

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

No. 08-207

Filed: March 12, 2012

XIANGDONG HE and BEE TAN, *
as parents and legal representatives of *
Enoch He, a minor, *

Petitioners, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

Autism; Statute of Limitations;
Speech and Language Delay;
First Symptom or Manifestation of
Onset; Dismissal

Sean Greenwood, Esq., Houston, TX, for petitioners.
Heather Pearlman, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION¹

Vowell, Special Master:

On March 25, 2008, Xiangdong He and Bee Tan [“petitioners” or “Mr. He” and “Ms. Tan”] 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, Enoch He [“Enoch”]. The petition was a “short form” petition authorized by Autism General Order #1.³ In essence, by filing a short

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims’ website, in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 § 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 #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

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

Respondent moved 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."] at 1. Petitioners contend that the petition was timely filed because Enoch's speech delay was not objectively recognizable by the medical community at large as a symptom of his autism spectrum disorder until July 18, 2005, 32 months before the petition was filed on his behalf. Petitioners' Response to Respondent's Motion to Dismiss ["Pet. Res."] at 2-3.

For the reasons stated herein, I find that the first symptom or manifestation of onset of Enoch'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.

Enoch'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 In their petition, petitioners requested that any entitlement decision be deferred until after the conclusion of the OAP test cases. Petition at 1-2.

In order to position this case for resolution once the test cases were concluded, the assigned special master⁶ ordered petitioners to file all of Enoch's medical records and a Statement Regarding Onset addressing the timeliness of the petition. Order, filed Apr. 1, 2008. Petitioners filed a Statement Regarding Onset on August 29, 2008. Medical records were filed September 2, 2008, and October 21, 2008.

No further activity occurred in this case until February 16, 2010, when petitioners filed additional medical records and their statement of completion. On March 25, 2010, respondent moved to dismiss this case as untimely filed. Res. Mot. at 1. Petitioners responded to the motion to dismiss on July 19, 2010, contending that the petition 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 not assigned to me until November 23, 2011.

timely filed because the first symptom or manifestation of onset of Enoch's autism spectrum disorder did not occur until July 18, 2005, or, alternatively, that Enoch's continued vaccinations "severely exacerbated"⁷ his autistic condition. Pet. Res. at 2-3.

As numerous other OAP cases presented similar factual and legal issues with regard to timely filing, the special master 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).⁸

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 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.⁹ 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

⁷ Petitioners appeared to be alleging a claim of "significant aggravation," pursuant to § 11(c)(1)(C)(i). However, petitioners provided absolutely no evidence that Enoch's autism spectrum disorder was significantly aggravated due to the vaccinations he received. See § 300aa-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). The filed medical records do not support the allegation that Enoch's condition worsened after additional vaccines. See *generally* Petitioners' Exhibit ["Pet. Ex."] 6 (containing the medical records of pediatrician Dr. Levy, who administered Enoch's vaccinations).

⁸ 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).

⁹ 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 at *2-3.

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.

Pursuant to this process, petitioners filed an amended petition on June 24, 2011, asserting that Enoch's autism spectrum disorder was caused by the vaccines he received or, alternatively, that Enoch continued to receive vaccinations which "severely exacerbated" his condition.¹⁰ Amended Petition ["Am. Pet."] at 2.

After the case was assigned to me, I ordered the parties to file additional pleadings addressing the Federal Circuit's decision in *Cloer* and to file any medical or scientific evidence addressing speech delay as a symptom of an autism spectrum disorder. Order, filed Dec. 8, 2011. Respondent filed a brief addressing *Cloer* along with Respondent's Exhibits ["Res. Exs."] A-E.¹¹ Petitioners filed a request for a hearing on the disputed facts.¹² Petitioners' Motion for Extension of Time to Request a Hearing on Disputed Facts, or in the Alternative, Request for a Hearing on Disputed Facts ["Pet. Mot."] at 1.

At a January 19, 2012 status conference, we discussed petitioners' request for a factual hearing. During the status conference, petitioners' counsel was unable to identify any factual disputes to be resolved in the requested hearing. It became apparent that petitioners were not challenging the accuracy of the medical records documenting Enoch's speech delay; rather, they challenged the conclusions respondent drew from the delays manifested. Petitioners' position was that there were alternate explanations for Enoch's speech delay, and that the court should therefore use the date of diagnosis, rather than when speech delay manifested.¹³ In an order memorializing the status conference, I advised petitioners' counsel that I was unlikely to grant the

¹⁰ The amended petition does not identify the specific vaccinations alleged to be causal of Enoch's autism spectrum disorder, nor does it present any theory of causation. The amended petition does refer briefly to Enoch's mercury levels, but this theory was considered and rejected in the Theory 2 OAP test cases. See *Dwyer*, 2010 WL 892250; *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

¹¹ 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.

