

# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-0370V

Filed: October 9, 2012

(Not to be Published)

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EMMANUEL WILLIAMS and	*	
REGINA WILLIAMS parents of	*	
TITUS E. WILLIAMS, a minor,	*	Autism; Dismissal of Claim
	*	as Untimely Filed; Equitable
Petitioners,	*	Tolling
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

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## DECISION<sup>1</sup>

On May 22, 2008, petitioners, on behalf of their son, Titus E. Williams (“Titus”), filed a claim for compensation pursuant to the National Vaccine Injury Compensation Program (“Vaccine Program” or “the Program”).<sup>2</sup> 42 U.S.C. §§ 300aa-1 to -34 (2006).

Petitioners filed the Short-Form Petition authorized by Autism General Order #1,<sup>3</sup> thereby joining the Omnibus Autism Proceeding (“OAP”). Short-Form Autism Petition for Vaccine Compensation at 1.

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<sup>1</sup> 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.

<sup>2</sup> 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.

Petitioners have the burden to demonstrate that their case was properly and timely filed under the Vaccine Act's statute of limitations. § 300aa-16(a)(2). Based on the undersigned's analysis of the evidence, petitioners have not met their burden, and thus **this case is dismissed as untimely filed.**

## I. Procedural History

The petition was filed by petitioners on May 22, 2008. Like most other cases in the OAP,<sup>4</sup> 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.<sup>5</sup>

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<sup>3</sup> Autism General Order #1 adopted the Master Autism Petition for Vaccine Compensation for use by petitioners filing claims intended to be part of the OAP. By electing to file a Short-Form Autism Petition for Vaccine Compensation petitioners alleged that:

[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 Omnibus Autism Proceeding 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 § 300aa-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](http://www.uscfc.uscourts.gov). Select the "Vaccine Info" page, then the "Autism Proceeding" page.

<sup>4</sup> A detailed discussion of the OAP can be found at *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at \*3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

<sup>5</sup> The Theory 1 cases are *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); *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009),

During the period between the test case hearings and the final appellate action on the test case decisions, petitioners, like others in the OAP, were ordered to file medical records. Petitioners filed some of the required records on July 15, 2008,<sup>6</sup> as well as several statements discussing Titus' medical history, a Statement of Onset, and a Statement of Completion. See Petitioners' Exhibits ["Pets.' Ex." A-G filed July 15, 2008. In response, respondent filed a Statement Regarding Whether this Claim Should Proceed in the Omnibus Autism Proceeding ["Respondent's Statement"] on August 28, 2008, indicating that respondent was unable to determine, based on petitioners' filed evidence to date, whether the petition was filed within the Vaccine Act's statute of limitations. Respondent's Statement at 1 citing §16(a)(2). On October 7, 2008, the court ordered petitioners to provide a response to Respondent's Statement and to file certain missing medical records in order to establish whether this claim was timely filed. To be timely filed the "first symptom or manifestation of onset or of the significant aggravation" of Titus' injury must have occurred on or after May 22, 2005.<sup>7</sup> §16(a)(2).

On December 8, 2008, petitioners filed a statement titled "Timeliness of our Petition" ["Petitioners' Timeliness Statement"] in response to Respondent's Statement as well as a summary of developmental assessments of Titus from his treating pediatrician David Fleece, M.D. ["Dr. Fleece's Summary"], labeled Pets.' Ex. J, and additional medical records, labeled Pets.' Ex. K-L. Petitioners claim that Titus' first symptom of autism (or autism spectrum disorder ["ASD"]) occurred on November 11, 2005. Petitioners' Timeliness Statement at 1. However, according to Dr. Fleece, Titus' speech delay was evident at 24 months of age which would have been on March 15, 2005.<sup>8</sup> See Pets.' Ex. J at 4. On September 21, 2009, respondent filed a Motion to

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*aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, 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. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *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). The petitioners in each of the three Theory 2 cases chose not to appeal.

<sup>6</sup> Petitioners filed medical records for Titus as well as some medical records for his two brothers, Emmanuel and Regis. See Pets.' Ex. C.

<sup>7</sup> Respondent *incorrectly* indicated in Respondent's Statement that for the case to have been timely filed the "first symptom or manifestation of Titus' alleged vaccine-related injury must have occurred on or before May 21, 2005." Respondent's Statement at 3-4. In her Motion to Dismiss filed on September 21, 2009, respondent acknowledged this error, explaining that she should have indicated the case would **not** have been timely filed if Titus' first symptom or manifestation occurred **on or before** May 21, 2005. Respondent's Motion to Dismiss at 2 n.1 (emphasis added).

