for the last month of the pregnancy due to high blood pressure. Ms. Hokkanen was taking the prescription medication Zoloft as well as medication to address her high blood pressure during the pregnancy. Ms. Hokkanen had a difficult delivery that resulted in a cesarean section birth. Andrew was not breathing for about one minute after his birth, but responded positively after that.

Pet’r Ex. 6 at 2.

In a subsequent evaluation, Ms. Gilfix noted further, “Miscellaneous information not reported in the initial report includes the fact that Andy was born jaundiced after a birth in which his skull reportedly became wedged.” Pet’r Ex. 6 at 4. Andrew’s medical records confirm that at eight days he was jaundiced and a “lag” was noted in his right eye. Pet’r Ex. 3 at 46. At five weeks Andrew had a “severe” papular rash on his face, neck, ears, upper chest and arms, as well as yellow scale on his eyebrows, chin and ears. Pet’r Ex. 3 at 54. He was prescribed an ointment containing 1% hydrocortisone. Id.

On March 30, 1998, the date of his birth, Andrew received his first Hepatitis B vaccination. Pet’r Ex. 3 at 51. He received two additional doses of the Hepatitis B vaccination on May 7, 1998, and October 9, 1998. Id. Andrew presented to his physician for a visit and received an inactivated polio vaccine, as well as the diphtheria-tetanus-acellular pertussis and haemophilus influenza b conjugate vaccinations. Pet’r Ex.3 at 51.<sup>5</sup> He received a DTaP, IPV, and Hib vaccination on August 27, 2009. Id.

### **Medical evidence for 1999**

On January 15, 2009, Andrew presented to his pediatrician for a visit and received a

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<sup>4</sup> An APGAR score is “a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, respiratory effort, muscle tone, reflex irritability, and color.” Dorland’s Illustrated Medical Dictionary 1670 (30th ed. 2003).

<sup>5</sup> The record reflects that Andrew received a tetramune vaccination, which is the trademark name for a preparation of the diphtheria-tetanus-acellular-pertussis (DTaP) vaccination. Dorland's Illustrated Medical Dictionary 1890 (30th ed.) See also Pet’r Ex. 3 at 51.

following vaccinations: Hepatitis B, diphtheria-pertussis-tetanus (DPT) and inactivated polio (IPV). Pet'r Ex. 3 at 66.

At his 15-month check up on July 14, 1999, Andrew's pediatrician, Sheldon Berkowitz, M.D., noted that Andrew is "A 15 ½ month-old overall in good health," but expressed a number of concerns, including:

"Diet: Still gagging fairly easily with food."

"Development: "Just been walking on his own for the last three weeks. Not saying any words but is babbling. Not using spoon or fork, but is drinking from a cup."

"Development: – continues to have slightly delayed speech and motor development – he is making progress on the motor, having not been walking at a year and now walking. Will want to watch this carefully. Speech is still delayed and I'm not hearing any actual words – if I'm not by 18-months of age, will want to go ahead and at least get an audiology evaluation." Pet'r Ex. 4 at 57 (emphasis added) .

In the same record, Andrew's pediatrician noted:

"Follow gross motor and speech development – if there is not significant progress so that he's starting to run and climb by 18-months and saying at least five words, I would like the mother to get back in touch. Otherwise, if he's doing well, we will just see him back at age two."

*Id.* at 58. In addition, the record states, "Continue to offer a wide variety of foods. If the gagging persists, mother is to get back in touch."<sup>6</sup> During his July 14, 2009 visit, Andrew received the DTaP, Varivax, measles-mumps-rubella (MMR) and oral polio (OPV) vaccinations. Pet'r Ex. 4 at 59.<sup>7</sup>

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<sup>6</sup> Mrs. Hokkanen, in her Affidavit filed May 6, 2008, stated that "not one of his physicians ever told us that they were concerned with [Andrew's] growth and development." She specifically stated, "Neither Dr. Berkowitz nor Dr. Burstein were concerned about Andrew's development." Pet'r Ex. 14 at 3. Mrs. Hokkanen's statement is not consistent with the medical records described herein. Medical records "warrant consideration as trustworthy evidence." Curcuras v. Sec'y of Dep't of Health & Human Services, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Moreover, because medical records are contemporaneous documentary evidence, conflicting oral testimony "deserves little weight." *Id.* (citing United States v. United States Gypsum Co., 333 U.S. 364, 396, 68 S.Ct. 525, 92 L.Ed. 746 (1948)).

<sup>7</sup> The Varivax vaccination is the trademark name for the varicella vaccination. See [http://www.merckvaccines.com/varivaxProductPage\\_frmst.html](http://www.merckvaccines.com/varivaxProductPage_frmst.html) (last checked on Nov. 2, 2009).

Andrew was not seen for a two-year well baby check up. Pet'r Ex. 4 at 16. We do know that the Hokkanens apparently later told Ms. Gilfix, the social worker who evaluated Andrew in 2002, that: "He said his first words around 14 months and walked alone 18 months of age." Pet'r Ex. 6 at 2; see also Pet'r Ex. 7 at 7 ("He walked alone at 18 months.") Most children "walk alone" by the age of 12 months. Nelson's Textbook of Pediatrics 44, Table 8-1 (18th ed. 2007).

On August 3, 1999, Andrew presented to Christy Sanford, M.D., at the Aspen Medical Group, as a 16-month-old, for "history of intermittent noisy breathing." Pet'r Ex. 4 at 3. Mrs. Hokkanen reported that Andrew "has had a difficult time handling textures. He seems easy to gag." Id.<sup>8</sup> Dr. Sanford also noted that Andrew would sometimes arch his back when drinking or taking a bottle. Id. The doctor noted "he was not heard to speak." Id. Dr. Sanford ordered a barium swallow to assist in diagnosing Andrew's "swallowing dysfunction." Id. at 4; Pet'r Ex. 9 at 148. On August 5, 1999, Andrew underwent an esophogram to evaluate: "Swallowing dysfunction, patient with wheezing." Pet'r Ex. 9 at 3. "No gastroesophageal reflux was observed during the examination." Id.

On August 13, 1999, Andrew presented to Dr. Sanford regarding questions that he was "tongue-tied." Pet'r Ex. 4 at 5. He was noted to have a "short frenulum." Id.<sup>9</sup> The doctor noted that Andrew "also has been difficult to feed in so far as he seems very sensitive to textures." Id. In addition, "He also is not speaking much." Id. He was treated for suspected gastro-esophageal reflux disease. Zantac appeared to resolve his symptoms. Id. Andrew was seen by Dr. Sanford for vomiting and a chief complaint of "ear pain" on December 7, 1999. Pet'r Ex. 4 at 7.

On December 28, 1999, at age 20 months, Andrew was seen by Dr. Lawrence Burstein at Children's Hospitals and Clinics. Pet'r Ex. 5 at 16. Dr. Burstein noted that Andrew "was born by cesarean section following a prolonged labor and some distress." Id. See also Ex. 12 at 45 ("Fetal stress was reported during labor."); Pet'r Ex. 13 at 46. Dr. Burstein noted further, "Developmentally, he has always made progress. He began walking at 14 months. He now has about six words." Dr. Burstein noted, "There are no concerns regarding vision or hearing and he has had no problems with cardiorespiratory or gastrointestinal systems." Id.

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<sup>8</sup> "Many ASD [autism spectrum disorder] children are highly attuned or even painfully sensitive to certain sounds, texture, tastes, and smells." National Institute of Mental Health, "Autism Spectrum Disorders (Pervasive Developmental Disorders) at Court Ex. 2 at 11. Sensitivity to food textures, causing feeding difficulties, is one of "[m]any other medical symptoms or disorders [] commonly reported in children with autism." Newschaffer, et al., "The Epidemiology of Autism Spectrum Disorders," *Annu. Rev. Public Health* 2007, 28:235-58 (2007). Court Ex. 1 at 4.

<sup>9</sup> The lingual frenulum is the vertical fold of mucous membrane attaching the tongue to the floor of the mouth. Dorland's Illustrated Medical Dictionary 30<sup>th</sup> ed. at 739. An "extremely tight" lingual frenulum (tongue-tie) may affect feeding and speech articulation, but will not prevent the acquisition of language abilities." Nelson's at 1521. A "short" lingual frenulum may be worrisome to parents but only rarely interferes with eating or speech . . . ." Id. at 1539.

On a Multidisciplinary Care Plan Review dated December 30, 1999, concurrent with Andrew's discharge from the hospital following his first seizure, the Hokkanens apparently answered "No" to the question "Do you have concerns about your child's growth and development?" Pet'r Ex. 9 at 30. They also stated that his Verbalization was "Age appropriate." When asked "How does your child communicate his/her needs?" they apparently responded "arching back to nap – cries." Id. Under Nutrition they indicated Andrew had no special likes and dislikes and that none of the conditions listed on the form were present, including no "Unusual eating patterns." Id.

### **Medical evidence for 2000**

Andrew was seen by Dr. Berkowitz on January 3, 2000, aged 21 months, to follow up on a recent hospitalization (December 29, 1999), for a urinary tract infection, a seizure and "primarily now because his vomiting continues." Pet'r Ex. 4 at 7-8. A history taken during a 2002 evaluation noted that, "Andrew's medical history is significant for ear infections, a later circumcision around two years of age due to a bladder issue, and atypical seizures at 18 months, 2 years, and 2 ½ years of age when he had both a viral and bacterial infection." Pet'r Ex. 6 at 2.

