IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 09-300V
Filed: June 25, 2014
(Not for Publication)

KIM CASTALDI and RICHARD CASTALDI, parents and next of kin to V.C., a minor,	*	
Petitioners,	*	Petitioners' Motion for Ruling on the Record; Onset; Symptoms of Autism; Statute of Limitations; Insufficient Proof of Causation.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew Downing, Esq., Hennelly & Steadman, P.C., Phoenix, AZ, for petitioners.
Darryl Wishard, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION[1]

Vowell, Chief Special Master:

On May 12, 2009, Kim and Richard Castaldi ["Mrs. Castaldi," "Mr. Castaldi," or "petitioners"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], on behalf of their minor son, VC. On January 21, 2014, petitioners filed a status report, in which they conveyed their belief that "the record is complete for the Court to rule on Respondent's Motion to Dismiss filed on August 27, 2009."

For the reasons set forth below, petitioners have failed to demonstrate that this case was timely filed. Assuming, *arguendo*, that this case was timely filed, I hold that petitioners have failed to establish entitlement to an award. This case is therefore dismissed.

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[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, this decision will be posted on the United States Court of Federal Claims' website, as required by the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 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] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

I. Procedural History.

On May 12, 2009, Mr. and Mrs. Castaldi filed a petition, alleging that the hepatitis A vaccine VC received on May 8, 2006, caused various adverse reactions, including irritability, fussiness, constant crying, right-sided weakness, speech regression, loss of fine motor skills, and changes in eating habits. Petition, preamble; ¶¶ 6-7. Although the petition did not allege that the vaccination caused VC's autism spectrum disorder diagnosis, the medical records and other filings reflect that these and other symptoms led to that diagnosis.[3]

Petitioners filed VC's medical records on June 25, 2009. On August 27, 2009, respondent moved to dismiss this case as untimely filed, arguing that the medical records demonstrated onset of symptoms of an autism spectrum disorder more than 36 months before the petition was filed. Petitioners requested and received a delay in responding to the motion to dismiss. Petitioners' response was filed on December 16, 2009, along with a medical report from Dr. Richard Hastings. The special master then assigned to this case agreed to conduct a hearing to resolve conflicts in the evidence. *See* Order, issued Sept. 17, 2010.

The case was reassigned to me on October 6, 2010. On October 25, 2010, petitioners filed a supplemental response to the motion to dismiss, requesting that any fact hearing be delayed until the U.S. Court of Appeals for the Federal Circuit issued its decision in *Cloer v. Sec'y, HHS*.[4] I concluded that this case presented legal and factual issues that could be affected by the decision in *Cloer* and suspended any further proceedings until that decision issued. *See* Order, issued Oct. 25, 2010. The en banc decision was issued on August 5, 2011, *Cloer v. Sec'y, HHS*, 654 F.3d 1322 (Fed. Cir. 2011)(en banc) ["*Cloer I*"], and I thereafter ordered the parties to file a joint status report proposing dates for a fact hearing. Order, issued Aug. 19, 2011.

The hearing was conducted in Tulsa, OK on December 14, 2011. At the conclusion of the fact hearing, I indicated that the parties could file additional evidence concerning the diagnosis of autism, including any relevant evidence from the Omnibus Autism Proceeding ["OAP"]. When the issue of filing OAP evidence was discussed at

[3] The precise diagnosis is either autistic disorder, or pervasive developmental delay-not otherwise specified ["PDD-NOS"]. Petitioners' Exhibit ["Pet. Ex."] 9, pp. 61, 71-72. The most recent medical record reflects the autism diagnosis. Pet. Ex. 8, p. 38. I note that it is not uncommon in children diagnosed with autism spectrum disorders for the specific diagnosis within the autism spectrum to fluctuate over time. *White v. Sec'y, HHS*, No. 04-337, 2011 WL 6176064, at *5 (Fed. Cl. Spec. Mstr. Nov. 22, 2011). It is also not uncommon for health care providers to be less than precise when referring to a diagnosis on the autism spectrum, using a general term such as PDD to refer to any disorder falling on the autism spectrum. *Id.*

[4] The U.S. Court of Federal Claims decision, *Cloer v. Sec'y, HHS*, 85 Fed. Cl. 141 (2008), was reversed and remanded by a panel of the U.S. Court of Appeals for the Federal Circuit. *Cloer v. Sec'y, HHS*, 603 F.3d 1341 (Fed. Cir 2010). The panel's decision was vacated and rehearing en banc was ordered. *Cloer v. Sec'y, HHS*, 339 Fed. Appx. 577 (Fed. Cir. 2010).

the hearing, petitioners did not object to the use of such evidence. *See* Tr. at 5, 125-26. Respondent filed five exhibits containing evidence from the OAP on December 16, 2011. On January 25, 2012, petitioners filed three articles and a motion to strike the three exhibits containing expert testimony from the OAP concerning behavioral symptoms of autism that respondent had filed.

On April 26, 2012, I issued my "Order and Ruling on Facts Pertaining to Onset." In my order, I acknowledged that "the parties' filings in this case contemplated that I would rule on the motion to dismiss in conjunction with this ruling setting forth factual findings." Ruling at 5. However, since the briefing on the statute of limitations issue occurred prior to the *Cloer I* decision and because "expert reports or other evidence that addresses the medical implications to be drawn from the facts found will inform a ruling on whether this case is timely filed" I elected to defer ruling on the motion to dismiss. *Id.*

Although I granted petitioners' motion to strike three of respondent's exhibits, I noted that, in light of petitioners' late-filed objection to the exhibits,[5] respondent would be permitted to file a report of "a qualified expert addressing the early behavioral symptoms of autism and how they apply to this case, as well as any additional documentary evidence addressing these issues." Ruling at 5. Additionally, given the limited focus of Dr. Hastings' opinion, I indicated that "petitioners, as well as respondent, may file an opinion of an expert regarding these matters." Ruling at 20.

I directed the parties to provide a copy of my ruling "to any expert retained to opine on whether the behaviors identified are recognized as symptoms of an autism spectrum disorder by the relevant medical community." Ruling at 20. I indicated that "[s]hould an expert disagree with any factual finding [contained in the ruling] that expert shall clearly state: (1) the finding involved; (2) the reasons for the expert's disagreement; and (3) the impact, if any, of my contrary finding on the expert's conclusions regarding onset of symptoms." *Id*. The parties were ordered to file any additional evidence pertaining to the diagnosis of autism spectrum disorders ["ASD"] or the import of my factual findings with regard to the onset of symptoms of ASD by no later than June 25, 2012. The parties were also given the opportunity to file a brief addressing the impact of the Federal Circuit's en banc decision in *Cloer I* on respondent's motion to dismiss.

On May 9, 2012, petitioners filed a motion for review of my factual findings. Respondent's response was filed on May 30, 2012, and petitioners filed their reply brief on June 7, 2012. No oral argument was held. On July 12, 2012, Judge Bruggink denied petitioners' motion because the case was not ripe for review.

[5] My December 20, 2011 order indicated that the parties were to file any additional evidence concerning the diagnosis of autism no later than January 13, 2012. Petitioners' motion was filed on January 25, 2012.

