In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 08-0199V
Filed: September 26, 2012
(Not to be Published)

SHANNON LIEW and FUHPOW LIEW, as parents of DEVIN LIEW, a minor,	*	
Petitioners,	*	Autism; Statute of Limitations; First Symptom or Manifestation of Onset; Untimely Filed
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew D. Downing, Rhodes, Hieronymus, et al., Tulsa, OK, for Petitoner.
Ann D. Martin, U.S. Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

GOLKIEWICZ, Special Master.

Shannon Liew and Fuhpow Liew ("petitioners") filed on March 21, 2008, a Petition pursuant to the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §§

[1] The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b) each party has 14 days within which to request redaction "of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

300aa-10 et seq. (Supp. 2000)[2] ("Vaccine Act" or "Program"). That Petition was a "Short Form" Petition authorized by Autism General Order # 1.[3]

Respondent has moved to dismiss petitioners' case as being untimely, claiming that the Petition was filed outside the Act's 36 month statute of limitations. Respondent's Motion to Dismiss ("R Mot.") at 1. See § 16(a)(2). Petitioners argue that the case was timely filed because Devin did not display any signs of his Autism Spectrum Disorder ("ASD")[4] until the last week in March 2005. Petitioners' Second Amended Petition[5] ("2nd Amnd. Pet.") at 1. As will be discussed below, after considering the entire case record, the undersigned finds that the first symptom of Devin's ASD occurred more than 36 months before petitioners filed their "Short Form" Petition which makes their case untimely filed.

PROCEDURAL BACKROUND

Significant development of the case followed the filing of the "Short Form" Petition. On March 26, 2008, petitioners were ordered to file medical records which would allow respondent to address petitioners' "Short Form" Petition. On May 28, 2008, petitioners filed a CD containing Devin's medical records which were labeled Exhibits ("P Ex") 1-160 and their First Amended Petition labeled P Ex 161. In response, respondent filed a Motion to Dismiss on June 30, 2008, claiming that according to Devin's medical records the Petition was untimely filed and the case should be dismissed for lack of jurisdiction. R Mot. at 1.

On July 16, 2008, petitioners retained Andrew D. Downing as counsel. On November 7, 2008, petitioners filed a Response to the Motion to Dismiss ("P Response") contending that Devin did not display any symptoms of ASD until the end of March and early April 2005. P

[2] This 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. (2006) (hereinafter "Program," "Vaccine Act," or "the Act"). Hereafter, individual section references will be to 42 U.S.C. §§ 300aa of the Act.

[3] 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.

Autism General Order #1, filed July 3, 2002, Exhibit A, Master Autism Petition for Vaccine Compensation at 2.

[4] Devin was diagnosed with autism on May 25, 2005 and with Pervasive Developmental Disorder Not Otherwise Specified ("PDD NOS"). In order to avoid any unnecessary confusion, Devin will be referred to as having ASD or autism throughout this decision.

[5] Petitioners filed their original Short Form Petition on March 21, 2008. When petitioners filed medical records on May 28, 2008, they included a Petition dated May 19, 2008 as Petitioners' Exhibit ("P Ex") 161. Although not filed separately as an amended petition, I will treat this Petition as the First Amended Petition ("1st Amnd. Pet.") and refer to it as such. After retaining counsel, petitioners filed a second Amended Petition on November 7, 2008. I will refer to this Petition as petitioners' Second Amended Petition ("2nd Amnd. Pet.").

Response at 9. When listing the symptoms of autism,[6] petitioners include "delay in … the development of spoken language" but argue that Devin's earlier speech delay and feeding aversion do not qualify as symptoms of his autism because it "would not cause members of the medical profession to begin to suspect autism absent other issues which were cause for concern." Id. at 2, 8. Attached as a part of this filing was petitioners' expert report ("Hastings Report") written by Richard Hastings II, D.O.

Respondent filed a Reply to Petitioners' Response ("R Reply") on February 9, 2009, arguing that "it is the first symptom or manifestation of onset, not the diagnosis, that is critical when determining whether a claim has been filed with the Act's statute of limitations." R Reply at 5. Respondent maintains that "[s]peech delay is a recognized symptom of ASD and argues that petitioners have failed to adequately show that Devin's speech delay was unrelated to his ASD."[7] Id.

On February 17, 2009, petitioners filed a Sur-Reply to Respondent's Reply ("P Sur-Reply") in which they claim that "[t]he standard for determining the occurrence of the first symptom which triggers the commencement of the statute of limitations period is not simply the appearance of any symptom." P Sur-Reply at 1. Petitioners argue that since Devin's speech delay was "discussed in relation to Devin's oral-motor development issues connected to his feeding disorder," it does not qualify as his first symptom of ASD.[8] Id. at 2.

On May 6, 2009, petitioners filed a Motion requesting leave to opt out of the OAP. This Motion was granted on June 25, 2009. On July 27, 2009, petitioners filed their Second Amended Petition in which they claimed that the DTaP vaccine Devin received on November 30, 2004, was the cause of his ASD. Along with this Petition, petitioners also filed the affidavit of Shannon Liew ("affidavit").[9] That same day, in a separate filing, petitioners filed the

[6] Petitioners refer to the Diagnostic and Statistical Manuel of Mental Disorders (American Psychiatric Association, 4th ed. Text revision 2000) ("DSM-IV-TR") for the list of symptoms used to diagnosis for ASD. These symptoms are discussed further in my analysis in this case. See infra Discussion.

[7] Respondent also argues that "[t]here is no indication that Dr. Hastings has any speciality or familiarity with pediatrics, neurology, or immunology. To date, petitioners have not provided any information that Dr. Hastings is qualified to opine on the significance of the timing of Devin's speech delay in the context of Devin's ASD diagnosis and his feeding disorder." Id. at 4.

[8] Petitioners incorrectly interpret the Markovich Court's conclusion, that "the first symptom … is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large," as requiring that Devin's doctors recognize his speech delay as caused by his autism before it can qualify as his first symptom. P Sur-Reply at 2 (quoting Markovich v. Sec'y of Health & Human Services, 477 F.3d 1353, 1360 (Fed. Cir. 2007) (emphasis omitted)). See infra Legal Standard.

[9] Petitioners in actuality filed 24 documents along with their Amended Petition. These documents were entitled exhibits 1-24. However, as mentioned above, petitioners had already filed exhibits 1-161 at this point. Since all of the documents filed with the Amended Petition, except for Mrs. Liew's affidavit, had previously been filed under different exhibit numbers the undersigned will use the original exhibit numbers when citing to those documents.

