

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-160V

(Filed: September 3, 2009)

CHAD EMKEY, by)	
FRANK EMKEY and MAILENE EMKEY)	
)	
Petitioners,)	TO BE PUBLISHED
)	Statute of limitations; <u>Markovich</u> ;
v.)	Autism spectrum disorder
)	
SECRETARY OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	

ORDER TO SHOW CAUSE¹

I. INTRODUCTION

Mr. and Mrs. Emkey allege that vaccinations caused their son, Chad, to develop autism. The issue presented is whether the Petition was filed more than 36 months after the first symptom of Chad's autism disorder. Chad's father, Frank Emkey, asserts that there was no sign or symptom of Chad's autism until he reached four years of age, following a vaccination. Chad's medical records, however, show that Chad's parents reported to his treating physicians that Chad was slow to speak, and that they noticed his speech delay at around two years of age. There are other signs of developmental delay in the record, even before Chad reached age two.²

¹ 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.

² Medical records "warrant consideration as trustworthy evidence." Curcuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). Moreover, because medical records are

The record contains expert medical opinion evidence as well as testimony admitted in the Omnibus Autism Proceeding 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. There is no medical evidence in the record to the contrary. The abundance and consistency of the expert evidence leave no doubt that the general medical community would recognize speech delay as an early symptom of an autistic disorder.

Putting together Chad's medical records, the reliable evidence that speech delay is a generally recognized early symptom of autistic disorders, and the binding precedent concerning application of the statute of limitations in Vaccine Act proceedings, the special master must dismiss the Petition as untimely filed.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. The Medical Record

On March 7, 2008, Chad Emkey, by his parents Frank B. and Mailene Emkey (hereinafter "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.³ Short-Form Autism Petition for Vaccine Compensation (hereinafter Pet.) at 1.⁴ Petitioners alleged that Chad developed autism as a result of vaccinations he received on February 5, 2003, and again on May 25, 2006, including the measles/mumps/rubella (MMR)

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)).

³ 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.A. §300aa of the Vaccine Act.

⁴ 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.

and polio (IPV) vaccines. Statement Regarding Onset (hereinafter “Statement”) at 1; Petitioners’ Exhibit 2 (hereinafter “Pet’r Ex.”) at 53.

Chad was born on January 24, 2002. In their Statement filed July 18, 2008, Petitioners state, “Mailene’s pregnancy and Chad’s subsequent delivery were relatively uneventful,” and “Chad’s newborn records do not note any problems of significance.” Statement at 2.⁵ There is a dearth of records concerning Chad’s development until September 29, 2006, when he was diagnosed with autistic spectrum disorder based on a Neurological Assessment at the University of Florida Developmental Pediatric Center in Jacksonville, Florida. Pet’r Ex. 3 at 140. The Neurodevelopmental Assessment (hereinafter “Assessment”) by David O. Childers, Jr., M.D., was performed at the request of Chad’s parents and his pediatrician, Dr. Don J. Alfonso, M.D. Id. at 133. The Assessment states that, “Initial concerns regarding Chad’s development began at ‘the age of 2 years old, he was not talking much.’” Id. at 135. Other developmental delays also appear to be noted in the Assessment. Id.⁶

The historical information set forth in the Assessment appears to be based on the report of Chad’s mother. Pet’r Ex. 3 at 140 (“This diagnosis is based on both the developmental history provided by Mrs. Emkey and the neurodevelopmental assessment of Chad which were consistent with each other.”)⁷ The Assessment notes, among other things, that Chad, as an infant, was “especially quiet and good.” Id. at 135. The medical community recognizes that some children who are eventually diagnosed as autistic are reported to have been exceptionally quiet babies. See, e.g., Chris Plauche Johnson, “Recognition of Autism Before Age 2 Years,” 28(3) Pediatrics

⁵ The records of Chad’s birth tell a different story. According to those records, Chad did not descend normally through the birth canal. Umbilical cord compression and heart decelerations were noted and an urgent Cesarean section was required. See Pet’r Ex. 6, part 2 at 240-242 (Progress notes from Franklin Square Hospital Center at pages 23-25 of 55 of the filing). Mr. Emkey was observed at the time to have been “quite upset” that the C-section had not been performed sooner. Id. at 23. At birth, Chad required resuscitation. See Pet’r Ex. 1 at 14 (progress notes from Franklin Square Hospital Center at page 14 of the filing). He was not breathing, was characterized as “floppy,” and “[t]hick meconium” had to be suctioned from his stomach. Pet’r Ex. 1 at 3 (medical records from Franklin Square Hospital, p. 5 of 56); Pet’r Ex. 1 at 14.

