

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-0599V

Filed: September 11, 2012

Unpublished

COLLETTE M. RIDGE,	*	
as Parent and Legal Representative of	*	
CAMERON RIDGE, a Minor,	*	Fact Ruling; Statute of
	*	Limitations; Reliance upon
Petitioner,	*	Contemporaneous Medical
	*	Records; Factual Predicate
v.	*	for Expert Report
	*	
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Gregory Allen Keyser, Cincinnati, OH, for Petitioner.

Heather Lynn Pearlman U.S. Department of Justice, Washington, D.C., for Respondent.

FACTUAL RULING AND ORDER¹

GOLKIEWICZ, Special Master.

On December 13, 2011, the undersigned conducted a fact hearing in this case to determine when Cameron’s first symptom or manifestation of onset of his alleged vaccine-related injury occurred and whether the facts upon which Dr. William E. Frye based his expert opinion are valid. During the fact hearing, testimony was taken from Cameron’s mother, Collette Ridge (petitioner); Speech Language Pathologist, Julie N. Roberts; Primary Level Evaluator, Kathy Alexander; Cameron’s father, Jeffrey Ridge; and Cameron’s maternal

¹ The undersigned intends to post this factual ruling and order 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.**

grandmother,² Patricia Favalora. The undersigned will compare this testimony to the current record of documents and exhibits³ which includes contemporaneous medical records.

The Federal Circuit and logic teach us to give great weight to contemporaneous medical records as the importance of the information and the recent memory combine to reflect the most accurate information. Cucuras v. Sec'y of the Dept. of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir.1993). These medical records are “generally contemporaneous to the medical events,” and “accuracy has an extra premium” because a patient's proper treatment is “hanging in the balance.” Id. That is not to say that medical records are sacrosanct. They are sometimes incomplete and even contradictory. The undersigned will consider the entire record and the testimony offered to reach conclusions in this decision with regard to the two issues presented for determination at the fact hearing.

I. Occurrence of Cameron’s First Symptom of Manifestation of Onset.

On September 11, 2009, petitioner filed a complaint (hereafter referred to as Petition) under the National Childhood Vaccine Injury Act (Vaccine Act)⁴ alleging that her son, Cameron, developed autism⁵ as a result of “receiving a series of childhood vaccinations.” Petition at 1. Petitioner claims that Cameron “was born with a condition of mitochondrial dysfunction,” received a series of vaccinations from October 1, 2004 until October 10, 2006, and exhibited his first signs of autism on October 28, 2006. Id. at 2-3. Respondent believes there is evidence that Cameron’s first symptom of autism occurred before that date. See, e.g., Respondent’s Response Regarding the Factual Record (R’s Response) at 2. Based on the evidence of an earlier onset of autism, respondent argues that it “is not clear that the petition in this case was timely filed” under the Vaccine Act’s statute of limitations. Respondent’s Rule 4(c) Report (R’s Report) at 11. Accord. R’s Response at 1.

² Cameron’s grandmother initially lived with Cameron and his parents in their house for about a year after Cameron was born. Tr at 8. She moved to her own apartment about 5 minutes away in October 2005 but still watched Cameron when his parents were working. She moved back to her home in New Orleans in July 2010. Tr at 202-03.

³ Petitioner’s exhibits which were filed with her complaint were labeled Exhibits 1-8, with the areas for Exhibits 6 & 7 being empty. Petitioner also filed records from Kentucky First Steps (First Steps) on April 2, 2012 which she named Exhibit 1 but labeled each page as PL00001-57 and several other documents on April 19, 2012 labeled PL00058-66. Those documents will be referred to by their document name and individual page number, PL00001-66.

⁴ The National Vaccine Injury Compensation 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.A. §§ 300aa-10 et. seq. Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

⁵ After an evaluation at Cincinnati Children’s Hospital Medical Center (Cincinnati Children’s), Cameron was diagnosed with Autism Spectrum Disorder (ASD) on September 11, 2007 by Dr. Susan Wiley. Pet. Ex. 2 at 170. Almost two years later on May 19, 2009, Ryan Macks, Ph.D. found that “Cameron does not ... meet full criteria for Autistic Disorder” but did qualify for a diagnosis of Pervasive Development Disorder (PDD). Pet. Ex. 3 at 66. In order to avoid any unnecessary confusion, Cameron will be referred to as having autism throughout this decision.

