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

**No. 04-337V**
**Filed: November 22, 2011**
**To Be Published**

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| NICOLE M. WHITE, parent of Kenneth D. White, a minor, | * | |
| Petitioner, | * | Autism; Statute of Limitations; |
| v. | * | Speech and Language Delay; |
| | * | First Symptom or Manifestation of |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Onset; Equitable Tolling; Dismissal |
| Respondent. | * | |
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## DECISION[1]

**Vowell,** Special Master:

On March 8, 2004, Nicole M. White ["Ms. White" or "petitioner"] 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 her minor son, Kenneth White ["Kenneth"]. The petition was a "short form" petition authorized by Autism General Order # 1.[3] In essence, by filing a short form petition, Ms. White

[1] Because this 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), a party has 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 that 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. 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 #1"], 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002).

asserted that (1) Kenneth had a disorder on the autism spectrum[4] and (2) that one or more vaccines listed on the Vaccine Injury Table[5] were causal of Kenneth's condition.[6]

Respondent has moved to dismiss petitioner's 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."] at 1. Petitioner contends that the petition was timely filed because Kenneth was not diagnosed with autism until May 3, 2001, 34 months before the petition was filed on his behalf, or, alternatively, that the claim should be subject to equitable tolling. Petitioner's Opposition to Respondent's Motion to Dismiss ["Pet. Opp."] at 1, 5.

For the reasons stated herein, I find that the first symptom or manifestation of onset of Kenneth's autism occurred more than three years prior to the date the petition was filed. In the absence of any circumstances warranting equitable tolling, I hold that the petition was untimely filed and is therefore dismissed.

## I. Procedural History.

Kenneth'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.[7] For the first four years after this petition was filed, there was very little case-specific activity, although in the OAP, discovery was completed and test cases were litigated. In order to position this case for resolution once the test cases were concluded, petitioner was ordered in January, 2008, to file all medical records from Kenneth's birth through the date the petition was filed. Order, filed January 15, 2008, at 7. Medical records were filed on May 14, 2008 and July 14, 2008. Additional records, including school records, were subsequently filed in 2009.[8]

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[4] Autism spectrum disorders are discussed in more detail in Section III, below.

[5] 42 C.F.R. § 100.3 (2010).

[6] 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.

[7] *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. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[8] Some of Kenneth's records were lost as the result of Hurricane Katrina in 2005. Petitioner's Exhibit ["Pet. Ex."] 2.

Based on the medical records, respondent moved on August 13, 2008, to dismiss this case as untimely filed. Petitioner responded to the motion to dismiss on November 14, 2008, contending that Kenneth's claim was timely filed because he did not experience the first symptom or manifestation of onset of autism prior to the date of his diagnosis of autism, May 3, 2001, and, alternatively, that the claim should be subject to equitable tolling, because petitioner did not and could not have known Kenneth had autism until his diagnosis. Pet. Opp. at 4-7.

As numerous other OAP cases presented similar factual and legal issues with regard to timely filing, I deferred acting 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 statute of limitation 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]

While these statute of limitations cases were being litigated, decisions in the OAP test cases were issued on February 12, 2009 (Theory 1) and March 12, 2010 (Theory 2). There were no motions for review filed with regard to the Theory 2 test cases and the appellate review process for the Theory 1 test cases concluded on August 27, 2010 when the Federal Circuit issued its decision in *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010), the last of the test cases with an appeal pending.

The special masters then began the next step in moving the 4800 remaining OAP cases for final resolution.[10] In general, petitioners were ordered to inform the court if, in light of the results in the test cases, they wanted to move forward with their claim or move to dismiss it. If petitioners wished to pursue their Vaccine Act claim, they were ordered to file an amended petition, setting forth a theory of how vaccines caused their child's condition.

[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 the statute of limitations runs from the first symptom or manifestation of onset recognized by the medical profession at large).