Neonatal resuscitation is performed to prevent “the morbidity and mortality associated with hypoxic-ischemic tissue (brain, heart, kidney) injury and to reestablish adequate spontaneous respiration and cardiac output.” Nelson Textbook of Pediatrics 723 (Robert Kliegman, MD., et al. eds., 18th ed. 2007). Meconium is a dark, viscous material that is normally passed within the first 48 hours of life. Nelson at 1521. Meconium staining of the amniotic fluid may be an indication of fetal stress and may require emergency medical attention. Nelson at 725-26.

⁶ See Resp’t Motion to Dismiss at 3-4 (noting developmental delays in the vaccinee.)

⁷ The actual events surrounding Chad’s birth apparently were not reported to Dr. Childers in response to specific questions on the Assessment. Instead, the Assessment form states, “Delivery was reportedly uncomplicated and resuscitation was not required.” Pet’r Ex. 3 at 79-80.

in Review 90 (2008) (“Some infants later diagnosed with autism are unusually quiet and make few vocalizations.”) (Court Exhibit 1002 at 5) (hereinafter “Court Ex.”); see also, R.L. Schum, Ph.D., “Language Screening in the Pediatric Office Setting,” 54 *Pediatr. Clin. of N. Amer.* 428 (2007) (Court Ex. 1001 at 4)(describing “Case 1: the child who has delayed onset of words: The parents might have described this child as a quiet baby who was not fussy or demanding.”).

On June 5, 2007, Chad was evaluated at Florida Hospital “for concerns over speech and language development.” Pet’r Ex. 3 at 130. That evaluation noted that Chad’s father reported: “Chad was not one of those children who developed language and then appeared to ‘lose it’. . . Chad has historically been slow to speak.” Id.

In contrast to the contemporaneous medical records described above, Chad’s father, in an Affidavit (hereinafter “Affidavit”) submitted August 5, 2008, stated that Chad developed “at what appeared to be a normal rate up through his second birthday,” and had no developmental delays at that time. Pet’r Ex. 12 at 1, ¶4 (Emkey Aff.). The Affidavit is silent as to Chad’s development between his second and fourth years, but states that Mr. Emkey noticed a marked change in Chad’s development after his immunizations in May 2006 (when he was age four and one-half years old) “with delays and an actual digression [sic] in his acquired language.”⁸

B. Evidence That Delayed Speech Is Recognized in the Medical Community As An Early Symptom Of Autism

The following materials were submitted by Respondent to prove that language and speech delays are among the first signs of autism disorder generally recognized in the medical community:

1. 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 2):

Delays and deficits in language acquisition are among the key diagnostic criteria for autism spectrum disorders (American

⁸ If Chad has autism, which seems to be undisputed, it is highly unlikely, based on the medical experts, that the manifestations of his condition suddenly occurred at age four and one-half. Autism generally manifests by the age of 36 months. Pet’r Ex. 7 at 1-2; Resp’t Ex. E at 21; Resp’t Ex. F at 20. Autism disorders are characterized by developmental problems in three areas: social reciprocity; social communication; and unusual circumscribed interests and repetitive patterns of behavior. “It’s the co-occurrence of those three plus the fact that the origin is in early life, which are the distinctive features.” Resp’t Ex. F at 16 (quoting Dr. Michael Rutter).

Indeed, Petitioners contention that Chad’s condition was “at least” aggravated by the vaccinations in 2006, see Petitioners Response to Respondent’s Motion to Dismiss at 6, impliedly concedes that Chad’s problems existed before those vaccinations.

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).

