

petitioners asserted that (1) Flora had a disorder on the autism spectrum⁴ and (2) that one or more vaccines listed on the Vaccine Injury Table⁵ were causal of this condition.⁶ No medical records were filed with their petition.

Respondent has 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. Respondent's motion relies in part on consult notes from Flora's 18 month well baby check-up. *Id.* at 3. Petitioners contend that the petition was timely filed because a professional speech and language pathologist indicated in August, 2001, that Flora's speech and language skills were grossly appropriate. Petitioners' Response to Motion to Dismiss ["Pet. Response"] at 1. Because Flora did not see any specialists between August 2001 and June 2003, when she was diagnosed with PDD-NOS, petitioners assert this claim was timely filed.⁷ *Id.* at 2. Additionally, petitioners argue that "academic articles that identified speech delay as an early sign of ASD were not published until 2008, [t]hus the petition was filed two years before the medical profession at large recognized speech delay as an early sign of ASD." *Id.*

Petitioners have the burden to demonstrate that their case was properly and timely filed. Petitioners have not met their burden and I therefore dismiss this petition as untimely filed.

I. Procedural History.

Flora'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.⁸ For the first three 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

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 I note that petitioners made a similar argument in the cover letter filed with a CD containing medical records in July 2009. They wrote "The exhibits show that our daughter was born healthy. Although Flora's attending pediatrician noted speech delays when Flora was one year old, a speech pathologist examined Flora when she was 19 months and found her speech to be grossly normal. Flora was diagnosed with PDD-NOS on June 4, 2003. This was the first indication that her delays were pervasive and chronic." Petitioners' Cover Letter, filed July 15, 2009.

⁸ *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). I incorporate these discussions of the history of the OAP by reference into this decision.

resolution once the test cases were concluded, petitioners were ordered in February, 2009, to file all medical records from Flora's birth through the date the petition was filed. Order, Feb. 13, 2009.

Petitioners complied with my order and filed Petitioners' Exhibits ["Pet. Exs."] 1-13 on July 15, 2009. Petitioners were ordered to file a statement of compliance with phase one medical records production, and respondent was ordered to file a statement regarding whether this claim should proceed in the OAP within 45 days of petitioners' filing of their statement of compliance. Order, filed May 27, 2009. Petitioners filed their statement of compliance on September 15, 2009, and on October 22, 2009, respondent filed a motion to dismiss, in lieu of the ordered statement. Petitioners did not file a response to the motion to dismiss.

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 that the 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 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 test case 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

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 at *2-3.

light of the results in the test cases, they wanted to move forward with their claims or move to dismiss them. If petitioners wished to pursue their Vaccine Act claims, they were ordered to file an amended petition or causation statement, setting forth a theory of how vaccines caused their child's condition.

Pursuant to this process, on October 22, 2010, petitioners indicated their intent to pursue their claim, and on November 24, 2010, petitioners filed their Statement of Theory of Causation ["Causation Theory"]. According to petitioners, Flora has a mitochondrial dysfunction which caused toxins to stay in her body. Causation Theory at 2. In particular, petitioners assert that aluminum from Flora's vaccines stayed in her body, resulting in nerve damage, and leading Flora to develop an encephalopathy. *Id.* at 3.

On October 25, 2010, the U.S. Court of Appeals for the Federal Circuit vacated the panel decision in *Cloer* (*Cloer v. Sec'y, HHS*, 399 Fed. Appx. 577 (Fed. Cir. 2010)), and ordered a rehearing en banc. Because the statute of limitations issues in this case appeared similar to those raised in *Cloer*, I suspended any further action in this case pending the en banc decision, which was issued on August 5, 2011.¹¹ I then ordered respondent to file any additional pleadings and evidence concerning her pending motion to dismiss by September 19, 2011, and petitioners to file a response to the motion to dismiss by November 2, 2011. Order, filed Aug. 22, 2011. Both parties complied with my order, and thus this case is ripe for decision on respondent's motion to dismiss. The evidence establishes that this case was untimely filed.

