

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-398V

Filed: November 8, 2013

TO BE PUBLISHED

DEBRA COMER, parent of, J.E.M., *
a minor, *

Autism; Statute of Limitations;
Untimely Filed.

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

DECISION¹

On March 24, 2005, Debra Comer (“Petitioner”), on behalf of her son, J.E.M., filed a claim for compensation pursuant to the National Vaccine Injury Compensation Program (“Vaccine Program” or “the Program”).² (Petition (“Pet”), p.1.)

Petitioner has the burden to demonstrate that her case was timely filed under the Vaccine Act’s statute of limitations. § 16(a)(2). Based on my analysis of the evidence, Petitioner has not

¹ Because this published decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² The Program comprises 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.* (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

met her burden, and thus **this case is dismissed as untimely filed.**

I

BACKGROUND—THE OMNIBUS AUTISM PROCEEDING

This case concerning J.E.M. is one of more than 5,000 cases filed under the Program in which it has been alleged that a child's disorder known as "autism," or a similar disorder, was caused by one or more vaccinations. A brief summary of one aspect of that history is relevant to this Decision.

In anticipation of dealing with such a large group of cases involving a common factual issue--*i.e.*, whether vaccinations can cause autism--the Office of Special Masters ("OSM") devised special procedures. On July 3, 2002, the Chief Special Master, acting on behalf of the OSM, issued a document entitled the Autism General Order # 1,³ which set up a proceeding known as the "Omnibus Autism Proceeding" (OAP). In the OAP, a group of counsel selected from attorneys representing petitioners in the autism cases, known as the Petitioners' Steering Committee ("PSC"), was charged with obtaining and presenting evidence concerning the general issue of whether those vaccines can cause autism, and, if so, in what circumstances. The evidence obtained in that general inquiry was to be applied to the individual cases. (*Autism General Order # 1*, 2002 WL 31696785, at *3, 2002 U.S. Claims LEXIS 365, at *8.)

Ultimately, the PSC elected to present two different theories concerning the causation of autism. The first theory alleged that the *measles* portion of the MMR vaccine can cause autism, in situations in which it was alleged that thimerosal-containing vaccines previously weakened an infant's immune system. That theory was presented in three separate Program "test cases," during several weeks of trial in 2007. The second theory alleged that the mercury contained in the thimerosal-containing vaccines can *directly affect* an infant's brain, thereby substantially contributing to the development of autism. The second theory was presented in three additional "test cases" during several weeks of trial in 2008.

On February 12, 2009, decisions were issued concerning the three "test cases" pertaining

³ The *Autism General Order # 1* is published at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365 (Fed. Cl. Spec. Mstr. July 3, 2002). I also note that the documents filed in the Omnibus Autism Proceeding are contained in a special file kept by the Clerk of this court, known as the "Autism Master File." An electronic version of that File is maintained on this court's website. This electronic version contains a "docket sheet" listing all of the items in the File, and also contains the complete text of most of the items in the File, with the exception of a few documents that are withheld from the website due to copyright considerations or due to § 300aa-12(d)(4)(A). To access this 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.

to the PSC's *first* theory. In each of those three decisions, the petitioners' causation theories were rejected. I issued the decision in *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Patricia Campbell-Smith issued the decision in *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Special Master Denise Vowell issued the decision in *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Those three decisions were later each affirmed in three different rulings, by three different judges of the U.S. Court of Federal Claims. *Hazlehurst v. HHS*, 88 Fed. Cl. 473 (2009); *Snyder v. HHS*, 88 Fed. Cl. 706 (2009); *Cedillo v. HHS*, 89 Fed. Cl. 158 (2009). Two of those three rulings were then appealed to the U.S. Court of Appeals for the Federal Circuit, again resulting in affirmances of the decisions denying the petitioners' claims. *Hazlehurst v. HHS*, 604 F. 3d 1343 (Fed. Cir. 2010); *Cedillo v. HHS*, 617 F. 3d 1328 (Fed. Cir. 2010).