2. 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 3):

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

3. Testimony of Dr. Eric Fombonne, Resp't Ex. D at 50 (see Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 811449, (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (Trial Tr. at 1266A, June 18, 2007) C, regarding "abnormalities in language and communication:⁹

[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 49 (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.

⁹ Transcripts for the Omnibus Autism Proceeding may be accessed at the following website: <http://www.usfc.uscourts.gov/omnibus-autism-proceeding> (last checked on August 27, 2009). The qualifications of the experts whose opinions are cited appear in the records of the OAP.

4. Testimony of Dr. Max Wiznitzer, Resp't Ex. E at 49 (see Cedillo, Trial Tr. at 1619A) , No. 98-916V, at , 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. E at 55 (Cedillo, Trial Tr. at 1642):

[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. E at 56 (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. E at 57 (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

5. Testimony of Sir Michael L. Rutter, M.D. (hereinafter “Dr. Rutter”):
Resp't Ex. E at 25 (see King v. Sec'y of Health & Human Servs., 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 Health & Human Servs., 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.

The special master also notes the following article, which has been entered into the record:

6. Chris Plauche Johnson, “Recognition of Autism Before Age Years,” *Pediatrics in Review* (2008) at 89 (Court Ex. 1002 at 4):

“Historically, delays and deviances in language development have been the most common presenting signs in children later diagnosed with autism.”¹⁰

C. Proceedings Regarding Timeliness of the Petition

On March 20, 2008, the special master ordered Petitioners to file the medical records required by 42 U.S.C. §300aa-11(c)(2). Order, March 20, 2008. Petitioners also were notified of the potential applicability of the statute of limitations, and that the Office of Special Masters (OSM) has no authority to compensate a case unless it is timely filed. *Id.* The special master instructed Petitioners to provide sufficient evidence, through medical records or the statement of a doctor, “to establish the ‘first symptom of onset’ that is ‘objectively recognizable as a sign of a vaccine injury by the medical profession at large,’ in order to demonstrate that Petitioners filed the instant case within 36 months following that ‘first symptom or manifestation of onset.’” *Id.* (citing and quoting *Markovich*, 477 F.3d at 1360) Petitioners also were required to file, with Chad’s medical records, a statement “clearly” stating when, in petitioners’ view, the first symptom or manifestation of onset or of the significant aggravation of Chad’s injury occurred. *Id.*

In their Statement, Petitioners contended that the onset of Chad’s symptoms did not occur “until the 2006 time frame,” after Chad received his final set of vaccinations, when “the family noticed significant differences in Chad’s behavior as compared to that of” other children. Statement at 2. In support of this Statement, Petitioners referred to the DSM-IV criteria for diagnosis of autism. Statement at 2; see also, Pet’r Ex. 7 at 1-2. Petitioners also asserted, as an alternative ground for awarding compensation, that the medical record “warrants at least a finding of aggravation of Chad’s condition.” *Id.* at 3. In support of this contention, Petitioners

¹⁰ Information concerning language delay as an early symptom of autism is widely available to the public. See, e.g., National Institute of Child Health and Human Development (NICHD) website, “Autism Overview: When do people usually show signs of autism?” <http://www.nichd.nih.gov/publications/pubs/autism/overview/showSigns.cfm> (last checked Aug. 31, 2009). The NICHD states that, “A number of the behavioral symptoms of autism are observable by 18 months of age,” including problems with language. “[I]n many cases, a delay in the child’s starting to speak around age two bring problems to parents’ attention, even though other, less noticeable signs may be present at an earlier age.” *Id.* (Footnotes omitted).

stated that his condition was aggravated by the administration of vaccines containing mercury “over the course of his young life, and even in May, 2006,” because he suffers, according to the Statement, from a toxic accumulation of mercury and other heavy metals in his system. *Id.* at 3; see also Pet’r Ex. 5 (analysis of urinary porphyrins).¹¹