Petitioners reported that Andrew was seen again by his neurologist, Dr. Burstein, in January 2000 and found to have "undeveloped tissues in the right pre-frontal cortex." Pet'r Ex. 6 at 2; see also Pet'r Ex. 7 at 7 for more medical history. During his hospitalization, on December 28, 1999, for a urinary tract infection (UTI) and seizures, Andrew was tested extensively and discharged on Tegretol, which his mother initially did not give "because of the vomiting for the last four days." Id. at 8-9. In an addendum to his report of the visit on January 3, 2000, Dr. Berkowitz stated:

I should also mention that when I looked in his chart at his 15-month checkup in July, he was noted to have slight developmental delay with both speech and motor development. I didn't get a lot more history on that today but will want to go through that, especially in view of the seizure now. The abnormality in the frontal lobe found on CT according to what Dr. Sanford told me is thought to be just a developmental anomaly and probably unrelated to his current problems. I do note that in Dr. Burstein's consultation, that supposedly he started walking at 14-months and that he was saying about six words at this point.

Id. at 10.

On May 5, 2000, Andrew was seen by Dr. Burstein "for follow-up of his seizure and abnormal cranial MRI scan." Pet'r Ex. 5 at 3. It is noted that his health "in general has been good, apart from some upper respiratory infections and sinus infections. He continues to be

followed by Dr. Reinberg for urology.” Id. Dr. Burstein also noted that Andrew “has been delayed with his speech development. He is now saying several words but not forming phrases. He will mainly make a variety of different sounds.” Id. Dr. Burstein recommended that Andrew have an audiogram and speech evaluation for further assessment of his “speech delay.” Id. Dr. Burstein noted that Andrew had a repeat cranial MRI scan on April 20, 2000, that this test “again demonstrated a right frontal lesion,” unchanged from a previous study in December (1999). Id. The doctor recommended repeating the brain scan in about six months. Id. at 004.

At this time, Andrew was about 25 months old, saying “several” words, as reported above. The average child speaks 10 to 15 words by age 18 months. Nelson’s Textbook of Pediatrics 44, Table 8-1 (18th ed. 2007). By age two, the child who is not making “word combinations” is recognized as having possible language problems. Nelson’s Textbook of Pediatrics 159, Table 32-5 (18th ed. 2007). “After the realization that words can stand for things occurs, a child’s vocabulary balloons from 10-15 words at 18 mo[nths] to between 50 and 100 at 2 yr.” Nelson at 49. When Andrew reached age two years and four months, having made “very nice progress with his development over the last couple of months,” he was “speaking at least sixty words” and was “able to form some phrases.” Pet’r Ex. 5 at 5. In short, his speech development appears to have been consistently delayed. See also infra, at p. 10 and note 12. (another treating physician, Dr. Berkowitz, reported that Andrew at 28 months was saying only 30 words. Pet’r Ex. 4 at 17.)

Andrew apparently underwent an evaluation by “Speech-Language Pathology Services” on June 30, 2000, but the record contains no report of that evaluation. Pet’r Ex. 9 at 113.

On July 12, 2000, Andrew was seen at age two years three months for evaluation of a bug bite. Pet’r Ex. 4 a 14. It was noted at that time that he had been taken to the emergency room three and one-half weeks previously (June 19, 2000) for a seizure “associated with fever.” Id. He was taking Tegretol. A cytoscopy and circumcision was canceled and rescheduled for August 8, 2000. It was also noted that the patient had missed his two-year checkup. Id.

In a pre-operative examination by Dr. Berkowitz on August 2, 2000, it was noted that Andrew was recovering from a cold, a slight cough, a runny nose and congestion. Id. at 16. He was scheduled to have a cytoscopy and circumcision. “This is all being done to follow-up a UTI that he had at 1 3/4 years of age, as well as a possible neurogenic bladder.” Id. It was noted that Andrew had a second seizure on June 19, 2000. Id. The same report noted under “Development” that Andrew, at age two years four months, was saying “at least 30 words, putting occasional 2 words together – this is significantly increased over the last 2 months.” Id. at 17 (emphasis added).<sup>10</sup>

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<sup>10</sup> On average, children attain this level of language development by the age of 19 months. Nelson at 44, Table 8-1 (noting that on average children aged 19 months speak two-word sentences and are “Beginning grammaticization, corresponds with 50+ word vocabulary.”)

When admitted to the hospital on August 8, 2000, for his cytoscopy and circumcision, Andrew was diagnosed with (1) neurogenic bladder with diverticula; (2) status post urinary tract infection; and (3) seizure disorder. Pet'r Ex. 9 at 93.

In a Registration Form for pre-school dated March 19, 2001, when asked whether Andrew had any medical problems of which the program should be aware, Ms. Hokkanen reported: "He has a small patch of unformed brain tissue on his right prefrontal cortex. This area affects his ability to sense where his head is when crawling – he bumps his head." Pet'r Ex. 12 at 3. She also reported Andrew's "Bladder insufficiency and diverticuli," his hospitalization for "Febrile seizures, virus, bacterial infection (combined)," as well as eczema, bladder infection, asthma ("related to reflux"), and swollen glands. Id. at 5.

### **Medical evidence for 2001**

On April 13, 2001, Dr. Berkowitz saw Andrew at age three. He noted that he had no further seizures since December of 1999 and June of 2000, and that, apart from "some bad breath and runny nose on and off for the last couple of weeks," he was "doing well." Pet'r Ex.4 at 23. Under the notation marked "Diet," Dr. Berkowitz stated that Andrew was: "Still is a little fussy on certain textures, and mother chops stuff up pretty small, but eating well rounded diet." Id. In a letter dated April 13, 2001, Dr. Berkowitz reported to Dr. Burstein that Andrew had been seizure free since being taken off Tegretol and, "At the time of this physical he is growing well and developing normally[.]" Pet'r Ex. 5 at 12.

By his four-year check-up, Andrew had "presumed pervasive developmental disorder," based on behavioral abnormalities. Pet'r Ex. 4 at 26. In a letter dated May 3, 2002, reporting on his follow-up with Andrew for "his seizures and right frontal intracerebral abnormality," Dr. Burstein stated: "He has had escalating problems with behaviors since 18 months of age." Pet'r Ex. 5 at 8.

### **Medical evidence for 2002**

An evaluation by Minneapolis Public Schools dated April 29, 2002, under the heading "Developmental History," stated: "Nancy Hokkanen, reported that some speech developmental milestones were achieved as expected. He did not point and has experienced some regressions." Pet'r Ex. 7 at 12; Pet'r Ex. 12 at 50.<sup>11</sup>

The same evaluation stated that Mrs. Hokkanen reported that Andrew: "has improved over the last six months." Pet'r Ex. 12 at 50. The same evaluator noted, "Andrew's parent's report indicated that Andrew's responses to movement, visual, taste-smell and auditory inputs

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<sup>11</sup> "Regression in language and social skills (autistic regression) occurs in approximately 30% of children with autism, usually before 2 yr of age." Nelson's at 156.

were not typical.” Pet’r Ex. 12 at 54. His parents also noted Andrew’s unusual dietary habits and that he “frequently gags on food with slimy textures.” Id.

A Comprehensive Evaluation Report dated April 29, 2002, noted that Ms. Hokkanen had “several concerns” about Andrew’s behavior, and that he had received a provisional diagnosis of PPDNOS, after an evaluation in February 2002, which had subsequently been changed to a diagnosis of autism. Pet’r Ex. 12 at 41-42.

A Pre-Sedation Assessment of Andrew on May 3, 2002, in connection with Andrew’s repeat MRI noted under Diagnosis: “seizures/developmental delay.” Pet’r Ex. 9 at 139; see also Pet’r Ex. 140.

In an evaluation by Associated Speech & Language Specialists, LLC, on July 25, 2002, it was noted that Andrew “has no history of Otitis Media or other relevant illnesses or injuries.” This evaluation found that “Andrew’s Receptive Language Skills are delayed.” Pet’r Ex. 10 at 2. The evaluator also stated that based on a score within “1 standard deviation of the mean,” “Andrew’s receptive language abilities are within the range of average in comparison to children of his same age.” Id. The same evaluation states that “Andrew’s expressive language skills are also significantly delayed” id. at 3, and that based on a score 1.5 standard deviations below the mean, “Andrew’s expressive language skills are mildly to moderately delayed in comparison to same-age peers.” Id. at 3.

On an evaluation from Pfeiffer Treatment Center dated November 19, 2002, it was noted under “Developmental Milestones,” that, with respect to “Motor Development” Andrew exhibited “delayed sitting never crawled.” Pet’r Ex. 8 at 8. Under “Speech,” it is noted that Andrew started to speak at age “6 months” stopped at age “8 months” and started again at age “14 months.” The report from Pfeiffer noted further that at “6 months quit saying mama dada – returned 18 months later.” Id. at 17.<sup>12</sup>

### **C. Proceedings Regarding Timeliness of the Petition**

On January 29, 2008, Respondent (hereinafter “Respondent” or the “Secretary”) filed a Motion to Dismiss (hereinafter “Respondent’s Motion”) alleging that the Petition was filed outside the statutorily prescribed limitations period. Respondent’s Motion to Dismiss (Resp’t

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<sup>12</sup> In the report of his five-year check on March 8, 2003, it was again noted by Dr. Sanford that “Andrew was delayed somewhat in development of speech.” Pet’r Ex. 4 at 46. “It is also noted in the chart review that he appeared unusually sensitive to textures in the diet and was fairly fussy about food . . .” Id. Based on the entire record, including Dr. Sanford’s treatment notes, see supra at 6, the special master rejects the suggestion made repeatedly by Petitioners that Andrew’s eating problems were attributable to gastro-esophageal reflux disorder (GERD) and resolved with medication. See, e.g., Petitioners’ View at 10.