In a July 23, 2012 status conference, I discussed resetting the deadlines for filing additional evidence on ASD and briefs addressing *Cloer I*. During the call, petitioners' counsel indicated that petitioners would file no additional evidence or briefs. I ordered respondent to file her expert report no later than August 22, 2012, and September 6, 2012 was set as the deadline for the parties' optional briefs addressing *Cloer I*. Order, issued July 23, 2012.

Respondent filed an expert report from Dr. Max Wiznitzer on August 22, 2012. Petitioners filed a response to Dr. Wiznitzer's report two days later. In their response, petitioners objected to the filing of the report, the "methodology" used in writing the report, and the lack of an opportunity provided to them to cross examine Dr. Wiznitzer. On September 6, 2012, respondent filed a brief addressing the impact of *Cloer I* on her pending motion to dismiss. Petitioners made no additional filings.

I held a status conference on October 3, 2012, during which I noted that the statute of limitations is no longer a jurisdictional bar to further proceedings. In view of the need to resolve apparent conflicts between Dr. Hastings and Dr. Wiznitzer regarding what behavioral symptoms constituted symptoms of autism, I suggested that an expert hearing might be necessary.

Following the status conference, petitioners were ordered to file their supplemental expert report no later than December 3, 2012, and respondent was ordered to file her supplemental expert report 60 days thereafter. Order, issued Oct. 4, 2012. On November 14, 2012, petitioners requested a suspension of their filing deadline while the Supreme Court considered *Sebelius v. Cloer*.[6] I granted their request on November 16, 2012. The Supreme Court issued its ruling on May 20, 2013. *Sebelius v. Cloer*, 133 S.Ct. 1886 (2013) ["*Cloer II*"].

On June 5, 2013, I ordered petitioners to file their supplemental expert report by no later than August 5, 2013. Instead of filing a supplemental expert report, on August 5, 2013, petitioners requested that I rule on respondent's motion to dismiss based on the record as it currently stands.

I held an extended status conference with the parties on October 11, 2013. During the call, I reiterated that the factual findings contained in my April 26, 2012 ruling were not set in stone and that if an expert disagreed with a finding, the expert could explain the basis for the disagreement and how it impacted the expert's opinion. *See* Order, issued Oct. 16, 2013, at 5. I also indicated that I would afford petitioners one final opportunity to file an expert report that addressed both vaccine causation and whether VC's behavior and actions prior to the vaccination in question were symptoms

[6] The issue presented in the Supreme Court's review was whether attorney fees and costs could be paid in untimely filed cases. Petitioners' concern that the expense of an additional expert report might not be reimbursable, given the timing issue, was an adequate basis to grant additional time.

recognized by the relevant medical community as symptoms of ASD. I noted that if petitioners elected not to file a report, I would rule based on the record as a whole.

On January 21, 2014, petitioners filed a status report, indicating that they would not be filing a supplemental expert report and that the record was complete.

II. Summary of Relevant Medical Records.

VC was born in April 2004. Pet. Exs. 11, p. 109; 14, p. 662. His Apgar[7] scores were 8 and 9, reflecting a healthy newborn. *Id.* He had normal growth and development throughout his first year of life. *See generally*, Pet. Ex. 11, pp. 109-38. Although he had some illnesses, including otitis media, upper respiratory infections, rash, and viral syndrome, he had no serious illnesses or hospitalizations. *Id.* He received the usual childhood vaccinations during the first year of his life. Pet. Exs. 2; 10, pp. 85-86.

At his nine-month well child visit in January 2005, VC was pulling to stand, cruising, and engaging in vocal play. Pet. Ex. 11, pp. 133-34. He had an upper respiratory infection at this visit. His pediatrician, Dr. Escobar, noted appropriate growth and developmental progress. *Id.*, p. 134.

In March 2005, VC fell and bit his tongue, prompting an emergency room visit.[8] Two days later, he began vomiting and acting as if he were ill, and was taken to see his primary care provider. Pet. Ex. 11, p. 136. Doctor Escobar indicated that he seemed slightly tired, but was reacting normally. *Id.* She thought he had mild dehydration, mild acidosis, and hypoglycemia, secondary to poor oral intake due to his sore mouth. *Id.*

At his 12-month well child visit on April 14, 2005, his mother reported that he had begun walking that week. He was imitating sounds, and Dr. Escobar recorded that his developmental progress was appropriate.[9] Pet. Ex. 11, p. 138. He received his fourth diphtheria-tetanus-pertussis ["DTaP"] and hemophilus influenza type b ["Hib"] vaccines, and his initial measles, mumps, and rubella ["MMR"] and varicella vaccines at this visit. Pet. Ex. 2.

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[7] The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"], at 1682; NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S "] at 536-37.

[8] The emergency room records were not filed.

[9] Doctor Escobar's records did not contain any checklists for developmental screening. She testified that she did not use formal checklists, but asked questions based on such checklists. Tr. at 32-33.

VC's next physician's visit was on July 20, 2005, for his 15-month well child visit. He was reported to be in good health and very active. VC's motor skills were satisfactory. He had a "few word" vocabulary and chattered "quite a lot." Pet. Ex. 11, p. 139. In her testimony, Dr. Escobar indicated that her notes on VC's vocabulary were based on parental reports, rather than her own observations. Tr. at 34.

There were no recorded physician's visits between his 15-month and 18-month well child checkups. Pet. Ex. 11, p. 137. At VC's 18-month well child check-up on October 17, 2005, Dr. Escobar recorded that his developmental progress was appropriate. In what appears to have been her usual reliance on Mrs. Castaldi's reports of VC's language development,[10] Dr. Escobar stated that "mother reports that speech development has been appropriate and is now using small phrases." Pet. Ex. 11, p. 140. VC received an influenza vaccine at this visit. Pet. Exs. 11, p. 140; 10, p. 86.

One month later, VC was ill with a runny nose, cough, congestion, and fever. At this November 15, 2005 visit, Mrs. Castaldi reported that VC's older sister had also been ill with pneumonia and tonsillitis. Doctor Escobar diagnosed VC with a probable viral illness. Pet. Ex. 11, pp. 141-43.

VC was ill with influenza and bronchitis in late January 2006. On January 27, 2006, at the only recorded visit for this illness, VC was reported to have been ill with cough and rhinorrhea for an unstated period of time, with a fever of 101° Fahrenheit developing in the 24 hours preceding his visit. Testing for the influenza virus was positive. Pet. Ex. 11, pp. 144-45, 180. The illness persisted, although the exact duration of the illness is difficult to determine.

VC's medical records contain an entry for March 17, 2006, reflecting a cancellation of an optometry appointment. Pet. Ex. 11, p. 146. This cancellation may reflect when concerns about his vision first arose.