Curriculum Vitae ("Hastings CV") and supplemental expert report ("Hastings Supp.") of Dr. Hastings.[10]

On September 25, 2009, respondent filed a CD containing exhibits A-I ("R Ex A-I"). Included in these exhibits were the expert report and the curriculum vitae of Amy Wetherby, Ph.D. and seven articles which discuss the symptoms of autism.

On March 4, 2010, the undersigned issued an order scheduling a fact hearing. Petitioners filed supplemental medical records, labeled exhibit 162, on March 29, 2010. The fact hearing was held on March 31, 2010. On April 9, 2010, the undersigned issued an order informing both parties that Mrs. Liew's testimony and affidavit could not be relied on as evidence and requesting petitioners file additional medical records and another supplemental expert report. On July 1, 2010, additional medical records were filed by petitioners.[11] On September 1, 2010, petitioners filed a status report informing the court that they would not be filing an additional supplemental expert report.

The proceeding was then stayed until Cloer v. Sec'y of Health & Human Services, 654 F.3d 1322 (Fed. Cir. 2011) cert. denied, 132 S. Ct. 1908 (U.S. 2012) was decided. On August 5, 2011, Cloer was decided and on November 30, 2011, the parties agreed that the case was now ripe for a decision.

MEDICAL RECORDS

This information is not in dispute. The relevant facts are as follows. Devin Liew was born on May 13, 2003. P Ex 27 at 1. Devin was born at 37 weeks of age after a pregnancy complicated by a torn placenta. E.g., P Ex 67 at 2.

Less than two months later on July 8, 2003, Mrs. Liew reported to Devin's Primary Care Physician ("PCP"), Dr. James Harrington, that Devin had been projectile vomiting, had increased gas, decreased eating and was not having bowel movements. P Ex 32 at 4. On July 14, 2003, during Devin's two month Well Child Checkup ("WCC") it was noted that Devin had not had a bowel movement for three days, that he had emesis (vomiting), and that there was an increase in his crying and pushing. Id. Despite all of this Devin received an assessment of "well child" and was given a DTaP vaccine, a Hepatitis B ("HepB") vaccine, an Inactivated Polio Vaccine ("IPV"), and a Pneumococcal Conjugate Vaccine ("PCV") called Prevnar. Id. at 3.

On July 21, 2003, Mrs. Liew reported to Dr. Harrington's office that Devin was pulling away from his bottle while feeding, was fussy during feedings, and was fussy slightly in between feedings. Id. at 4. Devin had also been forcefully spitting / vomiting at least once a day for the last four weeks. Id. Two days later on July 23, 2003, Mrs. Liew called to report that Devin was now spitting up about a third of every meal. Id. at 5. Mrs. Liew also informed Dr. Harrington

[10] Petitioners filed Dr. Hastings' CV and expert report as exhibits 12 and 13 respectively. However, as noted above exhibits 12 and 13 already exist. As such, the undersigned will refer to these two documents by their titles and not their exhibit numbers.

[11] These records were labeled exhibit 14 parts 1-5. Since exhibit 14 already exists within the record the undersigned will refer to this filing as the Virginia Feeding Records or "VFR".

that Devin had been put on ranitidine and that they were following the Gastroesophageal Reflux Disease protocol. Id. By July 29, 2003, Devin was vomiting 3-6 times a day, even though there had been a small improvement since using the ranitidine. Id. This improvement did not last, and by August 15, 2003, Devin was vomiting, eating only 2-3 oz of formula (as compared to 6oz only 2 weeks before), gagging on formula and juice, and throwing fits whenever someone tried to feed him. Id. at 6. On September 12, 2003, Mrs. Liew called and informed Dr. Harrington's office that Devin had been up the night before crying, vomiting, and suffering from congestion. Id.

Devin had his 4 month WCC on September 15, 2003. Id. at 7. During this evaluation Devin was given the assessment of "well child" with a feeding aversion. Id. Devin also received a DTaP vaccine, a HepB vaccine, an IPV and a PCV during this visit. Id. In response to his feeding problems Devin was sent to Toomey and Associates on September 22, 2003, where he was evaluated by Erin Ross an Infant Feeding Specialist and a Speech Language Pathologist. P Ex 46 at 1. A plan was developed to help Devin with his feeding issues. P Ex 162 at 25. One item on the plan was to have Devin evaluated by Jose M. Barrios M.D. a Pediatric Gastroenterologist. Id. On September 24, 2003, Devin was seen by Dr. Barrios who preformed an examination but did not find any significant problems. Id. at 38.

On September 26, 2003, Mrs. Liew reported to Dr. Harrington's office that Devin had been vomiting 1-2 times a day as well as experiencing diarrhea 2-3 times a day and he was showing symptoms of dehydration. P Ex 32 at 8. On October 23, 2003, Mrs. Liew informed Dr. Harrington's office that Devin had experienced an episode of full body tremors for 2-3 seconds after falling asleep with a bottle in his mouth. Id. at 9. Afterwards Devin slept for 15 minutes and then seemed to respond normally. Id. This led to the diagnosis of benign myoclonic jerks. Id.

On November 14, 2003, Devin had his 6 month WCC where he received an assessment of "well child" as well as a DTaP vaccine, an Influenza vaccine, and a PCV. Id. at 7. On January 2, 2004, Devin was taken to Dr. Harrington's office because he had been having episodes of diarrhea 8 times a day since December 30, 2003. Id. at 10. During this visit it was noted that Devin had not been eating and Mrs. Liew felt like she "spends life trying to feed child". Id.

On February 13, 2004, Devin was seen for his 9 month WCC. Id. at 11. During this check up Devin was again assessed as being a "well child". Id. Sometime in late March 2004 Devin started seeing Erin Ross for therapy sessions. P Ex 46 at 1. It appears that these sessions were strictly focused on Devin's feeding problems. Id. at 6.

On April 14, 2004, Devin and his parents went to Early Childhood Connections Colorado in order to participate in an Individualized Family Service Plan ("IFSP"). P Ex 81. Mr. and Mrs. Liew explained that Devin used to chew on toys but had stopped when his feeding issues started, was not exploring toys as much as he should, and that he wouldn't clap his hands by himself. Id. at 5. It was observed during the IFSP evaluation that Devin was not doing as much purposeful/ exploratory play as he should and that his fine motor skills seemed to be delayed because he did not release his toys on purpose. Id. at 6. Devin also did not use his tongue to push food to the

back of his mouth and it took him several hours to finish a bottle. Furthermore, Devin was not holding his own bottles independently at this time. Id. at 7. All of this led to the informed clinical opinion that Devin was experiencing a significant delay in his fine motor skills. Id. at 8.