Mot.) at 1. The Secretary asserted that the first symptom or manifestation of onset of Andrew's alleged vaccine-related injury occurred no later than October 1999, "but most likely occurred at some point between July 1999 and October 1999." Id. at 2. The Secretary based this assertion in part on treating physician records from Dr. Sanford, who examined Andrew for the complaint of "intermittent noisy breathing," on August 3, 1999. Id. The Respondent's Motion states further that during that visit Mrs. Hokkanen reported to Dr. Sanford that Andrew would choke while drinking, "'had 'a difficult time handling textures,' and would sometimes arch his back when using a bottle.'" Id. According to Respondent's Motion, Andrew returned to Dr. Sanford on August 13, 1999, due to concerns that he might be tongue-tied. Id. Dr. Sanford noted, according to the Respondent's Motion, that Andrew had "'been difficult to feed in so far as he seem[ed] very sensitive to textures' and was not speaking much." Id. at 2-3.

Respondent also relied on the records of Sheldon Berkowitz, M.D., who treated Andrew following the child's hospitalization for seizures. According to Respondent's Motion, Dr. Berkowitz reported on January 3, 2000, that Andrew's chart documented "'slight developmental delay with both speech and motor development'" as of Andrew's 15-month checkup in July 1999. Respondent's Motion at 3.

Respondent also noted that on May 5, 2000, Andrew was seen at the Noran Neurological Clinic in Minneapolis, by Lawrence Burstein, M.D. Id. at 3. Dr. Burstein, the Secretary asserted, "noted that Andrew had been delayed in his speech development, was 'saying several words but not forming phrases,' and 'would mainly make a variety of different sounds.'" Id. Dr. Burstein, according to Respondent's Motion, recommended an evaluation for further assessment of Andrew's alleged speech delay. Id. On May 3, 2002, Dr. Burstein reported that Andrew had been diagnosed with autism and had experienced "'escalating problems with behaviors since eighteen-months of age,'" or October 1999. Id.

The Secretary maintained that, using the date of October 1999 as a trigger for the statute of limitations, the Petition was filed more than "nine months after the expiration of the statutorily prescribed limitations period, as set forth in Section 16(a)(2)" of the Act. Id. at 1.

Petitioners filed a Response (hereinafter "Response") on March 5, 2008. Petitioners contended that the Secretary's references to Andrew's medical records were mere "snippets" taken out of context. Response at 3. Petitioners asserted that Andrew's pediatrician assessed his growth and development as normal at each of his physical examinations "up to and including his three-year-old exam on May 13, 2001." Id. at 4. Petitioners attached no significance to the notation in the records regarding the developmental delays documented at Andrew's 15-month check-up because his speech was noted to improve thereafter, and he was characterized at 3 years as "overall in good health and with normal G&D." Id. at 4-5 (emphasis in original).

Petitioners contended that Andrew's symptoms of choking while drinking, difficulty with food textures, arching of the back, and delayed speech were not early signs of an autistic spectrum disorder. Response at 6. They noted the alleged absence of "expert authority,

contemporaneous medical literature, or the contemporaneous opinions of Andrew’s medical treaters,” regarding the import of these symptoms. Id. Petitioners stated that Andrew’s physician blamed “gastroesophageal reflux with associated respiratory symptoms” and that Zantac resolved them. Id. Petitioners also noted that during this same time frame Andrew was treated for febrile seizure and bouts of otitis media. Id.

Petitioners asserted that Andrew’s vaccine injury was not “manifest,” until “sometime after his three-year-old well child examination on or about April 13, 2001.” Response at 6-7. Petitioners stated that the “first evidence of concern by any professional working with Andrew” was “in the fall of 2001,” when his pre-school teachers were concerned about his behavior in class. Id. Petitioners noted that Andrew was not given the diagnosis of PDDNOS until early 2002. Id.

Petitioners recognized that Andrew’s pediatrician commented “in January 2000 about a possible slight delay in speech at or around his 15-month mark,” but commented that “all concerns appeared to have resolved.” Response at 8. In support, they cited the following items: (1) a notation in Andrew’s “29-month examination and a three-year examination” in which the pediatrician stated that Andrew’s speech development was “significantly increased;” and (2) a notation from Andrew’s neurologist in September 2000 that Andrew was “now speaking at least 60 words and able to form phrases, good comprehension of language, no deterioration in his abilities.” Id. Petitioners contended that “the clock for Andrew’s claim would not start to run until September 2001 when he started pre-school,” and that his Petition, filed on July 22, 2003, was therefore timely. Id. at 9.

On July 7, 2009, the special master issued an Order directing the parties, if they so choose, to file any expert evidence regarding the timeliness issues on or before Monday, August 3, 2009.<sup>13</sup> Respondent filed additional evidence on August 3, 2009, consisting of medical literature and expert testimony admitted in the OAP. Notice of Filing, August 3, 2009. Petitioners filed a Status Report on August 3, 2009 (hereinafter “Status Report”), along with

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<sup>13</sup> Specifically, the July 7, 2009, Order required the parties to file, if they so chose, any additional expert evidence:

- (1) supporting their respective positions regarding the event that constitutes the first symptom or manifestation of petitioner’s autism spectrum disorder; and/or
- (2) bearing directly on the question of what events are generally considered by the medical profession to constitute the first symptoms or manifestations of onset of an autism spectrum disorder. See 42 U.S.C. 300aa-16(a)(2) (emphasis in original). The parties are not expected to retain experts for this purpose, but are instead encouraged to submit evidence admitted in the Omnibus Autism Proceedings (OAP) and/or obtained from other reliable sources readily available to the parties.

medical literature and expert testimony admitted in the OAP. Status Report, August 3, 2009.

By order dated November 20, 2009, the special master filed three exhibits (Court's Exhibits) into the record that have been used in the special master's consideration of the instant decision. Order dated November 20, 2009.<sup>14</sup> . Petitioners responded to the filing of the Court's Exhibits in a document entitled "Petitioners' View of the Recently Filed Court's Exhibits" (hereinafter "Petitioners' View").

In their response to the Court's Exhibits, Petitioners reiterated their position that delayed speech cannot be used to commence running of the statute of limitations. Instead, Petitioners insisted that the first symptom of an autistic disorder cannot be identified unless an individual exhibits developmental impairment in three areas: (1) social communication, (2) social problems, and (3) repetitive patterns of behavior. See Petitioners' View at 6-8. As stated herein, these factors, according to the expert testimony cited, are required for definitive diagnosis of autism. Because we are concerned with signs and symptoms of a disorder, not with diagnosis of the disorder, the special master declines to adopt the approach suggested by Petitioners.

Petitioners raised additional objections to the Court's Exhibits. Petitioners noted what "appears to be a marking" placed on Court Exhibit 1. See Petitioners' View at 9. The marking should not have been included in the exhibit as it was not so marked in the original, however, the special master does not perceive any "real danger" from the existence of this marking. Id. The article says what it says, whether or not it is marked. Speculation about how "the Court may interpret" evidence based on this apparent marking does not persuade us of the "danger." The special master has attempted to set forth herein, with some precision and in sufficient detail to enable meaningful review, the conclusions reached based on all of the evidence of record, and the rationale for those conclusions. If the special master has succeeded in articulating the rationale for this decision and in compiling a record on which the conclusions can be effectively reviewed, a marking that does not in any way obscure the document in question should be of minimal concern.<sup>15</sup>

Petitioners also objected that Court Exhibit 2 is not a peer reviewed, scientific paper. See Petitioners' View at 10. This is true; however, the exhibit was not introduced to establish

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<sup>14</sup> Special masters traditionally have supplemented the record where necessary and appropriate and, in accordance with due process, having provided the parties an opportunity to review and respond to the court's exhibits. See generally, Snyder ex rel. Snyder v. Sec'y of Dep't of Health & Human Services, 88 Fed. Cl. 706, 713-14, 2009 WL 2517755 (2009) (noting the legislative history establishing the special masters' "inquisitorial" role under the Vaccine Act.)

<sup>15</sup> Petitioners chided the special master for stating, in a decision in another case, that speech delay is a prominent symptom of autism in children between the ages of one and three. See Petitioners' View at 9-10 ("This is a gross misstatement and misinterpretation of the medical evidence.") The fact that the special master has reached the same conclusion in two different decisions does not invalidate that conclusion, if it is supported by the evidence in each case.

scientific facts. Court Exhibit 2 was entered into the record to illustrate that information concerning the role of speech delay in early identification of autism has been widely disseminated not only in the medical community but to the public at large. The widespread recognition of delayed speech as an early sign of autism makes it logical to use medically documented speech delay as one event that may, in an appropriate case, determine the commencement of the limitations period.<sup>16</sup>

**D. Evidence Regarding Speech Delay As An Early Symptom Of Autism Recognized in the Medical Community**

**PETITIONERS' EXPERT EVIDENCE**

The evidence submitted by Petitioners is noted below (see Petitioners' Status Report at 3-8 for complete citations to medical expert evidence submitted by Petitioners). This summary highlights the evidence submitted by Petitioners that appeared to be most pertinent to the question posed by Markovich v. Sec'y of Dep't of Health and Human Services, 477 F.3d 1353 (2007). All of the evidence submitted by Petitioners has been considered and is addressed by the Discussion below, see infra at 25.

**Petitioners' Medical Literature**

- **Diagnostic and Statistical Manual of Mental Disorders**: Abnormal development in three areas, social interaction, communication, and activity, is necessary to diagnose autism, and the manifestations of the disorder vary greatly. Periods of developmental regression may be observed in normal development as well as in individuals with autistic disorders. Pet'r Ex. 15 at 3.
- **Autism**: MayoClinic.com: Children with autism generally have problems in three areas of development, "social interaction, language and behavior." Pet'r Ex. 16 at 1.
- **Recognition of Autism Before Age 2 Years**, Chris Plauche Johnson: Diagnosing autism is difficult because "there are no pathognomonic clinical signs," and the DSM [Diagnostic and Statistical Manual of Mental Disorders]

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<sup>16</sup> Petitioners also objected (see Petitioners' View at 11), that the title page and publication information were omitted from Court Exhibit 3. That omission was corrected by a supplemental filing. We note that the entire exhibit consists of a few pages from a standard medical textbook, appropriate for judicial notice, in any event. See Hines v. Sec'y of Dep't of Health & Human Services, 21 Cl. Ct. 634 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991).

criteria serve as the “gold standard” for making a clinical diagnosis. Among the “four possible DSM-IV criteria” that may be applicable to children younger than 3 years of age is “Delay in or total lack of the development of spoken language.” There is currently no standardized autism-specific screening test for children younger than 18 months. Pet’r Ex. 17 at 1-2.