His two-year well child visit took place on May 8, 2006, when he was just under 25 months of age. Pet. Ex. 11, pp. 146-47. There were no physician's visits recorded between VC's January 2006 bout with the flu and this visit. Doctor Escobar's record of this visit begins, in accordance with her usual practice (*see* Tr. at 33), with her handwritten notes. They reflect that VC babbled more than his sister, but, overall, was quieter than his sister. VC had a good appetite, but disliked fruits. Doctor Escobar noted that Mrs. Castaldi was concerned about VC's close vision because VC bumped into things, especially on his left side. She reported that he seemed to have trouble focusing because he would look at something, rub his eyes, and then look at it again. Pet. Ex. 11, p. 146.

[10] Mrs. Castaldi is a speech and language pathologist who, at the time of the hearing, was the director of special services for the Sepulpa Public Schools. This position involves oversight of early intervention and gifted and talented programs. Tr. at 41.

The dictated notes[11] from this visit indicated that VC was in good health. Doctor Escobar recorded that he babbled and had a "few word vocabulary." He liked to "talk in sentences" as opposed to "labeling items." Pet. Ex. 11, p. 147. Doctor Escobar expanded on her handwritten comments on Mrs. Castaldi's reports about VC's vision, noting that Mrs. Castaldi described VC as having problems with his close vision. In looking at an object up close, VC would frequently rub his eyes and seem to try to focus again. *Id.* Doctor Escobar described VC as "very active" and "inquisitive" and indicated that he explored the exam room during the visit. *Id.* She referred VC for an ophthalmic evaluation. *Id*. VC received the allegedly causal hepatitis A vaccine at this visit. *Id.*; Pet. Exs. 2, p. 3; 10, p. 85.

VC saw Dr. Brown, an ophthalmologist, 15 days later, on May 23, 2006. Doctor Brown noted that VC was upset and cried constantly during the examination. He recorded that Mrs. Castaldi shared other concerns about VC's development, specifically his speech. Pet. Ex. 11, p. 211; *see also* Tr. at 81. He believed VC had a "mixed" developmental disorder, and indicated that VC should see a neurologist or developmental specialist. He reported that VC was farsighted.[12] Pet. Ex. 11, p. 211.

Doctor Escobar received Dr. Brown's report on May 25, 2006. Tr. at 24; Pet. Ex. 11, p. 211. She saw Mrs. Castaldi and VC again on June 8, 2006. The reason listed for the visit was "discuss vision test results" (Pet. Ex. 11, p. 148), but it is unclear who initiated the visit. During the visit, Mrs. Castaldi provided an additional example of why she believed VC had vision problems. She explained that VC would eat half the food on his plate and then want more food. When she turned the plate to place the uneaten food in front of him, he appeared surprised that there was still food on the plate.[13] Pet. Ex. 11, pp. 149-50. Doctor Escobar also recorded that Mrs. Castaldi had concerns that VC "has some speech delay," that he vocalized, but had limited verbalization. He turned to investigate sounds. *Id.*, p. 150; *see also* Tr. at 84.

During Dr. Escobar's June 8, 2006 examination of VC, she observed VC vocalizing and using a few understandable words. She recommended that petitioners observe VC for the next three to four months and if the symptoms persisted or progressed, she would consider a further evaluation and a possible neurology consultation. Mrs. Castaldi was directed to notify Dr. Escobar if there was any exacerbation of VC's symptoms. Pet. Ex. 11, p. 150.

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[11] Doctor Escobar testified that her usual practice was to take handwritten notes, and then dictate more complete notes on the same day as the visit occurred. Tr. at 33.

[12] A September 2006 report from another ophthalmologist, Dr. Siatwoski, did not indicate that VC was farsighted. Pet. Ex. 6, p. 18.

[13] The record does not indicate that this apparent inability to see all the food on his plate was a new symptom.

At some point, VC was referred to "Sooner Start," a state program for children with special needs. Tr. at 26. VC's initial evaluation occurred on July 31, 2006, a little less than two months after the June visit to Dr. Escobar where she indicated that VC should be observed for three to four months before referral. It appears that Dr. Escobar referred VC to Sooner Start, as the initial Sooner Start record indicates "Pediatrician felt it was best to eval—motor skills are OK, but everything else may be delayed. Possible vision problems," and indicated that Mrs. Castaldi had learned about the program from her doctor. Pet. Ex. 13, p. 467. The form also indicated "Epworth T & Th," likely referring to VC's attendance at a day care or preschool program those days. *Id.* I note that a later record reflects VC's attendance at Epworth "was not working out."[14] Pet. Ex. 11, pp. 151, 153; *see also* Tr. at 110. However, VC did attend a preschool program in the autumn of 2006. *See, e.g.*, Pet. Ex. 11, pp. 155-56 (note regarding possible seizure episode while "on the way to school").

As part of the evaluation, Mrs. Castaldi completed two questionnaires, one for children at 27 months of age and one for children at 30 months of age, consisting of a series of questions about developmental milestones.[15] Mrs. Castaldi indicated that VC could not follow any three-four word directions, could not correctly name at least one picture, and could not point to body parts. Pet. Ex. 13, p. 482. Mrs. Castaldi also reported that VC could, at one time, use a personal pronoun in the phrase "me drink," but that he stopped doing so in "late spring." She indicated that VC had been imitating three to four word sentences but that also stopped. *Id.* VC did not yet pretend that objects were something else (although he sometimes engaged in pretend play with a doll or stuffed animal), could not put things away, did not line up four objects, and could not identify a sketch as a person. *Id*., p. 484. He did not eat with a fork, use "I" or "me,"[16] or don a coat or shirt. *Id*., p. 485. Mrs. Castaldi felt that VC's vision issues might be connected to some of his "regression." She dated the regression as occurring around the time VC had the flu, which she placed in "late spring." *Id*.

On the questionnaire measuring 30 month skills, Mrs. Castaldi reported that VC "sometimes" looked at someone speaking to him and began to resist going to Sunday School (a church nursery program) in "late spring." Tr. at 87, 112. He rarely greeted familiar adults and did not like to be hugged or cuddled. Pet. Ex. 13, p. 489. She indicated that VC did not like stories. *Id*. VC seemed happy and did not engage in

[14] Petitioners were ordered to file any records for the period from January 2006-07 from Epworth and any other preschool program VC attended. Ruling at 11, 20. Petitioners indicated to the court that no such records exist. Status Report, filed May 11, 2012.

[15] According to the form, the 30 month questionnaire was used for children ages 27-32 months. Pet. Ex. 13, p. 487. On July 31, 2006, VC was between 27-28 months of age. The options for scoring each skill evaluated were "Yes," "Sometimes," and "Not Yet."

[16] Mrs. Castaldi checked the "Not Yet" block when asked if VC used words like "I," "me," or "mine." However, she noted that VC at one time used the phrase "me drink," but that he stopped doing so in "late spring." Pet. Ex. 13, p. 482. She also checked the "Not Yet" block for a question regarding the use of three to four word sentences, indicating that he "was imitating but also stopped." *Id.*

hand flapping or rocking or similar behavior. *Id*. However, he rarely followed directions, would not look where his mother pointed, stuffed his mouth with food, and was a picky eater. *Id*., p. 490. VC preferred to play by himself, rather than alongside other children. *Id*., p. 491. Based on Mrs. Castaldi's answers, VC's behavior fell above the cut off score, thus warranting a referral for further evaluation. *Id*., p. 493.

