

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

No. 2-1823V

Filed: April 12, 2012
(Not to be Published)

ROBIN CONNER and VIRGINIA
CONNER, as parents and natural
guardians of Matthew R. Conner,
a minor,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

Autism; Statute of Limitations; First
Symptom or Manifestation of Onset

Alan Pickert, Esq., Jacksonville, FL, for petitioners.
Voris Johnson, Esq., U.S. Dept. of Justice, Washington, D.C., for respondent.

DECISION¹

Vowell, Special Master:

On December 10, 2002, Robin and Virginia Conner [“petitioners” or “Mr. Conner” and “Mrs. Conner”] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² [the “Vaccine Act” or “Program”], on behalf of their minor son, Matthew R. Conner [“Matthew”]. The petition was a “short form” petition authorized by Autism General Order #1.³ In essence, by

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of the provision, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

³ The text of Autism General Order #1 can be found at <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf> [“Autism Gen. Order

filing a short form petition, petitioners asserted that (1) Matthew had a disorder on the autism spectrum and (2) that one or more vaccines listed on the Vaccine Injury Table⁴ were causal of Matthew's condition.

Respondent moves to dismiss petitioners' case, asserting that the petition was filed outside the Vaccine Act's 36 month statute of limitations. § 16(a)(2); Respondent's Motion to Dismiss ["Res. Mot."], filed July 21, 2008, at 1. Petitioners offer two arguments in support of the timeliness of the petition. First, petitioners contend that despite their retrospective statements to medical providers that Matthew's symptoms manifested at 18 months, or in February 1999, no contemporaneous medical records support this timeframe. Petitioners' Response to Respondent's Motion to Dismiss ["Pet. Res."], filed Aug. 4, 2008, at 2. Secondly, because an evaluation on February 3, 2000, did not diagnose Matthew with autism, neither petitioners nor the medical profession at large associated his symptoms with an autism spectrum disorder until after that date. Pet. Res. at 3.

For the reasons stated herein, I find that the first symptom or manifestation of onset of Matthew's autism spectrum disorder occurred more than three years prior to the date the petition was filed. I hold that the petition was untimely filed and it is therefore dismissed.

I. Procedural History.

Matthew's petition was one of approximately 5400 claims in the Omnibus Autism Proceeding ["OAP"]. A history of that proceeding was set forth in the two decisions I issued in the OAP test cases, and will not be repeated here.⁵ On January 21, 2003, the presiding special master⁶ stayed this case pending the resolution of the OAP test cases. Notice Regarding "Omnibus Autism Proceeding," filed Jan. 21, 2003.

On March 14, 2008,⁷ in order to position this case for resolution once the test cases concluded, the special master ordered petitioners to file all of Matthew's medical

#1], 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002). The two theories of causation specifically addressed in Autism Gen. Order #1 were that the measles, mumps, and rubella ["MMR"] vaccine was causal [the "MMR theory" or "Theory 1"] or that vaccines containing a mercury-based preservative called thimerosal [the "TCV theory" or "Theory 2"] were causal, or that a combination of the MMR vaccine and TCVs were causal.

⁴ 42 C.F.R. § 100.3 (2010).

⁵ *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044, at *4 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009) and *Dwyer v. Sec'y, HHS*, No. 02-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁶ The case was assigned to me on November 19, 2010.

⁷ Between January 21, 2003 and March 14, 2008, respondent filed a report pursuant to Vaccine Rule 4(c). Because petitioners had not yet filed any affidavits or medical records, respondent was unable to adequately review petitioners' claim. Respondent's Report ["Res. Rep."], filed Mar. 10, 2003, at 1. Additionally, on July 30, 2003, respondent filed a motion for appropriate relief contending that the special

records from birth until the date of the petition's filing or the date of his initial diagnosis of an autism spectrum disorder, whichever was later. Order, filed Mar. 14, 2008. Respondent was then ordered to file a statement indicating whether petitioners' claim should proceed in the OAP.

Petitioners filed six exhibits of medical records on June 6, 2008, along with a Statement Regarding Timely Filing. On July 21, 2008, respondent moved to dismiss the case as untimely filed. Res. Mot. at 1. Petitioners responded to the motion to dismiss on August 4, 2008, asserting that the claim was timely filed because the contemporaneous medical records did not associate Matthew's symptoms with an autism spectrum disorder until after February 3, 2000.⁸ Pet. Resp. at 2-3.

In an order memorializing an April 3, 2009 status conference, the special master ordered petitioners to file additional medical records including Matthew's prenatal and birth records, the results of a hearing test administered at 21 months of age, an Early Intervention report, and records of Matthew's speech pathologist. Order, filed Apr. 3, 2009. On May 28, 2009, petitioners filed these medical records as Petitioners' Exhibits ["Pet. Exs."] 7-10. Following a second status conference, respondent filed a brief in support of her earlier motion to dismiss along with Respondent's Exhibits ["Res. Exs."] A-F on April 12, 2010.

