

OFFICE OF SPECIAL MASTERS

Filed: July 22, 2005

MICHAEL and MELISSA MARKOVICH, *
as parents of ASHLYN M. MARKOVICH, *

Petitioners, *

v. * No. 03-2015V

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

Mark L. Krueger, Baraboo, Wisconsin, for Petitioners.

Traci R. Patton, United States Department of Justice, Washington, D.C., for Respondent.

DECISION¹

SWEENEY, Special Master

On August 29, 2003, Michael Markovich and Melissa Markovich, as the parents of Ashlyn M. Markovich (“Ashlyn”), filed a petition for compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2000 & Supp. II 2003), which alleges that Ashlyn sustained a seizure disorder and intractable epilepsy as the result of her July 10, 2000 diphtheria, tetanus, and acellular pertussis (“DTaP”),² inactivated polio virus (“IPV”),³ and haemophilus influenzae type b (“Hib”)⁴ vaccinations. The facts of this

¹ The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secret or commercial or financial information that is privileged or confidential or (2) medical information that would constitute “a clearly unwarranted invasion of privacy.”

² The DTaP vaccine is “a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis.” Dorland’s Illustrated Medical Dictionary 1998 (30th ed. 2003).

³ The IPV vaccine is “a suspension of formalin-inactivated poliovirus . . . administered intramuscularly or subcutaneously for immunization against poliomyelitis.” Dorland’s Illustrated

case present an onset issue; the disposition of which determines whether the special master can exercise jurisdiction over the petition.

According to the petition and Ms. Markovich's affidavit, repeated eye blinking episodes, which began on July 10, 2000, the date Ashlyn received her vaccinations, were the precursor of Ashlyn's seizure disorder. However, Ashlyn's first full-blown seizure did not occur until August 30 or 31, 2000.⁵ The parents claim that because they were unaware that the repeated eye blinking episodes were the harbinger of their daughter's seizure disorder, they lacked actual knowledge of a Vaccine Act injury or claim. Thus, the threshold question to be addressed is whether the date of onset is July 10, 2000, the date that the repeated eye blinking episodes began, or August 30, 2000, the date specified in the petition and medical records as the date of Ashlyn's first full-blown seizure. The evidence presented in lay and expert affidavits, expert reports, and expert testimony at hearing leads the special master to conclude that the first symptom or manifestation of onset of Ashlyn's seizure disorder occurred on July 10, 2000, the date that the repeated eye blinking episodes, clear neurological symptoms, began. Unfortunately for petitioners, they filed their petition 50 days after the expiration of the 36-month limitations period prescribed in 42 U.S.C. § 300aa-16(a)(2). As a consequence, the special master is compelled by statute and the well-settled binding precedent of the United States Court of Appeals for the Federal Circuit ("Federal Circuit") to dismiss the petition for lack of subject matter jurisdiction.

I. PROCEDURAL HISTORY

On August 29, 2003, Michael and Melissa Markovich filed a petition alleging that their daughter Ashlyn's seizure disorder and intractable epilepsy were caused by the DTaP, IPV, and/or HiB vaccines Ashlyn received on July 10, 2000. The petition alleges, *inter alia*, that after Ashlyn's July 10, 2000 vaccinations and continuing to August 30, 2000, the parents observed

Medical Dictionary, *supra* note 2, at 2000.

⁴ The haemophilus influenzae type b vaccine protects against infection by the haemophilus influenzae type b bacterium. Dorland's Illustrated Medical Dictionary, *supra* note 2, at 1999.

⁵ The date of onset as reflected in the contemporaneous medical records deviates by one day from the onset date specified in the petition. Petitioners claim Ashlyn's first seizure occurred on August 30, 2000. However, the records from the emergency department at Fairview Ridges Hospital document that the first pronounced seizure occurred on August 31, 2000. Pet. Ex. 14 at 30-33. Similarly, ambulance transfer records also date the first seizure as occurring on August 31, 2000. Pet. Ex. 18 at 5. Because the petition was filed on August 29, 2003, the determination as to whether the first seizure occurred on August 30 or 31, 2000, would not affect the statute of limitations analysis. Accordingly, despite the evidence in the medical records to the contrary, for the sake of simplicity, the special master will use the date specified in the petition, August 30, 2000, as the date of Ashlyn's first seizure.

Ashlyn rapidly blinking her eyes, realizing now that these episodes may have been seizures.⁶ Pet. at ¶ 3. At the time, her parents thought Ashlyn was merely tired; consequently, no medical attention was sought. *Id.* Ms. Markovich's affidavit supports the averments of the petition. Pet's Aff. at ¶ 4.

Petitioners filed Ashlyn's medical records, Ms. Markovich's affidavit, the expert affidavits of Frank J. Ritter, M.D.,⁷ Pet. Ex. 12, and Donald H. Marks, M.D., Ph.D.,⁸ Pet. Ex. 17, and an expert report from Jean-Ronel Corbier, M.D.,⁹ Pet. Ex. 20.

⁶ All references to the Petition shall be designated herein as "Pet. at ¶ ___." All references to the Affidavit of Melissa Markovich shall be designated herein as "Pet. Aff. at ¶ ___." All references to the pertinent Petitioners' Exhibit shall be designated herein as "Pet. Ex. ___ at ___."

⁷ On October 27, 2003, petitioners filed the signed affidavit of Frank J. Ritter, M.D., which differed from his unsigned affidavit submitted with the petition. Pet. Ex. 12. The signed affidavit, dated October 7, 2003, purports to establish onset within the statute of limitations, but does not support a causation theory; the affidavit indicates that the cause of Ashlyn's "seizure disorder and/or epilepsy is unknown at this time." *Id.* at 2.

⁸ Dr. Marks's affidavit, dated February 26, 2004, states that "[i]t is more likely than not (probable) that the DTaP vaccination that was given to Ashlyn Markovich on or about July 10, 2000, was causally responsible for the development of the seizure disorder which occurred on or about August 31, 2000." Pet. Ex. 17 at 2.

⁹ The expert report of Dr. Corbier, petitioner's testifying pediatric neurologist, recites that a review of Ashlyn's complete medical history reveals that Ashlyn's seizures were the result of multifocal cortical cerebral dysfunction and were caused by the vaccinations received on July 10, 2000. Pet. Ex. 20 at 3-4. Dr. Corbier's report notes that according to Ashlyn's parents, her rapid eye blinking episodes began the same day as her vaccinations and continued through August 30, 2000, the date of her first full-blown seizure. *Id.* at 1. Dr. Corbier opined that "there may be an underlying, perhaps undiagnosed neurometabolic defect, that, coupled with the two-month set of immunizations, triggered [Ashlyn's] epilepsy." *Id.* at 3-4. Regardless, Dr. Corbier's report makes clear that the timing of the July 10, 2000 vaccinations was a critical element of his opinion:

[T]here is a possibility that these rapid frequent eye blinking episodes may have represented seizures. These could have either been brief complex partial seizures or generalized absence seizures. From a timing standpoint, assuming these were in fact seizures, one has to consider that one or more of the vaccines given could have potentially served as a trigger factor for the development of epilepsy. Owing to what is known about pertussis and its neurological complications, including seizures, this would be a reasonable consideration. An alternative to this explanation would be that the eye blinking, again assuming that these might

Respondent's Rule 4(b) Report, filed on December 3, 2003, did not recommend compensation. In his report, respondent conceded that there is no mention in the medical records of Ashlyn's eye fluttering, which occurred between the vaccinations administered on July 10, 2000, and Ashlyn's first full-blown seizure on August 30, 2000. Pet. at ¶¶ 3-4, 11. However, respondent did focus on paragraph 3 of the petition, which alleges that, with hindsight, petitioners "now know [that the eye blinking episode] may have been seizures." Resp't Rep. at 2. The Rule 4(b) Report further notes that, "A record dated September 20, 2001, indicates that Ashlyn's mother understood that Ashlyn's eye blinking was seizure activity." *Id.* at 5; see also Pet. Ex. 7 at 42.