¹² According to petitioners, a hearing was required because "the medical records do not tell the whole story." Pet. Mot. at 2. However, despite being afforded an opportunity to provide information not addressed by the medical records, petitioners failed to file any additional evidence or a reply brief in support of this position.

¹³ The arguments set forth in petitioners' response to the motion to dismiss relied on petitioners' subjective belief that Enoch's speech delay was related to his prematurity or the bilingual nature of their household, rather than a symptom of autism. Pet. Res. at 2. As the court noted in *Markovich*, it is not a petitioner's subjective belief that is controlling; it is whether the medical community at large considers the behavior to be a symptom of the claimed vaccine injury. *Markovich*, 477 F.3d at 1360.

request for a hearing, but that my position could change if petitioners could point to factual disputes to be resolved. Order, filed Jan. 20, 2012. Neither petitioners nor respondent filed the optional reply briefs. 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.”].¹⁴

II. Medical History.

Enoch was born on August 12, 2002. Pet. Ex. 1, p. 16.¹⁵ Birth records indicate Ms. Tan had a fever shortly before going into premature labor. *Id.*, p. 15. Consequently, Enoch was born at only 31 weeks of gestation.¹⁶ *Id.*, p. 16. He spent his first 31 days of life in the Neonatal Intensive Care Unit. Pet. Ex. 6, p. 44.

Enoch received routine child immunizations from birth until August 18, 2005. Pet. Ex. 6, p. 55. In his first few years of life, Enoch was seen frequently for typical childhood illnesses, including upper respiratory infections and eczema. Pet. Ex. 2, pp. 30, 39, 120. Enoch was also diagnosed with macrocephaly.¹⁷ *Id.*, p. 123. After an ultrasound examination when he was about 10 months old, Enoch was diagnosed with an “external hydrocephalus,” or increased cerebrospinal fluid within the skull. *Id.*, p. 126. This was felt to be a benign “normal variation,” which “may be seen in infants between the ages of 9 months and 18 months.”¹⁸ *Id.*

Because of his prematurity, Enoch was referred to Pediatric Developmental Services.¹⁹ Pet. Ex. 2, p. 134. During an evaluation on February 12, 2003, Ms. Tan reported that Enoch “tends to use his right arm and left leg more than other extremities.” *Id.* Otherwise, Enoch appeared to be a healthy baby, smiling and beginning to laugh out loud. *Id.*

At nine months of age, Enoch’s pediatrician, Dr. Kathryn Levy, diagnosed him with “gross motor delay” and recommended he participate in an Early Childhood

¹⁴ 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.”

¹⁵ Petitioners’ exhibits contain handwritten and computer-generated page numbers. I refer to the computer-generated page numbers throughout this decision.

¹⁶ 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.

¹⁷ Macrocephaly, also referred to as megalcephaly, occurs when an individual has an unusually large head. See DORLAND’S, at 1092.

¹⁸ The physician who administered the ultrasound acknowledged that a CT scan would better evaluate Enoch’s macrocephaly, but the medical records do not indicate one was ever performed. Pet. Ex. 2, p. 126.

¹⁹ The February 12, 2003 record from Pediatric Developmental Services notes that Enoch’s pediatrician is Dr. Achala Ellepola. Pet. Ex. 2, p. 134. However, petitioners filed no records from Dr. Ellepola.

Intervention program. Pet. Ex. 2, p. 123. On August 12, 2003, during a 12-month well child visit, Dr. Levy reiterated Enoch's gross motor delay and also noted an "8 mo[nth] social delay." *Id.* Doctor Levy recommended that Enoch receive physical therapy. *Id.* Following a second developmental evaluation, Dr. Elaine Ellis of Pediatric Developmental Services diagnosed Enoch with "lack of coordination." *Id.*, p. 41.

On November 12, 2003, when Enoch was 15 months old, Dr. Levy noted that Enoch was learning two languages, Mandarin Chinese and English, and that he "knows and says at least 3-5 words." Pet. Ex. 2, p. 38. However, three months later at a developmental evaluation on February 10, 2004, Ms. Tan "expresse[d] some concern about [Enoch's] talking ability." Pet. Ex. 6, p. 108. During the evaluation, Dr. Ellis diagnosed Enoch with speech delay. *Id.*, pp. 108-09. According to Dr. Ellis, although Enoch was 18 months of age, his language skills were at only 12-14 months expressively and 14-16 months receptively. *Id.* at p. 109. Two days later, Dr. Levy noted Enoch's vocabulary consisted of "5-10 words." Pet. Ex. 2, p. 35. Doctor Levy's records indicate that she discussed speech development during the appointment. *Id.*

Doctor Levy referred Enoch to the Infant and Toddler Intervention Program of North Texas on April 15, 2004. Pet. Ex. 2, p. 42. Through the program, Enoch received weekly therapy related to "prelinguistic/communication training." *Id.* The enrollment records indicate that Enoch remained in the program for over one year, as Dr. Levy renewed his enrollment on April 25, 2005. *Id.*, p. 53.