On March 12, 2010, the same three special masters issued decisions concerning three separate "test cases" pertaining to the petitioners PSC's *second* causation theory. Again, the petitioners' causation theories were rejected in all three cases. *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed.Cl.Spec.Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed.Cl.Spec.Mstr. Mar. 12, 2010); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed.Cl.Spec.Mstr. Mar.12, 2010). None of the petitioners elected to seek review of those three decisions.

II

PROCEDURAL HISTORY

On March 24, 2005, Petitioner filed a "Short-Form Autism Petition for Vaccine Compensation," on behalf of her son, J.E.M., under the Vaccine Act. (Pet. at 1.) Petitioner thereby adopted the "Master Autism Petition for Vaccine Compensation" and provided no further details regarding the nature of the alleged vaccine-related injury. (*Id.*) This petition was therefore filed without all of the medical records required by Section 11(c)(2) of the Vaccine Act or Rule 2 of the Rules of the United States Court of Federal Claims, Appendix B.

On June 23, 2005, pursuant to Vaccine Rule 4, Respondent filed a report in response to Petitioner's claim. In that report, Respondent identified deficiencies in the record to date and affirmed that an additional report assessing the medical and legal merits of the claim would be filed once Petitioner submitted the statutorily required evidence. (Report, ECF No. 5.) On August 11, 2005, Petitioner filed medical records along with the "Declaration of Debra R. Comer In Support of Petition." (Comer Declaration of Aug. 11, 2005, ECF No. 7.)

On November 14, 2008, I ordered Petitioner to file additional medical records.

(Order, ECF No. 11.) That Order also directed Petitioner to file a “Statement of Compliance with Phase One Medical Records Production,” once Petitioner filed all of the medical records required by the Order. (*Id.*) Further, the Order directed Respondent to file a “Statement Regarding whether the Claim should proceed in OAP” within 45 days of the filing of the Statement of Compliance. (*Id.*)

On February 17, 2009, Petitioner filed a Statement of Completion and medical records. (Filing, ECF No.14.) On May 28, 2009, Respondent filed a “Motion to Dismiss,” alleging untimely filing of the petition. (Motion, ECF No. 17 at 1.)

On June 15, 2009, Petitioner filed a “Memorandum In Opposition to Respondent’s Motion to Dismiss Petition,” a sealed Declaration, and three additional exhibits. (ECF Nos. 18, 19.)

On January 25, 2011, I ordered Petitioner to inform the court within 30 days of the date of the Order whether she wished to proceed with her claim or exit the Vaccine Program. (ECF No. 20.) On February 24, 2011, Petitioner filed an Amended Petition, alleging that J.E.M. received a measles, mumps, and rubella (“MMR”) vaccination on May 5, 2000, and thereafter suffered an autism spectrum disorder (“ASD”). (Amended Pet. at p. 1.)

On March 3, 2011, I issued an Order stating that I would delay my ruling on the pending Motion to Dismiss until the resolution of the issues presented in *Cloer v. HHS*, 603 F.3d 1341 (Fed. Cir. 2010). (ECF No. 23.) On August 5, 2011, the Federal Circuit issued its *en banc* ruling in *Cloer*, 654 F.3d 1322 (Fed. Cir. 2011). On August 10, 2012, I issued an Order directing the parties that, in light of the *en banc* decision in *Cloer*, Petitioner would have 30 days to file a statement indicating whether (1) Petitioner desired a ruling on the record as it stood, concerning the timeliness of the petition, or (2) Petitioner wished to file additional arguments, in light of *Cloer*, concerning the timeliness issue. (Order, ECF No. 24.)

On September 13, 2012, I issued an Order noting that Petitioner had failed to respond to my previous Order of August 10, 2012, but that I would give Petitioner an additional 30 days to respond. (Order, ECF No. 25.) On October 15, 2012, Petitioner filed a Notice indicating that she did wish to file additional arguments in light of *Cloer*. (Notice, ECF No. 26.)