VC was also observed at home on July 31, 2006 by the Sooner Start evaluator. Pet. Ex. 13, p. 592. The evaluator explained that, based on the questionnaires completed by Mrs. Castaldi, VC had delays in all areas of development except motor skills. *Id*. The evaluator observed that VC appeared interested in toys. He vocalized, but used an unintelligible string of syllables, rather than words, throughout the evaluation. Mrs. Castaldi explained that VC had used words and imitated two word phrases, but stopped doing so "in late spring of this year." At this evaluation, Mrs. Castaldi also dated VC's regression to around the time he had the flu. Pet. Ex. 13, p. 593; *see also id*., p. 545 (Sooner Start provider notes from August 31 2006, indicating that VC was speaking in sentences before he had the flu in February); Tr. at 86-87. Sooner Start referred VC for an occupational therapy evaluation on September 14, 2006. Pet. Ex. 13, p. 579.

Doctor Escobar referred VC to Dr. Kukas, a developmental pediatrician, in late August, 2006. Tr. at 28; Pet. Ex. 11, p. 257. Doctor Kukas first saw VC on November 4, 2006. Pet. Ex. 11, pp. 257-60; Tr. at 28. In January 2007, Dr. Kukas discussed with Mrs. Castaldi the possibility that VC had an ASD. Pet. Ex. 11, p. 261.

VC was formally diagnosed with a pervasive developmental disorder in February 2007, after an evaluation at Cook Children's Medical Center. Pet. Ex. 12, p. 284. However, his parents expressed concern about an autism spectrum disorder during a November 4, 2006 developmental pediatrics assessment (Pet. Ex. 11, pp. 257-60) and Dr. Hille, a pediatric neurologist included autism in his differential diagnosis in his evaluation four days later, on November 8, 2006 (Pet. Ex. 7, p. 35).

III. Summary of Relevant Hearing Testimony.

A. Pediatrician's Testimony.

Doctor Escobar was VC's pediatrician from birth to about age three and a half. *See generally* Pet. Ex. 11. She is now retired. Tr. at 8. She testified that she took handwritten notes during appointments and then dictated more detailed notes the same day. Tr. at 33. She informally used the Denver Developmental Inventory ["DDI"] during well-child visits, meaning that she did not use formal checklists to monitor development, but the questions she asked parents about their child's development came from the DDI and other standard screening devices. Tr. at 32-33.

The descriptions of VC's development, particularly his speech and language, in Dr. Escobar's clinical notes reflect what was reported to her by VC's parents rather than

her own observations during the visit. Tr. at 34. Doctor Escobar was unable to quantify how many words corresponded to her notations of "a few words" that appear in the records from VC's 15 month (July 2005) and 2 year (May 2006) well child visits. Tr. at 34-35.

She testified that petitioners were responsible parents and she would have expected them to schedule an appointment if VC was showing signs of a neurological condition. Tr. at 8-9. She described Mrs. Castaldi as a "speech therapist, who's a reliable observer." Tr. at 36. However, Dr. Escobar also agreed that "a reliable observer [would] give fairly consistent accounts over time of the same event." Tr. at 38-39.

In reviewing her consultation note from May 8, 2006, Dr. Escobar agreed that based on her statement that VC "likes to talk in sentences as opposed to labeling items," and VC's age (2 years), it appeared as though he was exhibiting normal speech development at the time of the visit. Doctor Escobar later stated that as long as a child was vocalizing at 2 years of age, she would have no concerns about the child's development.[17] She would expect a two year-old to have a few understandable words, like mama and dada. Tr. at 35.

B. Mrs. Castaldi's Testimony.[18]

At the time of the hearing, Mrs. Castaldi was the Director of Special Services for Sapulpa Public Schools. She has a Bachelor of Science degree in education and communication science, a Master of Science in communication sciences and disorders, and a Master of Education in school counseling. She previously was employed by the public school system as a speech and language pathologist. Tr. at 41-42.

At 15 months, Mrs. Castaldi considered VC's speech development age appropriate. She had no concerns with either the number of words or the manner in which VC used them. Tr. at 47. With regard to his speech development at his two year well child visit (May 8, 2006), she testified that his vocabulary was "probably around 500 words," and that he "was speaking in at least three- to four-word sentences." Tr. at 52-53. She indicated that she first noticed a sign or symptom of speech impairment about

[17] I note that her testimony is similar to the conclusion drawn by Robert Schum, Ph.D. in his article *Language Screening in the Pediatric Office Setting*. After reviewing four of the standard evaluations for speech development, he concluded that a child should be referred for a formal speech and language screening if by 18 months the child is not using "mama" and "dada" and if by 24 months is not using 25 words. R. Schum, *Language Screening in the Pediatric Office Setting*, PEDIATR. CLIN. N. AM., 54: 425-36 (2007), filed as Pet. Ex. 18 ["Schum, Pet. Ex. 18"], at 432 (Table 1).

[18] After Mrs. Castaldi testified at the hearing, petitioners elected not to have Mr. Castaldi testify. They noted that Mrs. Castaldi was the primary historian at medical visits and therefore Mr. Castaldi's testimony would likely be redundant. Tr. at 122-24.

a week before VC's May 23, 2006 ophthalmologist appointment, specifically on May 19, 2006. Tr. at 58, 60.

Mrs. Castaldi testified that she frequently took VC to the school where she taught. Tr. at 58. In one of the offices in her school, there was a colorful alphabet poster. Tr. at 59. Whenever Mrs. Castaldi took VC to the office, he pointed at the poster and said the alphabet while pointing at each corresponding letter. *Id.* She testified that on May 19, 2006, she had brought VC with her while she cleaned out her office. She noticed he was "very agitated, upset, inconsolable." Tr. at 58. When she took VC past the poster, he stopped, looked at it, and "got really upset and started crying." He did not say or point to any of the letters. Tr. at 59.

On cross-examination, Mrs. Castaldi was unable to identify, even vaguely, the other times when VC had visited her school and recited the alphabet. Tr. at 80. She indicated that VC could "name" all of the alphabet letters and say his ABCs shortly before his second birthday (April 2006). She and her husband were working on letters and letter sounds with their older daughter and "felt that [VC] picked them up because of that." Tr. at 81.

Mr. Castaldi's November 2011 affidavit contradicts some aspects of Mrs. Castaldi's testimony. His affidavit indicates that, rather than naming all the alphabet letters or being able to point them out, VC was "singing typical songs (like the alphabet) and starting to say his ABCs" prior to May 2006. Pet. Ex. 17 at 700.

In discussing the vision concerns reported to Dr. Escobar in May 2006, Mrs. Castaldi recalled an incident when she was in the kitchen and VC "came running into the room and completely missed seeing the kitchen drawer pulled out and ran right into it." Tr. at 55. She could not remember any other specific incidents where he ran into something, but indicated he was bumping into things. Tr. at 55. She also could not identify the exact date or timeframe of the drawer incident, but placed it prior to the May 8, 2006 visit. Tr. at 78.