On January 27, 2004, the court held a status conference to discuss further proceedings. During the status conference, the special master stated that an onset hearing with expert testimony was necessary because the petition and Ms. Markovich's affidavit implicated the statute of limitations. Respondent's counsel stated her intention not to offer an expert witness to interpret the significance of the repeated eye blinking episodes, but rather to rely upon the contents of Ms. Markovich's affidavit. It is beyond the purview of a special master to determine what constitutes a "symptom" and to determine the significance of a symptom. In this case, expert testimony was crucial to determine whether Ashlyn's eye blinking episodes constituted the onset of her seizure disorder. The undersigned was unwilling to speculate on this issue. Therefore, petitioners' counsel agreed to produce an expert to opine on this issue and was given additional time to file an expert report concerning onset.

On June 2, 2004, petitioners' counsel filed the expert report of Dr. Corbier, a pediatric neurologist. Portions of Dr. Corbier's expert report highlighted the statute of limitations issue. Specifically, Dr. Corbier explained that the onset of Ashlyn's seizure disorder occurred on August 30 or 31, 2000, but that some symptoms may have occurred prior to that time. Because there can be only one date for the first symptom or manifestation of onset, the special master conducted an onset hearing on November 5, 2004, in Washington, D.C. Only one witness, Dr. Corbier, testified.

II. FACTUAL HISTORY

Ashlyn was born on May 12, 2000, in Edina, Minnesota, to Melissa and Michael Markovich.¹⁰ Pet. Ex. 1 at 1. According to Ashlyn's pediatrician, Jane O'Neil, M.D., Ashlyn

represent seizures, occurred coincidentally after the immunizations and were unrelated. In my opinion, this would be a much less likely possibility.

Id. at 3.

¹⁰ Prenatal records can be found at Petitioners' Exhibits 8 and 9. Delivery records can be found at Petitioners' Exhibit 10. Delivery was achieved by vacuum. Pet. Ex. 10 at 1.

was born fullterm and her first two well-baby examinations were normal. Pet. Ex. 3 at 1; see also Pet. Ex. 4 at 6.

On May 26, 2000, Ashlyn had her two-week well-baby examination at Fairview Cedar Ridge Clinic. Pet. Ex. 4 at 6. Mary Homan, M.D., noted that Ms. Markovich was concerned about Ashlyn's feeding, but the pediatrician found that Ashlyn was gaining an appropriate amount of weight. Id. Ashlyn's next visit to her pediatrician was for her two-month well-child visit on July 10, 2000. Pet. Ex. 4 at 3, 6. At this visit, Ashlyn received DTaP, IPV, and HiB vaccinations. Id.; Pet. Ex. 2 at 1-2.

At about 6:00 p.m. on August 31, 2000, one of Ashlyn's parents noted "extremity jerking & staring seizure activity." Pet. Ex. 18 at 5. The parents called the paramedics who arrived and stopped the seizure. Id. Ashlyn was taken to Fairview Ridges Hospital. Pet. Ex. 14 at 30. A head computed tomography scan ("CT scan")¹¹ was normal. Id. at 34. Ashlyn was discharged from Fairview Ridges Hospital with a diagnosis of seizure of unknown etiology and transferred to St. Paul Children's Hospital ("Children's Hospital"). Id. at 32; Pet. Ex. 3 at 1; Pet. Ex. 4 at 5; Pet. Ex. 18 at 5. The cause of the seizure was not identified. Pet. Ex. 4 at 5.

Ashlyn had another well-child examination on September 8, 2000. Pet. Ex. 4 at 5. After noting Ms. Markovich's report of the seizure activity, Tiffani Mullins, M.D., indicated that the examination was normal. Id. That finding notwithstanding, on or about September 14, 2000, Ashlyn had another seizure. Pet. Ex. 6 at 210. Ashlyn experienced additional seizures on October 11, 14, 18, 20, 21, and 22, 2000. Id. On October 16, 2000, Ashlyn was examined by Ronald H. Spiegel, M.D., of Children's Hospital regarding her seizures. Pet. Ex. 16 at 45-46. Ashlyn was started on Tegretol, an antiseizure medication, on October 21, 2000. Pet. Ex. 6 at 210. Ashlyn was also given three chiropractic treatments; but these were discontinued as her seizure activity increased in frequency. Id.

When Ashlyn was admitted to Children's Hospital on October 22, 2000, the Tegretol was discontinued, and a video electroencephalogram ("EEG")¹² was performed. Pet. Ex. 6 at 159-63;

¹¹ A CT scan is a "recording of internal body images at a predetermined plane by means of the tomograph." Dorland's Illustrated Medical Dictionary, supra note 2, at 1919. A tomograph is "an apparatus for moving an x-ray source in one direction as the film is moved in the opposite direction, thus showing in detail a predetermined plane of tissue while blurring or eliminating detail in other planes." Id. In a CT scan, "the emergent x-ray beam is measured by a scintillation counter; the electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube." Id.

¹² An EEG is "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic

210. According to Dr. Ritter, the EEG “clearly demonstrate[d] seizure onset from the right posterior quadrant.” *Id.* at 159. Ashlyn also underwent a magnetic resonance image (“MRI”)¹³ of her head. *Id.* at 164. The MRI report indicated “intracranial contents normal” and “small amount of fluid or mucosal thickening in the left mastoid air cells noted.” *Id.*

On November 9, 2000, Dr. Spiegel saw Ashlyn for another follow-up of her epilepsy. *Pet. Ex. 16* at 44. Then, on November 17, 2000, Ashlyn had a generalized seizure and was taken by ambulance to Fairview Ridges Hospital. *Pet. Ex. 14* at 23-26; *Pet. Ex. 18* at 12. Ashlyn was then transferred to Children’s Hospital in status epilepticus.¹⁴ *Pet. Ex. 14* at 26; *Pet. Ex. 16* at 4-5; *Pet. Ex. 18* at 12. At Children’s Hospital, Ashlyn underwent a video EEG, which was normal for a child her age. *Pet. Ex. 6* at 155-58. Ashlyn was discharged on November 20, 2000. *Pet. Ex. 16* at 4.

Ashlyn was not hospitalized again until January 8, 2001, when she was taken by ambulance to Fairview Ridges Hospital with a seizure. *Pet. Ex. 14* at 17-19. A chest x-ray was negative. *Id.* at 20.

Ashlyn visited her pediatrician’s office on January 25, 2001, with a two-to-three week history of cough, congestion, and low grade fevers. *Pet. Ex. 4* at 9, 11. A physician’s assistant noted that Ashlyn had a seizure with a high fever a couple of weeks prior and had been taken to the emergency room. *Id.* Ashlyn was diagnosed with a prolonged upper respiratory infection and probable acute bronchitis. *Id.* Then, later that same day, Ashlyn was taken to Fairview Ridges Hospital with a seizure. *Pet. Ex. 14* at 14-16. Several days later, on January 29, 2001, Dr. Spiegel saw Ashlyn for a follow-up visit. *Pet. Ex. 16* at 41-42. Dr. Spiegel reported that despite her seizures, Ashlyn was developing well. *Id.* at 41.

On March 3, 2001, Ashlyn was admitted to the Pediatric Intensive Care Unit (“PICU”) at Children’s Hospital “following multiple medications to stop seizure.” *Pet. Ex. 6* at 210. She was discharged within 24 hours. *Id.*

criteria.” Dorland’s Illustrated Medical Dictionary, *supra* note 2, at 596.