As numerous other OAP cases presented similar factual and legal issues with regard to timely filing, I deferred ruling on respondent's motion to dismiss until cases presenting similar issues could be heard on appeal. See, e.g., *Setnes v. United States*, 57 Fed. Cl. 175 (2003) (holding that when there is no clear start to an injury, such as autism, the statute of limitations hinges on manifestation of onset and not the occurrence of the first symptom), *abrogated by Markovich v. Sec'y, HHS*, 477 F.3d 1353 (Fed. Cir. 2007) (holding that the statute of limitations runs from either the first symptom or manifestation of onset); *Carson v. Sec'y, HHS*, 97 Fed. Cl. 620 (2010) (identification of the first symptom is determined with the benefit of hindsight), *appeal docketed*, No. 10-5089 (Fed. Cir. Mar. 4 2010); *Cloer v. Sec'y, HHS*, 85 Fed. Cl. 141 (2008).⁹

master's decision not to require petitioners' to satisfy the Vaccine Act's documentation requirement until after resolution of the OAP "frustrate[d] Congress's intent in creating the Program." Respondent's Motion for Appropriate Relief, filed Jan. 30, 2003, at 11-12. The motion was denied on February 10, 2004.

⁸ In their response to respondent's motion to dismiss, petitioners additionally claim that, "Matthew did not suffer from the . . . significant aggravation of his vaccine injury until after February 3, 2000." Pet. Resp. at 1. Petitioners appear to be alleging a claim of "significant aggravation," pursuant to § 11(c)(1)(C)(i). However, petitioners have produced no evidence that Matthew's autism spectrum disorder was significantly aggravated by any vaccinations. See § 33(4) (defining "significant aggravation"); *Loving v. Sec'y, HHS*, 86 Fed. Cl. 135, 143-44 (2009) (setting forth the six-part test for cases alleging significant aggravation of off-Table injuries).

⁹ The U.S. Court of Federal Claims decision was reversed and remanded by a panel of the U.S. Court of Appeals for the Federal Circuit. *Cloer v. Sec'y, HHS*, 603 F.3d 1341 (Fed. Cir. 2010). The panel's decision was vacated and rehearing en banc was ordered. *Cloer v. Sec'y, HHS*, 399 Fed. Appx. 577 (Fed. Cir. 2010). The en banc decision was issued on August 5, 2011. *Cloer v. Sec'y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011) (en banc) (rejecting a discovery rule and holding that the statute of limitations runs from the first symptom or manifestation of onset recognized by the medical profession at large).

Following the resolution of *Cloer*, I afforded the parties an opportunity to file additional briefs addressing the Federal Circuit's decision. Order, filed Jan. 6, 2012. On February 2, 2012, respondent filed a response maintaining that, under the standard articulated in *Markovich* and reaffirmed in *Cloer*, the petition was not timely filed. Respondent's Response to the Special Master's Order Dated January 1, 2012, filed Feb. 2, 2012, at 2. Petitioners did not file the optional brief. The issues are now fully joined and the case is ripe for decision. In this decision, I apply the summary judgment standard contained in Rule 56 of the Rules of the Court of Federal Claims ["R.C.F.C."].¹⁰

II. Medical History.

The pertinent portions of Matthew's medical history are broken into two sections, the records of treatment rendered before December 10, 1999, and the records of treatment rendered thereafter. Based on the date the petition was filed, symptoms of the alleged vaccine injury occurring prior to December 10, 1999, would render the petition untimely filed.

A. Medical Records from Treatment Prior to December 10, 1999.

Matthew was born on August 7, 1997, in a set of triplets delivered via a planned cesarean section. Pet. Ex. 7, p. 71.¹¹ Matthew and his siblings were born at 35 weeks of gestation¹² and, consequently, he weighed only slightly over 4 pounds at birth. *Id.* According to his father, his Apgar scores were 9 at both one and five minutes.¹³ *Id.*

Matthew received routine childhood immunizations from birth until March 8, 1999. Pet. Ex. 5(2), p. 153.¹⁴ When Matthew was approximately four months old, he began

¹⁰ According to R.C.F.C. 56, "the court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

¹¹ The medical records contained in Pet. Ex. 7 contain two sets of page numbers. I refer to the page numbers at the bottom center of the page.

¹² On average, a pregnancy lasts 288 days, or approximately 41 weeks, from the last menstrual period. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"], at 1509.

¹³ The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually take at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S, at 1682; NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON"], at 536-37.

¹⁴ Petitioners filed two portions of Pet. Ex. 5. Although the docket text indicates that the first is numbered 1-100 and the second from 101-256, the page numbers in the second portion do not continue from the first portion, but instead begin again with page 1. I thus refer to the second portion of Pet. Ex. 5 as Pet. Ex. 5(2).

experiencing frequent upper respiratory infections, coryza,¹⁵ ear infections, conjunctivitis, and intermittent rashes. See generally Pet. Ex. 3.

On December 12, 1998, when Matthew was 16 months old, his parents took him to the Flagler Hospital Emergency Room following four days of high fevers. Pet. Ex. 1, pp. 9, 14. According to the history provided, Matthew had been seen by his pediatrician, Dr. Angelita Capili, for an ear infection four days earlier. Pet. Exs. 1, p. 14; 3, p. 12. During this visit, Matthew received his initial measles, mumps, and rubella ["MMR"] vaccine and his fourth hemophilus influenzae type b ["Hib"] booster. Pet. Ex. 5(2), p. 153. Forty-eight hours after the appointment, Matthew's fever still ranged between 99° and 104° Fahrenheit. Pet. Ex. 1, p. 14. Doctor Capili saw Matthew again on December 11, 1998, when she changed his prescription. Pet. Ex. 3, p. 13. When Matthew's fever continued to reach 103°, Mrs. Conner was advised to take him to the emergency room. Pet. Ex. 1, p. 14.