During her direct examination, Mrs. Castaldi was questioned about the "several places in [VC's] medical chart where [her] history about when [his speech problems] started is different" than how she testified. Tr. at 62. She explained that when providing history to providers she did not spend a lot of time with VC's records in front of her and was primarily focused on getting him treatment . Tr. at 65. However, on cross examination, she agreed that, as a speech pathologist, it would be important for caregivers to provide an accurate history when seeking treatment. Tr. at 86.

IV. Untimely Filing.

A. The Statute.

The Vaccine Act's statute of limitations provides in pertinent part that, in the case of:

> a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury. . . ."

§ 300aa-16(a)(2). The date of occurrence "is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Cloer,* 654 F.3d at 1339. Additionally, the date "does not depend on the knowledge of a petitioner as to the cause of an injury." *Id.* at 1338. When drafting the Vaccine Act, Congress rejected a discovery rule-based statute of limitations, in favor of one that does not consider knowledge and runs solely from the date of the first symptom or manifestation of onset. *Id.*

Because petitioners filed their petition on behalf of VC on May 12, 2009, the first symptom or manifestation of onset of his autism must have occurred after May 12, 2006, in order for the petition to be considered timely. *See Markovich v. Sec'y, HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007) (holding that "either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first"); *Cloer,* 654 F.3d at 1335 (holding that the "analysis and conclusion in *Markovich* is correct. The statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset.").

B. Symptoms of Autism Spectrum Disorders.[19]

The diagnostic criteria found in the Diagnostic and Statistical Manual of Mental Disorders ["DSM"] have "served as the gold standard for making a clinical diagnosis" of ASD for more than three decades. C. Johnson, *Recognition of Autism Before Age 2 Years,* PEDIATRICS IN REVIEW, 29(3): 86-95 (2008), filed as Pet. Ex. 19 and Res. Ex. I ["Johnson, Pet. Ex. 19"], at 87. The criteria have served as the basis for the

[19] I have previously described the symptoms of ASD at length in *White v. Sec'y, HHS*, 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011). There does not appear to be any material dispute regarding what constitutes a symptom of an ASD in this case, but rather when the symptoms first presented.

development of numerous developmental exams.[20] The screening devices focus on the different categories of symptoms associated with ASD: deficits in speech and language, impaired social interaction, and presence of restricted, repetitive patterns of behavior, interests, or activities. *See* DSM-IV-TR, filed as Pet. Ex. 20.[21] There are no "pathognomonic clinical signs or confirming laboratory tests" for diagnosing ASD. Johnson, Pet. Ex. 19, at 86.

Speech delays are often the first symptom of ASD that parents report to their child's pediatrician. The parental reports often occur several months after the delays were first noticed. Johnson and Myers, Res. Ex. H, at 1190. The delayed reporting is sometimes attributable to parents believing their child is shy or simply a "late-talker." Johnson, Pet. Ex. 19, at 91. Some parents also fail to recognize that their child is reacting to social cues or gestures in addition to, or in place of, spoken words, and thus overestimate the child's receptive language abilities. *Id.*; *see also* Luyster, Res. Ex. A, at 1427. Additionally, a child's echolalia[22] is sometimes viewed as functional speech. However, repeating phrases or reciting nursery rhymes is not the same as having expressive language. Johnson, Pet. Ex. 19, at 92; *see also* Johnson and Myers, Res. Ex. H, at 1192.

Other early symptoms of ASD recognized by parents include exploring toys in unusual ways and poor motor skills. Normally developing children transition from sensory-motor play to pretend play around 16 to 18 months, while children with ASD often continue to mouth, throw, and bang objects and do not advance into pretend play. Johnson, Pet. Ex. 19, at 89; Johnson and Myers, Res. Ex. H, at 1193. Instead of pushing a toy car around on the ground, children with ASD will often turn the car over and spin the wheels. Johnson, Pet. Ex. 19, at 89. Some children will hold objects very close to their head or look at toys out of the corner of their eyes. *Id.* at 93. Due to

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[20] Johnson, Pet. Ex. 19, at 87; s*ee also* R. Luyster, et al., *Language Assessment and Development in Toddlers with Autism Spectrum Disorders*, J. AUTISM DEV. DISORD., 38: 1426-38 (2008) ["Luyster"], filed as Res. Ex. A, at 1428-30 (discussing seven of the standard assessment instruments); C. Johnson and S. Myers, *Identification and Evaluation of Children with Autism Spectrum Disorders*, Pediatrics, 120: 1183-1215 (2007), filed as Res. Ex. H ["Johnson and Myers, Res. Ex. H"], at 1200-01 (Table 3: Selected Level 1 and 2 ASD Screening Measures).

[21] The DSM-IV-TR has since been replaced by the DSM-V. However, VC was diagnosed based on the DSM-IV-TR criteria. The symptoms recognized by the medical community at large as those of an ASD have not changed, but the criteria for diagnosis have been refined, and the distinctions drawn in the DSM-IV among the diagnoses of autistic disorder, PDD-NOS, and Asperger's disorder have been eliminated. *See* American Psychiatric Association*, Autism Spectrum Disorder Fact Sheet*, available at http://www.dsm5.org/Pages/Default.aspx (highlighting the differences between DSM-IV and DSM-V).

[22] Echolalia has been described as "repeating verbatim what someone else has said. With immediate echolalia, the child repeats back what has just been said. With delayed echolalia, the child repeats a phrase, sentence, or even a passage that was previously heard, such as a line from a favorite movie." Schum, Pet. Ex. 18, at 706.

deficits in social interaction, children with ASD are content to play alone and do not seek interaction with other children or adults. Johnson, Pet. Ex. 19, at 90.

Although some children with autism appear to have advanced motor skills, others display subtle deficits in coordination. Johnson, Pet. Ex. 19, at 93; Johnson and Myers, Res. Ex. H, at 1194. Although not a definitive symptom, motor clumsiness has been described as a "distinguishing characteristic" of ASD. Johnson and Myers, Res. Ex. H, at 1194. The Autism Diagnostic Interview Revised (ADI-R), a standard assessment tool, accounts for loss of motor skills, such as posture, gait, and coordination. A.S. Meilleur and E. Fombonne, *Regression of Language and Non-language Skills in Pervasive Developmental Disorders*, J. INTELLECTUAL DISABILITY RESEARCH, 53(2): 115-24 (2009), filed as Res. Ex. J, at 119 Table 2 (including loss of motor skills among the "other skill loss" identified by the ADI-R used in the study).