¹³ An MRI is “a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments.” Dorland’s Illustrated Medical Dictionary, *supra* note 2, at 908.

¹⁴ Status epilepticus is “a continuous series of generalized tonic-clonic seizures without return to consciousness.” Dorland’s Illustrated Medical Dictionary, *supra* note 2, at 1756. A generalized tonic-clonic seizure is “the seizure of grand mal epilepsy, consisting of a loss of consciousness and generalized tonic convulsions followed by clonic convulsions.” *Id.* at 1676. Tonic convulsions are involuntary and are characterized by a “prolonged contraction of the muscles.” *Id.* at 415-16. Clonic convulsions are also involuntary and are characterized by “alternating contraction and relaxation of the muscles.” *Id.* at 415.

Ashlyn remained seizure free until March 29, 2001, when she was taken by ambulance to Fairview Ridges Hospital with a generalized tonic-clonic seizure. Pet. Ex. 14 at 4-7; Pet. Ex. 18 at 19. Ashlyn was transferred to Children’s Hospital. Pet. Ex. 14 at 5; Pet. Ex. 18 at 19. Several days later, on April 2, 2001, Ashlyn had another seizure and returned to the emergency room. Pet. Ex. 6 at 210. Ashlyn again returned to the emergency room on April 3, 2001, with yet another seizure. Id.; Pet. Ex. 19 at 2. On that date, Ashlyn was admitted to the PICU for observation and then discharged the following day. Pet. Ex. 6 at 210. But, on April 17, 2001, Ashlyn was again taken to the emergency room because of seizure. Id.

On May 18, 2001, Ashlyn visited Metropolitan Pediatric Specialists, P.A. for her twelve-month well-child visit. Pet. Ex. 5 at 19. Timothy Johanson, M.D., noted that Ashlyn had seizures since age three-and-one-half months and been hospitalized three times for status epilepticus. Id.

On June 8, 2001, Ashlyn was taken to St. Francis Regional Medical Center (“St. Francis”) due to a seizure. Id. at 99-100. Ashlyn was transferred to Minneapolis Children’s Hospital. Id. at 100-02. Then, on July 10, 2001, Ashlyn again was taken to St. Francis with a seizure. Id. at 89. Manuel Roman, M.D., gave Ashlyn antiseizure medication, which stopped the seizure after ten minutes. Id. at 90. Blood tests were normal except for a mildly elevated white blood cell count. Id. at 90-91. Ashlyn was discharged against medical advice. Id. at 91.

On July 12, 2001, Ashlyn saw Steven Janousek, M.D., at Noran Neurological Clinic on referral for a neurologic assessment. Pet. Ex. 7 at 71-72. Five days later, on July 17, 2001, Ashlyn returned to St. Francis with a seizure. Pet. Ex. 5 at 92-93. Between July 18, 2001, and April 26, 2002, Ashlyn’s mother frequently telephoned the Noran Neurological Clinic to update Dr. Janousek on Ashlyn’s progress, discuss adjustment of Ashlyn’s medications, inquire about seizure management, or discuss administrative matters. See generally Pet. Ex. 7.

On July 23, 2001, Ashlyn had her urine analyzed for organic acids,¹⁵ amino acids,¹⁶ and oligosaccharides.¹⁷ Pet. Ex. 5 at 34-36. The interpreting physician found, “This specimen was screened for all organic acids which are diagnostic of organic acidurias. The organic acid pattern

¹⁵ An organic acid is an acid that contains one or more carbon atoms. Dorland’s Illustrated Medical Dictionary, supra note 2, at 16.

¹⁶ An amino acid is “any organic compound containing an amino and a carboxyl group.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 16.

¹⁷ An oligosaccharide is “a carbohydrate that on hydrolysis yields a small number of monosaccharides.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 1306. A monosaccharide is a “simple sugar; a carbohydrate that cannot be decomposed by hydrolysis.” Id. at 1172.

seen is not consistent with that of a known aciduria.”¹⁸ Id. at 34. In addition, the physician wrote, “This urine amino acid pattern is not consistent with a known disorder of amino acid metabolism.” Id. Finally, the physician indicated that the oligosaccharides screen was normal. Id. at 35.

On July 31, 2001, Ashlyn again returned to St. Francis with a seizure. Id. at 97. James S. Parker, M.D., noted that Ashlyn had been seizing for approximately ten minutes at the time of arrival and administered antiseizure medication, which finally resolved the seizure. Id. at 97-98. Ashlyn was admitted to the hospital for further observation as she recovered from sedation and the antiepileptics. Id. at 98.

On August 7, 2001, Ashlyn had another brain MRI, which was normal. Pet. Ex. 7 at 27. Despite her normal MRI, Ashlyn returned to St. Francis on August 11, 2001, and August 24, 2001, with seizures. Pet. Ex. 5 at 31-32, 85-88; Pet. Ex. 18 at 31. On August 24, 2001, Ashlyn was transported by air to Minneapolis Children’s Hospital. Pet. Ex. 5 at 87-88; Pet. Ex. 7 at 25-26; Pet. Ex. 18 at 31. A repeat MRI was normal and Ashlyn was placed on antiseizure medication. Pet. Ex. 7 at 26. Ashlyn was discharged on August 25, 2001. Id. at 25-26.

On August 28, 2001, Ashlyn saw Dr. Janousek for a follow-up visit. Id. at 58. Subsequently, Ashlyn was admitted to the pediatric epilepsy ward at Children’s Hospital on September 10, 2001, with the goal of starting the ketogenic diet.¹⁹ Pet. Ex. 6 at 202-06, 209-13, 216. She underwent a video EEG throughout her admission. Id. at 150-54. Ashlyn also was evaluated by the Speech Pathology Department to assess her communication skills. Id. at 89. The speech pathologist found that Ashlyn had a mild receptive and expressive language delay. Id. Ashlyn was discharged on September 13, 2001. Id. at 202-05.

On September 17, 2001, October 5, 2001, and October 15, 2001, Ashlyn returned to St. Francis with further seizures. Pet. Ex. 5 at 79-84.

¹⁸ Aciduria is the “excess of acid in the urine.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 17.

¹⁹ According to The Epilepsy and Brain Mapping Program:

The ketogenic diet is a stringent, mathematically calculated diet high in fat and low in protein and carbohydrates that, when followed conscientiously, produces a by-product called ketones in patients’ blood and urine. High concentrations of ketones in the body control the frequency and severity of seizures, although the biochemical mechanisms for this phenomenon are not yet known.

The Epilepsy and Brain Mapping Program, The Ketogenic Diet, at http://www.epipro.com/k_diet.html (last visited July 21, 2005).

Between November 4, 2001, and June 27, 2003, Ashlyn's mother frequently telephoned the Minnesota Epilepsy Group, P.A., to update Dr. Ritter on Ashlyn's progress, discuss adjustment of Ashlyn's medications, inquire about seizure management, or discuss administrative matters. See generally Pet. Ex. 6.

On November 8, 2001, Ashlyn was taken to St. Francis with a seizure unresponsive to rectal Valium.²⁰ Pet. Ex. 18 at 24. Ashlyn had a chest x-ray that was normal. Pet. Ex. 5 at 28. Ashlyn was transferred to the PICU at Minneapolis Children's Hospital. Pet. Ex. 6 at 214-15; Pet. Ex. 18 at 24.

On November 13, 2001, Ashlyn saw Dr. Ritter for a follow-up to her hospital admission and for a second opinion. Pet. Ex. 6 at 116-19. Dr. Ritter reported that "Ashlyn continues to have ongoing seizures with frequent episodes of status epilepticus. Seizures typically do not stop with the administration of rectal Valium and therefore require[] emergency medical intervention." Id. at 119. Dr. Ritter planned to ascertain what testing regarding the etiology of the seizures had been done and adjusted Ashlyn's antiseizure medication. Id.