At the time of his admission, Matthew still had a low grade fever. Pet. Ex. 1, p. 14. The treating physician noted that Matthew "follows normal developmental milestones." *Id.*, p. 20. While in the emergency room, Matthew received antibiotics and fluids intravenously. *Id.*, p. 14. The treating physician ordered various tests, including a chest x-ray, urinalysis, and blood culture. *Id.* The chest x-ray revealed bilateral pneumonia, "particularly in the left lower lobe and probably the right middle lobe." *Id.* Matthew's urinalysis, urine culture, and blood culture were all normal. *Id.* He was discharged two days later with directions to follow up with his pediatrician in three days. *Id.*

Matthew visited Dr. Capili on December 16, 1998, for his pneumonia follow-up appointment. Pet. Ex. 3, p. 14. Matthew's systems were recorded as normal. *Id.* In the right margin of the record, a handwritten note indicates that on January 12, 1999, Matthew was referred to an ear, nose, and throat doctor ["ENT"] for a hearing test. *Id.* On March 26, 1999, Matthew was examined at the Audiology Clinic of Nemours Children's Clinic. Pet. Ex. 7, p. 74. During the appointment, Mrs. Conner expressed concern about Matthew's hearing because he was "not talking and currently [had] no words in his repertoire." *Id.* Matthew's hearing sensitivity was recorded as normal "in at least one ear," with middle ear function bilaterally normal. *Id.* He was described as having "an apparent speech and language delay by parental report." *Id.* The evaluator recommended Matthew receive a speech and language evaluation, and referred Mrs. Conner to the Early Intervention Program. *Id.*

On November 24, 1999, Matthew was evaluated at the University of Florida's Early Intervention Program. Pet. Ex. 10, p. 29. In a pre-evaluation questionnaire, Mrs. Conner reported that at around 18 months, or in February 1999, Matthew said a few words, such as "mama" and "dada," but then stopped. *Id.*, p. 9. She also indicated that Matthew whined and did not point. *Id.*, p. 7. During the evaluation, Matthew exhibited poor eye contact, impaired social interaction, and significant language delay with less

¹⁵ Coryza, also known as acute rhinitis, refers to congestion of the mucous membranes of the nose, followed by increased secretion which impairs nasal respiration. DORLAND'S, at 423, 1639.

than 10 words. *Id.*, p. 31. The speech therapist participating in the evaluation stated that Matthew “appears to be in the autistic spectrum.” *Id.*, p. 32.

B. Medical Records from Treatment Occurring On or After December 10, 1999.

On December 30, 1999, Matthew was seen by Dr. Capili for a follow-up of a previous episode of tonsillitis. Pet. Ex. 3, p. 35. A handwritten note indicates that, on January 27, 2000, one of Matthew’s parents called Dr. Capili’s office for authorization to have Matthew evaluated for developmental delay. *Id.* Dr. Capili’s office referred Matthew for a developmental evaluation. *Id.*

Although Matthew was evaluated in February, 2000, there are no records of a subsequent evaluation until March 28, 2000,¹⁶ when Matthew was seen at the Neurology Department of the Nemours Children’s Clinic. Pet. Ex. 7, pp. 70-72. Mr. Conner reported that concerns about Matthew’s language were “a static and significant problem since the first year of life.” *Id.*, p. 71. At the time of the evaluation, Matthew only made “nonspecific sounds,” rarely using an actual word. *Id.* He did not head bang or pull his hair, but tended to walk on his toes. *Id.* At times, he was overly aggressive and would bite others, but had no specific self-abusive behavior patterns. *Id.* The neurologist conducting the evaluation, Dr. Harry Abram, indicated Matthew demonstrated “some autistic tendencies,” with impaired social interaction, impaired language and communication, and poor object and toy use. *Id.*, p. 72. According to Dr. Abram, Matthew most likely fell within the autism spectrum. *Id.*

Over a year later, on May 15, 2001, Dr. Michael Sisbarro¹⁷ issued a psychological and development report based on four evaluations of Matthew which occurred in January, February, and March of 2001.¹⁸ Pet. Ex. 6, p. 1. Per the report,

¹⁶ In the report from the March 28, 2000 evaluation, Dr. Harry Abram, the neurologist performing the evaluation, noted that, in a “psychoeducational evaluation from 2-3-00, it was felt that [Matthew] had a significant language delay,” with his mental scoring at the 14-month level. Pet. Ex. 7, p. 71. However, using the Child Autism Rating Scale [“CARS”], Matthew scored in the non-autistic range. *Id.* No medical records were filed from the February 3, 2000 evaluation, but a summary of it is contained in a 2001 evaluation.

¹⁷ According to the letterhead, Dr. Sisbarro is a licensed school psychologist.