On April 20, 2004, Dr. Harrington wrote a letter suggesting that Devin needed Occupational and Speech Therapy. P Ex 31 at 1. In that letter Dr. Harrington points out that Devin suffers from a feeding aversion as well as oral and texture aversions. Id. On May 20, 2004, Devin had his 1 year WCC. P Ex 32 at 11. At this visit Mrs. Liew mentions "Autism" though in what context is unclear. Id. During this visit Devin received a diagnosis of "well child" as well as a HepB vaccine, an IPV, and a Varicella (Chicken Pox) vaccine. Id.

Also on May 20, 2004, Devin participated in an Occupational Therapy Evaluation at Children's Hospital Colorado. P Ex 43 at 5. It was noted that Devin was currently being seen at Toomey and Associates to address his oral motor skills and his progression in foods, while also being seen twice a week by Child Find for occupational therapy. Id. During the evaluation Mrs. Liew expressed concerns that Devin did not use both hands to play with his toys or feed himself. Id. Furthermore, Devin was still not holding his own bottle or cup. Id. Also during the evaluation it was observed that Devin was frustrated when learning new tasks, he suffered delays in his midline and fine motor skills, and he was behind in his feeding and play skills. Id. at 6. In fact even though Devin was a year old at this time his fine motor and self help skills were scored in the 4 to 8 month range. Id. at 8. However, Devin was making eye contact and smiling during the evaluation. Id. at 6.

On July 7, 2004, Devin was sent to the ER at Littleton Adventist Hospital due to dehydration. P Ex 56 at 5. He was sent home that night but the next day he was again in the ER due to dehydration. Id. On July 13, 2004, a fax from Dr. Harrington to Dr. Toomey stated that Devin was still having feeding problems and that NG feeds and Gastrostomy tubes were discussed in order to make sure Devin was getting the proper amount of nutrients. P Ex 42 at 1. Then on July 20, 2004, Dr. John Yazdi, a Pediatric Gastroenterologist, gave Devin an assessment of failure to thrive. P Ex 57 at 2. Dr. Yazdi decided that several follow up tests should be done to make sure there were no underlying difficulties causing Devin's feeding aversion and his failure to thrive. Id.

On July 22, 2004, Devin took part in a Pediatric Feeding Assessment given by Toomey & Associates Inc. P Ex 46 at 1. During this assessment it was noted that Devin's fine motor skills and bilateral coordination did not present at an age appropriate level. Id. at 4. Furthermore, Devin presented with tactile, visual, and possibly olfactory hypersensitivities. Id. at 5. These results led to the recommendation that further medical tests be done by either Dr. Harrington or Dr. Yazdi. Id. at 9.

On August 16, 2004, Devin had his 15 month WCC. P Ex 33 at 1. During this WCC, like all his previous WCC, Devin was evaluated under the Denver Developmental Screening Test ("DDST"). Unlike all the previous WCC however, this time Devin did not receive a normal assessment under the DDST. Neither did he receive an assessment of abnormal. However, underneath the word abnormal is the notation "lang. follow". Id. Additionally, on a pamphlet for the 15 month Checkup, there is a note to the side of the Development section where the word

"language" is circled and underlined. P Ex 37 at 14. Despite all this Devin was still given the diagnosis of "well child." On August 27, 2004, Dr. Yazdi sent a fax to Dr. Harrington explaining that the tests he had performed revealed that Devin was suffering from gastroesophageal reflux ("GER") and mild to moderate gastric emptying problems. P Ex 62 at 1.

On September 2, 2004, Mrs. Liew reported that Devin was still refusing to eat and she was concerned since his intake had dropped significantly. P Ex 34 at 2. That night Devin was taken to Presbyterian St. Luke's Hospital's ER because of dehydration. Id. On September 13, 2004, Devin was once again in the ER due to dehydration. Id at 3.

On October 7, 2004, Devin was enrolled in a Feeding Clinic through Children's Hospital in Richmond Virginia ("Virginia feeding clinic"). P Ex 72 at 3. Three weeks before going to Virginia, Devin was given an NG tube to help with his feeding problems. Id. at 2. During Devin's time at the Virginia feeding clinic he received treatments from a variety of different specialists, all focused on weaning him away from his NG tube, by increasing his ability to orally feed. VFR parts 1-5. During his stay Devin also participated in a Child Life Therapeutic Recreation program. VFR part 5. In those sessions Devin was observed and encouraged to participate in activities revolving around developmental play. Id. at 1. In addition to his feeding problems it was noted throughout Devin's Child Life sessions that he had problems with changes in his surrounding and experienced fine motor delays. VFR part 5. It was also noted that Devin originally did not initiate play, though this improved throughout his time at the Clinic. Id. Around November 1, 2004, Devin started to display a flat affect during his Child Life sessions. Id. at 18. This flat affect continued through his stay at the Virginia feeding clinic. Id. at 1-18. On November 24, 2004, Devin was discharged from the Virginia feeding clinic having been completely weaned off of his NG tube. VFR part 4 at 10. Upon his discharge Devin also received a Beckman Oral Motor Evaluation. Id. at 6. In a letter written by Dr. Purcell, directly after Devin's stay at the Virginia feeding clinic, it was explained that this evaluation showed that Devin was experiencing oral motor problems severe enough to affect both his feeding and his speaking abilities. P Ex 67 at 1.

On November 30, 2004, Devin had his 18 month WCC. For the first time ever Devin did not receive a "well child" diagnosis. P Ex 33 at 1. Furthermore, in regards to the DDST, Devin was given an abnormal assessment and underneath that diagnosis "mild language delay" was written. Id. At this time plans were being made to have Devin see a speech therapist and an occupational therapist 2 to 3 times a week as well as a diet/nutritionist 2 to 4 times a month. P Ex 34 at 5. Devin continued to experience problems with vomiting throughout December 2004. Id.

Sometime after December 16, 2004, but before January 1, 2005, [12] Devin received a Speech Language Evaluation from Robin Stueber a speech language pathologist at Children's Hospital in Colorado. P Ex 67 at 2. This evaluation was administered due to concerns regarding Devin's understanding of language and his limited use of words. Id. During the evaluation Devin was diagnosed with delayed receptive and expressive language. This diagnosis was based on observations, standardized test scores and parent reports. Id. It was recommended that Devin learn to point and exhibit more pretend play, Id. at 4, and that Devin receive individual speech

[12] This time frame was deduced from language used in P Ex 67 at 2.

language therapy once a week. Id. at 3. Since Devin had significant speech language needs, and since his occupational therapist would be working on his feeding skills, the speech therapist would only focus on Devin's receptive and expressive language skills. Id.

