In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 08-0532V
Filed: September 21, 2012

DENISE SANTILLAN, parent of EMILIO SANTILLAN, a minor	*	
Petitioner,	*	Autism, Statute of Limitations;
v.	*	Untimely Filed
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

DECISION[1]

On July 22, 2008, Denise Santillan ("petitioner"), on behalf of her son, Emilio Santillan ("Emilio"), filed a claim for compensation pursuant to the National Vaccine Injury Compensation Program ("Vaccine Program" or "the Program").[2] Petitioner filed the Short-Form Petition authorized by Autism General Order #1,[3] thereby joining the

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned intends 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, the undersigned agrees that the identified material fits within the requirements of that provision, the undersigned will delete such material from public access.

[2] The National Vaccine Injury Compensation Program ("Vaccine Program" or "the Program") is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. § 300aa-10 et seq. (2006) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

[3] Autism General Order #1 adopted the Master Autism Petition for Vaccine Compensation for use by petitioners filing claims intended to be part of the Omnibus Autism Proceeding ("OAP"). By electing to file a Short-Form Autism Petition for Vaccine Compensation petitioners alleged that:

Omnibus Autism Proceeding ("OAP").[4] Short-Form Autism Petition for Vaccine Compensation at 1.

Petitioner has the burden to demonstrate that her case was properly and timely filed under the Vaccine Act's statute of limitations. § 16(a)(2). Based on the undersigned's analysis of the evidence, petitioner has not met her burden, and thus **this case is dismissed as untimely filed.**

I. Procedural History

No medical records were filed with the Petition. Like most other cases in the OAP, the case remained on hold until discovery in the OAP was concluded, causation hearings in the test cases were held, and entitlement decisions were issued in the test cases.[5]

> [a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B(HIB) vaccinations; or by some combination of the two . . . .
>
> The petition is being filed within three years after the first symptom of the disorder, or within three years after the first symptom of a vaccine-caused significant aggravation of the disorder. (If the vaccine-related death is alleged, the petition is being filed within two years after the date of death and no later than 48 months after onset of the injury from which death resulted.)

Autism General Order # 1 filed July 3, 2002, Exhibit A, Master Autism Petition for Vaccine Compensation at 2. Autism General Order #1 is published at 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002). Documents filed into the OAP are maintained by the clerk of this court in the file known as the "Autism Master File." An electronic version of the file is available on the court's website. Accompanying the electronic version of the file is a docket sheet that identifies all of the documents contained in the file. The complete text of most of the documents in the file is electronically accessible, with the exception of those few documents that must be withheld from the court's website due either to copyright considerations or to the privacy protection afforded under § 12(d)(4)(A) of the Act. To access the electronic version of the Autism Master File, visit this court's website at www.uscfc.uscourts.gov. Select the "Vaccine Info" page, then the "Autism Proceeding" page.

[4] A detailed discussion of the OAP can be found at *Dwyer v. Secretary of Health & Human Services*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[5] The Theory 1 cases are *Cedillo v. Secretary of Health & Human Services*, 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); *Hazlehurst v. Secretary of Health & Human Services*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604

During the period between the test case hearings and the final appellate action on the test case decisions, petitioner, like others in the OAP, was ordered to file some medical records. Petitioner did not respond to that Order.

After the final test case appeal was decided, the undersigned ordered petitioner on September 27, 2010, to inform the court if she wished to pursue her claim. On November 1, 2010, petitioner responded that she wished to continue with her claim.

On March 1, 2011, petitioner was ordered to identify a theory of how she believes Emilio's vaccinations caused his Autism Spectrum Disorder ("ASD") and to file all medical records required under the Vaccine Act. *See* § 11(c)(2). Petitioner filed a response and some of the required medical records on June 1, 2011.[6] In her response, petitioner explains that she received a Hepatitis B vaccination when she was pregnant with Emilio and believes this vaccination[7] caused Emilio's autism. Petitioner's Exhibit ("Pet. Ex.") 1 at 3. Petitioner argues that the Vaccine Act's statute of limitations "should adhere" because her medical providers did not sufficiently inform her "regarding the harmful effects of vaccination." *Id.* at 4. The undersigned deferred any action on the issue of timeliness of this case pending the Federal Circuit's en banc decision in *Cloer v. Secretary of Health & Human Services,* 654 F.3d. 1322 (Fed. Cir. 2011).

Subsequent to the Federal Circuit's Decision in *Cloer,* the undersigned ordered petitioner to show cause why this claim should not be dismissed as untimely filed. Order to Show Cause filed July 18, 2012. Petitioner has failed to respond to that Order.

II. Facts.

Petitioner received a Hepatitis B vaccination on July 25, 2002, while three to five weeks pregnant with Emilio. Pet. Ex. 1 at 61-62. Emilio was born on April 1, 2003. *Id.*at 6. Although the medical records regarding pregnancy and delivery were not filed, in the history given to Dr. Rebecca Hanson during Emilio's evaluation for autism on December 8, 2005, petitioner informed Dr. Hanson that her pregnancy was "well monitored and

---

F.3d 1343 (Fed. Cir. 2010); *Snyder v. Secretary of Health & Human Services,* No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims. The Theory 2 cases are *Dwyer v. Secretary of Health & Human Services*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Secretary of Health & Human Services*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Secretary of Health & Human Services,* No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). The petitioners in each of the three Theory 2 cases chose not to appeal.