II. Evidence Concerning Vaccinations, Symptoms, and Diagnosis.

The medical records consist of the thirteen exhibits petitioners filed on July 15, 2009.

Flora was born on January 14, 2000. Her Apgar scores reflect that she was a healthy newborn.¹² Pet. Ex. 2, p. 4. Two days later, she was noted as "doing well," but had minimal jaundice on her face which would be followed clinically. *Id.*

On January 20, 2000, she was admitted to the hospital with a temperature of 102.3. Pet. Ex. 3, p. 15. Flora did not have any rashes, coughs, or other symptoms, and was feeding normally, but it was noted that her mother, Ms. DeLong, had a cold. *Id.*,

¹¹ *Cloer v. Sec'y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011) (en banc).

¹² The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken 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 ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"], at 1682; Robert Kliegman, Bonita Stanton, Joseph St. Geme, III, Nina Schor, and Richard Behrman, NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S"] at 536-37. Flora's scores were 8 and 9. Pet. Ex. 1, p.1.

pp. 7, 15. Flora was discharged from the hospital on January 22, 2000. *Id.*, p. 34. At her two-week well baby visit, she was doing well with good weight gain. Pet. Ex. 5, p. 1.

On March 16, 2000, at her two-month well baby visit, Flora was reported to be healthy, with normal growth and development. Pet. Ex. 5, p. 1. She received her first DTaP, Hib, and IPV vaccinations at this visit. *Id.*, Pet. Ex. 4, p. 1. Flora continued to receive routine child immunizations. See Pet. Ex. 4, p. 1.

At her four-month well baby visit, Flora was very clingy with some separation anxiety. Pet. Ex. 5, p. 2. It was also noted that she had anteriorly placed frenula with a creased tongue,¹³ and was consequently referred to an ear, nose, and throat ["ENT"] specialist. *Id.* Her growth and development was reported as normal. *Id.*

On June 8, 2000, Flora was seen by Dr. Lachman, an ENT, who noted "mild tongue-tie with decent tongue motion." Pet. Ex. 8, p. 1. He failed to find any sign of hearing loss, observing that Flora babbled as a response to sound. *Id.* He recommended a re-check of her tongue in six months. *Id.* The October 19, 2000 pediatric consult note references an ENT follow-up visit scheduled for 1/00 [*sic*], but no records from a January 2001 ENT appointment were filed. Pet. Ex. 5, p. 3. Flora underwent surgery for her ankyloglossia¹⁴ in March 2001. Pet. Ex. 8, p. 2.

On July 18, 2000, Flora was described as a very interactive, well six-month old who babbled and was starting to eat solid foods. Pet. Ex. 5, p. 2. At her nine-month well child check-up, Flora exhibited normal growth and development. *Id.*, p. 3. She did not understand "no" yet. *Id.*

Flora had her one-year well child visit on January 26, 2001. Pet. Ex. 5, p. 3. At this visit, her pediatrician, Dr. Marisa Rosania, noted that Flora's growth was normal and her development was "ok." *Id.* Doctor Rosania explained the "ok" in development with the comment that she "would like to see [Flora have] more receptive language skills." *Id.* On May 4, 2001, Flora, then 16 months of age, had good eye contact, normal growth, and her development was progressing. *Id.*, p. 4. However, she did not indicate her wants yet, nor did she try to follow commands. *Id.*

At her 18-month well child check-up, on July 31, 2001, her pediatrician recorded that Flora followed some directions, lacked a ten word vocabulary, and did not indicate her needs except for a sign she had to indicate thirst. Pet. Ex. 5, p. 4. Additionally, Flora had received an early intervention program ["EIP"] evaluation, and would be

¹³ "Frenula" is the plural form of "frenulum." See DORLAND'S at 745. The frenulum is the mucous membrane that runs from the floor of the mouth to the bottom of the tongue. *Id.*

¹⁴ Ankyloglossia is the medical term for restricted movement of the tongue that results in speech difficulty. DORLAND'S at 93. A complete ankyloglossia results from a fusion between the tongue and floor of the month while a partial ankyloglossia results from a either a short lingual frenum or one attached too close to the tip of the tongue. *Id.* at 93-94.

receiving EIP services once a week, as well as speech therapy. *Id.* However, during a speech and language evaluation administered by a different provider on August 29, 2001, Ms. Delong conveyed that “Flora qualified for Early Intervention services, but not for speech therapy since ‘she had not yet developed speech.’” Pet. Ex. 7, p. 1.