On January 5, 2005, Devin started his Occupational Therapy session at Children's Hospital in Colorado with Lynn Taylor an Occupational Therapist. P Ex 73 at 57. On January 19, 2005, Devin started his Speech Therapy sessions with Dr. Stueber. P Ex 79 at 11. In a letter dated May 4, 2005, Dr. Stueber mentions that Devin initially had trouble sitting and engaging for more than a minute, attending any activities, making even fleeting eye contact, and pointing at things. Id. at 5-6. These statements mirror what is found in Dr. Stueber's weekly progress notes taken during Devin's therapy sessions. Id. at 9 – 26. In addition the Progress notes also indicate that Devin was not looking at familiar objects or people when named with any great degree of accuracy, and that after a month and a half of therapy he was only responding to his name 50% of the time. Id. at 16.

On April 4, 2005, Dr. Harrington's office faxed a copy of Devin's patient history to JFK Partners Autism and Developmental Disorders Clinic ("JFK") so they could perform an evaluation to rule out Autism. P Ex 34 at 7. The JFK team diagnosed Devin as having Autism on May 25, 2005. P Ex 83 at 7. In order to get a second opinion the petitioners went to Creative Perspectives, Inc. Autism Center of Colorado ("Creative Perspectives"). P Ex 84. On June 16, 2005, Creative Perspectives diagnosed Devin as having Pervasive Developmental Disorder Not Otherwise Specified ("PDD NOS"). Id. at 18. This diagnosis was due to Devin not displaying enough symptoms to achieve a diagnosis of Autism. Specifically the Creative Perspectives team did not see Devin displaying the stereotypic and repetitive behaviors needed for a diagnosis of Autism. Id.

AFFIDAVIT OF SHANNON LIEW

On July 27, 2009, petitioners filed the affidavit of Shannon Liew. In summary, the affidavit, which was prepared over four years after the occurrence of the events in question, portrays the onset of Devin's ASD as being very acute and severe. Mrs. Liew states that in February 2005, "Devin was still neurologically normal. He was playing normally with others and interacting appropriately." Affidavit at 1. However, during the last week of March 2005, "Devin's demeanor underwent a marked change. His communication and social interaction reverted. Devin stopped talking and acted as if he were deaf." Id. As discussed below this rendition of the facts, four years after the events in question, is so discordant with Devin's medical records as to render it not credible. This is a major issue because petitioners' expert relies heavily on the Mrs. Liew's statements.

FACT HEARING

A fact hearing was held on March 31, 2010. Testimony ("T") was taken from petitioner Mrs. Liew, Devin's Primary Care Physician Dr. Harrington, and the Behavioral Psychologist who worked with Devin at the Virginia feeding clinic Dr. Purcell. Both Dr. Purcell's and Dr. Harrington's testimonies were useful in clarifying medical records and letters attributed to them. Mrs. Liew's testimony however, was inconsistent with Devin's contemporaneous medical

records. Since there was no reasonable basis in law or logic to credit the aged information over the contemporaneous records, the undersigned issued a Fact Ruling on April 9, 2010, directing the parties to rely only on the medical records and not on Mrs. Liew's subsequent testimony or affidavit.

SUMMARY OF EXPERTS

Petitioner: Richard Hastings II, D.O.

Petitioner presented the expert report of Richard Hastings II, D.O. Dr. Hastings CV reflects that he is board certified in Osteopathic Internal Medicine. Hastings CV at 1. Dr. Hastings CV did not provide what his current area of practice was. The last item indicated under the Professional Experience section of Dr. Hastings CV was that he completed course work for certification in the field of Osteopathic Occupational Medicine in April 1998. Id. at 2. Dr. Hastings CV does not reflect any other accomplishments after this date. Id. Furthermore there is nothing in Dr. Hastings CV which would indicate that he has had any experience working with autism.

Dr. Hastings' expert report was filed on November 7, 2008, and his amended report was filed on July 27, 2009. Dr. Hastings opined in his first report that Devin had a clinical psychological evaluation in October 2004 conducted by Donna Purcell at the feeding clinic in Virginia which, "did confirm the complete absence of any such Autistic Disorder." Hastings Report at 16. Furthermore, he claimed that Devin did not show any signs of autism until after he received his DTaP vaccine on November 30, 2004. Id. Dr. Hastings also states that Devin's first symptoms of ASD occurred in the last week of March, 2005. Id. at 17. In his supplemental report, Dr. Hastings clarifies that in his opinion Devin's speech delay was only due to his oral motor delay which was caused by his GI problems. Hastings Supp. at 3. Dr. Hastings also definitively states that the DTaP shot on November 30, 2004, was the cause of Devin's Autism. Id. Nothing else from his original report was changed.

Respondent: Amy Wetherby, Ph.D.

Respondent presented the expert report of Amy Wetherby, Ph.D. Dr. Wetherby's CV reflects that she received a Certificate of Clinical Competence in Speech-Language Pathology from the American Speech-Language-Hearing Association and that she has a Florida Department of Professional Regulation License in Speech-Language Pathology. R Ex B at 2. She was, at the time of the filing, currently employed as a professor at Florida State University (FSU) in the Department of Communication Disorders and she was also a professor in the Department of Clinical Sciences for the FSU College of Medicine. Id. at 1. In addition she was appointed as the director of the Autism Institute for the FSU College of Medicine and as the executive director for FSU's Center for Autism and Related Disabilities. Id. at 2. Her CV demonstrates extensive experience in the field of autism, specifically in identifying signs of autism in young children. R Ex B.

In her report, Dr. Weatherby states that Devin's "first sign of ASD was documented in his speech and language delay at 18 months of age" which would have been on November 14,

2004. R Ex A at 6. However, she points to particular entries in Devin's medical records which show what she claims are "red flags" of ASD and which she argues occurred prior to March 21, 2005. See, e.g., R Ex A at 4 (discussing the mildly delayed play skills and severely delayed receptive and expressive language skills noted by Robin Stueber). Dr. Weatherby concedes that "children who have feeding problems may also have motor weaknesses which slow speech development." R Ex A at 8. However, she argues that "a feeding problem would not cause delays or deficits in understanding of language, use of gestures, or delays in play skills, which were documented in Devin's records in December 2004 and January 2005." Id.