[10] Unlike either class actions or multi-district litigation in other state or federal court systems, the remaining OAP petitioners are not bound by the results in the test cases. Nevertheless, by design, the OAP test cases produced a body of evidence available to both petitioners and respondent to use in litigating OAP cases in which petitioners elected to go forward with their claims. *Dwyer,* 2010 WL 892250 at *2; *Snyder*, 2009 WL 332044 *a*t *2 - *3.

Pursuant to this process, Ms. White filed her amended petition on March 21, 2011, asserting the same theories considered and rejected in the OAP test cases. After an April 8, 2011 status conference, I issued an order advising petitioner's counsel "that in order to demonstrate a reasonable basis and good faith belief to move forward on these theories, petitioner will need to produce evidence not produced in the test cases that affects the persuasiveness of these theories." Order, filed April 8, 2011. Petitioner's counsel requested "an opportunity to identify an expert and produce an expert report that would provide this new evidence." *Id.* I afforded her that opportunity, ordering the expert report to be filed by June 7, 2011. *Id*. Petitioner failed to file the expert report,[11] and on June 15, 2011, I ordered petitioner to show cause why her case should not be dismissed. Petitioner responded with a motion to stay the proceedings, pending the outcome of the Federal Circuit's en banc rehearing in *Cloer*. Because the statute of limitations issues in this case appeared similar to those raised in *Cloer,* I suspended petitioner's expert report deadline and indicated no further deadlines would be set until *Cloer* was decided. Order, filed July 13, 2011.

The en banc decision in *Cloer* was issued on August 5, 2011. I ordered the parties to file simultaneous briefs addressing the impact of *Cloer* on this case and any additional evidence pertinent to the statue of limitations issue by September 19, 2011. Both parties filed briefs as ordered; respondent also filed Respondent's Exhibits ["Res. Exs."] A-E.[12] Neither party filed the optional reply briefs. The issues are now fully joined and the case is ripe for decision.

## II. Medical History.[13]

There does not appear to be any material dispute concerning what is contained in the medical records. Rather, any dispute centers on whether the symptoms recorded constitute the first symptom or manifestation of onset of Kenneth's autism.

[11] Petitioner filed a Motion for Extension of Time on June 7, 2011. On June 8, 2011, I denied the motion and granted leave for the petitioner to refile the motion, including an explanation about why more time was needed. Petitioner did not refile her motion.

[12] The exhibits included two medical journal articles and transcript excerpts from three witnesses who testified in the OAP test cases concerning the presenting symptoms and the diagnosis of autism spectrum disorders.

[13] This history is drawn from Kenneth's medical records, which are incomplete. *See* Pet. Ex. 2 (indicating that Kenneth's pediatric records from "The Children's Clinic" in Metairie, LA, were unavailable due to Hurricane Katrina). However, sufficient records are filed concerning Kenneth's diagnosis and the manifestation of the symptoms which led to that diagnosis to make the factual findings in Section IV. Should petitioner be in possession of any unfiled records that contradict these factual findings, she may file a motion for reconsideration. Such motion shall explain why these records were not filed in response to the orders to file medical records in this case. *See* Petitioner's Statement of Compliance, filed November 23, 2009.

Kenneth was born on March 7, 1998; thus, he was six years old at the time the claim was filed.[14] The medical records are incomplete, but those available indicate that Kenneth was seen repeatedly for atopic dermatitis. *See, e.g.*, Pet. Ex. 1, p. 6 (two visits for atopic dermatitis); *see also* Pet. Ex. 6 at 2 (Jefferson Parish School System initial evaluation on June 2, 2001, reflecting Ms. White's statement that Kenneth had no incidence of serious illness or injury over his lifetime). Few records reflect any other illnesses or injuries. *See generally*, Pet. Exs. 1, 3. He received routine childhood vaccinations between birth and five years of age. Pet. Ex. 5, Vaccine Record. No routine pediatric records reflect any developmental screening.