<sup>8</sup> Petitioners repeat respondent's erroneous language concerning the time period in which the first symptom or manifestation of Titus' injury must have occurred for the case to be timely filed found in Respondent's Statement and allege that Dr. Fleece's Summary illustrates that the case

Dismiss alleging that the petition was untimely filed under the Vaccine Act's statute of limitations.

After the final test case appeal was decided, the court ordered petitioners on September 24, 2010, to inform the court if they wished to pursue their claim. Petitioners responded that they wished to continue with the claim on October 18, 2010.

By order filed March 1, 2011, the court required that petitioners identify a theory regarding how they believe Titus' vaccinations caused his injury. On April 13, 2011, petitioners filed a response ["Petitioners' Statement of Causation"] indicating that they first became "concern[ed]" about Titus' "development" when he was 17 months old. Petitioners' Statement of Causation at 1. Petitioners allege that "mercury and other toxins contained in these [MMR and Varivax] vaccines when they were administered to Titus caused his brain injury, manifesting as ASD." *Id.* The court deferred any additional action on the timeliness of this case pending the Federal Circuit's en banc decision in *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d. 1322 (Fed. Cir. 2011), addressing the Vaccine Act's statute of limitations.

Subsequent to the Federal Circuit's en banc decision in *Cloer*, an Order to Show Cause was filed on July 19, 2012, directing petitioners to show cause why this claim should not be dismissed as untimely filed. Petitioners responded to that Order on August 22, 2012 arguing that the claim should not be dismissed as untimely filed. Petitioners' Response filed August 22, 2012 ["Pets.' Resp."].

## II. Facts.

Titus was born on March 15, 2003. Pets.' Ex. B(i) at 13.<sup>9</sup> During his first 18 months Titus received multiple vaccinations, including DTaP/DT, HiB, Hepatitis B, and MMR. Pets.' Ex. C(i) at 20. Titus had "[w]ell child" pediatric check-ups on June 28, 2004, at 15 months of age and September 22, 2004, at 18 months of age. *Id.* at 46-47.

On October 24, 2005, Titus was examined by an audiologist to "rule out hearing loss as a contributing factor" to his speech delay. Pets.' Ex. D(v) at 131. The audiologist's testing results were "consistent with borderline normal hearing sensitivity, bilaterally with abnormal [t]ympanometry." *Id.*

Titus' November 11, 2005, "Temple Pediatric Care" form indicates a diagnosis of "[d]evelopmental [d]elay." Pets.' Ex. D at 100. It appears at this visit Titus' pediatrician

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was timely filed. Petitioners' Timeliness Statement at 2. However, petitioners most likely are confused by respondent's earlier error. See discussion *supra* at note 7.

<sup>9</sup> Petitioners filed Exhibits A-G on July 15, 2008, and Exhibits J-L on December 8, 2008. Petitioners did not file any Exhibits labeled H, I, or K. It is noted that a significant portion of Titus' pediatric records, particularly those prior to his third birthday, have not been filed.

referred him to several specialists for further evaluations. *Id.* at 99; Pets.’ Ex. E at 136.<sup>10</sup>

On January 12, 2006, Titus was evaluated by early development specialists who concluded that he was developmentally delayed. Pets.’ Ex. D(i) at 118. During this evaluation Titus’ mother indicated that he had been on track for many early developmental milestones, but she became “concerned” when he stopped talking shortly before his second birthday, March 15, 2005. *Id.* at 109. This recollection is consistent with Dr. Fleece’s statement which indicates that Titus was diagnosed with speech delay at 24 months of age. Pets.’ Ex. J at 4.

Titus was seen by Lisa Dissinger, Ph.D, Psychologist on March 10, 2006, for a Childhood Autism Rating Scale [“CARS”] assessment. Pets.’ Ex. D(ii) at 121. Titus received a CARS score in the “severely autistic range.” *Id.* Dr. Dissinger concluded in her report that “[c]linical impressions support[ed] the diagnosis of autism.” *Id.*

On April 26, 2007, Hillary Kruger, M.D. at the Children’s Hospital of Philadelphia performed a developmental pediatric evaluation of Titus. Pets.’ Ex D(iv) at 126-130. Dr. Kruger indicated in her report that Titus met the “diagnostic criteria for autism.” *Id.* at 129. In a history taken from the purposes of Dr. Krueger’s evaluation Titus’ father indicated that he first became “concerned about his son’s development” when Titus was about 17 months old, or on August 15, 2004, when Titus stopped being able to say some of the single words he had previously spoken. *Id.* at 126. Petitioners likewise indicated to the court on April 13, 2011, that according to their filed medical records, they first began having concerns regarding Titus’ development when he was 17 months old. Petitioners’ Statement of Causation at 1.