A. Vaccine Act's Statute of Limitations.

The Vaccine Act provides that:

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

§ 16(a)(2) (emphasis added). The Court of Appeals for the Federal Circuit has affirmed that the statute of limitations begins to run on “the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury recognized as such by the medical profession at large.” Cloer v. Sec'y of the Dept. of Health & Human Servs., 654 F.3d. 1322, 1340 (Fed. Cir. 2011). This date is dependent on when the first sign or symptom of injury appears, not when a petitioner discovers a causal relationship between the vaccine and the injury. Id. at 1339. For the Petition in this case to be timely filed, Cameron's first symptom or manifestation of onset of autism must have occurred on or after September 11, 2006.

Although in Cloer, the Federal Circuit concluded that equitable tolling of the Vaccine Act's statute of limitations may occasionally occur, the language in Cloer clearly specifies that it would be appropriate only in “extraordinary circumstances,” such as when a petitioner files an improper tort claim or is the victim of fraud or duress. Id. at 1344-45 (citing Pace v. DiGuglielmo, 544 U.S. 408, 418 (2005)). See also Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96 (1990). Equitable tolling may not apply simply because the statute of limitations deprives a petitioner of his or her claim. Cloer, 654 F.3d at 1344. No evidence has been proffered which would trigger equitable tolling in this case.

B. First Symptom or Manifestation of Onset of Autism.

Respondent has submitted several articles and testimony from the Omnibus Autism Proceeding (OAP)⁶ regarding the identification of the first symptoms of autism. R's Report at 5-7, Exhibits A-E. See also, White v. Sec'y of the Dept. of Health & Human Servs., 04-337V, 2011 WL 6176064 (Fed. Cl. Spec. Mstr. Nov. 22, 2011). In White, the Special Master analyzed this same evidence and concluded that although not sufficient by itself to establish a diagnosis of autism, speech and language delay can constitute the first symptom or manifestation of onset of autism. White, 2011 WL 6176064 at *15-17. The undersigned agrees with this conclusion.

⁶ The Omnibus Autism Proceeding consists of a large group of petitions alleging that certain childhood vaccinations cause or contribute to the development of a serious neurodevelopmental disorder known as autism spectrum disorder (ASD) or autism. The Petitioners' Steering Committee (PSC), an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of autism. The OAP test case decisions can be found at <http://www.uscfc.uscourts.gov/node/5026>.

C. Cameron's First Symptom or Manifestation of Onset of Autism.

Cameron was born on October 1, 2004. He was seen at Pediatric Associates, PSC (Pediatric Associates) for all well child check-ups from his one month until his one year old check-up on October 10, 2005. See, e.g., Petitioner's Exhibit (Pet. Ex.) 2 at 34. The medical records for Cameron's one year old well child check-up indicate that he "[d]rinks from cup and bottle, [is] walking well, says 3-4 words and babbles, [and] feeds himself." Id. at 50.

Unfortunately, Cameron's medical records for the next year contain little or no evidence of his development as he did not attend another well child check-up until October 10, 2006 when he was two years old. See id. at 75. In an affidavit, petitioner explains that Cameron missed his 15 month old well child check-up because he was ill and his 18 month old well child check-up because she forgot. Petitioner's Third⁷ Affidavit filed June 28, 2010 (Pet. Affidavit # 3) at 1. She added that since Cameron saw his pediatrician shortly after turning 18 months old for a cold, she "thought that visit dismissed the need to reschedule the 18-month well visit." Id. Petitioner's explanation is supported by the medical records filed which show no paperwork for either well child check-up, but do contain paperwork from a visit to Pediatric Associates one week before Cameron turned 15 months old and a visit one month after Cameron turned 18 months old, both for colds.⁸ Pet. Ex. 2 at 59-62.