[6] Petitioner's medical records were not labeled as separate exhibits nor were they paginated. The records will be referred to as one exhibit, Petitioner's Exhibit 1 ("Pet. Ex.") and will be paginated in the order in which they were received and filed.

[7] In her response, petitioner notes that Emilio also received a Hepatitis B vaccination when he was approximately two weeks old. However, petitioner specifically alleges that the vaccination she received while pregnant is the cause of Emilio's autism. Pet. Ex. 1 at 3.

relatively uneventful" and that Emilio "was delivered by crash cesarean section … due to fetal distress (meconium)" but "required no resuscitation except for some suctioning." *Id.* at 27. Except for normal childhood illnesses,[8] Emilio was physically healthy and had normal height and weight development. *E.g.,* Pet. Ex. 1 at 6. *See also* Pet. Ex. 1 at 16. Emilio received normal childhood vaccinations from June 2, 2003, until January 6, 2004. Pet. Ex. 1 at 14, 18-19. On June 25, 2007, Emilio was given a hearing exam, the results of which were normal. *Id.* at 20.

It appears that Emilio's parents either called or visited his primary care physician, Dr. Javier Bustamante, on November 30, 2004, because they were concerned about his lack of speech. *Id.* at 22. In his notes, Dr. Bustamante indicated that Emilio exhibited "no speech, no motor development" and wrote developmental delay and neurology. *Id.* at 22-23. On January 3, 2005, it appears that Emilio's parents were given the telephone number for "affiliated speech pathology." *Id.* at 23.

During Emilio's 2 year old well child evaluation on April 5, 2005, Dr. Bustamante again noted his concern with Emilio's speech delay and neurological condition. *Id.* He referred Emilio for a neurology evaluation. *Id.*

On December 8, 2005, Emilio was seen by Dr. Rebecca Hanson at UCLA Medical Center. *Id.* at 27. Dr. Hanson diagnosed Emilio with autism that was characterized as "moderately severe."[9] *Id.* at 28.

According to Dr. Hanson's notes, Emilio was tentatively diagnosed with autism in April 2005. *Id.* at 27. Dr. Hanson also indicated petitioner informed her that Emilio developed normally during his first year of life but failed "to develop language as expected" during his second year and at 18 months of age made "no eye contact, no pretend playing, no sharing of emotions, and no language except to lead his caretaker to a desired object." *Id.* at 27. She added that Emilio "played with toys inappropriately" and began self-stimming behavior. *Id.*

In her response filed June 1, 2011, petitioner asserted that Emilio demonstrated signs of autism, recollecting that "**[b]efore and up to the age of 1.5 years** he did not respond to his name, engage in eye contact, [or] babble appropriately." *Id.* at 3 (emphasis added). Petitioner claimed that during this time Emilio would laugh or cry at inappropriate times and would stare at moving fans and wheels. *Id.*

[8] The medical records indicate that Emilio experienced chest congestion on several occasions and a rash when 9 months old. *Id.* at 11-12.

[9] According to Dr. Hanson, Emilio "was first evaluated by Regional Center and given a diagnosis of infantile autism" at 2 years of age which would have been in April 2005. *Id.* at 27.

III. Diagnostic Criteria for Autism Spectrum Disorders.

No evidence concerning the diagnostic criteria for autism spectrum disorders was filed by the parties in this case. Accordingly, I have relied upon the information contained in this section which is primarily drawn from OAP test case testimony[10] provided by three pediatric neurologists with considerable experience in diagnosing ASD.

"The terms 'autism' and 'autism spectrum disorder' have been used to describe a set of developmental disorders characterized by impairments in social interaction, impairments in verbal and non-verbal communication, and stereotypical restricted or repetitive patterns of behavior and interests." *Cedillo,* 2009 WL 331968, at *7 (an OAP Test Case). The specific diagnostic criteria for ASD are found in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed text revision 2000 ("DSM-IV-TR"), the manual used in the United States to diagnose dysfunctions of the brain. *See* testimony of Dr. Eric Fombonne in *Cedillo* ("Fombonne Tr.") at 1278A.[11] The manual identifies the behavioral symptoms recognized by the medical profession at large as symptoms of ASD.[12] The DSM-IV-TR contains specific diagnostic criteria for autistic disorder (often referred to as "autism"[13] 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.

[10] 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. Because omnibus test case decisions are not binding on the other omnibus participants, the primary advantage to both parties in conducting test case hearings is the creation of a body of evidence that can be considered in other cases. *Snyder*, 2009 WL 332044, at *2-3; *Dwyer*, 2010 WL 892250, at *2.

[11] Transcripts from the OAP test cases, including *Cedillo*, may be accessed at http://www.uscfc.uscourts.gov/omnibus-autism-proceeding (last checked on June 19, 2012).