¹⁸ Doctor Sisbarro’s report sheds additional light on the February 2000 evaluation, which he apparently conducted. See Pet. Ex. 6, p. 3. He summarized or quoted substantial portions of the February 2000 examination in his May 2001 report. According to Dr. Sisbarro, the February 2000 evaluation was administered to “rule out autism and related disorders,” since Matthew had “a history of significantly delayed development, especially within the language and communication areas.” Pet. Ex. 6, p.3. Although Matthew scored within the severely delayed range on the Bayley Scales of Infant Development, with an approximate developmental age of 14 months, his CARS score was within the non-autistic range. *Id.* Matthew’s did not, according to Dr. Sisbarro, meet the diagnostic criterion for autism in the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (4th ed. 1994). *Id.* He appeared to rely significantly on Mrs. Conner’s report of recent improvements in social skills in this determination. He recommended that Matthew receive continued speech and occupation therapy, but felt it was not “in [Matthew’s] best interests to consider him within the autistic spectrum” at that February 2000 evaluation. *Id.*

although Matthew used single words at 18 months, he then began to lose them, which was “possibly . . . attributed to autistic regression.” *Id.*, p. 1. Additionally, Matthew’s parents were concerned about his poor eye contact and impaired social skills. *Id.* Matthew’s approximate developmental age was scored at 25 months. *Id.*, pp. 6, 13. According to Dr. Sisbarro, “[n]oticeably absent were any expressive language skills.” *Id.*, p. 6. On the CARS, Matthew was scored in the “mildly to moderately autistic range,” and did meet the DIAGNOSTIC STATISTIC MANUAL OF MENTAL DISORDERS [“DSM-IV”]¹⁹ criteria for autism.²⁰ *Id.*, pp. 8-9.

More recently, Matthew began treatment with Dr. Jeff Bradstreet of the Good News Doctor Foundation. See Pet. Exs. 5, 5(2). On August 12, 2002, the history provided indicated that Matthew “was speaking single words around 18 months,” but “instead of building words he began to lose words.” Pet. Ex. 5(2), p. 149. According to the history, Matthew “appeared to regress after the MMR vaccine” he received on December 4, 1998. *Id.* Following an ear infection and his hospitalization for pneumonia, his parents noticed his regression “to an infantile position” and total isolation. *Id.*

III. Evidence Concerning Autism Spectrum Disorders.

Only respondent filed any evidence²¹ concerning the diagnostic criteria for autism spectrum disorders [“ASD”]. The information contained in this section is drawn from that evidence. The transcript excerpts contained in Res. Exs. C-E were from OAP test case testimony provided by three pediatric neurologists with considerable experience in diagnosis ASD.

“Autism Spectrum Disorder” or “ASD” is an umbrella term for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder – not otherwise specified [“PDD-NOS”], and

¹⁹ The DSM is the manual used in the United States to diagnose dysfunctions of the brain. Doctor Sisbarro refers to the fourth edition, or the DSM-IV, but does not specify which version. The fourth edition was published in 1994, and a text revision of the fourth edition was published in 2000. American Psychiatric Association, *DSM-IV-TR: The Current Manual*, <http://www.psych.org/mainmenu/research/dsmiv/dsmivtr.aspx> (last visited Apr. 11, 2012). Although section III (“Evidence Concerning Autism Spectrum Disorders”) of this decision relies on the DSM-IV-TR to illustrate the behaviors considered by the medical community at large to be symptomatic of an autism spectrum disorder, the DSM-IV-TR criteria do not markedly differ from those in the DSM-IV. *Snyder*, 2009 WL 332044, at *34 n.95.

²⁰ Doctor Sisbarro indicated that, based on Mr. Conner’s report, Matthew met the criteria for a diagnosis of autism. Pet. Ex. 6, p. 9. However, Mrs. Conner’s reports were “more indicative of Pervasive Developmental Disorder-Not Otherwise Specified.” *Id.* Based on Matthew’s history of “severe expressive language delay, difficulties (which still persist) in social relatedness, and periods of atypical behavior,” Dr. Sisbarro believed Matthew clearly qualified for an autism spectrum disorder. *Id.*, p. 10.

²¹ All of the evidence filed in the OAP test cases is available to any petitioner in the OAP, as well as to respondent. However, I note that there did not appear to be any material disputes in the OAP test cases about what constituted early symptoms of autism or other ASDs.

Asperger's Disorder. See R. Luyster, et al., *Language Assessment and Development in Toddlers with Autism Spectrum Disorders*, J. Autism Dev. Disord. 38: 1426-38, 1426 (2008) ["Luyster"] filed as Res. Ex. A. "Pervasive developmental disorders" is the umbrella term used in the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69, rather than ASD. I use the term ASD throughout this opinion rather than PDD because of the possible confusion between "PDD" (the umbrella term referring to the general diagnostic category) and "PDD-NOS" (which is a specific diagnosis within the general diagnostic category of PDD or ASD). I use the term "autism" to refer solely to the specific diagnosis of "autistic disorder."

The specific diagnostic criteria for ASD are found in the DSM-IV-TR, the manual used in the United States to diagnose dysfunctions of the brain. Res. Ex. C, excerpt of testimony of Dr. Eric Fombonne in the *Cedillo* OAP test case ["Fombonne Tr."], at 1278A. Thus, these are the behavioral symptoms recognized by the medical profession at large as symptoms of ASD. The DSM-IV-TR contains specific diagnostic criteria for autistic disorder (often referred to as "autism" or "classic autism"), Asperger's disorder, and pervasive developmental disorder-not otherwise specified (most frequently referred to as "PDD-NOS"). It is not uncommon for parents and even health care providers to use these terms in non-specific ways, such as referring to a child as having an "autism diagnosis," even though the specific diagnosis is PDD-NOS.