LEGAL STANDARD[13]

Under the Program, compensation awards are made to individuals who have suffered injuries caused by the vaccines they received. The statutory deadlines for filing Program petitions are provided in § 16. With respect to vaccinations administered after October 1, 1988, as were the vaccinations at issue here, § 16(a)(2) provides that a petition must be filed within "36 months after the date of the occurrence of the first symptom of manifestation of onset or of the significant aggravation of such injury."

In Cloer v. Sec'y of Health & Human Services, 654 F.3d 1322 (Fed. Cir. 2011) cert. denied, 132 S. Ct. 1908 (U.S. 2012), the Court of Appeals for the Federal Circuit, sitting *en banc*, interpreted the limitations statute found in § 16(a)(2). Noting that the respondent in vaccine cases is always the Government, the court held that

> As a matter of caution, we must recognize and respect that a "statute of limitations is a condition on the waiver of sovereign immunity by the United States" and courts should be "careful not to interpret [a waiver] in a manner that would extend the waiver beyond what Congress intended." *Stone Container Corp. v. United States*, 229 F.3d 1345, 1352 (Fed.Cir.2000) (quoting *Block v. North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287, 103 S.Ct. 1811, 75 L.Ed.2d 840 (1983) (internal quotation omitted)). We have consistently followed this admonition when interpreting the Vaccine Act's statute of limitations. *See, e.g.*, *Markovich*, 477 F.3d at 1360; *Brice*, 240 F.3d at 1370.
>
> Cloer, 654 F.3d at 1336.

[13] Equitable Tolling was not argued in this case because at the time it was not available. The U.S. Court of Appeals for the Federal Circuit recently overturned its prior precedent in Brice v. Sec'y of Health & Human Services, 240 F.3d 1367 (Fed. Cir. 2001), by finding that equitable tolling is applicable to the Vaccine Act. Cloer, 654 F.3d at 1340 (citing Irwin v. Department of Veterans Affairs, 498 U.S. 89, 96 (1990.)) However, the Cloer Court made it clear that equitable tolling should be used sparingly in federal cases, pointing out that in the past it has only been applied to cases involving deception or cases where the petition was timely filed but was procedurally defective. Id. at 1345 (citing Irwin, 498 U.S. at 96.) Furthermore, when deciding whether to apply equitable tolling to the petitioner's situation in Cloer the Court held that petitioner had put forward no basis for equity, such as being the victim of fraud or duress, or that some other extraordinary circumstance prevented her from diligently pursuing her rights. Cloer, 654 F.3d at 1344. Since none of the "extraordinary circumstances" mentioned in Cloer apply to petitioners, in the current case equitable tolling is not available in this instance.

Keeping this consideration in mind, the court found that "[f]irst and foremost, Congress selected a specific textual calendar date to trigger the statute of limitations." In determining when this specific calendar date occurs the court looked to the case of Markovich v. Sec'y of Health & Human Services, 477 F.3d 1353 (Fed. Cir. 2007), and found that the analysis and conclusion used there was correct. Cloer, 654 F.3d at 1335.

In Markovich the court provided clarification to the phrase "first symptom or manifestation of onset" as used in § 16(a)(2). The Court of Appeals for the Federal Circuit determined that Congress "intended a disjunctive meaning by using the disjunctive word 'or,'" therefore "we interpret the words 'first symptom' and 'manifestation of onset' as referring to two different forms of evidence of injury. Markovich, 477 F.3d at 1357. The difference between these two forms of evidence being that a "symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury. A manifestation of onset is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." Id. The Markovich court also found that "[t]he use of the words 'first' and 'or' require that the statute of limitations commence with whichever event (*i.e.*, symptom or manifestation of onset) occurs first. The statute does not require that both events occur before the running of the limitations period can commence." Id. at 1358.

The Markovich court then reasoned that an objective standard was required to establish which symptom or manifestation occurred first. The court determined that a subjective standard, depending on when petitioners had knowledge that something was wrong, was inappropriate since it "would result in an uneven and perhaps overly broad application of the statute of limitations" due to petitioners "having widely varying degrees of medical awareness or training." Id. at 1360. Instead the court found that an "an objective standard that focuses on the recognized standards of the medical profession at large" was more appropriate since such a standard "treats petitioners equally, without regard to their individual degree of medical awareness." Id. This reasoning led the court to the conclusion that "'the first symptom or manifestation of onset' for the purposes of § 300aa–16(a)(2), is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." Id.

In Wilkerson v. Sec'y of Health & Human Services, 593 F.3d 1343 (Fed. Cir. 2010), the court clarified that Markovich should not be read "as requiring in each case a showing of the date on which the medical profession at large had such a recognition." Id. at 1345-46. To the Wilkerson court "[t]he fact that such recognition may have occurred sometime after the symptoms first occurred does not undermine the medical judgment upon which the decision in this case was based." Id. at 1346. This conclusion is supported by the language used in § 16(a)(2) which states that the "time for filing runs from 'the date of the occurrence of the first symptom or manifestation of onset,' not the date of its recognition." Id. The phrase "medical profession at large" first appeared in Markovich and is not actually found in § 16(a)(2). Therefore the phrase "recognized as such by the medical profession at large" is meant to be an objective standard of review, not a date determining the beginning of onset. Id. at 1345.

In light of Markovich and Wilkerson it is no surprise that the Cloer court ruled "that the Vaccine Act does not itself contain a discovery rule, and . . . that a discovery rule cannot be read

by implication into the Vaccine Act's statute of limitations." Cloer 654 F.3d at 1337. Instead the Cloer court determined that the start date of the statute of limitations "is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition" nor does it "depend on the knowledge of a petitioner as to the cause of an injury." Id. at 1338-39.

The Cloer court 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. Wilkerson illustrates that this recognition need not occur at the time of the symptom. 593 F.3d at 1346.

DISCUSSION

The term "vaccine related injury" as used in § 16(a)(2) refers to the injury petitioners claim was caused by the vaccine. Cloer, 654 F.3d at 1334. In the current case, petitioners are alleging that Devin's vaccinations caused his ASD. Therefore the only issue being examined in this decision is whether the Petition in this case was filed more than 36 months after Devin showed any sign or symptom of his ASD. Petitioners filed their Petition on March 21, 2008. This means that for the Petition to be timely filed Devin could not have shown any symptoms of his ASD before March 21, 2005.