In the year between Cameron's one year and two year old well child check-ups, Cameron was seen at Pediatric Associates eight times for illnesses, most often for nasal congestion due to a cold, sinusitis, or allergies. See, e.g., Pet. Ex. 2 at 59. Cameron was given his first dose of amoxicillin on June 6, 2006 for acute sinusitis and prescribed an inhaler on August 22, 2006. Id. at 64. Cameron also was diagnosed with an ear infection during an October 25, 2005 visit and was taken to the emergency room on September 25, 2006 after ingesting mushrooms from the yard. Id. at 53, 117. Although there are numerous medical records during this time, all deal with Cameron's reason for his visit, his illness, and do not contain any information concerning Cameron's development.

The only indication of Cameron's development during this time can be found in Cameron's records from First Steps Kentucky (First Steps). On the form titled Parent/Guardian Report of Developmental History which appears to have been completed on the intake date, November 3, 2006, by the Initial Service Coordinator, Kathy Rudnick, there is an entry

⁷ This affidavit is actually titled Second Supplemental Affidavit of Collette M. Ridge. Since petitioner filed an affidavit with her Petition on September 11, 2009 and a second affidavit on June 7, 2010, this affidavit is actually the third affidavit filed by petitioner. Therefore, the affidavit will be referred to by the undersigned as the third affidavit filed by petitioner or Affidavit # 3.

⁸ In her testimony, petitioner indicated that Cameron missed both appointments due to illness and her understanding that he should not be vaccinated when ill. Tr at 9. However, the medical records do not show a visit to Pediatric Associates for any illness between the time of his 15 and 18 month old well child check-ups but only one visit for a cold on May 4, 2006, approximately one month after Cameron reached 18 months. See Pet. Ex. 2 at 61. Although Cameron could have been sick when he reached 18 months of age and his parents felt that a visit or call for that illness was not necessary, a more likely explanation is that petitioner's earlier and more detailed recollection in her affidavit filed on June 28, 2010 is more accurate. See Pet. Affidavit # 3. Regardless of the reason, it is apparent that Cameron did miss his 15 and 18 month old well child check-ups.

indicating Cameron's parents were concerned that although Cameron "vocalizes a lot," he has "no real words." First Steps' Records at PL00005. The form includes an entry that the concern was "identified or noticed" when Cameron was "18 mos," which would have been on April 1, 2006. Id. In addition, Cameron's father, Jeffrey Ridge, testified that he became concerned about Cameron's lack of speech when he was approximately 15 months old which would have been on January 1, 2006. Tr at 165.

Cameron's medical records do show that he had an appointment to see an audiologist, Dr. Bryon J. Krol, on the same day as his two year old well child check-up, October 10, 2006. Pet. Ex. 2 at 121. The medical records clearly indicate that the motivation for seeking the hearing evaluation was Cameron's lack of speech development. Pet. Ex. 2 at 121-22; Dr. Krol's Medical Records at PL00064. Although Cameron's parents provided differing reasons on several occasions,⁹ they both admitted in their testimony that they wanted the hearing evaluation because they were concerned that Cameron was behind in his speech development, that he was not using as many words as he should have been. Tr at 53, 166.

It is unclear whether Dr. Hsu referred Cameron to Dr. Krol for this hearing evaluation or if Cameron's parents made the appointment themselves. Compare Dr. Krol's Medical Records at PL00063 with Pet. Affidavit #2 at 1-2, Tr at 52, 166. However, Cameron's parents have consistently stated that they made this appointment themselves and it is conceivable that Dr. Krol input Dr. Hsu as the referring physician and prepared a follow-up letter for him on the information provided by Mr. Ridge. See Tr at 168. Petitioner testified that she "made 99.9 percent of all appointments" but could not remember exactly when she scheduled this appointment. Tr at 53-54. However, she believed it was a few weeks beforehand which would have been around September 26, 2006. Id. Therefore, it follows that Cameron's parents must have been aware of Cameron's speech delay for a period of time sufficient enough in duration to prompt them to seek a hearing evaluation. It would be highly unlikely that this period would be less than the 16 days. Therefore, the appointment with Dr. Krol supports the information in the records from First Steps and the testimony of Cameron's father that Cameron was exhibiting symptoms of speech delay prior to September 11, 2006.