[12] Pervasive developmental disorders ("PPD") is the umbrella term used in the DSM-IV-TR at 69. I use the term ASD 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. *See Dwyer,* 2010 WL 892250 at *1 n.4 & *29 n.108.

[13] I use the term "autism" to refer solely to the specific diagnosis of "autistic disorder."

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; testimony of Dr. Max Wiznitzer in *Cedillo* ("Wiznitzer Tr.") at 1589-91. There can be wide variability in children with the same diagnosis. One child might lack any 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* testimony of Dr. Michael Rutter in the *King*[14] 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 the *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.

[14] *King,* 2010 WL 892296.

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 was noted in the *Dwyer* OAP test case, this 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. Children who do not display "the full set of symptoms" are diagnosed with PDD-NOS. Fombonne Tr. at 1275A. 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.

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 Dr. Wiznitzer asked the child for his address. *Id.* at 1601.

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. Impaired communication abilities are one of the "most important and early recognized symptoms" of autism. *Dwyer* OAP test case at *31.

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. *See* 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 1602A-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 OAP 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. 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. Legal Standard.

The Vaccine Act provides that:

> 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…

§ 16(a)(2) (emphasis added). In *Cloer*, the Court of Appeals for the Federal Circuit affirmed that the "statute of limitations begins to run on a specific statutory date: the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large." 654 F.3d. at 1340. The date of the occurrence of the first symptom or manifestation of onset "does not depend on when a petitioner knew or reasonably should have known" about the injury. *Id*. at 1339. Nor does it depend on the knowledge of a petitioner as to the cause of the injury.

Id. at 1338.

The Federal Circuit also held that equitable tolling of the Vaccine Act's statute of limitations is permitted. *Id*. at 1340. However, citing to *Irwin v. Dep't of Veterans Affairs*, 498 U.S. 89, 96 (1990), the Circuit noted that equitable tolling is to be used "sparingly," and not applied simply because the application of the statute of limitations would otherwise deprive a petitioner the opportunity to bring a claim. *See Cloer*, 654 F.3d at 1344-45. Citing to *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005), the Circuit also noted that equitable tolling should be applied only in "extraordinary circumstance[s]," such as when petitioner timely filed a procedurally defective pleading, or was the victim of fraud, or duress, *Cloer*, 654 F.3d at 1344-45; *see also Irwin*, 498 U.S. at 96.

V. Analysis

Emilio's medical records and petitioner's statement filed on June 1, 2011, establish that this claim is untimely filed. The petition was filed on July 22, 2008. To be considered timely filed under the Vaccine Act's statute of limitations, the first medically recognized sign or symptom of autism must have occurred no earlier than July 22, 2005. However, petitioner's statement and filed medical records demonstrate that Emilio was exhibiting symptoms of autism prior to this date. Petitioner indicates that Emilio exhibited symptoms of autism on August 1, 2004,[15] when he was 18 months of age. Pet. Ex. 1 at 27. Additionally, Dr. Bustamante noted on November 30, 2004, that Emilio exhibited delayed speech and motor development and on April 5, 2005, referred Emilio for an evaluation for autism. *Id.* at 22-23. In the notes from her December 8, 2005 visit with Emilio, Dr. Hanson even indicates that Emilio initially was diagnosed with autism at that time, April 2005. *Id.* at 28.

Petitioner, in her response to the Order filed May 2, 2011, argued that the statute of limitations should not apply to her claim because petitioner was unaware that a Hepatitis B vaccine could cause fetal injury until "well after" Emilio's diagnosis, Pet. Ex. 1 at 3. However, *Cloer* affirmed that the statute of limitations begins to run on the date of the first onset of symptoms, not when a petitioner becomes aware of a possible causal link. 654 F.3d at 1325, 1339.

Additionally, petitioner has not presented any arguments that would support the application of equitable tolling to this claim, and the undersigned's examination of the record does not disclose any basis for applying equitable tolling to this case.

[15] In her response filed June 1, 2011, petitioner alleges that Emilio's symptoms began "before and up to age 1.5 years", indicating a date even earlier than August 1, 2004. Pet. Ex. 1 at 3.

VI. Conclusion.

Petitioner has the burden to show timely filing. She has 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. §16(a)(2).

For the reasons set forth above, **this case is dismissed as untimely filed. The clerk is directed to enter judgment accordingly.**[16]

IT IS SO ORDERED.

_____
Gary J. Golkiewicz
Special Master

[16] This document constitutes the undersigned's final "Decision" in this case, pursuant to § 12(d)(3)(A). If petitioner wishes to have this case reviewed by a Judge of the United States Court of Federal Claims, a motion for review of this decision must be filed within 30 days. After 30 days the Clerk of this Court shall enter judgment in accord with this decision. If petitioner wishes to preserve whatever right she may **have to file a civil suit (that is a law suit in another court) petitioner must file an "election to reject judgment** in this case and file a civil action" within 90 days of the filing of the judgment. § 21(a).