The first indication of any developmental concern is contained in a record from Children's Hospital Pediatric Gastroenterology and Nutrition Clinic. This report is dated March 13, 2001, but it reflects what transpired at a visit on February 22, 2001, when Kenneth was nearly three years of age. The report indicates that Kenneth was referred to the clinic by his pediatrician, Dr. Roberto Mendoza for "improper eating habits for one year" (Pet. Ex. 1, p. 12), although there is nothing in the medical records filed from Dr. Mendoza indicating this referral. The report reflected that Ms. White referred to Kenneth's diet as "junk food" and that she also "noted that Kenneth has poor communication with others. He does not talk, only saying 'mom' and 'dad.'" *Id*. The physician performing the gastroenterology examination "requested a neurology referral to rule out autism." *Id*.

The requested neurology evaluation took place on May 3, 2001, and resulted in a diagnosis of autism. Pet. Ex. 1, pp. 16-17. Petitioner contends that this diagnosis, and not the behavioral symptoms that preceded it, triggered the running of the statute of limitations. However, the history taken from Ms. White and her mother during this evaluation reflects that Ms. White had concerns about Kenneth's behavior before the neurology appointment. She reported that Kenneth had used only two words from one year of age. He played primarily by himself, paced back and forth, had temper tantrums, and was a picky eater. In observing Kenneth, Dr. Joachim Wong, a pediatric neurologist, also noted that Kenneth made poor eye contact, kept to himself during the exam, did not use any words and only made sounds, had major deficits in language and communication, exhibited a very limited range of interests and activities, had some repetitive movements, and was rigid and stubborn. *Id*. Other than the clear language delay from the age of one through the date of the evaluation, Dr. Wong did not record when the symptoms began. However, the report did not reflect that they were of recent or dramatic onset.

Kenneth was referred to the Jefferson Parish School District for evaluation and placement. The evaluation on June 2, 2001 reflects that Kenneth's developmental

[14] Some medical records reflect March 8, 1998 as Kenneth's date of birth, but his birth certificate lists it as March 7, 1998. *See* Pet. Ex. 4. The discrepancy may be attributable to the time of his birth, 12:00 AM. *Id.*

history was taken from a form completed by Ms. White.[15] Ms. White reported that Kenneth's speech and language "has always been delayed." Pet. Ex. 6 at 3. She reiterated the history she had provided to Dr. Wong that Kenneth had developed two words before one year of age ("mama" and "dada") but had not developed any other words. She reported that Kenneth could not dress himself, did not follow directions, had temper tantrums, had poor appetite and ate non-food items, and was both overactive and a slow learner. Although his exposure to other children was somewhat limited, Kenneth did not get along well with them. *Id*. at 3-4.

The evaluation also reflects Ms. White's suspicion that Kenneth was delayed in his development. *Id.* at 10. She described him as a typical child at 18 months of age who then lost motor skills, such as eating with a spoon.[16] She also indicated that he was more socially inclined toward other children earlier in his development than he was at the time of the evaluation. *Id*. Ms. White also described other unusual behaviors to the school system evaluator, including Kenneth's efforts to communicate needs by handing her a cup when he wanted to drink, spinning wheels on toys, and watching the ceiling fan spin. Kenneth sometimes walked around the house, yelling and screaming. *Id*.

The school system evaluator observed poor eye contact, no joint attention, and inappropriate play with objects. *Id.* at 11. When handed an object, Kenneth visually scrutinized the object, turning it over and over, and occasionally smelled the object. He did not play functionally with any toys; when given cars and trucks, he placed them in a circle or lined them up, but did not push them back and forth. Pet. Ex. 6 at 11-13. When stressed, he would sit on his mother's lap, but did not otherwise touch or look at her. *Id.* at 14.

Based on the Childhood Autism Rating Scale, the school evaluator scored Kenneth as severely autistic. Pet. Ex. 6 at 15. Although later school and medical records were filed, they do not provide any additional information pertaining to onset of Kenneth's condition.

## III. Diagnostic Criteria for Autism Spectrum Disorders.

Only respondent filed any evidence[17] concerning the diagnostic criteria for autism spectrum disorders ["ASD"]. The information contained in this section is drawn from

[15] The case history form completed by Ms. White was not included in the records filed.