C. Determining Onset of VC's Symptoms.

1. Summary of Factual Rulings and Reasons Therefor.

I issued findings of fact, based on the evidentiary record and the testimony of Mrs. Castaldi and Dr. Escobar at the December 14, 2011 fact hearing. The reasons for my findings were set forth in detail in my April 26, 2012 Ruling and I incorporate them herein by reference. In making my findings, I relied extensively on the filed medical records. I did not find sufficient indicia of reliability in the testimony of Mrs. Castaldi to credit her testimony over the evidence found in the contemporaneous records. Her testimony conflicted with histories she provided to various health care providers fairly closely in time to the events recorded. Additionally, her ability to observe and accurately recount what she observed is called into serious question by the incompatibility of her testimony that VC had a 500 word vocabulary at a time when his pediatrician recorded that he had a "few word" vocabulary, and the fact that she inflated over time the extent of VC's vocabulary before his hepatitis A vaccination. Although petitioners' counsel attempted to reconcile this discrepancy by arguing an alternate meaning of "had" in relationship to "vocabulary," I find the attempt unavailing. In this regard, Mrs. Castaldi's training as a speech pathologist is significant, in that such a professional would be unlikely to use such strained terminology in referring to a child's vocabulary skills.

2. Assessing the Medical Records.

The hearing testimony and the parties' briefs primarily focused on VC's speech and language abilities as the initial symptom of his autism. The first documentation of parental concern regarding VC's speech is found in the record from his May 23, 2006 ophthalmology appointment, but the record is silent as to when concerns about VC's speech first arose. Relying on Mrs. Castaldi's hearing testimony, and vague references in their affidavits, petitioners place onset after May 12, 2006 and before the visit to ophthalmologist Dr. Brown on May 23, 2006, specifically on May 19, 2006. In contrast,

relying primarily on the contemporaneous records and the histories provided in non-contemporaneous medical records from July 2006 onward, respondent contends that the behavioral symptoms of autism were present, at the latest, by April 14, 2006.

In their May 9, 2012 motion for review, petitioners correctly noted that treating physicians are often "in the best position to determine factual and medical issues surrounding vaccination and treatment, including onset of relevant symptoms." Petitioners' Memorandum of Objections at 2 (citing *Andreu v. Sec'y, HHS,* 569 F.3d 1367 (Fed. Cir. 2009); *Zatuchni v. Sec'y, HHS,* 69 Fed. Cl. 621 (2006)). However, the records of treating physicians can be questioned and the weight afforded to them depends on whether the physician is noting her own observations or merely recording statements made by the patient. *See McKellar v. Sec'y, HHS*, 101 Fed. Cl. 297, 304 (2011) (noting that some notations in medical records reflect statements made by the person being treated and do not signify medical conclusions of the physician); *Snyder v. Sec'y, HHS*, 88 Fed. Cl. 706, 745 n.67 (2009) (stressing that a statement of a treating physician is not "sacrosanct" and can be rebutted).

Thus, although she was VC's treating physician, Dr. Escobar's consultation notes and testimony must be considered alongside the record as a whole, and cannot be viewed as determinative on the issue of onset, as petitioners alleged in their motion for review. *See* Petitioners' Memorandum of Objections at 3-4. Doctor Escobar testified that she primarily relied on parental reporting when documenting VC's speech and language abilities in her visit notes. Her records are only as reliable as the parental reporting they are based on, and are less helpful than records from pediatricians who record the specific words being said by the child or who use developmental screening tools in a systematic way. Additionally, Dr. Escobar's May 2006 consultation notes are internally inconsistent. She described VC as babbling with a few word vocabulary and also as talking in sentences.

As I noted in my factual findings, the problem with most of the medical histories in VC's medical records is that they do not contain the contemporaneous recitation of symptoms then existing, the type of medical record that I find to be the most reliable. Additionally, the accuracy of the histories—even those provided closest in time to the events described—necessarily relies upon the reporter's ability to observe and accurately remember. Unfortunately, Mrs. Castaldi's ability to accurately and consistently report her observations of VC's language development is so questionable that I hesitate to rely upon histories she provided. [23] Nevertheless, the early histories—those closer in time to the events reported than Mrs. Castaldi's testimony—do contain relatively consistent reports.

Although not precisely contemporaneous to the events they describe, I place substantial importance on the parental statements regarding onset of VC's speech and

[23] The next section highlights the inconsistencies in her reporting.

language skills found in the visits to Sooner Start (July 2006), initial neurological examination with Dr. Hille (November 2006), initial pediatric visit with Dr. Morgan (April 2007) and initial visit with Dr. Koljack (July 2007). This is because one would expect parents to be as accurate as possible when conveying history about their child during developmental evaluation or initial consultation by a specialist. The medical histories in these records place onset of VC's abnormal speech development in March or April 2006, around the time of his second birthday. *See* Pet. Exs. 13, p. 598 ("lost a lot of words in March"); 11, p. 257 ("developmental milestones were progressing normally until shortly after his [second] birthday"); 7, p. 34 ("normal speech and language development until just after his second birthday"); 8, p. 52 (mom a speech pathologist did not notice any problems with his interactive or language skills until around 2 years of age); 10, p. 103 ("normal child until shortly before second birthday").

2. Evaluating the Testimony of Mrs. Castaldi.

Special masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy*, 23 Cl. Ct. 726, 733 (1991) (citation omitted); *see also Cucuras v. Sec'y*, *HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *See Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by "clear, cogent, and consistent testimony" explaining the discrepancies. *Stevens v. Sec'y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990).

a. May 19, 2006 incident.

In my fact ruling, I specifically rejected Mrs. Castaldi's testimony about the May 19, 2006 incident at her school. The event was alluded to in her May 11, 2009 affidavit, but not described in any detail until her hearing testimony. It was not mentioned in any of the histories she provided about VC's language delay or regression at medical visits in the summer of 2006, nor, indeed, at any other point in the many medical histories she provided thereafter, including one in which she asserted that VC previously knew the alphabet and had a 30 word vocabulary. *See* Pet. Ex. 11, p. 160.

After arguing in their post hearing brief that the absolute earliest that onset of loss of language could be flagged was May 19, 2006, noting it was "the very first incident where [Mrs. Castaldi] thought to herself that something might be wrong" (Pet. Post Hearing Brief at 1, 4), petitioners downplayed the significance of the event in their Motion for Review. They acknowledged that it "may not even be a sign or symptom of anything. Rather than recite the alphabet, the child cried and got upset when he saw the alphabet poster . . . ." Petitioners' Memorandum of Objections at 12. They stated

that Mrs. Castaldi did not remember "the event until she sat down with [her counsel] and [they] discussed day by day from May 8, 2006 to May 23, 2006." *Id.*

I find it highly unlikely than an attempt over five years later to recall precisely what happened in a specific week will produce reliable evidence. This is particularly true when this effort produces testimony about a dramatic event that went unreported for years, in spite of numerous visits to medical providers investigating VC's loss of language.

b. Vocabulary Skills.

In my Ruling, I described Mrs. Castaldi's account of VC's vocabulary skills at the time of his May 2006 vaccination as having grown to a point that strained credulity. I noted that her testimony differed substantially from the reports of VC's language abilities at 2 years of age that appear in the medical records. At the hearing she testified as follows (Tr. at 52-53):

> Q (Mr. Downing): Now, the next couple of sentences seem, at least in my mind, to be a little contradictory. We have a sentence that says, "He babbles and has a few-word vocabulary," which is also mirrored in earlier reports from Dr. Escobar. Then it says, "He likes to talk in sentences." So can you tell Special Master Vowell the level of speech development that [VC] had in May of 2006.
>
> A (Mrs. Castaldi): His vocabulary, I would say, was probably around 500 words. He was speaking in at least three- to four-word sentences at that point, sometimes longer if the occasion arose, but consistently probably three- to four-word sentences.