On December 7, 2001, Ashlyn was taken to St. Francis several times. Pet. Ex. 5 at 75-76. John Baker, M.D., stated that in the afternoon, Ashlyn's mother noted cluster seizure activity and brought Ashlyn to the hospital because Ashlyn became lethargic after the administration of Valium. Id. at 75. Ashlyn returned to the hospital later that afternoon with questionable seizure activity. Id. Within an hour of her discharge, Ashlyn returned again with a recurrence of seizure activity and was admitted for observation. Id.

On December 26, 2001, Ashlyn was admitted to Children's Hospital for "clarification of seizures, medication adjustment, PT, OT and speech evaluation to determine baseline developmental status and [etio]logic evaluation to determine cause for seizures if not done previously." Pet. Ex. 6 at 193-96. Michael D. Frost, M.D., noted that although Ashlyn had been treated with multiple anticonvulsant medications and the ketogenic diet, she still had daily seizures. Id.

During her hospitalization, Ashlyn "underwent prolonged evaluation with difficult to control seizures." Id. Her physicians performed a video EEG which "revealed generalized spike and polyspike and wave or frontally dominant epileptiform discharges." Id. at 141-49, 196. Before she was discharged, Ashlyn's physicians made additional changes to her medication regimen.²¹ Id. at 194-96.

²⁰ Valium is the trademark for the drug preparation of diazepam. Dorland's Illustrated Medical Dictionary, supra note 2, at 2003. Diazepam is a benzodiazepine used as, among other things, an anticonvulsant and as an antitremor agent. Id. at 512.

²¹ A listing of the antiepileptic medications tried by Ashlyn can be found at Petitioners' Exhibit 6 at 256-57.

Also during this admission, Ashlyn was evaluated by the Speech Pathology Department to reassess her communication skills. Id. at 87-88. Once again, the speech pathologist found that the gap between Ashlyn and her peers was growing slightly in communication skills. Id. at 87. Ashlyn also was evaluated by the Physical Therapy Department and the Occupational Therapy Department. Id. at 172-76. Ashlyn was discharged from Children’s Hospital on January 11, 2002, with diagnoses of intractable epilepsy, partial tonic seizures and complex-partial secondary generalized seizures, a history of status epilepticus, and a history of Todd’s paralysis.²² Id. at 196.

On January 11, 2002, after being discharged from Children’s Hospital, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 68. Brian Clarkowski, M.D., administered antiseizure medication which resolved her seizure. Id. at 69.

Ashlyn visited Metropolitan Pediatric Specialists, P.A. on January 17, 2002, for her eighteen month well-child visit and blood work. Id. at 15. Judith Snook, M.D., noted “normal growth, devel[opmental] delay, [and] intractable seizures.” Id.

On January 24, 2002, Ashlyn underwent a two-hour video EEG. Pet. Ex. 6 at 139-40. According to Dr. Ritter, “This EEG would suggest diffuse cortical dysfunction with multiple areas of potential epileptogenesis, as well as areas of more generalized and diffuse, but somewhat irregular spike-wave or polyspike wave.” Id. at 140.

Five days later, on January 29, 2002,²³ Ashlyn was admitted to the Mayo Clinic by Jeffrey R. Buchhalter, M.D., to determine whether “a single focus of seizure onset is likely that would be susceptible to surgical removal.” Pet. Ex. 15 at 8. Dr. Buchhalter discussed with Ms. Markovich the possibility of an immunologically-mediated seizure disorder. Id. at 16. Upon admission, neurologist Randa G. Jarrar, M.B.B.S.,²⁴ reported that Ashlyn experienced four types of seizures: (1) repeated eye blinking; (2) clonic movement of the face, arm, and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures. Id. at 12. Dr. Jarrar also noted that Ashlyn was developing appropriately for her age with the exception of her speech. Id. at 13. Dr. Jarrar diagnosed intractable epilepsy and discussed with Ms. Markovich the remaining treatment options, including other medications and surgery. Id. at 14. Ashlyn was admitted to the Epilepsy Monitoring Unit and had a computer-assisted prolonged video EEG from January 30, 2002, to February 3, 2002. Id. at 2-3, 14. The EEG revealed evidence of multifocal epileptic abnormalities. Id. at 2-3. Dr. Buchhalter noted that because Ashlyn’s seizures had different foci,

²² Todd’s paralysis, also known as postepileptic paralysis, is “hemiparesis or monoparesis lasting for a few minutes or hours, or occasionally for several days, after an epileptic seizure.” Dorland’s Illustrated Medical Dictionary, supra note 2, at 1366.

²³ Ashlyn had been referred to the Mayo Clinic by Dr. O’Neil on February 2, 2001. Pet. Ex. 4 at 10.

²⁴ An M.B.B.S. is the abbreviation for a bachelor of medicine and bachelor of surgery.

surgical intervention was not indicated. Id. at 20. Ashlyn was discharged on February 19, 2002. Id. at 19.

On February 17, 2002, February 22, 2002, twice on March 17, 2002, and April 5, 2002, Ashlyn returned to St. Francis with seizures. Pet. Ex. 5 at 52-55, 64-67. At the surgical conference held at Minnesota Epilepsy Group on April 9, 2002, Ashlyn was recommended for the implantation of a vagus nerve stimulator (“VNS”).²⁵ Pet. Ex. 6 at 242.

Ashlyn was admitted to Children’s Hospital on April 16, 2002, “for video EEG to clarify events and then determine treatment options.” Id. at 185-87. Multiple events were recorded on the EEG. Id. at 128. The EEG “strongly suggested a frontal onset to seizures.” Id. Ashlyn was discharged on April 18, 2002.²⁶ Id. at 186.

On April 29, 2002, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 48-49. Dr. Clarkowski noted that Ashlyn “had a focal seizure of just focal eye twitching and nystagmus for approximately 30 minutes.” Id. The antiseizure medication resolved the seizure. Id. at 49.

Ashlyn’s mother telephoned the Minnesota Epilepsy Group on April 30, 2002, because of a one-and-a-half hour long seizure Ashlyn had the previous night. Pet Ex. 6 at 5. Ashlyn’s mother reported a dramatic reduction in eye flutters, but felt that Ashlyn was out of control the previous night and wanted to speak with Dr. Ritter. Id.

²⁵ According to The Epilepsy and Brain Mapping Program:

The vagus nerve is one of the primary communication lines from the major organs of the body to the neck to the vagus nerve. Stimulation of the vagus nerve can stop seizures, reduce the intensity and frequency of seizures in some patients. The VNS periodically stimulates the vagus nerve, usually for a brief period.

The VNS is an implanted pacemaker-size stimulator. It has a wire lead that attaches to the vagus nerve by means of an incision. The incision is made on a naturally occurring crease on the neck, thereby making the healed scar practically invisible. The procedure takes a few hours and the patient is usually released from the hospital on the next day. After the patient stabilizes, the physician uses a wand to activate the VNS.

The Epilepsy and Brain Mapping Program, Vagus Nerve Stimulator, at <http://www.epipro.com/vns.html> (last visited July 21, 2005).

²⁶ A listing of the antiepileptic medications administered to Ashlyn between January 11, 2002, and April 17, 2002, can be found at Petitioners’ Exhibit 6 at 258-60.

After being free of seizures for three weeks, Ashlyn was taken to St. Francis on June 23, 2002, with a seizure. Id. at 46-47. Dr. Roman gave Ashlyn medication which resolved the seizure. Id. However, Ashlyn returned later that day after vomiting and resuming atypical seizure activity. Id. at 50-51. Antiseizure medication again resolved Ashlyn's seizure. Id. at 51. Ashlyn was again seen at St. Francis for another seizure on August 11, 2002. Id. at 29-30. On August 27, 2002, Ashlyn saw Dr. Ritter for a follow-up visit. Pet. Ex. 6 at 352-55.