[16] This reflects Ms. White's own assessment. However, a standard pediatric textbook indicates that by 18 months of age, a typical child would have 10-15 words. *See* Robert Kliegman, Bonita Stanton, Joseph St. Geme, III, Nina Schor, and Richard Behrman, NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S"] at 33.

[17] 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 the early symptoms of autism or other ASD.

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 diagnosing 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 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. The manual identifies 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. Of note, a child's diagnosis within the autism spectrum may change from autistic disorder to PDD-NOS (or vice versa) over time.

A. Diagnosing Autism Spectrum Disorders.

The behavioral differences in autism spectrum disorders encompass not only delays in development, but also qualitative abnormalities in development. Fombonne Tr. at 1264A; Res. Ex. D, testimony of Dr. Max Wiznitzer in the *Cedillo* OAP test case ["Wiznitzer Tr."] at 1589-91. There can be wide variability in children with the same diagnosis. One child might lack language at all, while another with a large vocabulary might display the inability to engage in a non-scripted conversation. Wiznitzer Tr. at 1602A-1604. However, both would have an impairment in the communication domain.

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 1272A-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*[18] 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 (Autism).

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

[18] *King v. Sec'y, HHS,* No. 03-584, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

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 syndrome 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.

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 he asked the child 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, 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. These children use language primarily for getting their needs met. *Id*. at 1609. A child with ASD 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 - 1603. An Asperger's diagnosis does not require a communication domain impairment. *See* Fombonne Tr. at 1275A -76. A PDD-NOS diagnosis requires an impairment in either this domain or the patterns of behavior discussed next. *See* 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 a toy car and spinning it, rather than playing with the toy 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. An Asperger's diagnosis also requires 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 behavioral abnormalities in each of the domains, and must exhibit at least six of the 12 behavioral criteria in the three domains. There must be at least two behaviors encompassed in the social interaction domain, reflecting the importance of impaired social interaction in diagnosing ASD. Of significance, the behavioral abnormalities must manifest before the age of 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.

For a diagnosis of Asperger's disorder, the child must display behavioral abnormalities similar to those of children with autistic disorder, but need not have a language abnormality. Fombonne Tr. at 1275A-76; *see also* DSM-IV-TR at 84 (requiring two impairments in social interaction and one in restricted, repetitive, and stereotyped patterns of behavior, interests, and activities for this diagnosis).

For a PDD-NOS diagnosis, the child must display behavioral abnormalities in all three domains. However, this diagnosis is given when the impairments fall short of the criteria required for a diagnosis of autism (autistic disorder). Fombonne Tr. at 1275A.

## IV. Analysis.

A. Legal Analysis.

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 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. . . ."

§ 300aa-16(a)(2). The date of occurrence "is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Cloer,* 654 F.3d at 1339. Additionally, the date "does not depend on the knowledge of a petitioner as to the cause of an 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. *Id.*

Because petitioner filed her petition on behalf of Kenneth on March 8, 2004, the first symptom or manifestation of onset of Kenneth's autism must have occurred after March 8, 2001, in order for the petition to be considered timely. *See Markovich*, 477 F.3d at 1357 (holding that "either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer,* 654 F.3d at 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 occurrence of the first symptom or manifestation of onset.").

B. Applying the Law to the Facts of this Case.

1. Was the Petition Timely Filed?

Petitioner asserts three arguments in support of timely filing. Petitioner's Supplemental Opposition to Respondent's Motion to Dismiss ["Pet. Supp. Opp."], filed September 19, 2011, at 2. First, she argues that "because no medical provider associated a deficit exhibited by Kenneth . . . with autism or confirmed that a deficit exhibited by Kenneth reflected the onset of autism prior to May 3, 2001," the claim was timely filed. *Id.* Second, she contends that the date Kenneth was diagnosed with autism, May 3, 2001, constitutes the "manifestation of onset." *Id*. Third, she claims that "a communication deficit alone is not an indicator of autism." *Id*. Petitioner is wrong, both factually and legally.

a. Opinion of a Health Care Provider.