Symptoms of ASD.[14]

Before continuing with this analysis it is important to discuss the symptoms of ASD. As petitioners indicate, the Diagnostic and Statistical Manuel of Mental Disorders (American Psychiatric Association, 4th ed. Text revision 2000) ("DSM-IV-TR") sets forth the symptoms used to diagnosis ASD.[15] P Response at 2. The DSM-IV-TR was used by both the JFK and Creative Perspectives evaluation teams when diagnosing Devin[16] and it was referred to by both parties' experts in their reports. What's more the symptoms listed in the DSM-IV-TR coincide with those found in the medical literature submitted by respondent.[17] Therefore, it is important to examine those symptoms when determining what a first symptom of ASD would be.

[14] The undersigned will focus on the symptoms of ASD which are relevant to the facts in this case. The discussion in this decision is not intended to be a comprehensive discussion of any and all symptoms of ASD.

[15] The DSM-IV-TR actually refers to the umbrella term of Pervasive developmental disorders ("PPD"). DSM-IV-TR at 69. The undersigned will 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 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.

[16] Devin was diagnosed by JFK as having autism while Creative Perspectives diagnosed him as having PDD-NOS. In diagnosing Devin both teams used the diagnostic criteria for ASD as listed in the DSM-IV-TR and as such the symptoms listed there are the ones which correspond to Devin's ASD.

[17] Respondent's expert is the only one who submitted medical literature in this case. Petitioners did not object to any of respondent's exhibits.

The DSM-IV-TR groups the symptoms which are used to diagnosis ASD into the following three areas:

1) Qualitative impairment in social interaction.
2) Qualitative impairments in communication.
3) Restrictive repetitive and stereotypical patterns of behavior, interest, and activities.

See P Response at 2 (citing the DSM-IV-TR).

Qualitative impairment in social interactions includes such behaviors as a lack of eye contact, lack of pointing out objects of interest, and a failure to respond to his/her name. R Ex C at 9-10. "Children with ASD … are content to be alone, ignore their parents' bids for attention, and seldom make eye contact or bid for others' attentions with gestures or vocalizations." Id. at 9. Rather than point to a desired object, children with ASD will "take the parent's hand to lead him or her to the object." Id. at 10. They also will not point to an interesting object or event to comment on or share it with another person, an action which is called protodeclarative pointing and usually occurs around 14 to 16 months of age. Id.

Qualitative impairments in communication include delay in speech which is not accompanied by nonverbal means to compensate such as pointing and lack of make-believe play. Id. at 10-12. "[L]ack of speech has been considered a hallmark of A[S]D, especially when it is associated with the lack of desire to communicate and the lack of nonverbal compensatory efforts such as gestures." Id. at 11. Many of the symptoms which show impairment in the area of social interactions also show impairment in the area of communications. As discussed, children with ASD will fail to make eye contact, respond to their name when called, or use protodeclarative pointing. In addition, they may not wave to others. Children with ASD may lack "varied, spontaneous, make-believe play or social imitative play appropriate to [their] developmental level." P Response at 3 (citing the DSM-IV-TR).

Finally, restrictive, repetive and stereotypical patterns of behavior, interest, and activities includes behaviors such as hand or finger flapping. Id. Children with ASD often adhere to routines or rituals. Id. They "may protest vigorously when forced to transition from an activity or topic of interest." R Ex C at 13.

Although not listed in the DSM-IV-TR as a symptom used to diagnose ASD, many children with ASD "demonstrate multaneous hyposensitivities and hypersensitivities for stimuli." Id. They may have oral aversions and be sensitive to the texture, color, or taste of certain foods. Id. They also may have atypical motor development or poor coordination. Id. A child with ASD may experience delays in either gross or fine motor skills. R Ex F at 5.

Most delays in these skills as well as delays in receptive and expressive speech occur between the child's first and second birthdays. R Ex E at 2. Although … social deficits occur earlier and may be more specific, they can be subtle and less often recognized or articulated by parents." R Ex C at 9. Therefore, speech delay is often one of the first symptoms that parents notice, prompting them to contact their child's doctor. Id. Children with ASD may "began to say words, but then stop speaking, often between the ages of 15 and 24 months." Id. at 11. They

can experience this type of regression in skills with regard to gestural communication and social skills as well. Id.

Devin's Symptoms of ASD.

There are multiple entries in Devin's medical records which show that he exhibited established symptoms of ASD prior to March 21, 2005. For example, Devin's IFSP dated April 14, 2004, includes notations that Devin was "not exploring toys as much as he could be," and was not "doing as much purposeful, exploratory play." P Ex 81 at 5-6. As discussed, this lack of play is considered to be a symptom of ASD. R Ex C at 10. See supra Symptoms of ASD. In addition, the IFSP also included entries indicating that Devin wouldn't "clap hands by himself," "purposefully release toys," or hold his bottle independently. P Ex 81 at 5-7. The IFSP contains a determination that Devin's "fine motor skills are delayed." Id. at 6. Accord. P Ex 81 at 8. All of these behaviors and delays are considered to be symptoms of ASD. R Ex C at 13; R Ex F at 5. See supra Symptoms of ASD. Therefore, any would be sufficient to trigger the Vaccine Act's statute of limitations.

In addition, it is noted that Devin was referred for "delayed fine motor skills" and could not "hold his own bottle or cup" on an occupational therapy evaluation dated May 20, 2004. P Ex 43 at 5. As noted by Dr. Weatherby, these delays in motor skills are "not necessarily specific to ASD" but are "an associated early deficit in children later diagnosed with ASD." R Ex A at 3.

Although the evaluation also contains notations indicating that Devin "adjusted quickly to a new environment," made eye contact and smiled, these notations do not diminish the importance or existence of these other symptoms. P Ex 43 at 2. It is important to note that every child will not exhibit every symptom of ASD. "One of the most challenging aspects in recognizing ASDs is the wide heterogeneity of features in individual children." R Ex C at 9. In addition, children with ASD will often regress as they lose communicative or social skills such as eye contact. Id. at 11. See supra Symptoms of ASD. As Dr. Weatherby explained, the fact that Devin was smiling and made eye contact when he was one year old still "is consistent with the history of many children later diagnosed with ASD." R Ex A at 3.

In the report from a feeding assessment performed on July 22, 2004, it is noted that Devin exhibited poor muscle tone and motor difficulties. P Ex 46 at 3. Not able to walk yet, he explored by crawling. Id. Devin had difficulty using his left and right hands together and would keep his right hand "clenched and help back" when "eating or touching food with his left hand." Id. As noted by Dr. Weatherby, "posturing of hands is a red flag of ASD." R Ex A at 3.