On September 2, 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 Mot.) at 1. The Secretary asserted that the first symptom or manifestation of onset of Chad’s alleged vaccine-related injury occurred no later than June 2003, when he was approximately 18 months old. Resp’t Mot. at 3, 5 note 1.¹² The Secretary based this assertion in part on treating physician records from 2006, *see supra*, which describe Chad as historically “‘slow to speak,’” and note that, according to his parents, “[i]nitial concerns regarding Chad’s development began at ‘the age of two years old, he was not talking much.’” *Id.* at 3-4. Piecing together the chronology from the treatment records, the Secretary maintained that the first symptom of Chad’s autism was apparent no later than 2004, and that the Petition, filed March 7, 2008, therefore was untimely. *Id.* at 5, note 1. With regard to the claim of aggravation, the Secretary maintained that there was no medical evidence linking a marked deterioration in Chad’s condition after May 25, 2006, to the vaccinations he received on that date. *Id.* at 6.

Petitioners filed a Response (hereinafter “Response”) on October 22, 2008. Petitioners argued that Chad’s vaccine injury was not manifested until his autism was diagnosed on September 29, 2006, and that, up until the date of his last round of vaccinations on May 25, 2006, there was no evidence of “even any concern that could be categorized as a ‘symptom’ of autism.” Response at 3-4. Petitioners’ Response did not dispute that Chad’s parents recognized as early as 2004 when Chad was two years old that his speech development was slow, but Petitioners maintained that delayed speech is irrelevant absent additional symptoms sufficient to

¹¹ Because the assertion of “hypersensitivity to heavy metals” is not linked to any injury other than autism, the same trigger for the statute of limitations appears to apply to the allegation of heavy-metal poisoning. *See Bono ex rel. Bono v. Sec’y of Health & Human Servs.*, 87 Fed. Cl. 98, 102 (2009). *See Bono*, 87 Fed. Cl. at 102.

¹² The date of June 2003 was based on a letter submitted by a treating physician, Don J. Alfonso, M.D., in which Dr. Alfonso stated that the first manifestation of the onset of Chad’s injury occurred when Chad was approximately 18 months old. Dr. Alfonso subsequently submitted a letter, dated October 20, 2008, stating that the information he had provided earlier was wrong, that his records did not reflect that Chad had autism spectrum disorder at the age of 18 months, and that “this statement should have indicated that Chad had been diagnosed 18 months prior to the time of the [first] letter,” which was written on April 14, 2008. *See* Pet’r Ex. 13 at 1; *see also* Pet’r Ex. 3 at 32 (Dr. Alfonso’s first letter dated April 18, 2008). The special master will not rely on either of Dr. Alfonso’s conflicting statements in considering whether the instant claim is time barred. They are unnecessary to the decision, in any event.

support a diagnosis of autism under the criteria set forth in the DSM-IV at 299.00. Id. at 4-6; see Pet'r Ex. 7.

On February 9, 2009, the Secretary filed a Reply to the Petitioner's Response (hereinafter "Reply"), asserting that the records of Dr. Childers, the neurodevelopmental pediatrician who examined Chad in 2006, indicate that Chad's parents were concerned about his language problems in 2004, and that he was noticeably delayed in meeting other developmental milestones. Reply at 3-4. The Secretary again asserted that under existing precedent a first symptom of a disorder triggers the statute of limitations even if it is not recognized at the time as symptomatic of a vaccine-related injury. Id. at 5. With regard to the claim that Chad's autism was aggravated by the vaccinations he received on May 25, 2006, the Secretary again asserted that there is no medical evidence that Chad suffered a substantial deterioration in health following those vaccinations. Id. at 6. According to the Secretary, "there is no reasonable basis to support petitioners' claim of significant aggravation." Id. at 2, 6.

On February 13, 2009, Petitioners filed a Surreply to Respondent's Reply (hereinafter "Surreply") arguing that the pertinent question is not when the first symptom of Chad's autism occurred, but when the first event occurred that is objectively recognizable by the medical profession at large as a sign of a vaccine injury. Surreply at 2, citing Markovich. Regarding the aggravation claim, the Petitioners stated that there "is no timeliness issue" because petitioners' allegations must be accepted at this stage of the proceedings, and they must be afforded the right to provide evidentiary support for their claims at a later date. Surreply at 3, citing Jones v. Sec'y of Health & Human Servs., 2008 WL 2156746 *9 (Fed. Cl. April 30, 2008).