Contrary to petitioner's legal assertions, neither a definitive diagnosis nor the opinion of a health care provider "associating a deficit exhibited by Kenneth . . . with autism" (Pet. Supp. Opp. at 2) is required in order to trigger the running of the statute of limitations. 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 an injury in a specific case." *Goetz v. Sec'y, HHS,* 45 Fed. Cl. 340, 342 (1999), *aff'd*, 4 Fed. Appx. 827 (Fed. Cir. 2001). The OAP transcript excerpts submitted by respondent establish that the deficits exhibited by Kenneth, as noted in his medical records and histories, include deficits recognized by the medical community at large as symptomatic of autism.

With regard to her assertion that no health care provider associated a deficit exhibited by Kenneth with autism prior to May 3, 2001, petitioner is also factually incorrect. The first symptom of Kenneth's autism was recognizable as such by a medical professional six weeks earlier than the date of diagnosis. On February 22, 2001, Kenneth's gastroenterologist was sufficiently concerned about his behavior and lack of communication skills to refer Kenneth to the pediatric neurologist who ultimately

made the autism diagnosis. The gastroenterologist wrote that the reason for the neurology referral was "to rule out autism." Pet. Ex. 1, p. 12. Although the gastroenterologist did not point to specific behaviors triggering his concern, he recorded several symptoms unrelated to Kenneth's eating problems, including poor communication with others, failure to talk, and a vocabulary of only two words. *Id*. These are all symptoms reflective of a disorder in the communication domain.

The gastroenterology consultation took place two weeks before March 8, 2001, Thus, Kenneth displayed symptoms of autism at a time that renders this claim untimely filed.

b. Date of Diagnosis as Manifestation of Onset.

There is no factual dispute regarding the date of diagnosis. The legal dispute centers on whether diagnosis constitutes the "manifestation of onset" pursuant to 42 U.S.C. § 300aa-16(a)(2).[19] "Manifestation of onset" is not defined in the statute. See § 300aa-33 (defining certain terms used in the Vaccine Act). 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).

However, even if petitioner is correct in her assertion that the diagnosis constitutes the manifestation of onset, the Vaccine Act's statute of limitations has two possible triggering events, the "first symptom" or "manifestation of onset." These triggers are worded in the disjunctive. As the Federal Circuit has interpreted this wording, the first of these events starts the clock running. *Markovich*, 477 F.3d at 1358; *Cloer,* 654 F.3d at 1335.

It is true that no health care provider pointed to a specific behavioral abnormality and stated that it constituted the first symptom of Kenneth's autism. However, both the pediatric neurologist and the school evaluator pointed to symptoms that manifested far earlier than May, 2001. Pet. Exs. 1, pp. 16-17; 6 at 7-18. Both noted that Kenneth's language development stalled after the age of one. Pet. Exs. 1, p. 16; 6 at 10. At a time when most children are rapidly acquiring language, Kenneth made no progress at all. Furthermore, in her interactions with the school evaluator, Ms. White indicated that she suspected Kenneth was delayed, and pointed to 18 months of age as when the delay began. Pet. Ex. 6 at 10.

[19] Petitioner's Supp. Opp. incorrectly cites the relevant statutory provision as part of Title 28 U.S. Code.

Additionally, Kenneth's diagnosis itself confirms that Dr. Wong believed that at least some autistic behaviors occurred prior to Kenneth's third birthday. By definition, for a diagnosis of autistic disorder (autism), the abnormalities in behavior must have occurred prior to three years of age. If they occurred before Kenneth turned three on March 7, 2001, the claim was untimely filed.

I thus reject petitioner's assertions that no health care provider associated Kenneth's behavioral deficits with autism prior to the date of diagnosis, as the facts establish otherwise. Furthermore, petitioner's assertion that a diagnosis or health care provider's association of behaviors with autism is required in order to trigger the running of the statute is contrary to the law. I note that in *Markovich*, the symptom that reflected onset of a seizure disorder was eye blinking, a symptom even more subtle than the failure of a child to acquire any additional language at all between one and three years of age. Here, just as in *Markovich*, there is evidence that health care providers considered symptoms with many possible causes—eye blinking in *Markovich* and speech and language delay here—as the first symptom of the later-diagnosed disorder.

c. Communication Deficit as an "Indicator of Autism."