On January 10, 2013, Petitioner filed a “Supplemental Memorandum In Opposition To Respondent’s Motion To Dismiss Petition.” (ECF No. 28.) Additionally on that same date, Petitioner filed the “Declaration of Leonard J. Good, M.D. In Opposition to Motion.” (ECF No. 29.)

On March 18, 2013, Respondent filed a “Response to Petitioner’s January 10, 2013 Supplemental Memorandum,” along with additional evidence designated Exhibits A

through E. (ECF No. 31.)⁴

III

FACTUAL HISTORY⁵

J.E.M. was born on February 5, 1999. (Petitioner's Filing of Feb. 17, 2009, p. 1.) He received routinely administered childhood vaccinations between February 22, 1999, and August 4, 2000. (*Id.* at pp. 2, 79.) On May 5, 2000, J.E.M. received the MMR vaccination at the office of Leonard J. Good, M.D., P.C. (Amended Pet., p. 1.)

A medical note dated April 1, 2003, notes that on October 5, 2000, when J.E.M. was 18 months old, J.E.M. "plateau[ed] in language" and experienced "+regression in eye contact and social skills." (Petitioner's Filing of Feb. 17, 2009, p. 24.) Similarly, a medical note dated October 7, 2002, indicates that around February 5, 2001, when J.E.M. was 2 years of age, J.E.M.'s speech began to regress; specifically, J.E.M. "started speaking on time and stalled completely at 2 years compared to [his] twin." (*Id.* at p. 16.)

On May 30, 2002, medical records from a Schneider Children's Hospital Psychological/Developmental Evaluation indicate that J.E.M. "demonstrated some of the behaviors that are characteristic of a Pervasive Developmental Disorder" and that his Childhood Autism Rating Scale (CARS) score "falls in the Severely Autistic Range." (Pet. Ex. B accompanying "Declaration of Debra R. Comer In Support of Petition" ("Comer Declaration"), filed on Aug. 11, 2005, p. 5.)

On August 14, 2002, Walter J. Molofsky, M.D., a pediatric neurologist, confirmed the diagnosis of an ASD, although he believed that J.E.M. was in the mild to moderate range of the spectrum. (Petitioner's Filing of Feb. 17, 2009, at pp. 13-15.) Dr. Molofsky observed that J.E.M. could be engaged, but "it was fleeting and inconsistent," and that J.E.M. had a "tendency to echolalia," and had "limited speech and expressive and receptive language skills." (*Id.*)

⁴ Exhibit A: Rhiannon J. Luyster, et al., *Language Assessment and Development in Toddlers with Autism Spectrum Disorders*, J. AUTISM DEV. DISORD. (2008); Exhibit B: Rebecca J. Landa, *Diagnosis of autism spectrum disorders in the first 3 years of life*, available at www.nature.com/clinicalpractice/neuro.; Exhibit C: Excerpts from the testimony of Eric Fombonne, M.D., from *Cedillo v. HHS* transcript, 98-916V; Exhibit D: Excerpts from the testimony of Max Wiznitzer, M.D., from *Cedillo v. HHS* transcript, 98-916V; Exhibit E: Excerpts from the testimony of Professor Sir Michael L. Rutter, M.D., from *King v. HHS*, 03-584V, and *Means v. HHS*, 03-215V.

⁵ I note that on February 17, 2009, Petitioner filed a "Statement of Compliance with Phase One Medical Records Production." Within this filing, there are 85 pages of medical records. Since no pagination scheme exists for the medical records filed in this case, I refer to the page numbers of these medical records by the order in which they are organized within this filing.