- **Language Screening in the Pediatric Office Setting**, Robert L. Schum, Ph.D.: “children who have autistic spectrum disorders usually show a pattern of language disorder as a key component of their impairment; however, the “pediatrician should be careful not to prematurely diagnose the child’s problem” before a specialist’s evaluation, “because autism is such a publicly recognized disorder, it is a common mistake for parents, and some professionals to assume that an early language disorder automatically signals autism.” Pet’r Ex. 18 at 9.
- **Language Disorders in Children: Classification and Clinical Syndromes**,” Mark D. Simms, M.D., MPH: Language delay in children is up to 17% at 24 months of age, and the cause varies, the most common being mental retardation. Pet’r Ex. 19 at 1.
- **The Onset of Autism: Patterns of Symptom Emergence in the First Years of Life**, Sally Ozonoff *et al.*,: Neither parent report nor home video analysis can be considered a gold standard method of documenting whether a child displayed early signs of autism. Pet’r Ex. 20 at 4.<sup>17</sup>

### **Petitioners’ Expert Testimony From the OAP**

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<sup>17</sup> In the same article quoted by Petitioners, Dr. Ozonoff *et al.*, noted two traditional patterns of autism onset. In the first prototype, “The most common initial symptom recognized by parents is delayed speech development . . . .” Pet’r Ex. 20 at 1 (citing De Giacomo & Fombonne, 1998). The second onset pattern identified by Dr. Ozonoff, regressive autism, involves what appears to be normal development until the second year of life when children “lose skills that they had previously acquired, accompanied by the onset of autistic symptoms.” *Id.* Dr. Ozonoff’s comments concerning the difficulty of using videotapes to determine onset relate to regressive autism. *Id.*

Dr. Ozonoff notes further that mixed patterns of onset are common. In one study of speech loss, for example, “over two-thirds of their sample with regression were already delayed in their language acquisition prior to the loss of skills.” *Id.* at 323. In another study, “two thirds of subjects with regression had some indication of delayed language or social development prior to the onset of their regression.” *Id.*

**Testimony from the Mead/King Test Case**<sup>18</sup>

**Testimony of Dr. Marcel Kinsbourne,**

Pet'r Ex. 21 at 22 (King/Mead Trial Tr. at 781):

There are different outcomes in children whose autism emerges gradually, “which is the usual situation,” and children who regress into an autistic state. (King/Mead Trial Tr. at 781).

Pet'r Ex. 21 at 25-48 (King/Mead Trial Tr. at 784-807):

Further discussion of regression.

**Testimony of Dr. Elizabeth Mumper:**

Pet'r Ex. 22 at 101 (King/Mead Trial Tr. at 1220):

The pediatrician is taught to ask questions, and at each monthly visit there are certain milestones you expect to see, and if you start seeing a pattern emerge where a child is delayed in speech, for example, or delayed in a motor skill, then you have to track that more carefully.

Parents' reports of developmental milestones fade “as the kids get older.”

Pet'r Ex. 22 at 102 (King/Mead Trial Tr. at 1221):

“In my population clear regression is in 50.6 percent of the kids.”

Pet'r Ex. 22 at 103 (King/Mead Trial Tr. at 1222):

“Classic autism, I'm more likely to find problems very early on. In classic autism, I will frequently get the story that the mom with babe in arms, you know, very early on in the first few weeks felt like the child didn't look at her, you know, even within the first few weeks.”

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<sup>18</sup> See Transcripts from joint hearing in King v. Sec'y of Dep't of Health and Human Services, No. 03-584V, and Mead v. Sec'y of Dep't of Health and Human Services, No. 03-215V (“King/Mead”).

“Or we’ll hear, yeah, the doctor was worried, you know, he mentioned at the four-month checkup that my baby wasn’t rolling over, and you know, it didn’t happen until like five and a half months, and then at the six-month checkup he said he wasn’t sitting yet, and that didn’t happen until he was nine months old.

Pet’r Ex. 22 at 104 (King/Mead Trial Tr. at 1223):

So my clinical experiences that I’m more likely to get more of an early encephalopathic picture where something was contributing to this developmental delay. So that to me is a very clearly different story from the most frequent story that I hear.”

Pet’r Ex. 22 at 116 (King/Mead Trial Tr. at 1235):

Dr. Mumper testifies about her method for evaluating developmental problems.

Pet’r Ex. 22 at 117 (King/Mead Trial Tr. at 1236):

Further testimony on the application of differential diagnosis to children with “autistic features.”

Pet’r Ex. 22 at 119 (King/Mead Trial Tr. at 1238-39):

Then we typically ask about development and we try to do that in several different quadrants. We look at motor development both from a fine motor standpoint which involves things like whether the child can use a spoon or manipulate objects, to gross motor skills like running or climbing stairs to interpersonal skills and self-help skills like being able to dress himself, and looking at language.” (p. 1238-39)<sup>19</sup>

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<sup>19</sup> The following testimony by Dr. Mumper, appearing on the same page, was not indicated as significant by the Petitioners (see Status Report, Aug. 3, 2009 at 7):

So here we see under the language milestone . . . there is a category called ‘Development’ . . . in terms of language development you typically expect a child around 15 months of age to have somewhere in the neighborhood of eight to 15 words, and then one of the landmarks we look for is that a child should put two words together by 18 months.

Pet’r Ex. 22 at 120 (King/Mead Tr. at 1239).

Pet'r Ex. 22 at 120 (King/Mead Trial Tr. at 1239):

“There is obviously a wide range of normal, and many normal children don't put two words together until 20 months of age or even later, and as long as other issues are okay you might feel reassured to watch that child.”

Pet'r Ex. 22 at 122 (King/Mead Trial Tr. at 1241):

“I want to make the point that in children speech and language isn't just words. We look at speech and language all through the first year. Cooing should start in the three-to-four-to-five-month range. Then we look for babbling, these consonant sounds, and then we look for jargonizing, which is the sort of talking in a foreign language stuff. And so it's not just a matter of looking at the words at one year versus the words at two years. It's looking at the fact that the cooing and the razzing and the babbling and the jargonizing preceded that in the normal way.”

Pet'r Ex. 22 at 135 (King/Mead Trial Tr. at 1254):

It would seem that the first evidence would be related to the fact that the physician documented loss of words. Then they went on to get evaluations where more specific information was gotten that looked at developmental assessments, and looked for things like eye contact and stereotypic behaviors and stimming behaviors.”

Pet'r Ex. 22 at 185 (King/Mead Trial Tr. at 1304):

Describing a case where “the first mention in the medical records made of what you would identify as a potential sign or symptom of autism” is “[a]t the two-year checkup when he was noted to have lost his words.”

King/Mead Trial Tr. at 1483:

So again, I'm going to resist the idea that we can on a clinical basis make a definition of regressive autism by an arbitrary number.<sup>20</sup>

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<sup>20</sup> Petitioners omit the testimony preceding the indicated portion, which makes it even clearer that Dr. Mumper is describing only the diagnosis of regressive autism and not the “most common” onset

King/Mead Trial Tr. at 1484:

Further testimony on factors to be considered “to determine whether regression had occurred.

**Testimony of Dr. Michael Rutter:**

King/Mead Trial Tr. at 3250-51

Describes the diagnostic criteria for autism.

King/Mead Trial Tr. at 3253:

Testifies that the social and communicative features of autism “tend to be much earlier than the repetitive stereotype behavior [which] “become more obvious” in the preschool years.<sup>21</sup>

King/Mead Trial Tr. at 3259:

A child’s parents typically begin recognizing development problems in their autistic child “around about 18 to 24 months. It varies. Of course, it does vary, as one might expect, as to whether they had had an earlier child with autism or whether there are other autistic children whom they knew, but the recognition is usually around and about that age period.”

King/Mead Trial Tr. at 3260:

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of autism characterized (according to Petitioner’s expert Dr. Ozonoff, see note 17, supra) by “delayed speech development.” See also Kinsbourne testimony, supra at 16 (noting different outcomes in children whose autism emerges gradually, “which is the usual situation.” Dr. Mumper states: A 15-month-old child would be expected to have “anywhere between eight and 15 [words] typically, but if there is a child who developed language late, and only had three words, and then at some point in the future lost all of those words, that would be very concerning to me.” King/Mead Trial Tr. at 1483. Dr. Mumper’s testimony does not support the implication that a child must have shown regression in order to manifest symptoms of an autistic disorder. Even if it did, there is evidence in this record that Andrew in fact suffered regression in the period prior to July 23, 2000. See Pet’r Ex. 8 at 17.).

<sup>21</sup> Petitioners do not highlight Dr. Rutter’s testimony on the same page that, by definition, “Some aspect of the autistic features have to be evident by [age] three by the standard classification criteria, yes.” (p. 3253)

The first symptoms typically recognized by parents are “Quite varied. The communication problems and the lack of social reciprocity are often the first things to be picked up, but it can be quite a range of different things.”

### Expert Reports from the Mead/King Case<sup>22</sup>

#### Expert Report of Dr. Eric Fombonne, M.D., F.R.C. Pysch.:

##### Page 7 of Dr. Fombonne’s Expert Report:

Pervasive developmental disorders “vary from one individual to the other, within an individual according to age, and according to the overall level of functioning or of intelligence.”