Doctor Cathleen Roberts evaluated Enoch on July 21, 2004, and diagnosed Enoch with language delay, noting that his expressive language remained at only the 12-14 month level. Pet. Ex. 6, pp. 104-07. Additionally, Dr. Roberts indicated that Enoch's language skills were better in Mandarin than English, as he followed simple commands in Mandarin but "seemed somewhat lost" when instructed in English. *Id.*, p. 105.

Enoch was examined approximately one month later, on August 26, 2004, by Dr. Levy who noted that he was "very good at comprehension in Manderin [*sic*] and English." Pet. Ex. 2, p. 33. However, during that same appointment, Dr. Levy diagnosed Enoch with "delayed milestones." *Id.*

On January 21, 2005, when Enoch was 29 months old, Ms. Tan reported to Dr. Roberts that Enoch was "still not talking" and "[did] not know really any words," other than "mama" and "papa." Pet. Ex. 6, pp. 102-03. Ms. Tan noticed Enoch was "becoming more frustrated with his lack of language." *Id.*, p. 103. Doctor Roberts diagnosed Enoch with a speech disorder, noting that he "clearly does have some expressive language delays" and that she "suspected some mild receptive language delays as well." *Id.*, p. 102. She recommended his weekly speech therapy be increased to two sessions per week. *Id.*

On July 18, 2005, the date which petitioners contend triggered the statute of limitations, Ms. Tan again complained of Enoch's speech delay. Pet. Ex. 2, p. 28. Ms.

Tan reported that Enoch was “tongue-tied,” but that he understood commands. *Id.* Although Dr. Levy did not agree that Enoch was “tongue-tied,” she noted that he had made “little progress with speech.”²⁰ *Id.* Dr. Levy diagnosed Enoch with delayed milestones, recommending that he continue speech therapy in school, and that his parents monitor him for any worsening symptoms. *Id.*

On February 24, 2006, when Enoch was over three years of age, Dr. Roberts described Enoch’s behavior as “consistent with autism spectrum disorder, which would include very high-functioning autistic spectrum disorder such as Asperger’s.” Pet. Ex. 6, p. 92. Doctor Roberts noted Enoch’s vocabulary was “somewhat limited,” and that his receptive language skills were still delayed. *Id.* Enoch was diagnosed with multiple disorders related to his speech development, including communication disorder, speech and language delay, and higher-functioning pervasive developmental disorder. *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 diagnosing ASD.

Pervasive Developmental Disorder-Not Otherwise Specified [“PDD-NOS”], Asperger’s Disorder, and autism (also referred to as autistic disorder) are encompassed in the umbrella term of “Autism Spectrum Disorder” or “ASD.” 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.

Enoch was diagnosed with an autism spectrum disorder on February 24, 2006. Pet. Ex. 6, p. 93. From the diagnostic code used by Dr. Roberts, it is unclear if Enoch was diagnosed with PDD-NOS or Asperger’s Disorder. However, based on the speech and language delays exhibited by Enoch, it is more likely that he was diagnosed with PDD-NOS. See DSM-IV-TR at 80 (stating that, in individuals with Asperger’s Disorder,

²⁰ The medical records do not indicate whether Dr. Levy reached this conclusion based on her own interactions with Enoch, or if Ms. Tan reported Enoch’s lack of speech progression during the appointment.

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 the early symptoms of autism or other ASD.

“there are no clinically significant delays or deviance in language acquisition”).

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 autism 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.

A. Domains of Impairment and Specific Behavioral Symptoms

To be diagnosed with autism, a child must display abnormal development in three different domains: (1) language and communication; (2) social interaction; and (3) repetitive patterns of play, behavior, or interests. *Snyder*, 2009 WL 332044 at *36. To be diagnosed with PDD-NOS, however, a child need only display impairments in the first and third domains. See Res. Ex. D, testimony of Dr. Max Wiznitzer in the *Cedillo* OAP test case [“Wiznitzer Tr.”] at 1592.