On October 9, 2008, Titus’ pediatrician, Dr. Fleece, provided a “summary of [his] developmental assessments of Titus from infancy and early childhood.” Pets.’ Ex. J at 4. Dr. Fleece’s summary indicates that Titus could speak 5 words at 15 months old, but that Titus had made no further progress at 18 months old. *Id.* Dr. Fleece’s summary indicates that Titus was diagnosed with speech delay at 24 months old, or on March 15, 2005. *Id.*

### **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, the undersigned relies in this section upon information primarily drawn from OAP test case testimony<sup>11</sup> provided by three pediatric neurologists with considerable experience in diagnosing ASDs.

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<sup>10</sup> It is noted that November 11, 2005, is the date that petitioners indicated as the onset of Titus’ autism in the Statement of Onset filed July 15, 2008, and their Petitioners’ Timeliness Statement filed December 8, 2008. See Pets.’ Ex. E at 136; Petitioners’ Timeliness Statement at 1.

<sup>11</sup> All of the evidence filed in the OAP test cases is available to any petitioner in the OAP, as well as to respondent. However, the undersigned notes that there did not appear to be any material

“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. (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (an OAP Test Case). The specific diagnostic criteria for these disorders 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.<sup>12</sup> The manual identifies the behavioral symptoms recognized by the medical profession at large as symptoms of an ASD.<sup>13</sup> The DSM-IV-TR contains specific diagnostic criteria for autistic disorder (often referred to as “autism”<sup>14</sup> or “classic autism”), Asperger’s disorder, and pervasive developmental disorder-not otherwise specified (most frequently referred to as [“PDD-NOS”]). It is not uncommon for parents and even health care providers to use these terms in non-specific ways, such as referring to a child as having an “autism diagnosis,” even though the specific diagnosis is PDD-NOS. Of note, a child’s diagnosis within the autism spectrum may change from autistic disorder to PDD-NOS (or vice versa) over time.

#### A. Diagnosing Autism Spectrum Disorders.

The behavioral differences in autism spectrum disorders encompass not only delays in development, but also qualitative abnormalities in development. Fombonne Tr. at 1264A; 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

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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 v. Sec’y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044, at \*2-3 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *Dwyer v. Sec’y of Health & Human Servs.*, No. 02-1202V, 2010 WL 892250, at \*2 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

<sup>12</sup> 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).

<sup>13</sup> Pervasive developmental disorders [“PPD”] is the umbrella term used in the DSM-IV-TR at 69. the undersigned uses 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 v Sec’y of Health & Human Servs.*, No. 03–1202V, 2010 WL 892250 (Fed.Cl.Spec.Mstr. Mar. 12, 2010), at \*1 FN. 4 & \*29 FN. 108.

<sup>14</sup> The undersigned uses the term “autism” to refer solely to the specific diagnosis of “autistic disorder.”

language altogether, 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*<sup>15</sup> 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.

#### 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

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<sup>15</sup> *King v. Sec’y of Health & Human Servs.*, No. 03-584, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

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*<sup>16</sup> OAP test case, this is the most prevalent of the disorders on the autism spectrum. *Dwyer* 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

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<sup>16</sup> *Dwyer v. Sec’y of Health & Human Servs.*, No. 03–1202V, 2010 WL 892250 (Fed.Cl.Spec.Mstr. Mar. 12, 2010).

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 also described the failure of autistic children to share discoveries using language. Wiznitzer Tr. at 1606A. Children with ASDs and 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 an 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 ASDs 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 an 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 an ASD might lead a parent to the cookie jar, but would not lead a parent to a caterpillar crawling along the sidewalk.

Children with ASDs 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 an 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. Applying the Facts to the Law.**

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 an injury." *Id.* at 1338.

Petitioners' medical records and filed statements demonstrate that petitioners' claim was not timely filed. Petitioners' own statements, as well as Dr. Fleece's

Summary establish that the first symptom of Titus' autism occurred on or before March 15, 2005, when Titus was 24 months of age.