On October 8, 2002, Ashlyn had a physical examination in preparation for the implantation of her VNS. Id. at 181-84. Then, on October 10, 2002, Ashlyn had the VNS implanted by Mary E. Dunn, M.D., at Children's Hospital. Id. at 96, 178-80. Unfortunately, the VNS flow sheets dated from October 15, 2002, to April 10, 2003, indicate that minimal to no improvement occurred with Ashlyn's seizures.²⁷ Id. at 165-71. Ashlyn was discharged on October 11, 2002. Id. at 180.

On January 3, 2003, Ashlyn underwent a speech and language evaluation at St. Francis Rehabilitative Services by Michelle Laurent, CCC-SLP. Pet. Ex. 5 at 43-45. Ashlyn's mother's primary concerns at this evaluation included Ashlyn's language production and cognitive skills. Id. at 43. Ms. Laurent found that Ashlyn demonstrated significant speech and language delays and recommended that Ashlyn receive therapy to encourage development of her speech and language skills. Id. at 44.

On February 2, 2003, Ashlyn was taken to St. Francis with seizure activity. Id. at 41-42. Dr. Roman tried several medications and eventually was successful in arresting the seizure. Id.

Ashlyn was admitted to Children's Hospital on March 19, 2003. Pet. Ex. 6 at 190-92. The purpose of the admission was to determine other treatment options and to obtain a baseline recording to determine whether Ashlyn's seizures had changed. Id. at 190. During her admission, Ashlyn was started on various antiseizure medications. Id. at 191. In addition, the

²⁷ On January 27, 2003, Ashlyn saw Dr. Ritter for a follow-up of her intractable epilepsy and for additional adjustment of her VNS. Pet. Ex. 6 at 307-10. In his assessment, Dr. Ritter reported:

At this time, although Ashlyn has had the vagal nerve stimulator only for approximately a three-month period of time, seizure frequency, intensity, and quality of life remain unchanged. . . . Family has considerable concerns regarding frequency of seizures despite all the medication changes and placement of the vagal nerve stimulator. Mother also has questions that during her pregnancy at approximately 34 to 35 weeks gestation, fetal bradychardia was noted on two to three occasions; was this related to seizure activity.

Id. at 310.

surgical option of an anterior two-thirds corpus callosotomy²⁸ was discussed. Id. Ashlyn was discharged on March 22, 2003. Id. at 190-92.

On April 25, 2003, and June 19, 2003, Ashlyn was taken to St. Francis with a seizure. Pet. Ex. 5 at 37-40. As a result of his treatment of Ashlyn during her previous visits to the emergency department for seizure activity, Dr. Clarkowski tried several antiseizure medications until Ashlyn's seizure was resolved. Id. at 37-38, 40.

On July 28, 2003, an MRI of Ashlyn's brain revealed:

1. Small ill-defined focus of signal abnormality is seen in the deep right mid frontal white matter. This is nonspecific, but is compatible with nondescript gliosis.
2. Possible mild-to-moderate atrophy of the right hippocampal complex.
3. Intracranial contents otherwise unremarkable.
4. Inflammatory changes noted bilaterally in the ethmoid and maxillary paranasal sinuses.

Pet. Ex. 11 at 4.

III. DISCUSSION

A. The Vaccine Act and Waiver of Sovereign Immunity.

“The United States, as sovereign, is immune from suit save as it consents to be sued.” United States v. Sherwood, 312 U.S. 584, 586 (1941). Specifically, “a statute of limitations is a condition on the waiver of sovereign immunity by the United States, and courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.” Brice v. Sec’y of HHS, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (citations and internal quotations omitted). “The court cannot expand on the waiver of sovereign immunity explicitly stated in the statute.” McGowan v. Sec’y of HHS, 31 Fed. Cl. 734, 740 (1994) (citing Broughton Lumber Co. v. Yeutter, 939 F.2d 1547, 1550 (Fed. Cir. 1991)). Moreover, the statute of limitations may not be waived by either the court or the parties. Forman v. United States, 329 F.3d 837, 841-42 (Fed. Cir. 2003).

The Vaccine Act is a waiver of the sovereign immunity of the United States because it permits people with vaccine-related injuries, as well as the legal representatives of people who have suffered a vaccine-related death, to sue the United States for compensation. The right to sue is not unconditional—the Vaccine Act contains a statute of limitations that places a condition

²⁸ A corpus callosotomy is the “surgical transection of the fibers in the corpus callosum . . . ; formerly used to treat intractable epilepsy.” Dorland’s Illustrated Medical Dictionary, *supra* note 2, at 423.

on the waiver of sovereign immunity. The express limitations provision of the Vaccine Act provides that for vaccines listed in the Vaccine Injury Table (“Table”):²⁹

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

....

42 U.S.C. § 300aa-16(a)(2) (emphasis added). In other words, the United States waives its sovereign immunity only for 36 months in instances of vaccine-related injury. After 36 months, the United States is immune from suit.

The court is obligated to dismiss a petition as soon as it finds that it lacks jurisdiction to decide the merits of a case. See Steel Co. v. Citizens for a Better Env’t, 523 U.S. 83, 94 (1998) (“Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.”), citing Ex parte McCordle, 74 U.S. (7 Wall.) 506, 514 (1868).

B. Threshold Jurisdictional Issue.

The threshold question presented in this case is whether the August 29, 2003 petition was filed within the three-year limitations provision specified by the Vaccine Act. To satisfy the limitations provision of the Vaccine Act, Ashlyn’s symptoms must have begun on or after August 29, 2000; otherwise the petition is untimely. The petition, coupled with Ashlyn’s mother’s affidavit and petitioners’ expert reports, implicates the statute of limitations. Specifically, the petition avers:

At times after the immunization of July 10, 2000, until August 30, 2000, Michael and Melissa Marckovich observed Ashlyn having episodes in which Ashlyn would rapidly blink her eyes. Petitioners now know that these episodes may have been seizures although at the time they thought she was tired. The first episode was approximately July 10, 2000. No medical attention was sought during this time due to there being no apparent cause for concern.

Pet. at ¶ 3. Further, Ms. Markovich’s affidavit explained that on July 10, 2000, after Ashlyn had received her vaccinations at the Fairview Cedar Ridge Clinic, she “thought . . . Ashlyn was just sleepy, [but] I am now aware she may have been having seizures between the time of the immunization and August 30, 2000, when she had her first serious episode.” Pet. Aff. at ¶ 4. Therefore, the critical jurisdictional issue to be resolved is whether the repeated eye blinking

²⁹ 42 C.F.R. § 100.3(a). The DTaP, IPV, and Hib vaccinations are included on the Table.

episodes, which began on July 10, 2000, were, in fact, the first symptom or manifestation of onset of Ashlyn's seizure disorder, thus triggering the statute of limitations.

The parties provided differing views as to the date of onset. Petitioners contend, relying on the contemporaneous medical records, that the first symptom or manifestation of onset occurred on August 30, 2000, the date Ashlyn was rushed to the hospital with her first seizure. To support their assertion, petitioners argue that although the first eye blinking episode, which occurred on July 10, 2000, may have been the harbinger of Ashlyn's seizure disorder, as laypersons, they lacked the requisite medical education and training to comprehend the significance of the first episode. The parents observed the repeated rapid eye blinking episodes, but assumed that, on those occasions, Ashlyn was fluttering her eyes because she was sleepy. Sadly, they were unaware that what they had begun to witness was the first neurological symptom that either signaled their daughter's brain disorder or was a subtle seizure. According to the petition and Ms. Markovich's affidavit, it was not until after the August 30, 2000 seizure that the petitioners became aware of the significance of the earlier eye blinking events. Thus, the parents argue, it was impossible for them to make the necessary linkage between rapid eye blinking and injury. For this reason, petitioners urge the special master to find August 30, 2000, as the date of onset. In essence, petitioners argue that their inability to recognize the significance of the first symptom of their child's debilitating disorder delays the running of the limitations period.