##### Pages 8-9:

Describes diagnostic criteria for childhood autism.

##### Page 11:

The onset of Autistic Disorder is difficult to measure. The diagnostic criterion of the DSM-IV is that “onset” of some abnormalities must occur before the third birthday. Rather than being a direct measure of the onset of the disorder, this criterion refers to the time at which parents become aware that the development of their child is not entirely right. Age of parental recognition is influenced by several factors that pertain to the child’s disorder, as well as to other contextual factors. For example, children who have autism and severe mental retardation are more likely to be identified as abnormal by their parents at an earlier age because the child fails very early in his development to achieve some important milestones (i.e., sitting or walking) that are hard to miss. Other studies have shown that when the autistic child is not the parents’ first-born, the parents’ recognition of autistic symptoms occurs earlier, as they have gained more experience about normal childhood development through their first child; they know what to expect; and they are more quick to

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<sup>22</sup> We note that Petitioners and Respondent have chosen to present evidence from several of the same experts, including Drs. Rutter and Fombonne. As a result, there can be no dispute as to the qualifications of these experts to opine authoritatively as to the early symptoms of autism.

recognize deviance or delay in the development of their subsequent child (De Giacomo & Fombonne, 1998). As in many disorders in medicine (such as cancer), it is therefore likely that the onset of the disorder occurs long before the age at which the first symptoms become manifest to parental eyes.

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Page 12:

“Analysis of home videos and of first birthday parties have allowed early developmental abnormalities to be identified at the end of the first year of life, which characterize children later diagnosed with autism, and that separate them from both typically developing peers and non autistic mentally retarded controls . . . At 12 months of age, children later diagnosed with autism were more abnormal than control children in such behavior as looking at faces, orientation to their name, communicative babbling, and poorer joint attention behavior. . . . [S]tudies . . . have since confirmed that abnormalities can be detected at 12 months of age in eye contact and visual tracking, social orienting, imitation, social interest and smiling, fixation of objects, and motor and language skills. . . These abnormalities may or may not be recognized by parents at the time.” p 12.

• **Expert Report of Michael Rutter, M.D.**

Page 1 of Dr. Rutter’s Expert Report:

Regarding diagnostic criteria for autism, functioning in the “three main areas of symptomatology that become manifest during the first three years of life” “is not just delayed in relation to what is expected in normal development but is abnormal, or deviant, in quality.”

Page 5:

Precise “boundaries of the diagnostic concept remain somewhat uncertain.” Dr. Rutter testifies that diagnosis of autism can be uncertain well into the childhood years and beyond.

Page 30:

“Because retrospective recall is likely to be influenced by later knowledge, one must expect that the reported age at first parental

concern may well be earlier than was actually the case at the time.”<sup>23</sup>

### **RESPONDENT’S EXPERT EVIDENCE**

The following materials were among those submitted by Respondent to establish the first signs of autism disorder recognized in the medical community:

#### **Respondent’s Medical Literature**

Rhiannon J. Luyster et al., “Language Assessment and Development in Toddlers with Autism Spectrum Disorders,” 38 J. Autism Dev. Disord. 1426 (2008) (Resp’t Ex. A at 1):

Delays and deficits in language acquisition are among the key diagnostic criteria for autism spectrum disorders (American Psychiatric Association 1994), and the absence of first words and phrases is the foremost reason reported by caregivers of children with ASD for their initial concern about their child’s development (DeGiacomo and Fombonne 1998; Wetherby et al. 2004).

Rebecca J. Landa, “Diagnosis of autism spectrum disorders in the first 3 years of life,” 4(3) Nature Clinical Practice Neur. 138 (March 2008) (Resp’t Ex. B at 2):

Parental concerns that a child has an ASD can arise as early as the first year of life, but they are most likely to arise when a child who is later diagnosed with an ASD is at a mean age of 18 months. Approximately 80% of parents of children with ASDs notice abnormalities in their child

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<sup>23</sup> Petitioners do not highlight the sentence immediately following, which states: “Nevertheless, in spite of that, the data reported by Fombonne and Chakrabarti on three separate samples all reported a mean age of about 19 months.”

Petitioners also quote paragraph 54 of Dr. Rutter’s report as stating “home videos are not reliable.” Petitioners’ Status Report at 8. The special master does not find that phrase in paragraph 54 or elsewhere in Dr. Rutter’s report. Dr. Rutter’s report does, however, question the usefulness of these sources as tools to identify the “Early manifestations of ASD.” See King v. Sec’y of Dep’t of Health and Human Services, No. 05-834, Resp’t Ex. GG at ¶54. The pertinence of this and similar expert evidence submitted by Petitioners is unclear, since no videotapes of Andrew have been entered into evidence in this case. In any event, the special master’s findings are based strictly on medical documentation pertaining to Andrew’s condition during the relevant time period and expert medical evidence in the record. Andrew’s medical records “speak for themselves” and do not call for any independent evaluation by the special master of the symptoms recorded therein.

by 24 months of age, which usually involve delays in speech and language development . . . .

### **Respondent's Expert Testimony From the OAP**

Testimony of Dr. Eric Fombonne, Resp't Ex. C at 29-30(see Cedillo v. Sec'y of Dep't of Health & Human Services, No. 98-916V, 2009 WL 811449, (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (Trial Tr. at 1266A-1267A , June 18, 2007), regarding "abnormalities in language and communication:<sup>24</sup>

[P]articularly as they present young infants, for instance, often there is language delay. There is no babbling. There can be no babbling in a young infant or the babbling can be very limited.

For instance, you could recognize that the amount of babbling is reduced or the quality of the babble is also altered. There would be very little babbling not directed to communicate. It would be self-directed, not used with a communicative intent.

From the same testimony, id. at 48 (see Cedillo Trial Tr. at 1284):

[O]ne of the first concerns which is often noted by parents is the lack of development of language.

Typically at age 15, 16, 18 months parents become worried because their child is not talking yet, and they can see that other children have started to develop words, many words by then.

Testimony of Dr. Max Wiznitzer, Resp't Ex. D at 48 (see Cedillo, Trial Tr. at 1619A), describing a "typical timeline" for the progression of children with autism:

This is a pattern that children may follow where in the second year of life the children really don't have well developed imitation. They don't have good language. There's a problem with socialization.

Resp't Ex. D at 54 (Cedillo, Trial Tr. at 1642):

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<sup>24</sup> Transcripts for the Omnibus Autism Proceeding may be accessed at the following website: <http://www.usfc.uscourts.gov/omnibus-autism-proceeding> (last checked on November 6, 2009). The qualifications of the experts whose opinions are cited appear in the records of the OAP.

[W]hen we are looking at communicative ability, we look at – not only do we look at what sounds they are making, whether they are making vowel sounds when they are young in infancy, whether they are babbling when they are in the later portion of infancy, and whether they are using words when they are in the second year of life, but also what they are doing with it and how much they are doing with it.

Resp't Ex. D at 55 (Cedillo, Trial Tr. at 1643):

If I have a child who does vocalize, but the vocalization that is present is minimal, it's not as much as I would expect, in other words, the quantity is not as much as I would expect, that's something that raises questions in my mind about what's going on.

Resp't Ex. D at 56 (Cedillo, Trial Tr. at 1644):

[R]ealizing that these early features may not be as flagrant as the autistic features that we will see at age 2 or 3 years, but they will be different than what we would normally expect for the behavior of an infant or a young child in the second year of life . . . .

3. Testimony of Sir Michael L. Rutter, M.D. (hereinafter "Dr. Rutter"):

Resp't Ex. E at 25 (see King v. Sec'y of Dep't of Health & Human Services, No 03-583V (Tr. 3259): a child's parents typically begin recognizing developmental problems in a child who turns out to be autistic at around 18 to 24 months.

Resp't Ex. E at 26 (see King v. Sec'y of Dep't of Health & Human Services, No 03-583V (Tr. 3260): "The communication problems and the lack of social reciprocity are often the first things to be picked up . . . They are picking up the social and communicative abnormalities as a rule.

### **SPECIAL MASTER'S EVIDENCE**

The special master also has considered the following sources of evidence concerning the early symptoms of autism:

- The Nelson Textbook of Pediatrics: "Combined language and social delays and regression in language or social milestones are important early red flags for ASD, and should prompt an immediate evaluation. Early signs include unusual use of language or loss of language skills . .

..” (Court Ex. 3 at 3).

- Craig Newschaffer, et al., The Epidemiology of Autism Spectrum Disorders, 28 Annu. Rev. Public Health 235 (2007): “Many other medical symptoms or disorders commonly reported in children with autism:” include seizures, immune system dysregulation, gastrointestinal symptoms, feeding difficulties (e.g. refusal, selectivity, sensitivity to textures) and sleep disruption. (Court Ex. 1 at 4).
- Prachi E. Shah, et al., Autistic Disorder, in Nelson Textbook of Pediatrics, 133-36 (Kliegman et al. eds, 2007). (Court Ex. 3)
- Autism Spectrum Disorders - Pervasive Developmental Disorders, Department of Health and Human Services, National Institute of Mental Health (2008): “Many ASD [autism spectrum disorder] children are highly attuned or even painfully sensitive to certain sounds, texture, tastes, and smells.” (Court Ex. 2 at 10)

### **III. DISCUSSION**

There is persuasive evidence in the medical records that Andrew experienced developmental delays from at least age 15 ½ months, in particular, speech delays.<sup>25</sup> The special master finds that Andrew exhibited speech delay no later than July 1999, four years before the Petition was filed, he continued to demonstrate early symptoms of autism thereafter, and his symptoms are recognized in the medical profession as symptoms of autistic disorders. Petitioners’ contention that, as a factual matter, Andrew’s developmental problems resolved and he appeared normal until diagnosed with autism on April 4, 2002, is contradicted by the medical records. Petitioners’ assertions that (1) Andrew’s parents did not recognize any symptom of autism before he reached age three years, and (2) Andrew’s early symptoms could not have resulted in a diagnosis of autism, are irrelevant under binding precedent regarding the statute of limitations. Accordingly, the Petition is dismissed as untimely filed. See Pet’r Ex. 6 at 10.