Speech pathologist Lisa Bove evaluated Flora on August 29, 2001, when she was 19 months old, because of concerns regarding delayed speech and language development. Pet. Ex. 7, p. 1. Ms. Bove concluded that Flora had “grossly appropriate receptive language skills and appropriate receptive language skills.” *Id.*, p. 2. Additionally, Flora’s articulation skills were judged to be age appropriate, verbal output skills were grossly age appropriate, and speech intelligibility at the word level was fair. *Id.* Flora was noted to have a vocabulary of 15 words. *Id.* However, the diagnosis on this report is “Receptive Language Disorder.” *Id.*, p. 1. Flora inconsistently followed single step directions, and slight weaknesses were noted in her understanding of words, verbs, naming, and response to command with gestures. *Id.*, pp. 1-2. Ms. Bove deferred beginning speech and language therapy, and recommended a re-evaluation in six months. *Id.* It is this evaluation that petitioners rely upon to support their contention that this case was timely filed.

On January 16, 2002, Flora’s pediatrician considered her a healthy two year old, with a language delay. Pet. Ex. 5, p. 5. Flora had about a ten word vocabulary (the same number of words she had at 18 months of age), was sociable, and exhibited good eye contact. *Id.* Flora was in daycare five days a week, and received EIP services once a week.¹⁵ *Id.*

At her three-year well child check-up, on January 21, 2003, Flora was starting to speak in sentences and had a vocabulary of around 50 words. Pet. Ex. 5, p. 5. Her pediatrician noted Flora had a speech and language delay, in both her expressive and receptive language, and recommended Flora receive additional speech therapy. Doctor Rosania also noted the need to plan for preschool. *Id.*

In March 2003, Flora’s daycare staff providers reported concerns about her functioning in their program. See Pet. Ex. 10, p. 1. For example, they reported that she “sometimes shows inappropriate behavior e.g. standing or climbing on to furniture,” “often cannot wait and is easily frustrated,” and “does not often communicate verbally.” *Id.*

Flora was diagnosed with pervasive developmental disorder, not otherwise specified [“PDD-NOS”]¹⁶ on June 4, 2003, by Dr. Lawrence Taft. Pet. Ex. 10, p. 3. It is this evaluation that petitioners contend triggers the running of the statute of limitations.

¹⁵ Flora’s EIP records were not filed. See Pet. Exs. 1-13. However, based on the notation in Dr. Rosania’s July 21, 2011 consult note it appears that Flora had been receiving EIP services for about five months at the time of her two-year well child check-up.

¹⁶ Doctor Taft also described her as having an autistic spectrum disorder of a mild nature. Pet. Ex. 10, p. 3.

His report indicates petitioners requested the evaluation due to concerns about “Flora’s speech delay and poor socialization.” *Id.*, p. 1. Doctor Taft noted that although Flora occasionally spoke in full sentences, it was rarely in an attempt to communicate with her parents. *Id.* Instead, she used short phrases, such as “I want.” *Id.* Doctor Taft also indicated that Flora was not interested in interacting with her peers and tended to isolate herself. *Id.* He also reported that Flora liked to line things up, although not to the extent that he observed with her sister. *Id.*

Doctor Taft noted that Flora had been receiving twice weekly speech therapy for the past year. Pet. Ex. 10, p. 2. During the evaluation, Flora rarely responded when asked a direct question. *Id.*, p. 3. She also had poor eye contact, and jumped up and down with her hands flapping. *Id.*