Conversely, respondent contends that because Ashlyn's July 10, 2000 rapid eye blinking was the first symptom of Ashlyn's seizure disorder, the plain language of the statute requires that the 36-month period began running on that date. According to the respondent, the limitations period is triggered by the first symptom or manifestation of onset, not by petitioners' actual knowledge or awareness of a claim arising under the Vaccine Act. Indeed, respondent argues that petitioners need not know that their child suffered a vaccine-related injury. Rather, respondent contends, it is sufficient that these parents were aware of the July 10, 2000 eye blinking episode—the Markovichs need not have been aware of the significance.

Because the resolution of this factual issue is critical to the court's exercise of subject-matter jurisdiction, the court conducted an onset hearing. As explained below, because petitioners' expert witness conceded that the rapid eye blinking episode witnessed by Ashlyn's parents on July 10, 2000, was the first symptom or manifestation of onset of Ashlyn's seizure disorder, the special master is required to dismiss the petition as beyond the limitations period.

1. Dr. Corbier's Testimony Makes Plain that the July 10, 2000 Rapid Eye Blinking Episodes Constituted the Onset of Ashlyn's Seizure Disorder.

Petitioners offered only one witness at hearing, Dr. Corbier. Dr. Corbier was awarded his medical degree in 1995 and became board-certified in pediatric neurology in 2000.³⁰ Tr. at 5-6. Dr. Corbier treats both adults and children with seizures. Id. at 6. Dr. Corbier explained that a seizure disorder and epilepsy are the same thing; however, with seizure disorders, an individual can experience multiple seizures daily. Id. at 7.

Dr. Corbier also opined that DPT vaccinations can cause seizure disorders in susceptible individuals. Id. Based upon his review of Ashlyn's medical records and her clinical picture, Dr. Corbier confirmed the opinion of his May 19, 2004 report that on August 30, 2000, Ashlyn had a generalized tonic-clonic seizure that lasted at least 20 minutes. Id. at 9. With regard to the rapid eye blinking episodes, which were the focus of the onset hearing, Dr. Corbier testified:

Well, they play an important part, in the sense that from my understanding of the records it seems that on July 10th, 2000, the very day of her vaccinations, there was some blinking of the eye. What is unclear is whether it could have been the beginning of some small unrecognized seizure activity.

That could sometimes be subtle, or it could be some type of beginning of a brain dysfunction that would have culminated to a full-fledged, first full seizure on August 30th.

So my professional opinion is that the time line of when something first [] may have started on August 10th, [sic]³¹ that was due to some type of cerebral dysfunction, and then the results culminated in her having a seizure, a generalized tonic, or grand mal seizure as we call it, on August 30th.

Id. at 10 (emphasis and footnote added). Dr. Corbier explained that although rapid eye blinking alone is insufficient to establish a seizure disorder diagnosis, as a neurologist, the eye blinking episode would have raised his suspicions and he would have pursued further investigation:

If we had a situation where someone started having eye blinking for no apparent reason, then we start to ask questions. There are certain things beyond the eye blinking that would raise our level of suspicion more and more in terms of seizure

³⁰ All references to the Transcript of the November 5, 2004 proceedings shall be designated herein as "Tr. at ___."

³¹ Dr. Corbier misstated the date of the eye blinking episode and almost immediately corrected the record to reflect the correct date, July 10, 2000. Tr. at 10.

activity, such as observation of a loss of consciousness, ideation, and what we call post-spectral changes.

For instance, if someone has a lot of eye blinking, and then subsequently become[s] very tired or confused, that would be some of the traditional clinical findings that would raise my level of suspicion.

So eye blinking by itself would not lead necessarily to seizures, but would at least lead to a suspicion and the need for further questioning and evaluation.

Id. at 11 (emphasis added). Dr. Corbier further testified that he could not state with certainty whether the eye blinking episodes themselves constituted seizure activity, explaining:

It is hard for me to say definitively that it was or was not a seizure, . . . the only way to be certain would be to have an EEG done at that time while the eye blinking was going on and correlating it with EEG changes.

Short of that, what we can do is suspect that there are one or two possibilities. One is that the eye blinking could have either been some small seizures, subtle seizures if you will, or there is also the possibility that it could have been some type of brain dysfunction that started at that time, and manifesting as involuntary eye blinking.

And with progressive dysfunction, that person then on August 30th had a full-fledged seizure, and went on to have . . . more and more seizures, and you can see that there was a progression of symptoms.

Id. at 12 (emphasis added). This testimony is significant for two reasons. First, either possibility posited by Dr. Corbier, a subtle seizure or a brain dysfunction, reflects that the child had a malady that was manifested by a clear neurological symptom—eye blinking.³² Therefore, regardless of the ultimate conclusion—subtle seizure or brain dysfunction—it was clear and unmistakable that Ashlyn’s rapid eye blinking was not normal. It is not relevant to the onset

³² Later in his testimony, Dr. Corbier again confirmed his prior testimony that Ashlyn’s July 10, 2000 rapid eye blinking reflected cerebral dysfunction. Id. at 15-16. Specifically, Dr. Corbier testified that he thought it likely that a brain dysfunction caused the July 10, 2000 eye blinking episode, that the brain dysfunction led to the development of the seizure disorder, and that the first full-blown seizure occurred on August 30, 2000. Id. at 18-19. Finally, Dr. Corbier testified that the eye blinking and development of seizure disorder were all part of the same process. Id. at 19. The special master find this evidence compelling.

query that the parents were unaware that the blinking episodes were a neurological symptom that served as the precursor to the seizure that Ashlyn would experience on August 30, 2000. What is relevant to the present discussion is that the parents were aware that the blinking episodes began on July 10, 2000, and continued until the August 30, 2000 seizure.

Second, Dr. Corbier makes plain that the eye blinking episodes were part of a progression of symptoms, which culminated in the August 30, 2000 seizure. This point is further illustrated by the following portion of Dr. Corbier's testimony:

The part that is very suspicious to me is, number one, the first full-fledged seizure on August 30th was preceded by the eye blinking that according to the record started on July 10th.

In terms of timing, it appears like there was some type of precipitating event in this case with the vaccine and on that same day you have the eye blinking episodes, []regardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure.

And that they progressed on August 30th to a full-blown seizure, and then according to the record the patient continues having a lot of seizures, and what we would term refractory seizures.

So there have been a lot of evaluations to try to look for alternative diagnoses or causes, and I could not detect any alternative explanations. So looking at that time line, to me, I would say that it was a vaccine related injury causing seizures that could be documented here.

Id. at 14-15 (emphasis added). In arriving at his theory of causation, Dr. Corbier ruled out other causes for Ashlyn's injury. In so doing, Dr. Corbier concluded that the eye blinking episodes, which started on July 10, 2000, marked the onset of first symptom of injury. Therefore, according to Dr. Corbier, Ashlyn's injury was directly tied to the vaccinations, particularly the DTaP vaccine, administered that same day. Specifically, when pressed for an answer as to when the first symptom of the seizure disorder occurred, Dr. Corbier conceded that the first symptom occurred with the July 10, 2000 eye blinking episode: "Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th." Id. at 19.