#### **A. Burden of Proof**

Petitioners maintain that the special master must accept their allegations as true and construe the facts in the light most favorable to them, citing Figueroa v. U.S., 57 Fed. Cl. 488, 492 (2003), and Scheuer v. Rhodes, 416 U.S. 232, 236 (1974). See Petitioners’ Status Report at

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<sup>25</sup> Although the record indicates that Andrew’s speech delay improved during certain periods of his development, he persistently lagged in attaining speech milestones throughout his early years. See supra at 8.

3. Petitioners' view of the evidentiary burden is erroneous given the procedural posture of this case.

The statute of limitations under the Act is jurisdictional. See, e.g., Brice v. Sec'y of Dep't of Health and Human Services, 358 F.3d 865, 868 (Fed. Cir. 2004) ("Brice II"); Kay v. Sec'y of Dep't of Health and Human Services, 80 Fed. Cl. 601, 603-04 (2008), aff'd per curiam, 298 F. App'x 985 (Fed. Cir. 2008) (unpublished). See generally, John R. Sand & Gravel v. U.S., 552 U.S. 130 (2008), 128 S.Ct. 750,753 (2008) (distinguishing between the treatment of typical limitations defenses and jurisdictional statutes of limitations). As a result, the burden is on Petitioners to establish that their claim is timely. Initially, the party asserting jurisdiction must make a prima facie showing of jurisdictional facts to defeat the motion to dismiss. See, e.g., Reynolds v. Army & Air Force Exch. Serv., 846 F.2d 746, 748 (Fed. Cir. 1988) and cases cited therein (under Tucker Act, plaintiff bears burden of establishing waiver of sovereign immunity).

Where there is "a factual attack on jurisdiction the court 'is obliged to look beyond the pleadings and decide for itself those facts, even if in dispute, which are necessary for a determination of [the] jurisdictional merits.'" Raymark Industries, Inc. v. U.S., 15 Cl. Ct. 334, 335 (1988); see also Figueroa, 57 Fed. Cl. at 492 ("If, however, the motion challenges the truth of the jurisdictional facts alleged in the complaint, the court may consider relevant evidence in order to resolve the factual dispute.") (citing Rocovich v. U.S., 933 F.2d 991 (Fed. Cir. 1991)). Precedent under Rule 12 requiring that factual assertions be construed in a light most favorable to the complainant is true "[w]hen a federal court reviews the sufficiency of a complaint before the reception of any evidence, either by affidavit or admissions . . . ." Scheuer, 416 U.S. at 236 (emphasis added). As explained further below, once the facts underlying jurisdiction are challenged and evidence is taken on the point, the complainant must establish jurisdiction by a preponderance of the evidence.

In its Motion to Dismiss, Respondent challenged the factual basis for the Petitioners' assertion of jurisdiction, pointing to evidence in the record indicating that the first symptoms of Andrew's autistic disorder preceded the filing of Petitioners' claim by more than 36 months. The standards applicable to a motion to dismiss based solely on the pleadings, therefore, no longer applies. Instead, the special master must look beyond the pleadings to determine the facts necessary to establish whether the Petition is timely. See Rocovich, 933 F.2d at 993-94 ("In determining whether a motion to dismiss should be granted, the Claims Court may find it necessary to inquire into jurisdictional facts that are disputed."). In addition, where the movant makes a factual showing challenging the timeliness of a claim, the burden of going forward with the evidence shifts back to the party seeking to establish jurisdiction to show that the claim is within the applicable limitations period. The burden of proof, "i.e., the burden of ultimate persuasion," never shifts. Cf., e.g., Grapevine Imports, Ltd., et al., v. U.S., 71 Fed Cl. 324, 343 (2006) (describing shifting burden of production under a non-jurisdictional statute of limitations). The result is that Petitioners may not rest on prima facie allegations but must respond with persuasive evidence to counter Respondent's showing that Andrew exhibited the first symptoms of autism more than 36 months before the Petition was filed.

To prevail, moreover, Petitioners must establish jurisdiction by a preponderance of the evidence. When a decision on jurisdiction requires consideration of facts beyond those alleged in the pleadings, the "appropriate quantum of the burden that the plaintiff [i.e., the non-moving party] must clear" in order to resist a motion to dismiss "will rest upon such factors as the nature of the proceeding and the type of evidence that the plaintiff is permitted to present." Raymark, 15 Cl. Ct. at 337 (citations omitted). "[T]he limits imposed by the trial judge upon pretrial proceedings will dictate the burden the plaintiff is required to meet." Id. Where proceedings are limited to written materials, the plaintiff's written materials "must make only a prima facie showing of jurisdictional facts." Id. at 338. Where proceedings are not so limited and the court accepts evidence in order to resolve contested factual issues, the plaintiff must then be put to its full burden of proof. Id. In that circumstance, "plaintiff must establish the jurisdictional facts by a preponderance of the evidence, just as [it] would have to do at trial." Id. See Data Disc, Inc. v. Systems Tech. Ass'n, Inc., 557 F.2d 1280, 1285 (9th Cir. 1977).

Petitioners' contention that they need to make only a prima facie showing to establish jurisdiction is incorrect in the context of this proceeding, in which both sides have submitted evidence well beyond the pleadings. Petitioners and Respondent have availed themselves of the opportunity to present additional evidence on the timeliness issue. See Status Report at 3-8, Resp. Ex.s A-E. A full evidentiary hearing has not been held; both parties, however, agreed at the status conference on September 29, 2009, that no such hearing is necessary and that the issue is appropriate for decision based on the record. See Order dated October 27, 2009. Contrary to Petitioners' contention that the special master must accept all of their allegations as true, in these circumstances Petitioners fairly are held to the burden of demonstrating that jurisdiction exists by a preponderance of the evidence.

### **B. Applicable Law Regarding the Statute of Limitations**

In pertinent part, Section 300aa-16(a)(2) of the Vaccine Act states:  
[i]n the case of . . .

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

The statute of limitations under the Vaccine Act must be "strictly and narrowly construed" because it is a condition of the waiver of the government's sovereign immunity. Markovich, 477 F.3d at 1360 (quoting Brice v. Sec'y of Dep't of Health and Human Services, 240 F.3d 1367, 1370 (Fed. Cir. 2001) ("Brice I"). Under the Act, the statute of limitations may be triggered by a "first symptom" or "manifestation of onset." A symptom "may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the

medical significance of a symptom with regard to a particular injury.” Markovich at 1357. “[A]ny observable ‘symptom or manifestation’ may be the first evidence of injury.” Markovich at 1358 (quoting Shalala v. Whitecotton, 514 U.S. 268, 274 (1995)) (emphasis in original). As the court stated in Markovich at 1359 (citing Brice v. Sec’y of Dep’t of Health and Human Services, 36 Fed. Cl. 474, 477 (1996)), “Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act.”<sup>26</sup>

These binding authorities establish that diagnosis of a disorder allegedly caused by a vaccine is not required to trigger the statute of limitations. See Cloer v. Sec’y of Dep’t of Health and Human Services, 85 Fed. Cl. 141, 144-45 (2008), appeal docketed, No. 2009-5052 (Fed. Cir. Mar. 9, 2009); Lemire v. Sec’y of Dep’t of Health and Human Services, No. 01-0647V, 2008 WL 2490654 (Fed. Cl. Spec. Mstr. June 3, 2008) (holding that recognizable signs of autism occurred well before diagnosis). Even where the medical community would not have been able to diagnose the symptoms as manifesting a particular disorder, the statute of limitations commences “on the date the first symptom or manifestation of onset occurs.” Cloer, 85 Fed. Cl. at 145. “[T]he limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming.” Cloer, 85 Fed. Cl. at 149 (citing Markovich, 477 F.3d at 1358-59).

Further, to trigger the statute of limitations, a symptom or manifestation of an injury need not be accepted by the medical profession at large as an injury linked to a vaccine; it need only be identifiable as a symptom or manifestation of an injury. See Bono ex rel. Bono v. Sec’y of Dep’t of Health and Human Services, 87 Fed. Cl. 98, 102-03 (2009). As stated in the Bono decision, “The Congressional intent, statutory language, and etymology of the Markovich holding all support the argument that the critical event for determining the onset of the statute of limitations is the occurrence of an injury recognizable by the medical community, rather than recognition by the medical community that an injury is linked to a vaccine.

The pertinent language states: “For the reasons discussed above, we hold that ‘the first symptom or manifestation of onset,’ for the purposes of § 300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.” Markovich, 477 F.3d at 1360.

If the Court in Markovich had intended to designate the time when an injury is recognized as being related to a vaccine as the trigger for commencing the statute of limitations, the Court would have used the word “recognized.” Instead, Markovich used the word “recognizable,” that

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<sup>26</sup> Accord, e.g., Hebert v. Sec’y of Dep’t of Health and Human Services, 66 Fed. Cl. 43, 47, 49 (2005); Wilkerson v. Sec’y of Dep’t of Health and Human Services, 2009 WL 1583527 (2009), appeal docketed No. 2009-5090 (Fed. Cir. June 4, 2009) ; Hedrick v. Sec’y of Dep’t of Health and Human Services, 2008 WL 5049439 at \* 3 (Fed. Cl. Nov. 3, 2008); Staley v. Sec’y of Dep’t of Health and Human Services, 2007 WL 268779 at \* 3-4 (Fed. Cl. 2007).

is, capable of being recognized, as opposed to actually being recognized. Several consequences flow from the difference in meaning between “recognized” and “recognizable.”