Finally, a referral form from First Steps dated October 4, 2006 indicates that Cameron was referred to First Steps by someone at his daycare,¹⁰ Abby's DayCare, because of speech delay. First Steps' Records at PL00009. This referral form contains a notation of "speech delay – says no words – concerned about autism." Id. The same logic applies here in that Cameron's daycare provider must have witnessed Cameron's speech delay for a period of time sufficient

⁹ In their affidavits filed June 7, 2010 which are almost identical, both parents indicated that Mr. Ridge took Cameron to see Dr. Krol for "an annual hearing examination." Affidavit of Collette Ridge (Pet. Affidavit # 2) at 1; Affidavit of Jeffrey Ridge at 1. In petitioner's third affidavit filed June 28, 2010, she indicates that she made the appointment with Dr. Krol because Cameron "seemed to suffer recurring ear infections." Pet. Affidavit # 3 at 1-2.

¹⁰ Both Cameron's parents testified that Cameron's father learned about First Steps from a lady he met at a special needs event which petitioner indicates was in mid-October. Tr at 33-34, 177-78. They claim that they initiated contact with First Steps though a phone call on October 30, 2006. Id. However, this testimony is contradicted by the existence of this referral form and notations on the First Steps Contact Sheet which indicate a phone call with Cameron's father on October 6, 2006 and further communication concerning an appointment for evaluation which was scheduled for October 25, 2006 and but later canceled. First Steps' Records at PL00001.

enough in duration to prompt Cameron's referral to First Steps on October 4, 2006. The speech delay was significant enough in extent and duration to cause a concern that Cameron was autistic.

There is evidence that Cameron exhibited symptoms of speech delay prior to September 11, 2006. At the fact hearing, Cameron's father testified that he noticed Cameron's speech delay eight months earlier when Cameron was 15 months old. The records from First Steps indicate that Cameron's speech delay was identified five months earlier when Cameron was 18 months old. In addition, for petitioner's case to be timely filed, petitioner and Cameron's daycare provider both would have needed to have witnessed Cameron's speech delay for less than a month before his symptoms prompted them to seek, respectively, an evaluation from Dr. Krol on October 10, 2006 and a referral to First Steps on October 4, 2006. It is exceedingly unlikely that Cameron's symptoms were witnessed for less than a month. When considered with the other evidence of delay at 15 and 18 months respectively, it is clear beyond doubt that Cameron's symptoms existed well before September 11, 2006, thus prompting the Dr. Krol evaluation and the referral to First Steps.

The undersigned finds by preponderant evidence that Cameron experienced symptoms of speech delay, most likely when he was 15 to 18 months of age, but definitely prior to September 11, 2006. Petitioners have failed to file any persuasive evidence to the contrary.¹¹

II. Validity of Facts Upon Which Dr. Frye's Based his Expert Opinion.

Dr. Frye provided a total of three expert reports in this case. Dr. Frye indicates that he based his expert reports on a review of Cameron's medical records, tests administered to Cameron, and the factual record of events as told to him by Cameron's parents, primarily the petitioner.¹² The Federal Circuit has found that an expert's opinion is only as good as its factual predicate. Perreira v. Sec'y of the Dept. of Health & Human Servs., 33 F.3d 1375, 1377 n. 6 (Fed. Cir. 1994). Therefore, it is important to address the validity of the facts upon which Dr. Frye relied.

¹¹ Dr. Hsu diagnosed Cameron with "[d]ysphasia, dysarthria, and other speech disturbance" at his two year old well child check-up on October 10, 2006. Pet. Ex. 2 at 77. That same day, Dr. Krol concluded that Cameron's hearing was normal as did Dr. Thomas J. Kereiakes approximately seven months later. Pet. 2 at 121-22. Petitioner testified that others in Cameron's family experienced speech delay but has not provided evidence of any other illness or condition to which Cameron's speech delay can be attributed. Tr 19-20.