A. Diagnosing Autism Spectrum Disorders.

Diagnostic testing for the presence of an ASD involves the use of standardized lists of questions about behavior directed to caregivers and parents, as well as observations of behaviors in standardized settings by trained observers. Fombonne Tr. at 1272-74A. One behavioral symptom alone, such as hand-flapping, would not be diagnostic of an ASD, but if present, it would be a symptom that would be part of the diagnostic picture. As Dr. Fombonne explained, in diagnosing an ASD, "we try to observe symptoms, and when we have observed enough symptoms, then we see if the child meets these criteria." Fombonne Tr. at 1278A-79; see *also* Res. Ex. E, testimony of Dr. Michael Rutter in the *King* OAP test case ["Rutter Tr."], at 3253-54 (describing diagnostic instruments and their use in clinical settings).

Typically in children with autism spectrum disorders, the symptoms have been present for weeks or months before parents report them to health care providers. Fombonne Tr. at 1283. The most common age at which parents recognize developmental problems, usually problems in communication or the lack of social reciprocity, is at 18-24 months of age. Rutter Tr. at 3259-60. The development of symptoms of an ASD occurs very gradually, and it is not uncommon for the parents to be unable to date the onset very precisely. Fombonne Tr. at 1285A-1286A.

1. Autistic Disorder.

A diagnosis of autistic disorder requires a minimum of six findings from a list of impairments divided into three domains of impaired function: (1) social interaction; (2) communication; and (3) restricted, repetitive, and stereotyped patterns of behavior, interests, and activities. At least two findings related to social interaction and at least one each in the other two domains are required for diagnosis. To meet the diagnostic criteria for autism, the child must have symptoms consistent with six of the twelve listed types of behavioral impairments. Furthermore, the abnormalities in development must have occurred before the age of three. Fombonne Tr. at 1264A, 1279; Wiznitzer Tr. at 1618; Rutter Tr. at 3250. Although the majority of children with autism have developmental delays, many are of normal intelligence. Fombonne Tr. at 1276; Rutter Tr. at 3256. In testimony in *Cedillo* OAP test case, Dr. Wiznitzer described the three domains as the “core features” of a diagnosis on the autism spectrum. Wiznitzer Tr. at 1589-92. Children with autism are most symptomatic in the second and third years of life. Wiznitzer Tr. at 1618.

2. Pervasive Developmental Disorder-Not Otherwise Specified.

The DSM-IV-TR defines PDD-NOS as “a severe and pervasive impairment in the development of reciprocal social interaction,” coupled with impairment in either communication skills or the presence of stereotyped behaviors or interests. DSM-IV-TR at 84. The diagnosis is made when the criteria for other autism spectrum disorders, or other psychiatric disorders such as schizophrenia, are not met. *Id.* It includes what has been called “atypical autism,” which includes conditions that present like autistic disorder, but with onset after age three, or which fail to meet the specific diagnostic criteria in one or more of the domains of functioning. *Id.* As I noted in *Dwyer*, it is the most prevalent of the disorders on the autism spectrum. *Dwyer*, 2010 WL 892250 at *30.

3. Asperger’s Disorder.

Asperger’s disorder is a form of high-functioning autism. It presents with significant abnormalities in social interaction and with restricted, repetitive, and stereotyped patterns of behavior, interests, and activities. See DSM-IV-TR at 84. Diagnosis of Asperger’s disorder requires two impairments in social interaction and one impairment in restricted, repetitive, and stereotyped patterns of behavior. *Id.* Of note, it does not require language or communication abnormalities. *Id.*

B. The Domains of Impairment and Specific Behavioral Symptoms.

1. Social Interaction Domain.

This domain encompasses interactions with others. Fombonne Tr. at 1264A. There are four subgroups within this domain. Wiznitzer Tr. at 1594. The subgroups

include: (1) a marked impairment in the use of nonverbal behavior, such as gestures, eye contact and body language; (2) the failure to develop appropriate peer relations; (3) marked impairment in empathy; and (4) the lack of social or emotional reciprocity. Wiznitzer Tr. at 1594-96. To be diagnosed with autism (autistic disorder), the patient must have behavioral symptoms from two of the four subgroups. Wiznitzer Tr. at 1594. For an Asperger's diagnosis, there must be two impairments in this domain as well. DSM-IV-TR at 84. For PDD-NOS, there must be at least one impairment in this domain. Fombonne Tr. at 1275A.

Doctor Wiznitzer described the degrees of impairment in interactions with others as a continuum, with affected children ranging from socially unavailable to socially impaired. A child who is socially unavailable may exhibit such behaviors as failing to seek consolation after injury or purposeless wandering, or may simply appear isolated. Wiznitzer Tr. at 1598. A less impaired child might be socially remote, responding to an adult's efforts at social interaction, but not seeking to continue the contact. This child might roll a ball back and forth with an adult, but will not protest when the adult stops playing. Wiznitzer Tr. at 1599. Given a choice between playing with peers and playing by himself, a child with impairments in social interaction will play by himself. *Id.* Some children with ASD demonstrate socially inappropriate interactions, such as pushing other children in an effort to interact. Wiznitzer Tr. at 1600. A higher functioning child might attempt interaction, but does so as if reading from a script. As an example, Dr. Wiznitzer discussed a patient who, when asked where he lived, could not answer, but responded appropriately when asked for his address. *Id.* at 1601.