As a practical matter, it is unclear when, if ever (especially in the context of the Vaccine Program, which often involves novel assertions of linkage between vaccines and injuries) the term “recognizable” could be applied to the relationship between a vaccine and an injury. The time when such a link could be recognized, *i.e.*, is “recognizable,” is too indefinite to furnish a workable benchmark for measuring the limitations period.<sup>27</sup>

A particular injury, in contrast to a vaccine-related injury, is “recognizable” by the medical community at large based on symptoms known to doctors and documented in a historical record of a particular patient. The definition of the word “recognizable” commonly includes this very notion of the perception or appreciation of the existence of a particular condition based on known facts. See, e.g., The American Heritage College Dictionary at 1141 (defining “recognize” as “To know or identify from past experience or knowledge.”) While this is not the only sense in which we use the word,<sup>28</sup> it is a common, natural and sensible reading of the Court’s use of the word “recognizable” in the context of identifying “objectively” the first symptoms or manifestations of an injury.<sup>29</sup> In applying Markovich, therefore, we review the medical record for an injury that is recognizable by the medical community, not for actual recognition by the medical community that an injury is in fact related to a vaccine.

We note as well that a contrary reading would eliminate the statute of limitations in a great many cases, since the statute might never be triggered in a case unless the medical

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<sup>27</sup> Use of the term “objectively” recognizable to refer to the relationship between a vaccine and an injury would add another layer of uncertainty to the effort to find a date for starting the statute of limitations. There is no guidance as to when a purported link between a vaccine and an injury would be “objectively” recognizable, as opposed to being simply recognizable. It is unlikely that the Court in Markovich intended to inject multiple levels of uncertainty into the process for determining when the statute of limitations starts to run. It is more likely that by using the term “objectively” the Court meant to communicate clearly its decision in Markovich that the running of the statute of limitations is not dependent on the subjective awareness of petitioners concerning the onset of an alleged injury.

<sup>28</sup> To recognize also can mean to perceive or appreciate a condition for the first time. See The American Heritage College Dictionary at 1141 (providing as a subsidiary definition of the word “recognize” “To perceive or show acceptance of the validity or reality of.”)

<sup>29</sup> Dorland’s Illustrated Medical Dictionary contains no definition for “recognize” or “recognizable,” but defines “recognition” at p. 1586 as “1. the act of recognizing (seeing something as familiar). 2. the state of being seen as familiar.” The Court’s use of the term “recognizable” in the Markovich holding comports with the usage of the term to indicate a physician’s evaluation of a patient’s condition based on symptoms that the physician has observed and learned about in the past. See also <http://wordnetweb.princeton.edu/perl/webwn?s=recognizable>, defining “recognizable” as “easily perceived; easy to become aware of,” as in “this situation produces recognizable stress symptoms.”

community at large had actually recognized a relationship between a vaccine and a particular injury. The accepted rules of statutory construction weigh against the supposition that Markovich intended, simply by employing the term “vaccine injury,” effectively to delete the statute of limitations from the Vaccine Act. Fundamental dictates of statutory construction hold that in interpreting the plain meaning of a statute it is a “cardinal principle” that every clause and word of a statute must be given effect, if possible. TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001); Williams v. Taylor, 529 U.S. 362, 404 (2000). Similarly, statutory construction ceases if the language is unambiguous and the statutory scheme is “coherent and consistent.” Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002). Knowing these well-worn canons of statutory construction, it is highly unlikely that the Court in Markovich intended (without saying so) to adopt a construction of § 300-aa 16(a)(2) that is impossible to apply. Much more likely, the Court used the term “vaccine injury” to describe the injury alleged by a petitioner to have resulted from administration of a vaccine and for which compensation may be awarded. This is precisely the usage employed by the Markovich Court throughout its opinion. See, e.g., 477 F.3d at 1359 (“the terms of the Vaccine Act demonstrate that Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that *the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act.*”) (Emphasis added.) Indeed, the Court in its holding itself defines what it means by the term “vaccine injury” when it states:

Because the testimony of Dr. Corbier and others confirms that Ashlyn’s eye blinking episode on July 10, 2000 was objectively recognizable by the medical profession at large as constituting the first evidence of vaccine injury onset, *i.e.*, ***the first symptom of injury***, and because the Markoviches filed their petition on August 29, 2003, more than 36 months after the initial symptoms, the petition is time-barred under § 300aa-16(a)(2). (Emphasis added.)

See also 477 F.3d at 1359 (“The eye blinking episodes in this case began promptly after the vaccination and were connected ***to the injury of seizure disorder*** within ample time to have filed a timely claim.”) (Emphasis added.)

### **C. Application of the Law to the Record in This Case**

In the Order dated July 7, 2009, the special master offered the parties the opportunity to submit additional expert evidence on the issues surrounding application of the statute of limitations. Respondents have provided reliable evidence that the medical profession at large would recognize speech delay in a 15-month-old as a first symptom of an autism spectrum disorder (the injury alleged by Petitioners). See Russell v. Sec’y of Dep’t of Health & Human Services, No. 02-747 (Spec. Mstrs. July 10, 2009) (dismissing for untimely filing where first symptom of autism was lack of speech at 15 months). Petitioners have submitted evidence that speech delay alone cannot be used reliably to diagnose autism, but no persuasive evidence that speech delay is not one of the early symptoms of autism recognized by the medical community.

Under the rules governing allocation of the burden of proof on timeliness, Petitioners have failed to carry their burden of persuasion.

### **1. Respondent's Expert Evidence**

Respondent's submissions of expert evidence focused appropriately on the early symptoms of autistic disorders that are recognized by the medical community. The evidence in the medical literature identified speech delay as one of the first symptoms of autistic disorders. See, e.g., Resp't Ex. A at 2 ("the absence of first words and phrases is the foremost reason reported by caregivers of children with ASD for their initial concern about their child's development"); Resp't Ex. B at 3 ("Approximately 80% of parents of children with ASDs notice abnormalities in their child by 24 months of age, which usually involve delays in speech and language development . . ."); Court Ex. 2 at 4 (Johnson) ("Historically, delays and deviances in language development have been the most common presenting signs in children later diagnosed with autism.")

The expert testimony from the OAP similarly demonstrated that the medical community recognizes language delay as a common early symptom of autism. Dr. Eric Fombonne testified that children who are later diagnosed as autistic present as "young infants" with language delay. Resp't Ex. D at 50 ("There is no babbling. There can be no babbling in a young infant or the babbling can be very limited.") Dr. Fombonne testified further that speech delays "typically" concern parents of autistic children at age "15, 16, 18 months." Id. ("They can see that other children have started to develop words, many words by then.") Dr. Max Wiznitzer echoed the testimony that children who turn out to have autism follow a pattern such that, "in the second year of life," they "don't have good language." Resp't Ex. E at 49. Dr. Wiznitzer's testimony took account of the normal variation in child development but made it clear that, notwithstanding the acknowledged variation, children later diagnosed as autistic typically exhibit impairment of language skills as "an infant or a young child in the second year of life. . . ." Id. at 57. Dr. Rutter similarly opined that "a child's parents typically begin recognizing developmental problems in a child who turns out to be autistic at around 18 to 24 months, when "communication problems and the lack of social reciprocity" are "the first things to be picked up." Resp't Ex. E at 25-26.

This reliable medical evidence establishes that speech delay, in particular, is an "event objectively recognizable as a sign" of an autism spectrum disorder "by the medical profession at large." Markovich, 477 F.3d at 1360. No persuasive evidence has been submitted to the contrary, as discussed below.

### **2. Petitioners' Expert Evidence**

Petitioners' submissions did not negate the evidence that speech delay is one of the earliest recognized symptoms of autism. See Petitioners Status Report at 3-5. Petitioners erred in focusing principally on the diagnostic criteria instead of the early symptoms of autism. For

example, Petitioners cited the statement in the DSM that abnormal development in three areas is necessary to diagnose autism, and that diagnosis can be complicated.<sup>30</sup>

Authorities relied upon by Petitioners indicated that language delay does not automatically signal the presence of an autistic disorder and that, to the contrary, it would be erroneous to diagnose autism based on early speech problems. Again, these sources caution against premature diagnosis of autism. See, e.g., Status Report, Aug. 3, 2009 at 8, (Excerpts from the expert report of Michael Rutter, M.D. at p. 5) (precise “boundaries of the diagnostic concept remain somewhat uncertain,” and uncertainty as to the diagnosis can extend “well into the childhood years and beyond”). Petitioners also emphasized variation in presentation among individuals with early symptoms of autism, and the unreliability of parental observations fixing a point in time for the onset of the disorder. See, e.g., Rutter testimony at 3260 (noting that the first symptoms typically recognized by parents are “Quite varied . . . it can be quite a range of different things”); Mumper testimony at 1239 (“there is obviously a wide range of normal”).

As highlighted by Petitioners in their Status Report, language delay in children is not invariably predictive of an autistic disorder, and many children with language delay develop normally. See, e.g., Petitioners’ Status Report at 6. Further, there is no standard methodology for screening young children for autism. (“Currently, no standardized autism-screening tests for children younger than 18 months of age are available . . . surveillance, coupled with a high degree of suspicion, is very important . . .”). Id. at 5 (citing and quoting Chris Plauche Johnson, M.D., MEd., “Recognition of Autism Before Age 2 Years,” *Pediatrics in Review* Vol. 29, No. 3, March 2008). Other citations offered by Petitioners indicated that speech and language delay alone, without evidence of social deficits, are not sufficient to establish autism. Id. at 5-6.