Flora was referred to St. Joseph’s Children’s Hospital by the Morris School District for a pediatric neurodevelopment consultation. Pet. Ex. 11, p. 1. On February 1, 2005, at this consultation, Flora’s parents reported that she walked “a little late” and said a few words at age one but then her speech did not evolve well. *Id.* Flora was noted to be receiving speech and language therapy along with occupational therapy, and to be making steady progress. *Id.* Doctor Holahan concluded that Flora’s history and current behavior was “consistent with a diagnosis of an autistic spectrum disorder, with her functioning in the PDD/NOS range at this time.” *Id.*, p. 3.

The most recent medical records are from the Stockton Family Practice, where Flora was seen for biomedical treatments. During her initial visit to the practice, on May 16, 2005, petitioners reported that when Flora was two years old they noticed sensitivity to loud noises and increased irritability. Pet. Ex. 12, p. 2. By three years of age, she had decreased eye contact, frequent tantrums, difficulty socializing, and a tendency to line things up. *Id.* She also began to toe-walk. *Id.* Petitioners indicated there was no immediate regression, but reported a gradual change in Flora’s disposition and a delay in developing speech. *Id.* On June 22, 2005, at her first follow-up appointment, petitioners suggested they became first concerned when Flora was “around 2 years of age [and had] slow development of language and then sensitivity to loud noises.” *Id.*, p. 3. According to the most recent record filed, from April 24, 2006, Flora participated in telling jokes, liked to read, and was spelling words. *Id.*, p. 7.

III. Diagnostic Criteria for Autism Spectrum Disorders.

Only respondent filed any evidence¹⁷ concerning the diagnostic criteria for autism spectrum disorder [“ASD”]. The information contained in this section is drawn from that evidence. The transcript excerpts contained in Respondent’s Exhibits [“Res. Exs.”] C-E were from OAP test case testimony provided by three pediatric neurologists with considerable experience in diagnosing ASD.

¹⁷ All of the evidence filed in the OAP test cases is available to any petitioner in the OAP, as well as to respondent. 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.

“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. 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.

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* 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 ASD. Of significance, the behavioral abnormalities must be 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, the diagnosis is given when the impairments fall short of the criteria for a diagnosis of autism (autistic disorder). *Fombonne Tr. at 1275A.*

IV. Arguments and 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 petitioners filed their petition on behalf of Flora on March 27, 2006, the first symptom or manifestation of onset of Flora's PDD-NOS must have occurred after March 27, 2003, 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.

In this decision, I apply the summary judgment standard contained in Rule 56 of the Rules of the Court of Federal Claims ["RCFC"].¹⁸ I note that there are no genuine disputes as to the material fact, except perhaps regarding when Flora began receiving speech therapy.

Rather, the dispute in this case concerns the implications to be drawn from the facts. Petitioners contend that a grossly normal speech and language evaluation by Ms. Bove in August, 2001, somehow cancels out any observations of behaviors used to diagnose ASD exhibited by Flora prior to and after that August evaluation. They contend that only an evaluation by another specialist, Dr. Taft, in June, 2003 could trigger the running of the statute of limitations.

In making this argument, petitioners confuse symptoms with diagnosis, and ignore Ms. Bove's diagnosis of receptive language delay. Furthermore, they do not address, much less challenge, the factual accuracy of their statements to medical providers about Flora's development and behavior between the two evaluations. Likewise, they do not address their own accounts to health care providers, such as those at Stockton Family Practice, about when their concerns about Flora's behavior and development first arose.

1. Was the Petition Timely Filed?

Petitioners assert two main arguments in support of timely filing. First, they assert that I should not consider the July 2001 pediatric record, indicating a speech delay, because in August 2001 a speech and language pathologist concluded that Flora's speech and language skills were grossly appropriate. Pet. Response at 1. Essentially, petitioners urge me to weigh the opinion of a medical specialist above that of a pediatrician. *Id.* at 2. Consequently, because Flora did not see any specialists between August 2001 and June 2003, the date of her diagnosis of PDD-NOS,¹⁹ petitioners argue that the date she was diagnosed with PDD-NOS is the date of occurrence for purposes of applying the statute of limitations. *Id.* at 2. Second, petitioners argue that speech delay was not recognized by the medical profession as an early sign of ASD in 2001. *Id.*

a. Onset of Flora's Speech Delay.