Symptoms used to identify young children with impairments in the social interaction domain include lack of eye contact, deficits in social smiling, lack of response to their name, and the inability to respond to others. Fombonne Tr. at 1269A-70A. Others include a lack of imitation, lack of interest in other children, and infrequent seeking to share with others. R. Landa, *Diagnosis of autism spectrum disorders in the first 3 years of life*, NATURE CLINICAL PRACTICE NEUROLOGY, 4(3): 138-47 (2008) ["Landa"], filed as Res. Ex. B, at Table 1.

2. Communication Domain.

The communication domain involves both verbal and non verbal communication, such as intonation and body language. Fombonne Tr. at 1263; Wiznitzer Tr. at 1602A. Language abnormalities in ASD encompass not only delays in language acquisition, but the lack of capacity to communicate with others. Fombonne Tr. at 1267A. "Delays and deficits in language acquisition" are "among the key diagnostic criteria for autism spectrum disorders." Luyster at 1426.

There are four criteria within the communication domain. Wiznitzer Tr. at 1602A. They include: (1) a delay in or lack of development in spoken language, without the use of signs or gestures to compensate; (2) problems in initiating or sustaining conversation; (3) stereotypic or repetitive use of language, including echolalia and repeating the script

of a video or radio presentation, such as singing a commercial jingle; and (4) the lack of spontaneous imaginative or make-believe play. Wiznitzer Tr. at 1602A-05.

Language delay, limited babbling, lack of gestures, and a lack of pointing to communicate things other than basic wants and desires (lack of “protodeclarative” vs. “protoimperative” pointing), are all early symptoms used to diagnose impairments in the communication domain. Fombonne Tr. at 1266A-68A. Doctor Wiznitzer described the failure to share discoveries via language in autistic children as well. Wiznitzer Tr. at 1606A. Children with ASD who have more developed language skills may display difficulties in social communication outside their limited area of interest. *Id.* at 1607.

Within the communication domain, children with ASD have difficulties in joint attention, which Dr. Wiznitzer described as sharing an action or activity with another person or even an animal. They also have problems with what he called metalinguistic skills, referring to the meaning behind the language used, which may be conveyed by tone, body language, humor or sarcasm. Children with ASD may understand visual humor, illustrated by the cartoon of an anvil falling on the coyote’s head, but lack the ability to understand a joke. Wiznitzer Tr. at 1607-09. They focus on the literal, rather than the figurative, meaning of words: telling a child with ASD to “hop to it” may elicit hopping, rather than an increase in speed in completing a task. Children with ASD use language primarily for getting their needs met. *Id.* at 1609. Such a child might lead a parent to the cookie jar, but would not lead a parent to a caterpillar crawling along the sidewalk.

Children with ASD often have impairments in specific types of play. They may understand cause and effect play, but have difficulties in imitative or representational play. In other words, they can push a button to make a toy figure pop up, but have difficulty with holding a tea party, putting a stuffed animal to bed, or feeding a doll. Wiznitzer Tr. at 1610-11. They also have impairments in symbolic play, in which an object such as a stick represents another object, such as a magic wand or sword. *Id.* at 1612.

Speech and language delays are the symptoms most commonly reported by parents as a concern leading to a diagnosis of ASD. Luyster at 1426; *see also* Fombonne Tr. at 1284 (one of first concerns noted by parents is the lack of language development); Rutter Tr. at 3253 (problems in social and communication domains tend to be observed much earlier than stereotyped behaviors).

A deficit in at least one of the subgroups in the communication domain is required for an autism diagnosis. Wiznitzer Tr. at 1602 A. An Asperger’s diagnosis does not require a communication domain impairment and a PDD-NOS diagnosis requires an impairment in either this domain or the patterns of behavior discussed next. See Fombonne Tr. at 11275A-76; Wiznitzer Tr. at 1592.

3. Restricted, Repetitive, and Stereotyped Patterns of Behavior Domain.

There are four categories within this domain. They include (1) a preoccupation with an interest that is abnormal in intensity or focus, such as spinning a plate or a wheel or developing an intense fascination with a particular interest, such as dinosaurs, cartoon characters, or numbers; (2) an adherence to nonfunctional routines or rituals, such as eating only from a blue plate, sitting in the same seat, or walking the same route; (3) stereotypic or repetitive motor mannerisms, such as finger flicking, hand regard, hand flapping, or twirling; and (4) a persistent preoccupation with parts of an object, such as focusing on the wheel of the toy car and spinning it, rather than playing with it as a car. Wiznitzer Tr. at 1613A-15; Fombonne Tr. at 1271A-72A.

As Dr. Fombonne explained, this domain reflects abnormalities in the way play skills develop, as well as repetitive and rigid behavior. Fombonne Tr. at 1264A. A typical toddler may flick a light switch a few times, but the child with ASD performs the same action to excess. Wiznitzer Tr. at 1616. Doctor Rutter described one child who would not turn right; to make a right turn at a crossroads, he would have to make three left turns. Rutter Tr. at 3252-53.