The validity of the information submitted by Petitioners is unquestioned, but is largely beside the point. Under Markovich, we are not looking for symptoms that result in a diagnosis of autism but for symptoms that the medical community would recognize as characteristic of individuals who are later diagnosed with autism. Without doubt, there are many children with speech delays who eventually reach or exceed the norm for their age. The individual whose speech delay turns out to be insignificant, however, is not before the Court. Instead, we have before us an individual who in fact suffers from an autistic spectrum disorder and we must decide, as to that individual, when he showed signs of the disorder. To determine the date for the onset of Andrew’s condition we engage in a historical inquiry, not a predictive exercise. Prediction, admittedly, is problematic, but that difficulty does not preclude us from determining as a historical matter “what happened.” In this context, the key fact is that Andrew’s treating physicians identified very early in his life symptoms, including the absence of appropriate language development, that are well-recognized in the medical community as typical features of children later diagnosed with autism.

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<sup>30</sup> The citations to MayoClinic.com and the excerpt from the article by Dr. Johnson similarly are directed toward the complexity of autism diagnosis, not to recognition of early symptoms of the disorder. See supra at 14.

In respect to the pertinent inquiry, Petitioners' experts actually concur in identifying speech delay as one early symptom of autistic disorders. See, e.g., R.L. Schum, Ph.D., "Language Screening in the Pediatric Office Setting," 54 *Pediatr. Clin. of N. Amer.* 428 (2007) (Pet'r Ex. 18 at 2). ("Delayed and disordered language can occur as a primary condition . . . .") The Johnson article submitted by Petitioners' states: "Historically, delays and deviances in language development have been the most common presenting signs in children later diagnosed with autism." Chris Plauche Johnson, "Recognition of Autism Before Age Years," *Pediatrics in Review* (2008) at 89 (Pet'r Ex. 17 at 5). And Dr. Mumper describes in detail the attention paid by physicians to the development of language in discerning abnormalities that can signal autism. See Mead/King Trial Tr. at 1241.

Additional evidence weighing against Petitioner's arguments comes from Dr. Fombonne, who is recognized as an expert by both Petitioners and Respondent. He stated in the expert report submitted by Petitioners that "The diagnostic criterion of the DSM-IV is that "onset" of some abnormalities must occur before the third birthday." Status Report, Aug. 3, 2009 at 7-8. Petitioners maintain that identification of autistic symptoms before age three is impossible because of the inherent variability of human development, the absence of standard measures of developmental abnormalities, the unreliability of parental reports, and the variations of the disorder itself. As Dr. Fombonne's testimony indicates, however, the opposite actually is true from a medical standpoint: autism will manifest itself symptomatically before the age of three or it will not be autism. Thus, while children who exhibit symptoms of autism before age three will not necessarily be diagnosed as autistic, according to Dr. Fombonne and the DSM, children who are autistic by definition will have exhibited symptoms before age three. See also Pet'r Ex. 20 at 6 (Petitioner's expert Dr. Ozonoff noting that "prospective studies are consistent with retrospective studies in finding that for many, perhaps most, children with autism, symptoms emerge gradually over the first 18 months or so of life.")

The special master concludes that the authorities submitted by Petitioners do not negate the evidence cited above that speech and language delays are recognized in the medical community as early symptoms of autistic disorders. Many of Petitioners' citations actually support that proposition while noting the fact, which is not in dispute, that problems in speech and language development do not invariably signal the presence of an autistic disorder and may be evidence of many unrelated conditions.

The special master appreciates and shares the concern, underlying many of Petitioners' arguments, that the symptoms identified herein as early manifestations of autistic disorders are overly inclusive and that, as a result, application of the statute of limitations will improperly cut off many claims. In examining the expert medical evidence concerning the early symptoms of autism, a bias in favor of over-identification sometimes can be discerned, driven by the recognized fact that early intervention can greatly improve the outcome for autistic children. We agree that medical bias in favor of early identification should not result in the special master's adoption of an onset date for applying the statute of limitations that is too early.

In this case, the special master adopts documented speech delay as of age 15 months as the trigger for commencing the statute of limitations because speech delay in the second year of life is a reliable and readily discernible manifestation of autism, according to the experts cited herein. See supra at 23. Like the eye-blinking episodes in Markovich, see 477 F.3d at 1357, Andrew’s documented speech delay “is not so readily confused with typical child behavior,” that it would be inappropriate to use it as the benchmark for determining the onset of the limitations period. Further, the special master relies on other symptoms characteristic of autism that are documented in Andrew’s records, including delayed motor development and sensitivity to food textures, to avoid placing undue emphasis on speech delay alone. In addition, the special master has noted the persistence of speech delay documented in Andrew’s medical records; this was a consistent characteristic, not an isolated phenomenon. The weight of the evidence clearly points to the initial, unequivocal record of Andrew’s speech delay documented at his 15 ½ month check up as an appropriate point for commencing the limitations period.

The record contains reliable medical evidence that speech delay is an “event objectively recognizable as a sign” of an autism spectrum disorder “by the medical profession at large.” Markovich, 477 F.3d at 1360. There is an abundance of evidence that early speech delay does not automatically presage autism but no evidence rebutting the proposition that early speech delay is one of the first symptoms in a child who is eventually diagnosed with autism.<sup>31</sup> In so stating, the special master recognizes that Andrew’s autism might not have been diagnosed based solely on his early speech delay. Applicable law plainly holds, however, that diagnosis is not required to trigger the statute of limitations under the Vaccine Act.

### **3. Early Symptoms of Autism Documented in Andrew’s Medical Records**

As described in detail above, the medical record contains contemporaneous documentation of Andrew’s speech delay and other early symptoms of autism, starting with his pediatrician’s notes on July 14, 1999, at Andrew’s 15 ½ month well-baby checkup. Pet’r Ex. 4 at 57. In those notes, Dr. Berkowitz documented his concerns with Andrew’s motor development, speech development, and sensitivity to food textures. All of these difficulties in early life are common symptoms experienced by children later diagnosed as autistic, according to the medical evidence discussed above. Delayed speech, in particular, is consistently identified in the medical community as an early symptom of autistic disorders. Andrew’s speech delay (as well as other developmental problems) continued to be reported following the July 1999

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<sup>31</sup> A special master may draw conclusions from medical literature even if medical experts have not commented on the literature during that particular Vaccine Program proceeding. Cf. Moberly v. Sec’y of Health & Human Services, 85 Fed. Cl. 571, 597-98 (2009), appeal docketed, No. 2009-5057 (Fed. Cir. Mar. 17, 2009) (“Court has no trouble concluding that a special master may interpret and apply the conclusions of a medical study introduced into the record by a party, without the guidance of expert witnesses”).

pediatrician visit in the records of other physicians and treating professionals.<sup>32</sup> In August 1999, the doctor treating Andrew's breathing difficulties again noted that he had difficulty handling food textures, and that he was "not speaking." Pet'r Ex. 4 at 3. The fact of Andrew's continuing developmental delays, despite his steady "progress," was again noted in December 1999, by Dr. Burstein. See Pet'r Ex. 5 at 16. In the records for 2000, Dr. Berkowitz and Dr. Burstein noted Andrew's continuing developmental problems. In May 2000, Dr. Burstein noted that Andrew's speech was not age-appropriate, that he said a few words but was not forming phrases and instead was mainly "making a variety of different sounds." Pet'r Ex. 5 at 3.

The record contradicts Petitioners' assertion that Andrews early developmental problems resolved. See Response at 6. As set forth above, Andrew was consistently delayed in reaching speech milestones. He continued to be "a little fussy on certain textures." See supra at 9. He was noted to have escalating problems with behaviors from the age of 18 months. Pet'r Ex. 5 at 8; supra at 9.<sup>33</sup> Admittedly, the record is not entirely consistent, as is to be expected. But any suggestion that Andrew's difficulties were transient, attributable to extraneous conditions such as infection or injury, or otherwise not symptomatic of early autistic features, would be incorrect. The medical evidence is consistent, reliable and more than sufficient to persuade the special master that Andrew exhibited early autistic symptoms from the age of 15 ½ months.

On this record, the statute of limitations commenced to run on July 14, 1999, when Andrew was aged 15 ½ months and, according to his treating physician records, exhibited early symptoms of autism. The Petition, filed July 23, 2003, therefore is one year out of time.<sup>34</sup>

#### **IV. CONCLUSION**

For the foregoing reasons, Respondent's motion to dismiss on the grounds of the statute

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<sup>32</sup> We have no occasion to contradict the expressions by some of Andrew's physicians that he was generally healthy. See Response at 4-5. See, e.g., Pet'r Ex. 4 at 24; Pet'r Ex. 5 at 12. ("At the time of this physical he is growing well and developing normally[.]" In context, however, it is plain that Andrew was characterized as healthy despite pertinent developmental and other significant health issues. Based on the record as a whole, the evidence does not preponderate in favor of the conclusion that Andrew, during the relevant time period, was a normally developing child. See 42 U.S.C. § 300aa-13 (compensation to be awarded based "on the record as a whole"); Grant v. Sec'y of Dep't of Health and Human Services, 956 F.2d 1144, 1146 (1992).

<sup>33</sup> Petitioners contended that Dr. Berkowicz's notation was unsupported by contemporaneous records. See Response at 6. It is nevertheless the statement of a treating physician and is therefore to be afforded some weight.

<sup>34</sup> Equitable tolling does not apply to ameliorate the effect of the statute of limitations in Vaccine Act cases. Brice I, 240 F. 3d at 1368. Dismissal of this Petition as untimely indicates no fault whatsoever on the part of Petitioners.

of limitations is **GRANTED**. Petitioners' claim is dismissed. The Clerk shall enter judgment accordingly.

**IT IS SO ORDERED.**

s/ Dee Lord  
Dee Lord  
Special Master