Nowhere in the medical records was VC reported to have had a vocabulary of 500 words in early May 2006. In their motion for review, petitioners addressed the discrepancy between Mrs. Castaldi's hearing testimony and the medical records. They explained that "there is a significant difference between the number of words known (words in the vocabulary) versus the number of words the child uses in common parlance. At two years of age, a **normal** (emphasis in original) developing child will have a vocabulary of approximately 300 words.[24] However the child will only typically

[24] As support for this statement, petitioners cited to a handout found on the website for the Thornapple Kellogg Schools in Middleville, MI. The handout states that a two year old "has about 300 words in speaking vocabulary." http://www.tkschools.org/SiteCollectionDocuments/The%20Two%20Year%20Old%20Child.pdf at 1 (last visited May 15, 2014). No citation was given for this assertion or the other developmental skills listed on the document. In contrast, a standard pediatrics textbook indicates that the typical two year old has a vocabulary of 50 to 100 words and is using three word (subject, verb, object)

speak in two word sentences, and even then, likely only uses the same 20 to 30 words in communicating, mainly names of things, actions, people and situations (i.e., Mom, Dad, dog, drink, toy)." Petitioners' Memorandum of Objections at 8.

Petitioners' explanation for the discrepancy is hampered by the inconsistency of the extent of VC's vocabulary in the medical records. If his vocabulary was always reported as 500 words or 30 words, I could find that VC had an overall vocabulary of 500 words at two years of age, but only routinely used 30 words. However, the reports regarding his vocabulary at two years of age have grown from a few words, to 30 words, to 75 words, to 200 words, to the 500 words claimed at the hearing.[25] Additionally, it is noteworthy that petitioners' reports of VC's use of multi word sentences in the medical records each use the term "imitate."[26] This strongly suggests a type of echolalia, rather than advanced language skills.

3. Evaluating the Experts' Assertions.

a. Qualifications.

Expert qualifications play a significant role in the weight given to expert opinions, particularly when the opinions expressed are otherwise inadequately supported by reliable evidence. *See Moberly*, 592 F.3d 1315, 1325 (Fed. Cir. 2010) ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.") (citations omitted).

Petitioners' expert, Dr. Hastings, has a Ph.D. in anatomy as well as a degree in osteopathic medicine. He is board certified in internal medicine.[27] He has past experience in academics serving as an adjunct associate professor at Baylor College of Medicine (1992-1993) and a clinical professor and lecturer at the Oklahoma State

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phrases. NELSON'S at 32-33; *see also* Schum, Pet. Ex. 18, at 428 (noting that a typical 18-24 month old uses 100 to 200 words and combines them in short phrases).

[25] Pet. Exs. 11, p. 147 (May 2006, "few word vocabulary); p. 257 (November 2006, "observed a 30 word vocabulary" before VC regressed in his skills); p. 161 (December 2006, "prior to onset of symptoms [VC] knew his alphabet and had at least a 30-word vocabulary"); p. 268 (April 2007, "three and four word sentences reliably and had vocabulary of 75 words"); 10, p. 103 (July 2007, "two to three word sentence 200+ words"); Tr. at 52 ("500 words").

[26] Pet. Exs. 11, p. 217 (On a developmental questionnaire, in response to "Does your child make sentences that are three or four words long?" Mrs. Castaldi wrote "Was imitating, but also stopped."); 13, p. 593 (Sooner Start record indicating that Mrs. Castaldi reported that "at one time [VC] was using words & imitating 2 word phrases . . . .').

[27] As a D.O., his certification is through the American College of Osteopathic Internists (https://www.acoi.org) and not through the American Board of Internal Medicine (http://www.abim.org).

University College of Osteopathic Medicine (1981-1996), but it is unclear if he has any current academic appointments. Doctor Hastings' research and publications seem to focus on anatomy, hyperlipidemia, and cardiac medicine; he does not appear to have any publications regarding or expertise in diagnosing or treating autism spectrum disorders. *See generally* Curriculum Vitae of Dr. Hastings, filed as Pet. Ex. 16.

In contrast, respondent's expert, Dr. Max Wiznitzer, specializes in treating children with autism. He is board certified in three disciplines with a high degree of relevance to the issues: pediatrics; psychiatry and neurology, with special qualifications in child neurology; and neurodevelopmental disabilities. Doctor Wiznitzer is an associate professor of pediatrics, neurology and international health at Case Western Reserve University, and has hospital appointments in pediatrics and neurology at the University Hospitals of Cleveland. He previously was the Director of the Rainbow Autism Center at the Rainbow Babies and Children's Hospital, also in Cleveland, OH. Doctor Wiznitzer serves on the editorial boards of several medical journals, and has authored a number of articles and book chapters about various aspects of autism, including diagnosis and assessment of the condition. *See generally* Curriculum Vitae of Dr. Wiznitzer, filed as Res. Ex. G.

Based on their medical backgrounds, I placed a greater weight on the expert opinions of Dr. Wiznitzer regarding onset of VC's autistic symptoms than the opinions of Dr. Hastings.

b. Doctor Hastings' Opinions.

Doctor Hastings was retained by petitioners to "provide a medical evaluation regarding the onset of symptoms of [VC's] subsequent Autism and its relationship and temporal framework to his Hepatitis A vaccine of May 8, 2006." Pet. Ex. 15 at 675. In particular he was asked to review "the conflicting reports of onset and how encephalitis may have gotten inserted into the medical chain." Tr. at 3. Whether as a result of parental histories so reporting or a misunderstanding as to what petitioners reported to them, several physicians recorded that VC's autism symptoms began after a "bout with encephalitis" in January 2006. Pet. Ex. 15 at 686-92 (referring to records of Drs. Mattox and Koljack). Doctor Hastings correctly notes that the medical records regarding VC's influenza in January-February 2006 do not reflect any encephalitis. Pet. Ex. 15 at 685-86; Pet. Ex. 11, pp. 144-45).

In his report, filed prior to the hearing and the issuance of my fact ruling, Dr. Hastings concluded that onset of VC's ASD symptoms occurred after the May 8, 2006, vaccination. He stated that "Dr. Escobar's May 8, 2006 examination findings both eliminate the January 2006 viral infection as a causative adverse event and confirms (*sic*) the absence of and (*sic*) Autism or Autism like symptoms predating May 8, 2006." Pet. Ex. 15 at 693. He summarized Dr. Escobar's findings as "unequivocally support[ing] a normal developmental child with normal speech patterns, talking in sentence, awake, active, alert, and inquisitive and without any of the clinical

manifestations of Autism." *Id.* His report did not address the other histories provided by petitioners that conflicted with the history provided at the May 2006 visit and that describe an earlier onset of speech and language concerns.[28]

Without explaining why, Dr. Hastings stated that "[w]ithin 8 days following [VC's] Hepatitis A Vaccination, [VC] did begin to exhibit outwardly noticeable adversities that included becoming increasingly irritable, fussy, crying, and the development of a right-sided weakness." Pet. Ex. 15 at 677. Eight days after the vaccination is May 16, 2006, three days earlier than the alleged event at Mrs. Castaldi's school.