For a diagnosis of autism, a child must display behaviors in at least one of the categories included in this domain. Wiznitzer Tr. at 1613A. For an Asperger's diagnosis there must be at least one behavioral impairment encompassed in this domain. See Fombonne Tr. at 1275A-76. A PDD-NOS diagnosis requires either an impairment in this domain or an impairment in the communication domain. See Wiznitzer Tr. at 1592.

D. Summary.

The evidence establishes that a diagnosis of ASD is based on observations of behavioral symptoms. The symptoms are categorized into three domains.

For a definitive diagnosis of autism, the child must display specific behavioral abnormalities in each of the domains, with six behaviors from the list of twelve present. There must be at least two behaviors encompassed in the social interaction domain, reflecting the importance of impaired social interaction in diagnosing an ASD. Of significance, the behavioral abnormalities must be manifest before age three.

Thus, the absence of any specific symptom would not rule out the diagnosis, so long as the requisite numbers of impairments in each domain of functioning are present. Conversely, autism cannot be diagnosed by any single abnormal behavior, but the ultimate diagnosis is based on an accumulation of symptomatic behaviors. The existence of any one behavioral abnormality associated with autism is sufficient to trigger the running of the statute of limitations.

IV. Analysis.

A. Untimely Filing.

1. Statutory Requirements.

The Vaccine Act's statute of limitations provides in pertinent part that, in the case of:

a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if 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 . . .

§ 16(a)(2).

2. Interpreting the Statute of Limitations.

In *Cloer*, the court defined the first symptom or manifestation of onset as “the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.” *Cloer*, 654 F.3d at 1335. This is an objective standard, and thus the statutory date “does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition.” *Id.* at 1339. Furthermore, the date “does not depend on the knowledge of a petitioner as to the cause of the injury.” *Id.* at 1338. When drafting the Vaccine Act, Congress rejected a discovery rule-based statute of limitations, in favor of one that does not consider knowledge and runs solely from the date of an event, the first symptom or manifestation of onset.

Additionally, in *Markovich*, the court explained the differences between “symptom” and “manifestation of onset,” as those words are used in the Vaccine Act. *Markovich*, 477 F.3d at 1357. A symptom may be associated with more than one condition, and it can be difficult for a lay person to connect a symptom with a particular injury. *Id.* Manifestation of onset, on the other hand, is something more clearly associated with an injury. *Id.* Neither requires a doctor making a definitive diagnosis of the injury. *Id.* at 1358 (quoting *Brice v. Sec’y, HHS*, 36 Fed. Cl. 474, 477 (1996)). Either a symptom or a manifestation can trigger the statute of limitations, “whichever is first.” *Id.* at 1357.

3. Applying the Law to the Facts of the Case.

To determine if the case was timely filed, I must determine when the first symptom or manifestation of onset of the alleged vaccine injury occurred. Once that date is ascertained, I then compare it to the filing date of Matthew's petition to determine if the petition was filed within the Vaccine Act's 36 month statute of limitations.

Because petitioners filed their petition on behalf of on behalf of Matthew on December 10, 2002, the first symptom or manifestation of onset of Matthew's ASD must have occurred on or after December 10, 1999, in order for the petition to be considered timely. See *Markovich*, 477 F.3d at 1357 (holding that "either a 'symptom' or 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer*, 654 F.3d 1335 (holding that the "analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of the occurrence of the first symptom or manifestation of onset.").

Petitioners contend that the first symptom or manifestation of onset of Matthew's ASD did not occur until after February 2000, as no contemporaneous medical records prior to that date reference his speech delay. In support of their claim, petitioners rely on Dr. Abram's and Dr. Sisbarro's oblique references to a February 3, 2000 evaluation in which Matthew scored below the autistic range on the CARS scale. Pet. Exs. 7, pp. 71-72; 6, pp. 1-3. Additionally, petitioners attempt to discredit their own retrospective statements to multiple providers that Matthew's speech delay manifested when he was 18 months old, or in February 1999, due to an absence of supporting contemporaneous records. See Pet. Resp. at 2. However, Matthew's medical records clearly establish concerns about Matthew's speech delay as early as March 1999. See Pet. Ex. 7, p. 74.

a. Symptoms.

Petitioners contend that that I should disregard their statements in medical histories indicating that Matthew's symptoms arose when he was 18 months of age, or in February 1999, because their statements are not supported by the contemporaneous medical records. However, even if I were to accept petitioners' disavowal of their prior statements,²² there is ample evidence that Matthew exhibited speech delay and other symptoms of ASD at a point that renders this claim untimely.

The earliest reference to speech delay occurred on March 26, 1999, during Matthew's audiology exam at the Nemours Children's Clinic. Pet. Ex. 7, p. 74. During the examination, Mrs. Conner expressed concern about Matthew's hearing because he was "not talking and currently [had] no words in his repertoire." *Id.* The evaluator

²² These histories are quite consistent over time. Mrs. Conner reported in a questionnaire completed for the November 1999 early intervention evaluation that Matthew used words such as "mama" and "dada" at 18 months, or in February 1999, but then stopped. *Id.*, p. 9. On March 28, 2000, Mr. Conner described Matthew's speech delay as "a static and significant problem since the first year of life." Pet. Ex. 7, p. 71. The history communicated to Dr. Bradstreet indicated that Matthew "was speaking single words around 18 months," but "instead of building words, he began to lose words." Pet. Ex. 5(2), p. 149. Mr. and Mrs. Conner estimated Matthew's regression occurred as early as December 1998. *Id.*

described Matthew as “having an apparent speech and language delay by parental report,” and recommended Matthew receive a speech and language evaluation. *Id.* This parental report explains why Matthew was receiving hearing testing, and references symptoms currently exhibited by Matthew.