Dr. Corbier acknowledged that the eye blinking episode was, in fact, medically recognized as a neurological symptom of a mild seizure or subtle brain dysfunction. Id. at 22, 24. A symptom that is "subtle" is, nevertheless, manifestation and cannot be ignored. Consequently, the subtlety of the dysfunction notwithstanding, Ashlyn's July 10, 2000 eye blinking episode evidenced the first symptom or manifestation of onset of her seizure disorder. Throughout his testimony, Dr. Corbier stated that Ashlyn's eye blinking would have made him suspicious and prompted him to ask further questions and conduct an evaluation and order testing. Id. at 11-12,

14, 16, 22, 24. This conclusion is reinforced by the following testimony elicited during cross-examination:

Q But as far as the eye blinking alone, . . . is [it] not your opinion that that alone is evidence of a seizure disorder?

A There is no question that there was a mild seizure, but in terms of a seizure disorder, and seeing signs or symptoms of a seizure disorder, we would want to see signs or symptoms to strengthen that suspicion.

So the choices really are that it could be mild seizures, or that instead of seizures that there could be some subtle cerebral dysfunction that was starting, and will culminate in a more organized seizure activity down the road. So it is hard to sort those two out.

...

Q Dr. Corbier, just to clarify for me, would it be your opinion that the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations?

A Yes, I think that is a likely—that is a good possibility.

Id. at 24-25 (emphasis added). This testimony highlights that Ashlyn's eye blinking was a neurological symptom that marked onset. Dr. Corbier made clear that even though he could not have said with absolute certainty on July 10, 2000, that Ashlyn had a seizure disorder, he was able to testify that problematic neurological symptoms were present. This adverse testimony by petitioners' expert, a highly qualified neurologist and a credible witness, was critical to the special master's decision. It proved that from an objective standpoint, onset was manifest even though the parents did not recognize its significance. It is readily apparent from his testimony that Dr. Corbier found that Ashlyn's eye blinking was a sign of neurological injury. It is irrelevant that a neurologist would not have been able to make an immediate diagnosis of the specific injury on July 10, 2000. It is enough that the eye blinking episodes represented the beginning of a seizure disorder.

It is also worth noting that Dr. Corbier stressed the importance of the eye blinking episodes occurring on the same day as the vaccinations. Dr. Corbier explained that if there had been no evidence of brain dysfunction between July 10, 2000, and August 30, 2000, it would be more difficult to prove that the vaccinations Ashlyn received on July 10, 2000, were the cause of her seizure disorder. Id. at 21-22. Ironically, if the first symptom or manifestation of onset was August 30, 2000, a date which is approximately 51 days postvaccination, petitioners would face a much more difficult battle in proving that the DTaP, IPV, and/or Hib vaccinations caused Ashlyn's seizure disorder. However, for purposes of calculating the limitations period, it is

beyond dispute that there can be only one date of the first symptom or for the manifestation of onset. Shalala v. Whitecotton, 514 U.S. 268, 274 (1995).

2. A Formal Diagnosis Is Unnecessary to Commence the Running of the Limitations Period.

Vaccine Act cases uniformly hold that the 36-month limitations period “does not require a diagnosis of a condition to start the running of the statute of limitations.” Goetz v. Sec’y of HHS, 45 Fed. Cl. 340, 342 (1999), aff’d, 4 Fed. Appx. 827 (Fed. Cir. 2001) (stating further that “the occurrence of an event recognizable as a sign of vaccine injury by the medical profession at large, not the diagnosis that actually confirms such an injury in the specific case” triggers the running of the statute of limitations); Setnes v. United States, 57 Fed. Cl. 175, 181 (2003) (“The court is not holding that a medical or psychological diagnosis or verification of the ‘occurrence of the first symptom or manifestation of onset’ begins the running of the statute of limitations.”). Indeed, petitioners concede this well-settled point of law.³³ Pet. Br. at 4. In a similar vein, petitioners also recognize that the Vaccine Act “does not require knowledge that the vaccine caused the symptom or manifestation of onset in order for the statute of limitations to start running.” Id.; see also Childs v. Sec’y of HHS, 33 Fed. Cl. 556, 558 (1995).

Those concessions notwithstanding, petitioners argue that their claim is timely because they “were neither aware, nor should they have been aware, that Ashlyn had a disease or a condition as of July 10, 2000.” Pet. Br. at 5. By framing the issue in this manner, petitioners divert the inquiry from its proper focus. The critical point on which the limitations issue is decided is when onset was manifest. The special master is not holding that the parents were obligated to recognize or diagnose their child’s disorder from the first moment it occurred. To the contrary, the special master is applying an objective standard as to what the medical community at large would recognize as the first symptom of Ashlyn’s seizure disorder. Dr. Corbier testified that the first symptom or manifestation of onset occurred on July 10, 2000, even though petitioners did not fully comprehend what they saw at the time. As the petition and Ms. Markovich’s affidavit reflect, petitioners observed the rapid eye blinking episodes, but did not realize they were neurological signs manifesting the initial onset of symptoms until after the August 30, 2000 seizure. The parents’ failure to identify Ashlyn’s eye blinking episodes as the manifestation of initial onset of an illness or condition is insufficient to postpone the running of the statute of limitations.

3. Pegging Onset to the Repeated Rapid Eye Blinking Episodes, Which Began on July 10, 2000, Does Not Impose a Heavier Burden on Petitioners.

Petitioners essentially ask that the special master toll the limitations period, which began when they first observed the initial onset of symptoms on July 10, 2000. This she cannot do. Brice, 240 F.3d at 1368, 1373-74. The testimony of petitioners’ expert has demonstrated that

³³ All references to Petitioners’ Brief in Support of Onset Date of August 30, 2000, shall be designated herein as “Pet. Br. at ____.”

Ashlyn's July 10, 2000 eye blinking episode was the first neurological symptom of Ashlyn's seizure disorder. Contrary to their argument, pegging the date of onset to the eye blinking, as required by statute, does not impose a heavier burden on petitioners. The Vaccine Act does not require that the petitioners know the precise moment that Ashlyn suffered a seizure disorder. Nor are petitioners required to identify one or any combination of vaccines that Ashlyn received as having caused her injury. An objective reading of the statute reveals that Congress did not craft language that required knowledge of a specific vaccine-related injury. Rather, Congress specified that the limitations provision of the Vaccine Act is triggered by the first symptom or manifestation of onset of the injury. Here, the petition, Ms. Markovich's affidavit, and the testimony of Dr. Corbier reflect that the eye blinking episodes began on July 10, 2000. As explained above, Dr. Corbier identified the July 10, 2000 eye blinking episode as the first neurological symptom marking the onset of a vaccine-related injury. Importantly, Dr. Corbier admitted that even if he could not confirm a seizure disorder on July 10, 2000, Ashlyn's symptoms "would at least lead to a suspicion and the need for further questioning and evaluation." Dr. Corbier stated that the eye blinking could have been either "subtle seizures . . . or some type of brain dysfunction." Regardless of the specific neurologic injury flowing from vaccination, Dr. Corbier explained that given that the eye blinking episodes continued over time until the seizure on August 30, 2000, "you can see that there was a progression of symptoms." This testimony conclusively demonstrates that the only possible date of onset is July 10, 2000.