IV

DIAGNOSTIC CRITERIA FOR AUTISM SPECTRUM DISORDERS

Concerning this issue, I have relied upon the information submitted by Respondent in this case on March 8, 2013, much of which is drawn from OAP test case testimony provided by three pediatric neurologists with considerable experience in diagnosing ASDs. (*See* R. Ex. C, pp. 1242A-86A; Ex. D, pp. 1566a-1644; Ex. E, pp. 3236-64.) I further note that a lengthy discussion of this issue was first compiled and published by my colleague, Special Master Vowell, in *White v. HHS*, 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011.)

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. (*See Cedillo*, 2009 WL 331968, at *7 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (an OAP “test case.”)) The specific diagnostic criteria for ASDs are found in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000 (“DSM-IV-TR”)),⁶ the manual used in the United States to diagnose dysfunctions of the brain. (*See* R. Ex. C, p. 1278A.) The manual identifies the behavioral symptoms recognized by the medical profession at large as symptoms of ASD. The DSM-IV-TR contains specific diagnostic criteria for the various disorders within the autism spectrum, including “autistic disorder,” “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. (R. Ex. C, p. 1264A; R. Ex. D, pp. 1589-91.) There can be wide variability in children with the same diagnosis. One child might

⁶ I am aware that the American Psychiatric Association has recently released the fifth edition of the DSM. It is my understanding that the DSM-V has somewhat revised the diagnostic criteria to pertaining to Autism Spectrum Disorders. However, based upon my review of this revision to the DSM, it appears that the symptoms discussed in this Decision still clearly were the first symptoms or manifestation of onset of J.E.M.’s ASD.

lack language at all, while another with a large vocabulary might display the inability to engage in a non-scripted conversation. (R. Ex. D, pp. 1602A-1604.) However, both would have 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. (R. Ex. C, pp. 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 one expert 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.” (R. Ex. C, pp. 1278A-79; *see also* R. Ex. E, pp. 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. (R. Ex. C, p. 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. (R. Ex. E, pp. 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. (R. Ex. C, pp. 1285A-1286A.)

1. Autistic Disorder (“Autism”)

A diagnosis of “autistic disorder,” sometimes described as “classical autism,” 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 “autistic disorders,” 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. (R. Ex. C, pp. 1264A, 1279; R. Ex. D, p. 1618; R. Ex. E, p. 3250.) Although the majority of children with “autistic disorder” have developmental delays, many are of normal intelligence. (R. Ex. C, p. 1276; R. Ex. E, p. 3256.) In testimony in the *Cedillo* OAP test case, one expert described the three domains as the “core features” of a diagnosis on the autism spectrum. (R. Ex. D, pp. 1589-92.) Children with autism are most symptomatic in the second and third years of life. (*Id.*, p. 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 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 Disorder, also known as “Asperger’s syndrome,” is a form of high-functioning autism. Though often the individual functions at a high *cognitive* level, the disorder 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. (R. Ex. C, p. 1264A.) There are four subgroups within this domain. (R. Ex. D, p. 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. (*Id.* at pp. 1594-96.) To be diagnosed with autism (“autistic disorder”), the patient must have behavioral symptoms from two of the four subgroups. (*Id.* at p.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. (R. Ex. C, p. 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. (R. Ex. C, pp. 1269A-70A.)

One expert 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. (R. Ex. D, p. 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. (*Id.* at p. 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. (R. Ex. D, p. 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 p.1601.)

2. Communication Domain

The communication domain involves both verbal and non-verbal communication, such as intonation and body language. (R. Ex. C, p. 1263; R. Ex. D, p. 1602A.) Language abnormalities in ASD encompass not only delays in language acquisition, but the lack of capacity to communicate with others. (R. Ex. C, p. 1267A.) Impaired communication abilities are one of the “most important and early recognized symptoms” of autism. (*Dwyer*, 2010 WL 892250 at *31.)

There are four criteria within the communication domain. (R.s Ex. D, p. 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. (*Id.* at pp. 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. (R. Ex. C, pp. 1266A-68A.) One expert described the failure to share discoveries via language in autistic children as well. (R. Ex. D, p. 1606A.) Children with ASD who have more developed language skills may display difficulties in social communication outside their limited area of interest. (*Id.* at p. 1607.)