On July 31, 2001, at her 18-month well child check-up, Flora's pediatrician, Dr. Rosania, expressed concern over Flora's limited vocabulary and ability to communicate

¹⁸ According to RCFC 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."

¹⁹ A diagnosis in June, 2003, means that ASD symptoms were present before then, as people do not see a specialist without some reason. Additionally, as Dr. Fombonne noted in the OAP test cases, ASD symptoms are typically present for weeks or months before parents report them to a physician. Fombonne Tr. at 1283.

her needs. Pet. Ex. 5, p. 4. About a month later, on August 29, 2001, Flora was evaluated by a speech pathologist, Ms. Bove, to address these concerns. Pet. Ex. 7, p. 1. Ms. Bove concluded that Flora had “grossly appropriate receptive language skills and appropriate receptive language skills,” but recommended a re-evaluation in six months. *Id.*, p. 2. However, Ms. Bove also diagnosed Flora with receptive language disorder. *Id.*, p. 1.

At her three-year well child check-up, on January 21, 2003, Dr. Rosania again noted concerns about Flora’s speech and language skills and recommended she receive “additional” speech therapy. Pet. Ex. 5, p. 5. The evidence is unclear whether Dr. Rosania was recommended speech therapy commence or whether she was recommending it in addition to the EIP services (which may or may not have included a speech component) Flora was already receiving. The July 31, 2001 pediatric record states Flora was receiving EIP once a week and speech therapy, while the August 29, 2001 speech pathology evaluation indicates that Ms. DeLong reported that “Flora qualified for early intervention services, but not for speech therapy since ‘she had not yet developed speech.’” Pet. Exs. 5, p. 4; 7, p. 1.

At some point, probably by June, 2002, Flora began receiving speech therapy, as Dr. Taft’s June 4, 2003 report noted “Flora has been receiving speech therapy for the past year about twice a week.”²⁰ Pet. Ex. 10, p. 2.

Petitioners’ argument that the opinion of a specialist (Ms. Bove) trumps that of a pediatrician (Dr. Rosania) might be persuasive if the July 31, 2001 well child visit and the August 29, 2001 report were the only two records reflecting speech delay. However, delays were noted again by Dr. Rosania after Ms. Bove’s evaluation. Thus, even if Ms. Bove’s opinion somehow erases Dr. Rosania’s opinion that Flora had delayed speech at 18 months of age as a statute of limitations triggering event, Dr. Bove’s August, 2001 opinion cannot affect Dr. Rosania’s concerns about speech and language at Flora’s three-year well child visit in 2003. Additionally, the report of specialist Dr. Taft indicates that Flora experienced speech problems prior to March 27, 2003, as he notes that Flora had been receiving speech therapy for over a year.

b. Speech Delay as a Sign of ASD.

Petitioners argue that the journal articles filed by respondent identifying speech delay as an early sign of ASD were not published until 2008, and therefore this claim was

²⁰ I note that Dr. Taft recommended Flora “receive speech therapy,” which could be read as in conflict with the history that Flora had already been receiving speech therapy. His statement could also be interpreted as an indication that the therapy must continue. I need not resolve this possible conflict because there is sufficient evidence in Dr. Rosania’s noted concern of speech and language delay at the January 21, 2003 well child visit to conclude that Flora’s speech delay was present at a time that renders this petition untimely filed.

filed two years before the medical profession at large recognized speech delay as a symptom of ASD. See Pet. Response at 2. Thus, they conclude this petition was timely filed. *Id.* Petitioners read too much into the date of the articles filed.