4. The Vaccine Act Does Not Differentiate Between Subtle and Pronounced Symptoms.

In the Vaccine Act, Congress made no distinction between subtle and pronounced symptoms for the date of onset. If Congress had intended such a distinction, the Vaccine Act would contain such language, but it does not and the special master will not engraft such a provision. As respondent correctly points out in his posthearing brief, there are numerous cases where the established first manifestation of symptoms was subtle. For example, in Lynch v. Secretary of HHS, No. 90-3767V, 1992 WL 365457, at *4 (Fed. Cl. Spec. Mstr. Nov. 12, 1992), the special master noted that even though the parents did not recognize it as significant at the time, the first symptom or manifestation of onset was the child's slumping over in a chair, which marked the child's first seizure. Other decisions have noted that brief eye blinking or fluttering constituted the onset of symptoms even though the symptoms were subtle. See Gruber v. Sec'y of HHS, No. 95-34V, 1998 WL 928423, at *8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998), rev'd on other grounds, 61 Fed. Cl. 674 (2004); Lara v. Sec'y of HHS, No. 90-1655V, 1993 WL 215068, at *13 (Fed. Cl. Spec. Mstr. June 4, 1993). As explained by the Court of Federal Claims in Goetz, "[I]t is clear that Congress intended the cause of action . . . to accrue upon occurrence of the first symptom of an injury, not upon the first identification of a link between the injury and the vaccination." 45 Fed. Cl. at 342.

5. The Setnes Decision Does Not Apply to the Facts of This Case.

Petitioners urge the undersigned to apply their interpretation of the holding in Setnes v. United States. Setnes, instructive but non-binding Court of Federal Claims precedent, is

inapposite here.³⁴ In Setnes, the injured child, AJ, suffered from autism, a condition that went undiagnosed by his physicians for many months despite their best efforts and years of education and training. 57 Fed. Cl. at 177. Specifically, AJ’s behavior changed after his 15-month vaccinations—he made a constant humming noise and was doing a lot of babbling. Id. at 176-77. Other changes in behavior included kicking, screaming, and even instances when AJ ate videotape cardboard boxes. Id. at 177. Despite being examined by his pediatrician and his obvious change in behavior, AJ went undiagnosed for many months. Id. It was not until ten months after the vaccinations in question had been administered that AJ’s pediatrician expressed concern that he might suffer from a pervasive developmental disorder. Id. Finally, nearly 16 months postvaccination, AJ was diagnosed with autism. Id.

In order to prevent the dismissal of their petition on statute of limitations grounds, AJ’s parents argued that “because of the unique nature of autism spectrum disorder, there can be no ‘manifestation of onset’ until such time as the medical and psychological professionals verify through reliable medical and psychological means that a constellation of behaviors presented in a specific child meet the criteria for autism spectrum disorder.” Id. at 179. Although not accepting all of the parents’ arguments, the court agreed that:

As distinguished from other medical conditions, . . . the beginning stages of autism cannot be reduced to a single, identifiable symptom. Many of the initial ‘symptoms’ are subtle and can easily be confused with typical child behavior. Where there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the ‘occurrence of first symptom.’

Id. (footnotes omitted) (emphasis added). The court stated that the onset of AJ’s autism was not manifest for a number of months after the first symptoms occurred because the injury was not manifest. Id. at 181. The court reasoned that if AJ’s pediatrician were unable to diagnose an injury, then it would be unfair to apply the statute in a mechanical way that required the parents to have greater skill and training than the pediatrician. Id. In reaching its conclusion, the court reasoned that Congress’s use of the word manifest was not surplusage. Id. at 180.

The Setnes court held that “in a situation such as that before the court, where the symptoms of autism develop ‘insidiously over time’ and the child’s behavior cannot readily be connected to an injury or disorder, the court may rely on the child’s medical or psychological evaluations for guidance in ascertaining when the ‘manifestation of onset’ occurred.” Id. at 181. The Court further remarked that: “It is one thing to be unaware that an obvious injury or its onset was caused by a vaccination. It is quite another to lack knowledge, through no assignable fault,

³⁴ “Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.” Hanlon v. Sec’y of HHS, 40 Fed. Cl. 625, 630 (1998), aff’d, 191 F.3d 1344 (Fed. Cir. 1999).

of the existence of the onset. This is especially true where the treating physician does not associate the behavior as an onset of an injury.” Id.

Although not a treating physician, Dr. Corbier identified the rapid eye blinking episodes, which began on July 10, 2000, as a neurological indicator of mild seizure or other brain dysfunction. Although it was not until after the August 30, 2000 seizure that Ashlyn’s parents realized that they may have been observing possible subtle seizures beginning on July 10, 2000, that does not alter the reality that those mild seizures or brain dysfunction episodes were manifest. As explained earlier herein, petitioners need not understand the significance of a first symptom, the symptom merely must be manifest. To hold otherwise would open the door to many who would conveniently argue that while they observed certain activity shortly after vaccination that was later explained to be the first symptom or manifestation of the onset of an injury, because they lacked medical training, they failed to recognize those first symptoms as the manifestation of an injury.

Unlike Setnes, this case does not involve autism. Another distinguishing feature is that in the instant case, petitioners’ expert pediatric neurologist testified that the eye blinking episode was part of the same process as the dysfunction that culminated on August 30, 2000 in a seizure. Thus, unlike the child in Setnes, Ashlyn had a clear and defined neurological event—repeated rapid eye movement. There can be no serious disagreement that neurological symptoms are not equivalent to typical childhood behaviors. A pediatrician might well expect to see a young child like AJ babble and kick. However, as Dr. Corbier testified, rapid eye movements would raise his suspicions.³⁵ In sum, Dr. Corbier’s testimony was unmistakable that the rapid eye blinking episodes that began on July 10, 2000, and the August 30, 2000 seizure were all part of the same process. Therefore, petitioners’ contention is unpersuasive that because they were not so alarmed by Ashlyn’s eye blinking episodes as to seek medical attention, the statute of limitations did not begin to run. As described above, this reasoning is not in accord with other Vaccine Act decisions. As the Federal Circuit cautioned in Brice v. Secretary of HHS, courts must be “careful not to interpret [a waiver of sovereign immunity] in a manner that would extend the waiver beyond that which Congress intended. 240 F.3d at 1372-73 (quoting Stone Container Corp. v. United States, 229 F.3d 1345, 1352 (Fed. Cir. 2000)).

³⁵ Petitioners’ counsel tried to lead Dr. Corbier through a Setnes analysis. However, those efforts were not successful. After being asked whether “the beginning states of epilepsy [can] be reduced to a single identified symptom,” Dr. Corbier responded: “Yes, in a sense that instead of what is called a grand mal . . . seizure, you may have situations where instead of having a full-blown episode, you may have something that is less mild at first, and then may build up into a more conspicuous and remarkable episode, such as a grand mal seizure.” Tr. at 11. Thus, Dr. Corbier did make a direct connection between the rapid eye blinking that began on July 10, 2000, and culminated with Ashlyn’s August 30, 2000 seizure.

Petitioners are devoted and caring parents. That their little girl is afflicted with a terrible condition, which at times is life-threatening, is heart wrenching. Magnifying their pain is the fact that the reason petitioners had their child vaccinated was to preserve her good health, not to jeopardize it. And now, because they filed their petition 50 days too late, they face dismissal of their petition in the very program designed to compensate parents who believe that their child sustained a vaccine-related injury. If another option were available to her, the special master would take it with alacrity. But the special master is constrained by the law written by Congress. The Vaccine Act, contains a specific limitations period which unambiguously states that the clock begins to run on the date of the occurrence of the first symptom or manifestation of onset of injury. Petitioners' evidence proves that although they may not have understood their significance, they nevertheless were aware that the eye blinking episodes began on July 10, 2000.

IV. CONCLUSION

Petitioners bear the burden of proving that the petition was timely filed. Unfortunately for petitioners, the petition, Ms. Markovich's affidavit, the expert affidavits and reports, and the expert testimony at hearing make clear that the first symptom or manifestation of onset of Ashlyn's seizure disorder occurred on July 10, 2000, a date which is more than three years prior to the filing of the August 29, 2003 petition. Therefore, the special master finds that the court does not have jurisdiction to decide the merits of this case and petitioners' claim is **DISMISSED** for failure to satisfy the statute of limitations.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment dismissing the case as barred by the statute of limitations.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master