Within the communication domain, children with ASD have difficulties in joint attention, which one expert described as sharing an action or activity with another person or even an animal. They 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. (R. Ex. D, pp. 1607-09.) They focus on the literal, rather than 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 p. 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. 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. (R. Ex. D, pp. 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 p. 1612.)

Speech and language delays are the symptoms most commonly reported by parents as a concern leading to a diagnosis of ASD. (R. Ex. C, p. 1284 (one of first concerns noted by parents is the lack of language development); R. Ex. E, p. 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. (R. Ex. D, pp. 1602A-1603.) An Asperger's diagnosis does not require communication domain impairment. (R. Ex. C, pp. 1275A-76.) A PDD-NOS diagnosis requires an impairment in either this domain or the patterns of behavior discussed next. (R. Ex. D, p. 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. (R. Ex. D, pp. 1613A-15; R. Ex. C, pp. 1271A-72A.)

As one expert explained, this domain reflects abnormalities in the way play skills develop, as well as repetitive and rigid behavior. (R. Ex. C, p. 1264A.) A typical toddler may flick a light switch a few times, but the child with ASD performs the same action to excess. (R. Ex. D, p. 1616.) Another expert described one child who would not turn right; to make a right turn at a crossroads, he would have to make three left turns. (R. Ex. E, pp. 3252-53.)

For a diagnosis of autism, a child must display behaviors in at least one of the categories included in this domain. (R. Ex. D, p. 1613A.) An Asperger's diagnosis also requires at least one behavioral impairment encompassed in this domain. (R. Ex. C, pp. 1275A-76.) A PDD-NOS diagnosis requires either an impairment in this domain or an impairment in the communication domain. (R. Ex. D, p. 1592.)

C. Summary

The OAP evidence, as filed into the record of this case, 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 example, 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. (Resp't's Ex. C, pp. 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 "autistic disorder." (Resp't's Ex. C, p. 1275A.)

V

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***.

(§ 300aa-16(a)(2) (emphasis added)). In *Cloer*, the Court of Appeals for the Federal Circuit, acting *en banc*, 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.)⁷

⁷ The *Cloer* case recently was appealed to the United States Supreme Court, but only regarding the *attorneys' fees and costs* component of timeliness cases. The Supreme Court's resulting opinion is not relevant to the issues at hand in this case. *See Sebelius v. Cloer*, 133 S. Ct. 1886 (2013).

VI

ANALYSIS OF THIS CASE

The medical records and evidence presented in this case establish that this claim was untimely filed. The petition was filed on March 24, 2005. Therefore, to be considered timely filed under the Vaccine Act's statute of limitations, the first medically recognized sign or symptom of J.E.M.'s autism must have occurred no earlier than March 24, 2002. However, the medical records demonstrate that J.E.M. was exhibiting symptoms of autism prior to that date. A medical record dated October 7, 2002, indicates that J.E.M. "started speaking on time and stalled completely at 2 years compared to [his] twin." (Pet. filing of Feb. 17, 2009, p.16.) Another medical record dated April 1, 2003, indicates that J.E.M. was developing normally until 18 months of age, and "then plateau[ed] in language" and experienced "+regression in eye contact and social skills." (Pet. Filing of Feb. 17, 2009, p. 24.) J.E.M. was 18 months of age on October 5, 2000, and two years of age on February 5, 2001, obviously well prior to the key date of March 24, 2002.

In Petitioner's "Declaration of Debra R. Comer In Opposition to Motion," filed on June 15, 2009, Petitioner stated that the medical note, of April 1, 2003, is inaccurately portrayed because Petitioner only used the word "plateaued," when giving J.E.M.'s history during consults, to chart J.E.M.'s social and verbal development in relation to his gifted fraternal twin brother. (Comer Declaration of June 15, 2009, pp.1- 2.) Petitioner stated that J.E.M.'s brother is now known to be verbally gifted. (*Id.*) Additionally, Petitioner stated that the medical note from October 7, 2002, indicating that J.E.M.'s speech "stalled," again referred to J.E.M.'s verbal and social development in comparison to his brother. (*Id.* at pp.2-3.)