On November 24, 1999, Matthew was evaluated by the University of Florida’s Early Intervention Program. Pet. Ex. 10, p. 29. During the evaluation, Matthew exhibited poor eye contact, impaired social interaction, and significant language delay, with a vocabulary of fewer than 10 words. *Id.*, p. 31. A speech therapist participating in the evaluation stated that Matthew “appears to be in the autistic spectrum.” *Id.*, p. 32. This evaluation, conducted 11 days prior to the critical date of December 10, 1999, sufficiently establishes that Matthew exhibited symptomatic behaviors of ASD before the time permitted by the statute of limitations. Consequently, petitioners’ later statements regarding onset are superfluous to determining the timeliness of the petition.

The OAP transcript excerpts and medical literature submitted by respondent establish that the speech and language delays, impaired social interaction, and poor eye contact exhibited by Matthew in March-November 1999 are recognized by the medical community at large as symptomatic of ASD. The evidence thus establishes that Matthew’s first symptoms of ASD manifested prior to December 10, 1999.

b. The February 2000 Evaluation.

The medical records from two treating physicians indirectly refer to an evaluation Matthew received on February 3, 2000 from an Early Intervention Program. Pet. Exs. 6, p. 3; 7, p. 71. Petitioners did not file the record from the actual evaluation. At the time of this evaluation, Matthew was approximately two and half years old. Pet. Ex. 6, p. 1. According to Dr. Sisbarro’s 2001 summary of his February 2000 evaluation, Matthew was referred to “rule out autism and related disorders,” as he had “a history of significantly delayed development, especially within the language and communication areas.” *Id.* Matthew scored within the severely delayed range on the Bayley Scales of Infant Development, with an approximate developmental age of 14 months. *Id.* His score on the CARS, however, was in the non-autistic range. *Id.* He did not meet the diagnostic criteria for ASD. *Id.* Although the report summary does not precisely spell out why, it appears that Dr. Sisbarro did not find enough behaviors in the two domains other than the communication domain to support an ASD diagnosis. Although Matthew was recommended for continued speech and occupational therapy, Dr. Sisbarro did not feel it was “in [Matthew’s] best interests to consider him within the autistic spectrum,” based on his CARS score and Mrs. Conner’s recent report of improved social interaction. *Id.*

With regard to their assertion that the February 2000 evaluation somehow reset the statute of limitations clock, petitioners are essentially arguing for the discovery rule explicitly rejected in *Markovich*. Although Dr. Sisbarro concluded that Matthew did not meet the diagnostic criteria for ASD on February 3, 2000, the statute of limitations begins to run from 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 injury in a specific case.” *Goetz v. Sec’y, HHS*, 45 Fed. Cl. 430, 342 (1999), *aff’d*, 4 Fed. Appx. 827 (Fed. Cir. 2011) (emphasis added). According to the summaries of the February 2000 evaluation, there was clear evidence of delayed development, particularly in speech and language and communication. Matthew also had problems in social interaction, although Mrs. Conner felt he was improving in that area.

Two health care providers who saw Matthew about seven weeks apart from one another came to different conclusions about whether Matthew had an ASD. The neurologist, Dr. Abrams, concluded that he had an ASD; Dr. Sisbarro, a psychologist determined that he did not. Both observed or noted behaviors consistent with ASD, with Dr. Sisbarro concluding that there were not enough behaviors to justify the diagnosis. However, the Vaccine Act does not require a diagnosis to trigger the statute of limitations. Symptoms of the vaccine injury alleged are sufficient to start the clock running. I note that when Dr. Sisbarro concluded in 2001 that Matthew had an ASD, he referred to the same behavioral symptoms involving the communication domain to make his diagnosis.

B. Equitable Tolling

In *Cloer*, the Federal Circuit held that equitable tolling of the statute of limitations is permitted in Vaccine Act cases. However, the court declined to equate equitable tolling with a discovery rule. *Cloer*, 654 F.3d at 1345. Instead, the court discussed the applicability of equitable tolling in cases involving fraud or duress (citing to *Bailey v. Glover*, 88 U.S. 342, 349-50 (1874)), “extraordinary circumstances” adversely affecting an otherwise diligent litigant (citing to *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005)), and cases of timely filing of a procedurally defective claim (citing to *Irwin v. Dep’t. of Veterans Affairs*, 498 U.S. 89, 96 (1990)).

Although likely not exhaustive, these examples provide no basis to apply equitable tolling under the circumstances of this case. There is no evidence of fraud, duress, or extraordinary circumstances here.

V. Conclusion.

The statute provides that “no petition may be filed . . . after the expiration of 36 months after the date of the occurrence of the first symptom . . . of such injury” § 16(a)(2). The evidence establishes that Matthew displayed a recognize symptom of ASD, speech and language delay, more than 36 months before this claim was filed. By the plain language of the statute, and the interpretations of the Federal Circuit of that language, **this claim was untimely filed and is therefore dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk is directed to enter judgment accordingly.**

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell

Special Master