Finally, Devin presented with tactile, visual, and possibly olfactory hypersensitivities, symptoms often seen in children with ASD. Id. at 5. In a report from Dr. Ted A. Williams at Children's Hospital to Dr. Harrington dated October 7, 2004, Dr. Williams notes that Devin's father informed him that Devin has "a strong dislike for sticky or mushy food on his fingers and significant aversion to any tactile stimulation of his face or mouth." P Ex 65 at 3. As Dr. Weatherby indicates, "[t]his is an associated feature of ASD." R Ex A at 4.

Finally, in January 2005,[18] during Devin's speech-language evaluation, Dr. Stueber concluded that "Devin demonstrates delayed **receptive** and expressive language."[19] P Ex. 67 at 2 (emphasis added). In her "[l]ong term goals for Devin," Dr. Stueber included the goal that Devin "exhibit receptive language skills commensurate with his age." Id. at 3. To accomplish that goal, she then listed several particular tasks which Devin currently was unable to do. In her "[s]hort term goals for Devin," Dr. Stueber listed pointing "to objects named," looking "at familiar objects and people when named," and following "simple commands." Id. Dr. Stueber suggested that petitioners help Devin with his receptive language skills, noting that they should "help Devin understand language." Id. Dr. Steuber explained that "Devin's comprehension of language was not consistent with his nonverbal functioning and play skills." The report indicates that Devin was referred for speech-language evaluation due to concern for understanding as well as use of language. Id. at 2. A delay in receptive language skills is indicative of ASD and cannot be attributed to Devin's GER.[20]

There is another undated report by Dr. Steuber in the medical record which appears to be attached to a fax from Dr. Harrington to Aetna sent on January 21, 2005. See P Ex 41. In that report, Dr. Steuber notes that Devin "should learn to point, and exhibit more pretend play, such as dancing, or pretending to feed a doll, hug a bear, etc…" Id. at 4. "Based on observation and description of behavior at home," Dr. Steuber surmised that Devin would lead his parents to objects when he needed help. Id. at 3. As Dr. Weatherby explained this behavior "is a red flag of ASD." R Ex A at 4.

In her notes from Devin's speech therapy sessions, Dr. Stueber notes on February 16, 2005 that Devin "still needs hands shaped to point." P Ex 79 at 13. On March 2 and 16, 2005 she indicates that Devin responded to his own name only 50% of the time. Id. at 17. Failure to respond to his/her name when called, delay in motor skills, and a lack of pointing are all considered to be symptoms of ASD. See R Ex A at 4-5.

Given the multitude of recognized symptoms of ASD contained in Devin's medical records, the undersigned finds by the preponderance of the evidence that Devin exhibited numerous symptoms of ASD prior to March 21, 2005. Petitioners presented no persuasive rebuttal to this evidence.

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[18] The report from the speech-language evaluation by Dr. Steuber is undated and missing the first page. However, the report appears to have been prepared in January 2005. In the report itself, Dr. Steuber notes that Devin was referred when he was 1 yr and 7 months old which would have been on December 13, 2004. P Ex 67 at 2. Dr. Stueber later notes that she began Devin's treatment on January 19, 2005. P Ex 79 at 11.

[19] Because Devin suffers from GER, a separate physical condition which could have affected his **expressive** speech, the undersigned will not discuss or rely upon Devin's expressive speech delay as being a symptom of his ASD when determining whether the Petition was untimely filed. See infra Devin's Expressive Speech Delay.

[20] Petitioners argue only that Devin's "feeding aversion, partly due to poor oral motor skills, obviously impacted his **speech**." P Response at 8 (emphasis added). In a letter, Dr. Purcell, who treated Devin at the Virginia feeding center, explained that Devin lacked strength in his jaw, cheeks, and tongue. P Ex 62 at 1. She opined that this lack of strength would affect Devin's **oral speech**. Id. The undersigned does not dispute this conclusion but notes that the lack of strength in Devin's jaw, cheeks, and tongue would not affect his receptive speech.

Devin's Expressive Speech Delay.

The medical records clearly show that Devin experienced speech delay which became apparent when he was 12 to 15 months old. See, e.g., P Ex 47 at 1 (referring Devine for a feeding[21] and speech evaluation). The record from Devin's 15 month WCC on August 16, 2004 clearly indicates language delay. P Ex 33 at 1. Petitioners do not dispute these events but argue since Devin's expressive speech delay was discussed in conjunction with his feeding issues it does not qualify as a first symptom of his ASD. P Sur-Reply at 2. In a letter concerning her treating Devin during the fall of 2004, Dr. Purcell explains that Devin lacked strength in his jaw, cheeks, and tongue and opines that this lack of strength would affect his oral speech. P Ex. 62 at 1.

When diagnosing Devin with ASD on May 25, 2005, the evaluators at JFK recognized "the enormous impact that Devin's reflux and feeding difficulties have had on his development" but did "not believe that those difficulties fully account for the deficits we observed in his communication and social reciprocity." P Ex 83 at 7. As such, the JFK evaluators saw Devin's ASD as being partially responsible for his language delays. However, these individuals evaluated Devin after March 21, 2005 so the undersigned will not rely on their observations and report.

Since the medical record clearly shows that Devin exhibited multiple other symptoms of ASD prior to March 21, 2005, the undersigned need not address this issue further. The evidence regarding the relationship of the expressive speech delay to the feeding issues or ASD is not entirely clear and would benefit from further development. Given the clear symptoms of ASD evident prior to March 21, 2005, it is not necessary to determine if Devin's **expressive** speech delay is a symptom of his ASD, attributed solely to his GER, or affected by both his GER and ASD.

Additional Arguments Raised by Petitioners.

In addition to claiming that the medical records do not contain any reference to symptoms which would trigger the Vaccine Act's statute of limitations, petitioners also argue that Virginia feeding clinic thoroughly evaluated Devin and found no symptoms of ASD and that Dr. Hastings' medical opinion supports their contention that Devin's symptoms did not occur until the end of March 2005.

[21] The medical records also show that Devin experienced feeding issues from birth and respondent has submitted information indicating that many children with ASD also suffer from feeding problems. However, it is noted in this information that "[d]espite longstanding clinical experience of unusual feeding difficulties in children with autism, there is no published literature describing their association." Id. at 2. Devin's feeding issue could be caused by his oral aversion and oral motor delay both of which may be attributed in part to his ASD. Respondent has submitted information that links feeding issues with ASD. See R Ex D. However, Devin has been diagnosed as having GER, a condition which clearly would affect Devin's feeding. Although Dr. Yazdi considers the possibility that Devin's "feeding disorder could have a good behavioural component to it," he does opine that "it is quite possible that the refluxing led to his feeding disorder." P Ex. 62 at 1. Given the clear symptoms of ASD occurring prior to March 21, 2005, it is unnecessary to resolve the relationship of feeding issues to ASD.

a) The Virginia Feeding Clinic ruled out any symptoms of ASD.