Petitioner asserts that "a communication deficit alone is not an indicator of autism." Pet. Supp. Opp. at 2 (emphasis added). Petitioner is factually incorrect. A communication deficit alone is insufficient to diagnose autism, but, as Drs. Fombonne and Wiznitzer testified in the OAP test cases, a communication deficit is one of the criteria by which autism is diagnosed. In fact, there must be some impairment in communication in order for autism to be diagnosed.

Kenneth was not a child who had a mild communication impairment or one easily attributed to illness, poor hearing, or some physical impairment in his ability to form words. Even by his mother's report, he did not acquire any new words after 12 months of age. Pet. Ex. 6 at 3. The physicians who evaluated him just before and just after his third birthday noted that Kenneth "did not talk" (Pet. Ex. 1, p. 12, observation of Drs. Zhang and Udall, the pediatric gastroenterologists), and used "no words," only sounds (Pet. Ex. 1, p. 17, evaluation conducted by Dr. Wong, pediatric neurologist). Doctor Wong assessed Kenneth as having "major deficits" in communication and language, and these deficits were signaled in part by his lack of vocabulary development in the preceding 24 months. Pet. Ex. 1, pp. 16-17.

Furthermore, communication deficits were not Kenneth's only symptoms of autism. In the May 3, 2001 evaluation, there were many other behavioral abnormalities observed and reported. Kenneth was reported to play by himself, to engage in repetitive motion (pacing back and forth), and to have a limited range of interests and activities, all behaviors appearing in the three domains of behavior used to diagnose autism. *Id.* While it is true that only the speech and language delay had a time frame associated with it in the records, there is no notation in any of the records that the other behaviors were of recent origin or sudden onset. Doctor Wong noted that there had

been no language regression, as did the school system's evaluator. Pet. Exs. 1, p. 16; 6 at 10. As the school system assessed his language skills, both receptive and expressive, as that of a child under one year of age, Kenneth's communication delays were open and obvious, and had been so for some time.

The most comprehensive evaluation was performed by the school system in June, 2001. This evaluation assessed Kenneth's motor skills as those of a child of 12-15 months of age, at a time when he was 38 months old. Pet. Ex. 6 at 8. This coincides closely with Ms. White's observations that Kenneth lost motor and social skills at about 18 months of age.

The school evaluator recorded or observed a wide range of behaviors associated with autism, including temper tantrums, not following requests, aggressive behavior, inability to get along with other children, using nonverbal communication to meet needs, poor eye contact, spinning wheels on toys, fascination with ceiling fans, lack of appropriate play, lining up objects, and not seeking consolation when he was stressed. Pet. Ex. 6 at 10-14. Once again, there was no indication that these behaviors were of recent or sudden onset, although no specific time frame for their manifestation was assigned for symptoms other than the expressive communication delays and loss of some motor and social skills. I conclude that these behavioral abnormalities were observable prior to March 8, 2001.

I also conclude that the first symptoms of onset of Kenneth's autism occurred between 12-18 months of age, when he failed to acquire any additional words, and experienced a loss of skills. As these behavioral abnormalities are clearly identified by experts as ones that are included in the diagnostic criteria for autism, the timing of Kenneth's first symptoms makes this claim untimely filed.

2. Equitable Tolling.

Finally, although she acknowledges that *Cloer* held to the contrary, petitioner argues that equitable tolling applies to her case. She asserts that, until a petitioner knows of an injury and the causal link between an injury and the administration of a vaccine, the statute of limitations does not begin to run or is otherwise equitably tolled. Pet. Supp. Opp. at 2.

Assuming, arguendo, that petitioner did not become aware of Kenneth's injury until his diagnosis, and that her knowledge of any "causal link" between this injury and a vaccination did not occur until after the diagnosis on May 3, 2001, I must still reject her argument that application of equitable tolling renders this claim timely filed.