1. Language and Communication

The first domain, language and communication, involves both verbal and non verbal communication. Language delay, limited babbling, lack of gestures, and lack of pointing to communicate things other than basic wants and desires are all early symptoms used to diagnose impairments in the communication domain. “Delays and deficits in language acquisition” are “among the key diagnostic criteria for autism spectrum disorders.” *Luyster* at 1246.

There are four subgroups 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. Res. Ex. C, excerpt of testimony of Dr. Eric Fombonne in *Cedillo* OAP test case [“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.

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 in the *King* OAP test case [“Rutter Tr.”] at 3253 (problems in social and communication domains tend to be observed much earlier than stereotyped behaviors).

2. Social Interaction

Symptoms used to identify young children with impairments in the second domain, social interaction, 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.

3. Repetitive patterns of play, behavior, or interests.

The third domain, repetitive patterns of play, behavior, or interests, is broken into four categories: (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.

B. Diagnosing an Autism Spectrum Disorder.

Diagnostic testing for 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 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* Rutter Tr. at 3253-54 (describing diagnostic instruments and their use in clinical settings).

Thus, by itself Enoch’s exhibited signs of speech delay are insufficient to render a diagnosis of an ASD. However, Enoch’s delayed speech constitutes a portion of the diagnostic picture; other symptoms—such as the stereotypical behaviors and patterns

of interest Dr. Roberts noted on the date of his diagnosis—are required to diagnose an ASD such as PDD-NOS. It is clear that Dr. Roberts considered Enoch’s speech delay as one of the factors leading to her diagnosis. Pet. Ex. 6, p. 92.

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 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).

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. *Id.*

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 this Case.

To determine if this 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 Enoch'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 Enoch on March 25, 2008, the first symptom or manifestation of onset of Enoch's ASD must have occurred on or after March 25, 2005, 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 Enoch's ASD did not occur until July 18, 2005, as prior to that date his speech delay could be attributed to exposure to two languages, Mandarin and English, rather than ASD. Pet. Res. at 2. Similarly, in *Markovich*, the petitioners asserted that eye blinking—later discovered to be a reflection of the onset of a seizure disorder—did not trigger the statute of limitations, because it "could not reasonably alert the Markoviches that anything was wrong." *Markovich*, 477 F.3d at 1357.

As the court did in *Markovich*, I reject petitioners' claims. The possibility of a symptom's potentially innocuous cause does not preclude the running of the statute of limitations. While it is true that no health care provider pointed to Enoch's speech delay and stated that it constituted the first symptom of ASD, 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 as injury in a specific case." *Goetz v. Sec'y, HHS*, 45 Fed. Cl. 430, 342 (1999), *aff'd*, 4 Fed. Appx. 827 (Fed. Cir. 2001). The OAP transcript excerpts and the medical literature submitted by respondent establish that the speech and language delays exhibited by Enoch, as noted in his medical records and histories, are recognized by the medical community at large as symptomatic of ASD, including PDD-NOS.

Moreover, the medical records are replete with references to Enoch's speech delay prior to the critical date of March 25, 2005. On February 10, 2004, Enoch was diagnosed with speech delay during a developmental evaluation. Pet. Ex. 6, p. 109. During the same evaluation, Ms. Tan herself expressed concerns regarding Enoch's speech and language development. *Id.*, p. 108. On January 21, 2005, Ms. Tan reported that Enoch was "still not talking" and "[did] not know really any words." *Id.*, pp. 102-103. By March 25, 2005, Enoch had been enrolled in weekly speech therapy for nearly one year. *Id.* Doctor Roberts' diagnosis of an ASD on February 24, 2006, referenced Enoch's speech problems, including his limited vocabulary and delayed

receptive language. *Id.*, p. 92. Additionally, Enoch's ASD was diagnosed in conjunction with communication disorder and speech and language delay. *Id.*, p. 92. Petitioners offered no cogent explanation for why I should consider the July 18, 2005 diagnosis of speech delay as triggering the running of the statute of limitations and not the many earlier dates when Enoch's speech delay was discussed or diagnosed. I note that there is no challenge to the accuracy of these medical records.

I thus conclude that the first symptom of onset of Enoch's ASD occurred prior to March 25, 2005. The DSM-IV-TR requires at least one impairment in communication for a diagnosis of autistic disorder or PDD-NOS. Furthermore, the evidence establishes that a delay in speech is often the first symptom of what is later diagnosed as an ASD. Thus, the timing of Enoch's first symptoms render this claim untimely filed.

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. Petitioners' initial belief that Enoch's speech delay was related to his prematurity or the bilingual nature of their household, is not grounds for me to apply equitable tolling.

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" § 300aa-16(a)(2). The evidence establishes that Enoch displayed a recognized symptom of an 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 a 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