Although petitioners were afforded the opportunity to have an expert address my findings of fact, petitioners did not submit any supplemental expert report.

c. Doctor Wiznitzer's Opinions.

Doctor Wiznitzer's report was submitted after I issued my ruling on facts. He did not identify any problems with those factual findings. *See generally* Pet. Ex. F at 6-8. Based on his review of VC's medical records, the hearing testimony, and Dr. Hastings' report, Dr. Wiznitzer concluded that VC displayed "a history of regression of language skills in March-April 2006." Pet. Ex. F at 7.

In addition to exhibiting impaired speech and language, Dr. Wiznitzer noted that VC demonstrated deficits in his motor skills and coordination prior to the May 6, 2006 well child visit. Doctor Wiznitzer opined that VC's reported visual problems ("being clumsy, running into things and bumping into things") "mo[r]e likely than not, represented an early manifestation of [VC's] motor incoordination." Pet. Ex. F at 7. In his initial neurology evaluation of VC, Dr. Morgan also indicated that VC's motor and coordination issues predated his May 8, 2006 well child visit. Pet. Ex. 8, p. 52 (recording that "beginning in [April 2006 VC] began to exhibit some problems with general incoordination, stumbling about . . . ."). Additionally, Dr. Kukas noted that petitioners "started noticing periods of clumsiness . . . or unusually tipping back without falling about the time that [VC's] regressions started" (Pet. Ex. 11, p. 258) and Dr. Hille recorded Mrs. Castaldi observation that just after his second birthday VC would often wake-up jittery and clumsy and that "he would fall down often and bump into things" (Pet. Ex. 7, p. 34).

Doctor Hastings' report did not place any significance on, or even mention, the vision and coordination anomalies described by petitioners in his initial report.

[28] As noted in petitioners' memorandum in support of their motion for review, Dr. Hastings did state in his report that "[c]ompiled innuendoes based upon erroneous historical inserts and further historical and erroneous causation conclusion to the onset or causation of this child's Autism can not be lumped together in a combined fashion to be used as a basis to deny this child's legitimate immunization/vaccination injury." Pet. Ex. 15 at 694. However, this somewhat incomprehensible statement was made in relation to the inclusion of encephalitis in VC's medical records and not petitioners' reports of when his impaired speech and language first presented.

Petitioners have not filed anything to rebut Dr. Wiznitzer's pointing to vision issues, which arose before the allegedly causal vaccination, as a symptom of VC's subsequently diagnosed ASD.

D. Applying the Law to the Facts.

Autism cannot be diagnosed by any single abnormal behavior, but by 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. *Carson v. Sec'y, HHS,* 727 F.3d 1365, 1369 (Fed. Cir. 2013) ("[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations under § 300aa-16(a)(2).").

I have reviewed the expert opinions submitted by the parties and considered the arguments advanced by petitioners subsequent to my Ruling, including those put forth in their Motion for Review, and they do not alter my prior findings regarding when VC began to exhibit impairments in his communication skills. After reviewing the expert opinion of Dr. Wiznitzer, I find that VC's reported vision issues reflect early symptoms of his autism. Additionally, VC's lack of reaction to the probable splinter in his foot in November 2005 (Pet. Ex. 11, pp. 141-42) may also represent an early symptom of his subsequently diagnosed autism. *See* Johnson, Pet. Ex. 19, at 93 (stating that children with ASD "may be indifferent to noxious stimuli and injuries that typically are painful to others. The dichotomy is puzzling, but it is believed to be due to an abnormal arousal level or sensory gating system.").

Because I find that VC exhibited impaired speech and language skills, as well as deficits in motor skills and coordination and an indifference towards pain, prior to May 12, 2006, this case must be deemed untimely filed.

V. Petitioners' Theory of Vaccine Causation.

Under the Vaccine Act, the petitioner bears the burden of proving a vaccine-caused injury. There are two ways causation may be demonstrated. First, a petitioner may establish a "Table"[29] injury. Alternatively, a petitioner may prove that a vaccine listed on the Table actually caused or significantly aggravated an injury (an "off-Table" injury). Petitioners in this case have not alleged a Table injury (and no Table injury is identified for the hepatitis A vaccine), and thus must prove that VC suffered an "off-Table" injury.

To establish actual causation in an off-Table injury case, a petitioner must show preponderant evidence of "(1) a medical theory causally connecting the vaccination tand the injury; (2) a logical sequence of cause and effect showing the vaccination was the

[29] *See* § 11(c)1(C); 42 C.F.R. § 100.3 (2010).

reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). *See* §§ 11(c)(1)(C)(ii); 13(a).

Petitioners filed an expert report on December 16, 2009. The report conveys Dr. Hastings' general belief that VC's hepatitis A vaccine caused his autism, but does not include any specifics concerning the mechanism or causation theory:

> [T]he child's autis[m] Disorder has a temporal relationship to his Hepatitis A vaccination on May 8, 2006, and the proximal temporal relationship to his Hepatitis A vaccination and the onset of this Autism disorder symptoms only occurred following the Hepatitis A administration. We further confirm there is a medically established sequence of cause and effect that implicates the vaccine in the development of this child's Autism. I would further confirm the cause and effect is in fact logical and medically supported by the medical records.

Pet. Ex. 15 at 690. The report notes that "[f]urther reports relative to the mechanism of injury regarding [VC's] post Hepatitis A vaccination injuries and adverse clinical outcomes will be the subject of future narrative." *Id.* at 675. Although petitioners were afforded several opportunities to supplement Dr. Hastings' initial report, no supplemental report was filed.

I cannot accept Dr. Hastings' conclusory statements as reliable evidence that the hepatitis A vaccine can cause autism or that it did so in VC's case. As the Supreme Court has noted, a trial court is not required to accept the *ipse dixit* of any expert's medical or scientific opinion, because the "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). I note that there is nothing in Dr. Hastings' CV that suggests he has any expertise in the cause or treatment of ASD, and nothing to support his assertions other than a temporal relationship between vaccination and the first mention of speech delay to Dr. Escobar. A temporal relationship, standing alone, is insufficient to prove vaccine causation. *Grant v. Sec'y*, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Despite being afforded several opportunities to do so, petitioners have not put forth a medical theory causally connecting any vaccination VC received to his developmental delays and ASD diagnosis. Therefore, petitioners cannot establish they are entitled to compensation.

VI. Conclusion.

Because VC exhibited symptoms of autism more than 36 months before Mr. and Mrs. Castaldi filed this petition on his behalf, this case is untimely filed. Assuming, *arguendo,* that it was timely filed, petitioners have failed to put forth a causation theory that satisfies *Althen* and therefore are unable to establish that they are entitled to compensation.

The clerk shall dismiss this case for untimely filing and for failure to establish entitlement to causation.

IT IS SO ORDERED.

s/Denise K. Vowell
Denise K. Vowell
Chief Special Master