Further, in Petitioner's "Supplemental Memorandum In Opposition To Respondent's Motion To Dismiss Petition," filed on January 10, 2013, Petitioner argued that reports such as "plateau" or "stalling" are only discernible in hindsight, and do not signal the type of event that would begin the tolling of the statute of limitations. (Petitioner's Supplemental Memorandum of June 10, 2013, pp. 2-3.) Petitioner also argued that, "[A] 'plateau' in J.E.M.'s progress, etc., as compared to that of his fraternal twin brother Rudy, [], i.e., a gradual divergence in development in verbal and social skills between J.E.M. and his gifted brother, is not an "event" in any sense." (*Id.* at p. 3.)

However, Petitioner's arguments are not persuasive. For example, Drs. Fombonne, Wiznitzer, and Rutter provided, in the OAP test cases, extensive testimony regarding the signs and symptoms that are used to identify and diagnose ASD's. (Resp't's Ex. C, pp. 1242A-86A; Ex. D, pp. 1566a-1644; Ex. E, pp. 3236-64.) Their testimony establishes that the initial signs of an ASD are not the same in every child, but often involve language and other developmental delays that typically emerge in the second year of life. (*See generally* Resp't's Exs. C-E.) Specifically, testimony from Dr. Wiznitzer in the case of *Cedillo* states:

. . . the early features, of an autistic disorder, especially when you are looking at individuals in the first year of life, in the first 15 months of life, are not necessarily at the same level of severity that you will see as the children progress. In other words, they are almost never at this same level of severity as what we would see in children who are two years old, two and a half years old. And it's important to remember it's not necessarily the severity, but whether this dysfunction is present.

(Resp't's Ex. D, p. 1641.) Additionally, Dr. Fombonne notes in his OAP testimony from the *Cedillo* case that, “[a] mean age of parents’ recognition of the first symptoms, [] is anywhere between 14 months, 16 months, 18 months, 19 months***.” (Resp't's Ex. C, p. 1285A.)

The medical note dated April 1, 2003, *specifically* indicates that J.E.M. was developing normally until 18 months of age, and “then plateau[ed] in language” and experienced “+regression in eye contact and social skills.” (Pet. Filing of Feb. 17, 2009, p. 24.) This note alone indicates that J.E.M., in addition to not being as advanced as his brother at age 18 months, clearly experienced *autism-like symptoms* at this time, although he was not formally diagnosed with autism until May 30, 2002, when he was three years old. (Pet. Ex. B accompanying Comer Declaration of Aug. 5, 2011, p. 5.)

Based on my review of the medical records and evidence submitted from Respondent, pertaining to the identification of the first signs or symptoms of an ASD, I find that the onset of J.E.M.'s ASD occurred sometime between August 5, 2000, and February 5, 2001 (between the ages of 18 months and 2 years).

As discussed earlier, speech and language delay is a recognized symptom of autism. (*See* Section IV above; *see also White v. HHS*, 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (the Special Master concluded that although not sufficient by itself to establish a diagnosis of autism, speech and language delay can constitute the first symptom or manifestation of onset of autism).) Since J.E.M. displayed his first symptoms of speech, language, and behavioral delay between the ages of 18 months and 2 years—*i.e.*, between October 5, 2000 and February 5, 2001--then to be timely filed, the petition must have been filed between October 5, 2003, and February 5, 2004. The petition in this case, however, was not filed until March 24, 2005. Accordingly, this case was not timely filed.

VII

CONCLUSION

I have great sympathy for the tragic disorder from which J.E.M. suffers. Under the

applicable law, however, Petitioner has the burden to show timely filing. Petitioner has 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, § 16(a)(2). **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.**

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master