Petitioners acknowledged in their filings with the court that they first became "concern[ed]" about Titus' "development" when he was 17 months old. Petitioners' Statement of Causation at 1. This statement is consistent with the history given by Titus' father for the April 26, 2007 evaluation indicating that Titus' speech development appeared to regress at about 17 months. Pets.' Ex D(iv) at 126. Dr. Fleece's summary reflects that Titus could speak 5 words at 15 months old, but that Titus had made no further progress at 18 months old. Pets.' Ex. J at 4. Further, Dr. Fleece's summary indicates that Titus was diagnosed with speech delay at 24 months of age, or on March 15, 2005. *Id.* Accordingly, the first symptom of Titus' autism occurred by no later than March 15, 2005, when Titus was 24 months old. The undersigned notes, however, based on Titus' developmental history discussed above, that Titus' first symptom of autism likely occurred even earlier than March 15, 2005.

In response to the court's Order to Show Cause, petitioners argue that Dr. Fleece was "not sure" of Titus' speech delay at 24 months of age and thus did not refer Titus to a specialist at that time. Pets.' Resp. at 1. As support for this proposition, petitioners point to Dr. Fleece's notations that at 24 months, Titus "had little to no progress with language;" and at 30 months, Titus showed "no progress" and required referral for "audiology and early intervention." *Id.* Petitioners assert that Dr. Fleece's diagnosis of speech delay should not trigger the statute of limitations. Instead petitioners urge that Dr. Fleece's referrals for Titus when he was 30 months of age rendered the claim timely filed. *Id.* at 2. Petitioners observe that Dr. Fleece did not refer Titus to a developmental pediatrician until 32 months of age because he was not "fully confident" of the speech delay diagnosis he gave to Titus at 24 months of age. Finally, petitioners urge that because Dr. Fleece "is not a developmental pediatrician specialized in autism, language and speech. . . . the timing of his referral . . . [is] more definitive." Pets.' Resp. at 2.

Petitioners' arguments are not persuasive. As an initial matter, the undersigned notes that Titus' speech delay was documented as worse at 30 months than it was at 24 months. However, nothing in Dr. Fleece's summary indicates that he lacked confidence in his diagnosis of Titus' speech delay at 24 months. Associated with Temple University's Department of Pediatrics, Dr. Fleece possesses the qualifications to make a diagnosis of speech delay. *Id.* The Act's statute of limitations is triggered not by the date of the vaccinee's diagnosis of injury or referral for diagnosis; but rather "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." *Cloer*, 654 F.3d at 1340.

The ASD diagnostic evidence discussed above from the OAP test cases demonstrates that developmental delay, speech delay, and speech regression are recognized by the medical community at large as symptomatic of autism. The evidence further establishes that a delay in speech is often the first symptom of what is later diagnosed as an ASD. Based on all of the evidence filed in this case, the undersigned

finds that the first symptom of Titus' autism occurred no later than Titus' second birthday, or on or before March 15, 2005. To have been timely filed the petition must have been filed by March 15, 2008. But, the petition here was not filed until May 22, 2008, more than two months too late.

The Federal Circuit has recognized that equitable tolling of the Vaccine Act's statute of limitations is permitted. *Cloer*, 654 F.3d at 1340. However, citing *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 from bringing a claim. See *Cloer*, 654 F.3d at 1344-45. Citing *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.

Petitioners have not asserted any extraordinary circumstances that would merit equitable tolling of the Vaccine Act's statute of limitations in this case. Additionally, an examination of the record reveals no basis for applying the doctrine in this case.

#### V. Conclusion.

Petitioners have the burden to show timely filing. Petitioners here have failed to do so. There is preponderant evidence that this case was not 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). Petitioners have also failed to demonstrate any extraordinary circumstances warranting equitable tolling. **Therefore, this claim is dismissed as untimely filed under the Vaccine Act's statute of limitations. §16(a)(2). The clerk is directed to enter judgment accordingly.** <sup>17</sup>

**IT IS SO ORDERED.**

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Patricia E. Campbell-Smith  
Chief Special Master

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<sup>17</sup> This document constitutes the undersigned's final "Decision" in this case, pursuant to § 12(d)(3)(A). If petitioners wish 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 petitioners wish to preserve whatever right petitioners may have to file a civil suit (that is a law suit in another court) petitioners 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).