On July 8, 2009, the undersigned issued an Order directing the parties, if they so choose, to file any additional evidence regarding the timeliness issue on or before Thursday, August 13, 2009.¹³ Respondent filed additional evidence on August 3, 2009, consisting of medical literature and expert testimony admitted in the OAP. As of the date of this Order, Petitioner has not filed additional evidence, nor sought an extension of time in which to do so.

III. DISCUSSION

On this record, the special master is prepared to grant the Respondent's motion to dismiss

¹³ Specifically, the July 8, 2009 Order requires the parties to file, if they so choose, 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.

based on the evidence in the medical records that Chad's parents identified a speech delay in their son in 2004, four years before they filed the Petition, that Chad demonstrated additional early symptoms of autism even in infancy, and that such symptoms, based on the evidence submitted by the Respondent, generally are recognized in the medical profession as symptoms of autism.¹⁴ Petitioners' arguments that (1) Chad's parents did not recognize any symptom of autism before he reached age 4 and one-half, and (2) Chad's early symptoms could not have resulted in a diagnosis of autism, are foreclosed by binding precedent.¹⁵

A. Burden of Proof

The statute of limitations under the Act is jurisdictional. See, e.g., Brice v. Sec'y of Health & Human Servs., 358 F.3d 865, 868 (Fed. Cir. 2004) ("Brice II"); Kay v. Sec'y of Health & Human Servs., 80 Fed. Cl. 601, 603-04 (2008), aff'd per curiam, 298 F. App'x 985 (Fed. Cir. 2008) (unpublished). As a result, the burden is on Petitioners to establish that their claim is timely. 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

¹⁴ Petitioners correctly note that the pertinent language in the Markovich decision speaks of a symptom or manifestation of onset of a "vaccine injury," not a disorder. Surreply at 2. In keeping with the decisions applying Markovich, however, and consistent with the facts in Markovich, the event triggering the statute of limitations must be the first symptom of the autism disorder that Petitioners claim resulted from a vaccine, whether or not the disorder is linked to a vaccine. See Bono, 87 Fed. Cl. at 102-03.

¹⁵ Petitioners' allegation in the alternative that the vaccinations in May 2006 caused a significant aggravation of Chad's autism also must be dismissed. The allegation of significant aggravation is merely an attempt to circumvent the statute of limitations by asserting facts that are inconsistent with the Petitioners' contentions regarding their causation case. Either Chad had symptoms of an autistic disorder before May 2006, in which case the Petition is out of time, or he had no symptoms of an autistic disorder before May 2006, in which case there was no condition to be aggravated. Petitioners cannot allege inconsistent facts to make an "end run" around the statute of limitations. The Act provides a cause of action for vaccinees whose pre-existing condition was aggravated by a vaccine; the significant aggravation cause of action cannot be used simply to avoid the effect of the statute of limitations in a causation case. Permitting evasion of the statute of limitations is inconsistent with the well-established principle that the "jurisdictional" limitations period governing suits against the United States in the Court of Federal Claims limits "the scope of a governmental waiver of sovereign immunity." See John R. Sand & Gravel Co. v. United States, 552 U.S. 130, 753; 128 S.Ct. 750, 753 (2008) (citing United States v. Dalm, 494 U.S. 596 (1990)); Brice, 240 F.3d at 1370 ("courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended."); Markovich, 477 F.3d at 1360 (citing and quoting Brice). The limits upon federal jurisdiction "must be neither disregarded nor evaded." RHI Holdings, Inc. v. United States, 142 F.3d 1459, 1461 (Fed. Cir. 1998) (citing and quoting Owen Equip. & Erection Co., v. Kroger, 437 U.S. 365 (1978)).

establishing waiver of sovereign immunity).¹⁶ This allocation of the burden of proof is consistent with the provisions of the Act requiring that the petition “shall contain” evidence that the “first symptom or manifestation” of onset occurred within the period prescribed by the Act. See 42 U.S.C. § 300aa-11(c)(1)(C)(I); § 300aa-14(a); Markovich, 477 F.3d at 1359.