¹² Petitioner's post hearing briefs indicate that "Dr. Frye's opinion was informed by facts from Cameron's medical file, objective tests by Genova Laboratories and Baylor College of Medicine, and Cameron's history provided by his parents." Petitioner's Posthearing Memorandum (Pet. Memo) at 1; Petitioner's Posthearing Reply Memorandum (Pet. Reply Memo) at 1. In his second expert report, Dr. Frye makes it clear that he obtained his understanding of the events following Cameron's October 10, 2006 vaccinations from "Cameron's medical records, as well as consistent anecdotal evidence from Cameron's mother." Supplemental Report of Dr. Frye filed June 7, 2010 (Expert Rep. # 2) at 9.

A. Dr. Frye's Expert Reports.

Attached to the Petition, petitioner included the first expert report¹³ from Dr. Frye. In this report, Dr. Frye concluded that Cameron suffers from an underlying mitochondrial dysfunction and, therefore, experienced “developmental regression and brain injury” as a result of childhood vaccinations. Pet. Ex. 5 at 1-2. Dr. Frye based his opinion, in part, on the assertion that “[a]t approximately 2 years of age, Cameron Ridge was given 8 vaccines,¹⁴ after which he developed a persistent low grade fever that developed into a viral type illness with high fever.” Id. at 1.

In response, respondent alleged that Dr. Frye was not qualified to opine in this case and had based his opinion on the unproven assertion that Cameron has a mitochondrial dysfunction which respondent argued “is not established from Cameron’s numerous records.” R’s Report at 15. Respondent insisted that petitioner has not demonstrated that Cameron’s autism was caused by his vaccinations. Id. at 17.

On June 7, 2010, petitioner filed a second expert report, titled Supplemental Report by Dr. Frye (Expert Rep. # 2). In this report, Dr. Frye clarified that he believes Cameron “suffered autism as a direct result of the administration of a series of vaccinations that culminated in a series of childhood vaccinations on October 10, 2006.”¹⁵ Expert Rep. # 2 at 1. He explained that because Cameron’s immune system was already weakened by his mitochondrial dysfunction, the “battery of vaccinations” that he received at his two year old well child check-up on October 10, 2006¹⁶ particularly insulted his immune system. Id. Dr. Frye clearly based his opinion on “Mrs. Ridge’s credible description of post-vaccination fever, illness, lethargy and a **sudden and profound** loss of communication and relational skills in the 2 ½ - 3 weeks following the administration of the vaccines on October 10, 2006.” Id. at 9 (emphasis added). In this second expert report, Dr. Frye included an explanation of his credentials. He explained that he believes Cameron to have a mitochondrial dysfunction based on his medical history, tests performed by Genova Laboratories which were attached to his first expert report, and additional blood and urine tests which he ordered performed at Baylor College of Medical at Houston, Texas which he discusses but which were not filed. Id. at 1-7.

On June 25, 2010, respondent filed a response in which she insisted that “Dr. Frye’s opinion that Cameron suffered an encephalopathy is inconsistent with the medical records” and that “some of petitioner’s statements regarding Cameron’s condition are not corroborated by the medical record.” R’s Response at 3. In particular, respondent pointed to the confusion

¹³ Petitioner and respondent also refer to this document as Dr. Frye’s affidavit. See, e.g., Petition at 4; R’s Report at 14.

¹⁴ Throughout the record, including Dr. Frye’s expert reports, there seems to be confusion as to which vaccinations Cameron received during his two year old well child check-up. See discussion infra Part II.B.1.

¹⁵ This claim more closely mirrors what petitioner alleges in her Petition, that Cameron’s autism was caused by the vaccinations that he received between October 1, 2004 and October 10, 2006. See Petition at 1-2.

¹⁶ Dr. Frye lists 5 vaccinations which he says Cameron received on that date. In his first expert report, Dr. Frye stated that Cameron received 8 vaccinations. Pet. Ex. 5 at 1.

surrounding the vaccines given to Cameron during his two year old well child check-up and different allegations as to which vaccines caused Cameron's autism. Id. at 3. Respondent also questioned the duration and extent of Cameron's fever following his October 10, 2006 vaccinations and the occurrence of the sudden regression that petitioner claimed occurred on October 28, 2010. Id. at 4-5. Respondent noted that Dr. Frye failed to address the evidence of Cameron's prior speech delay and the fact that he had "missed milestones recorded during the October 10, 2006 well child visit." Id. at 4. See also supra Part I.C.