The Diagnostic and Statistical Manual of Mental Disorders [“DSM”] is the manual used in the United States to diagnose dysfunctions of the brain. The American Psychiatric Association is currently overseeing the drafting of the fifth edition of the manual, which will be published in May 2013.²¹ The fourth edition of the manual (DSM-IV) was published in 1994 and DSM-IV-TR, a text revision of the fourth edition, was published in 2000.²² Therefore, the DSM-IV-TR is a proper source to determine what the medical community at large viewed as symptoms of ASD in 2001, and also in 2007 and 2008, when Drs. Wiznitzer, Fombonne, and Rutter testified in the OAP test cases.

Section III (“Diagnostic Criteria for Autism Spectrum Disorders”) of this decision relies on the DSM-IV-TR and the testimony of Drs. Wiznitzer, Fombonne, and Rutter,²³ to illustrate that one of the behaviors the medical community at large considers symptomatic of PDD-NOS is speech delay. Additionally, I note that although the two medical journal articles respondent filed in this case are from 2007 and 2008, both include numerous citations to articles published prior to 2001 that discuss speech delay and the diagnosis of ASD.²⁴

c. Other Symptoms of ASD.

In addition to delayed speech, Flora exhibited other symptoms of PDD-NOS prior to March 27, 2003. For example, she had decreased eye contact, difficulty socializing, and tended to line things up at age three (January 2003). Pet. Ex. 13, p. 2. Since Flora

²¹ American Psychiatric Association, *DSM-5 Development*, <http://www.dsm5.org/Pages/Default.aspx> (last visited March 22, 2012).

²² American Psychiatric Association, *DSM-IV-TR: The Current Manual*, <http://www.psych.org/mainmenu/research/dsmiv/dsmivtr.aspx> (last visited March 22, 2012). The text revisions made the diagnosis criteria for PDD-NOS more specific. *Snyder*, 2009 WL 332044 at *34 n.95.

²³ Petitioners were given the opportunity to file evidence regarding the symptoms of ASD. See Order, filed Aug. 22, 2011. However, they produced no evidence of when the medical community at large recognized speech delay as a symptom of ASD.

²⁴ See, e.g., A. De Giacomo and E. Fombonne, *Parental Recognition of Developmental Abnormalities in Autism*, EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 7:131-136, 136 (1998) (“The most common parental concerns were for speech and language development, followed by abnormal socio-emotional response, and medical problem or delay in milestone”); Wendy Stone, et al, *Can Autism Be Diagnosed Accurately in Children Under 3 Years?*, Journal of Child Psychology and Psychiatry, 40:219-226, 219 (1999) (“Social deficits and delays in spoken language were the most prominent DSM-IV characteristics evidenced by very young children with autism”); P.A. Filipek, et al, *Practice Parameter: Screening and Diagnosis of Autism-Report of the Quality Standards Subcommittee of the American Academy of Neurology and the Child Neurology Society*, NEUROLOGY, 55:468-479 (2000) (noting that a failure to meet verbal milestones “is associated with a high probability of a developmental disability”).

experienced symptomatic behaviors associated with PDD-NOS more than 36 months before this petition was filed, this petition was untimely filed and must be dismissed unless the doctrine of equitable tolling applies.

2. Does Equitable Tolling Apply?

The doctrine of equitable tolling is a legal principle that acts to overcome a statute of limitations problem in certain situations. If a case is untimely filed and the doctrine of equitable tolling applies, then the case will be permitted to continue.

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 “due to unawareness of a causal link between an injury and administration of a vaccine.” *Id.* at 1345.

Petitioners have not presented any arguments that would support the application of equitable tolling to this claim, and my examination of the record does not disclose any basis for applying equitable tolling to this case.

V. Conclusion.

Petitioners have the burden to show timely filing. They have failed to establish that this case was filed within “36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury” as required by the Vaccine Act. § 300aa-16(a)(2).

Flora’s first symptoms of what was eventually diagnosed as PDD-NOS occurred before March 27, 2003. 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.

Denise K. Vowell
Special Master