Petitioner must therefore make a prima facie showing that the Petition was timely filed. Once a prima facie case has been established, the burden of going forward with evidence shifts to Respondent to show that the claim is untimely. Where Respondent makes such a showing, the burden of going forward with the evidence then shifts back to Petitioner to show that the claim is within the applicable limitations period. The burden of proof, “i.e., the burden of ultimate persuasion,” never shifts from Petitioner. Cf., e.g., Grapevine Imports, Ltd., et al., v. United States, 71 Fed Cl. 324, 343 (2006) (describing shifting burden of production under a traditional (non-jurisdictional) statute of limitations).

Respondent in this case has presented reliable and persuasive evidence that the general medical community would recognize Chad’s speech delay at age two as a symptom of autism. At this point in the proceedings, Petitioners must produce evidence to the contrary, or their Petition will be summarily dismissed.

B. Applicable Law

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 Health and Human Servs., 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

¹⁶ The Vaccine Act represents the same conditional waiver of sovereign immunity as the Tucker Act. Kay v. Sec’y of Health & Human Servs., 80 Fed. Cl. 601, 604 (2008), aff’d per curiam, 298 F. App’x 985 (Fed. Cir. 2008) (unpublished). See generally, John R. Sand, 552 U.S. at ___, 128 S.Ct. at 753 (distinguishing between the treatment of typical limitations defenses and jurisdictional statutes of limitations).

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 Health & Human Servs., 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.”

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 Health and Human Servs., 85 Fed. Cl. 141, 144-45 (2008); Lemire v. Sec’y of Health & Human Servs., 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 Health & Human Servs., 87 Fed. Cl. 98, 102 -03 (2009).

Based on the clear precedent, resolution of the issue requires only the application of established law to the facts in the record. Because there appears to be no genuine issue of fact regarding the recognition by the medical profession of speech delay as an early symptom of autism, it is the special master’s intention to decide this case without further proceedings, unless persuaded by Petitioners that additional expert medical evidence and/or factual development is necessary and appropriate.

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

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 no evidence to the contrary.¹⁷ In so stating, the special master recognizes that Chad’s autism could not have been diagnosed based solely on his early speech delay. Applicable law plainly holds, however, that diagnosis is not required to trigger the

¹⁷ A special master may draw conclusions from medical literature even if medical experts have not commented on the literature during the particular Vaccine Program proceeding. Cf. Moberly v. Sec’y of Health & Human Servs., 85 Fed. Cl. 571, 597-98 (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”).

statute of limitations under the Vaccine Act.

Consistent with the cases cited above, in applying the statute of limitations, we do not look forward as if on the date of Chad's documented speech delay to decide whether his condition necessarily would result in autism. We know that delayed speech does not invariably presage an autistic disorder, but that is not the proper focus of the inquiry. Instead, we look back from the date the Petition was filed to determine, as a historical matter, when the symptoms of the autism that we know will eventually be diagnosed were established in the record. The statute of limitations begins to run from the date the first symptom of autism appeared that would generally be recognized in the medical community. Markovich, 477 F.3d at 1360.

The medical record here reveals that Chad's speech was delayed and that the delay was observed by his parents at about the age of two. The speech delay (as well as other developmental deviations from the norm) was reported to Chad's medical providers, including the neurodevelopmental pediatrician who diagnosed his autism. On this record, the statute of limitations commenced to run, at the latest, on January 24, 2004, when Chad reached the age of two. The Petition, filed on March 7, 2008, therefore is out of time.

IV. CONCLUSION

In the Order dated July 8, 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 generally would recognize speech delay in a two-year-old as a first symptom of an autism spectrum disorder. Petitioners have submitted no evidence to negate the Respondent's submission. Under the rules governing allocation of the burden of proof on timeliness, Petitioners have failed to carry their burdens of production and persuasion.

Accordingly, **on or before Wednesday, October 7, 2009**, Petitioners shall file a response to this order to show cause explaining why a decision dismissing their Petition should not be entered.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master