Petitioners contend that the Virginia feeding clinic Devin attended provided him with a thorough work-up which did not reveal any "neurological condition or cause, vaccine-related or otherwise, even remotely suspected by any of the medical professionals at Children's." P Response at 4. Petitioners' expert, in support of this claim, points to Dr. Purcell's March 27, 2008 letter as proof that an "in-depth clinical psychological evaluation" was performed on Devin. Hastings Report at 4. In his opinion this evaluation "100% confirmed the absence of any Autism features" shown by Devin. Id. at 13.

Petitioners and their expert are factually incorrect. In her testimony Dr. Purcell states that she never conducted an in-depth psychological evaluation of Devin. T 31, lines 13-20. She explains that none of the clinical tests used to rule out ASD were ever administered to Devin during his 2004 stay at the feeding clinic. Id. Dr. Purcell's testimony is further supported by the records she submitted. The Virginia Feeding Records show that Dr. Purcell's consultations only focused on Devin's eating ability and how best to improve his oral food intake. VFR part 4. She did not discuss Devin in regards to any other developmental delays he might have had besides his oral feeding problems.

Dr. Purcell also makes it clear that the two letters she wrote were merely her observations of Devin, not actual evaluations. T 35, lines 11-12. Furthermore, Dr. Purcell admits that not all of the observations found in the March 27, 2008 letter were her own. Since a span of about 3.5 years occurred between the time she first saw Devin and the time she wrote that letter, Dr. Purcell used Devin's Feeding Records from his first time at the Virginia feeding clinic to help with her recall. T 36, lines 16-19 and T 37, lines 12-19. For instance Dr. Purcell's observation in the March 27, 2008 letter that Devin was communicating with "single word responses" was not her own. This observation came from the Child Find Therapeutic Recreation notes. VFR part 5 at 19.[22] Dr. Purcell herself does not remember Devin speaking a word during his sessions. T 37, lines 8-11. This explains the differences between her March 27, 2008 letter and her letter written directly after Devin's 2004 stay where she states that "Devin has no words and is not even babbling with appropriate consonant sounds to be able to make words." P Ex 67 at 1.

Dr. Purcell's testimony and the records she submitted show that outside his feeding problems, none of Devin's other developmental delays were evaluated while he was at the Virginia clinic. Dr. Purcell's March 27, 2008, does not reflect any ASD evaluations performed by her. Petitioners and their expert's contentions that Devin received neurological evaluations at the Virginia feeding clinic are simply wrong. Any statements in regards to Devin's ASD found in the March 27, 2008, letter are merely Dr. Purcell's non-clinical observations. As such Dr. Purcell's March 27, 2008, letter cannot be used as "evidence to demonstrate that the complaints now made by Petitioners as being vaccine-related were not present in October of 2004." P Response at 5.

[22] The undersigned notes that within the approximately 250 pages of feeding records submitted this is the only notation of Devin using any words.

b) Dr. Hastings opined that Devin had a sudden onset of ASD symptoms in the last week of March, 2005.

Petitioners also argue that Dr. Hastings medical opinion supports their assertion that Devin first started displaying symptoms of ASD at the end of March. P Response at 6-7. However, petitioners' expert comes to these conclusions based upon statements made by Mrs. Liew. In his first report, Dr. Hastings claims that upon interviewing Mrs. Liew he found her to be a "very capable and supportive parent" and for this reason he contends that the statements she made about Devin's onset were likely accurate. Hastings Report at 11. This is quite frankly a simplistic, thinly supported conclusion. The undersigned does not doubt Mrs. Liew's capability or supportiveness as a parent. What is doubtful is Mrs. Liew's ability to accurately identify, with any clinical precision, what the first symptoms of Devin's ASD were and when they occurred. This is why Dr. Hastings was asked to opine in the first place. As a medical expert, the expectation is that Dr. Hastings would use his medical knowledge to examine the medical records and to compare the various sources of information in explaining why he believed Devin's first symptoms of ASD occurred in the last week of March, 2005. Dr. Hastings did not do this.

In fact, the undersigned did not find any medical or even scientific theories espoused anywhere in either of Dr. Hastings reports. His conclusions seemed only to be based on his misinterpretation of Dr. Purcell's March 27, 2008, letter and Mrs. Liew's statements. Outside of these two sources, Dr. Hastings does not provide any reasons for why he came to the conclusions he did. In fact, besides a quick summary of Devin's medical history, Dr. Hastings does not refer to any of Devin's medical records in coming to his conclusions.[23] This explains why Dr. Hastings' report does not match the testimony of Dr. Harrington who confirmed that he could not find anything in his charts, and he himself did not remember, a sudden onset like that described by petitioner. T 92, lines 10-11 and 17-18. Dr. Hastings also did not provide any scientific or medical studies to support his claim that Devin was not showing any signs or symptoms of ASD. In light of the above deficiencies, and since his CV reflects no experience with treating or working with children who have ASD, Dr. Hastings' "expert report" can at best be viewed as representing his unsubstantiated opinion.

Petitioners' contentions that Devin either did not have or did not display an "objective, 'recognizable sign' of autism or other developmental disorder" until the last week of March, do not coincide with what is found within Devin's medical records. 2nd Amnd. Pet. at 4. Petitioners' arguments are based on their misinterpreting several documents and failing to address several others. To the contrary, the undersigned finds that the records do show that Devin was displaying several recognizable symptoms of ASD prior to March 21, 2005.

[23] Dr. Hastings makes reference to several videos he reviewed which support his claim that Devin was not showing any signs of ASD before the last week in March, 2005. However these videos were never filed with the court. Furthermore, this claim seems to be in conflict with what is written in the evaluation done by Creative Perspectives. P. Ex84 at 5. Since these videos are not part of the record they cannot be used to support Dr. Hastings claims.

CONCLUSION

The undersigned finds that Devin displayed multiple symptoms of ASD as recognized by the medical profession at large prior to March 21, 2005, any one of which would qualify as a symptom of ASD. Under Cloer, the first of these symptoms starts the running of the Vaccine Act's statute of limitations. Since Petitioners filed the Petition on March 21, 2008, this case was filed more than 36 months after the first symptom of onset.

Petitioners have the burden to show timely filing. Petitioners 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, § 16(a)(2). To date, petitioners have not demonstrated 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).

IT IS SO ORDERED.

s/Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master