In *Cloer*, the Federal Circuit acknowledged that equitable tolling applies in Vaccine Act cases, but under very limited circumstances, such as when a petitioner was the victim of fraud or duress, or when a procedurally deficient pleading was timely filed. *Cloer*, 654 F.3d at 1344-45. It squarely rejected the applicability of equitable tolling in

the circumstances petitioner urges. "[E]quitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable." *Id.* at 1345.

Decisions of the Federal Circuit interpreting the Vaccine Act are binding on special masters.[20] Accordingly, I must reject petitioner's argument that equitable tolling is applicable to Kenneth's case.

## V. Conclusion.

Petitioner has the burden to establish timely filing of her claim. She has failed to adduce any evidence or legal support for her claims that speech and language delay cannot be the first symptom or manifestation of onset of autism; that a diagnosis is necessary to trigger the running of the statute of limitations; or that a clear statement by a medical professional that a specific behavior constitutes the first symptom is required to trigger the running of the statute. In contrast, respondent has filed substantial evidence to demonstrate that speech and language delay is often the first symptom of autism and often the first symptom noted by parents or caregivers. While not sufficient in and of itself for a diagnosis, some evidence of a communication abnormality, which includes language delay or other qualitative impairment in communication, is required for an autism diagnosis.

I recognize that "speech delay" is a behavioral manifestation that can have many possible causes, including hearing loss, malformations of the mouth, palate, or vocal cords, or even non-medical conditions such as living in a multi-lingual household. Unfortunately, identifying the "first symptom" involves considerable use of hindsight, particularly in autism cases. A slow-growing cancer, the insidious beginning of a bipolar disorder, or the gradual rise of blood glucose levels and autoantibodies in Type 1 diabetes also present diagnostic challenges, and only in retrospect may the first symptom of these disorders be recognized as such. In this case, however, Kenneth's impairments were sufficiently obvious to a gastroenterologist to cause him to make a differential diagnosis of autism by a date that makes this claim untimely.

The Vaccine Act's statute of limitations is by no means generous. However, it likely represents one of the many trade-offs inherent in reconciling the competing legislative schemes proposed in 1985, which eventually became the Vaccine Act in 1986.[21] Other aspects of the Act are highly favorable to petitioners, including the Table

[20] *Guillory v. Sec'y, HHS*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 Fed. Appx. 712 (Fed. Cir. 2004). Decisions issued by special masters and judges of the Court of Federal Claims constitute persuasive, but not binding, authority. *Hanlon v. Sec'y, HHS*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999).

[21] *See* H.R. 1780, 99th Congress (1985); S. 827, 99th Congress (1985); S. 1744 99th Congress (1986), incorporating H.R. 5546, 99th Congress (1986). The initial bills proposed in the House and Senate differed on such matters as the appeal rights of petitioners, the monetary source for payment of damage

causation presumption, the no-fault nature of actual causation claims, and the extremely generous attorney fee provisions that make obtaining representation in these cases much easier.

Petitioner delayed filing this case until 34 months after Kenneth's diagnosis. Petitioner has not offered any explanation for the delay in filing the petition that would implicate equitable tolling. She has produced no evidence in support of her arguments, and has not directly addressed the differential diagnosis of autism suggested by Kenneth's gastroenterologist. Her legal arguments, which are themselves unsupported by the case law, thus also lack any factual predicate.

Kenneth's first symptoms of what was eventually diagnosed as autism occurred before March 8, 2001. 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

awards, and whether the Vaccine Program would be the exclusive court for suits regarding vaccine injury. *See* STAFF OF H. SUBCOMM. ON HEALTH AND THE ENVIRONMENT, 99TH CONG., REP. ON CHILDHOOD IMMUNIZATIONS (Comm. Print 1986) at *Appendix A: Vaccine Compensation Legislation in the 99th Congress*, pgs 93 – 101. The legislation that ultimately created the Vaccine Program borrowed from both the Senate and the House versions of the initial bills.