Petitioner filed Dr. Frye's final expert report, titled Second Supplemental Report of Dr. Frye (Expert Rep. # 3) on September 7, 2010. Dr. Frye reiterated the opinion he stated in his second expert report that "Cameron suffered autism as a direct result of the administration of a series of childhood vaccinations that culminated in a battery of vaccinations on October 10, 2006." Expert Rep. # 3 at 1. He emphasized "an unbroken chain of (1) vaccination (2) persistent fever, and (3) sudden regression, each occurring in rapid succession" as demonstrating "a causal connection between the events." Id. at 3. Dr. Frye also cited to medical literature which he says shows "that many of the children with mitochondrial dysfunction experienced developmental regression resulting in autism following a fever of at least 101 lasting 3 or more days." Id.

B. Analysis.

Since Dr. Frye has based his expert opinion on this unbroken chain of events, it is important to determine if those events did in fact occur in this case. Although Dr. Frye also based his opinion on his conclusion that Cameron suffers from a mitochondrial dysfunction, the fact hearing did not address that issue. Therefore, this decision will not address the validity of the medical opinion, but will analyze only the factual predicate for that opinion.

1. Vaccinations.

The contemporaneous medical records in this case clearly show that at his two year old well child check-up on October 10, 2006 Cameron received the following vaccinations: diphtheria-tetanus-acellular pertussis vaccine (DTaP), Hepatitis B/Haemophilus influenza vaccines (Hep B/Hib), and measles, mumps, and rubella vaccine (MMR).¹⁷ Pet. Ex. 1 at 1. Therefore, Cameron received 3 vaccinations, containing a total of 8 antigens on that date.

However, in his first expert report which was filed with the Petition, Dr. Frye claimed that Cameron received 8 vaccines when he was two years old. Pet. Ex. 5 at 1. In his second expert, Dr. Frye reduces this number to 5 which he lists by name. Expert Rep. # 2 at 9. He erroneously includes two vaccines: inactivated polio (IPV) and Prevnar, also known as pneumococcal conjugate vaccine (PCV). Id. Cameron's medical records indicate that Cameron

¹⁷ When filing this claim, petitioner alleged that Cameron developed autism after receiving a "series of vaccinations" between October 1, 2004 and October 10, 2006. Petition at 1-2. In her Petition, she listed each vaccination and the date it was given. Id. at 2-3. Petitioner's list perfectly mirrors what is shown in Cameron's medical records. Compare Petition at 2-3 with Pet. Ex. 1.

received the required dose¹⁸ for those vaccinations at his one year old well child check-up on October 10, 2005. Pet. Ex. 1 at 1-3. See also, Petition at 2-3.

It appears that Dr. Frye obtained his erroneous information from petitioner. With regard to his claim that Cameron received 8 vaccines, there are two handwritten notes in Cameron's medical records indicating that he received "8 vaccines" at his October 10, 2006 well child check-up. Pet. Ex. 2 at 75, 83. Petitioner testified that she made at least one of those notations. Tr at 65. Given the similar handwriting, it is logical to conclude that she made the other notation as well. Also, petitioner testified that Cameron "got four shots on October 10 that consisted of eight different viruses." Tr at 26. With regard to Dr. Frye's claim that Cameron received the IPV and PCV vaccinations on October 10, 2006, there is another handwritten note in Cameron's medical records which lists the vaccines that he received on October 10, 2006 by name and includes these two extra vaccines. Pet. Ex. 2 at 77. In addition, petitioner consistently incorporates these extra two vaccines in all filings after the Petition. See, e.g., Petitioner's Prehearing Submission at 2.

Dr. Frye is clearly relying on the information told to him by petitioner and/or contained in handwritten notes which were added later and are not a part of the contemporaneous medical records. Since any doctor who reviewed these medical records would be able to tell that the statements contained in Dr. Frye's expert reports were incorrect, it indicates that Dr. Frye either did not carefully review all of the medical records or chose to ignore the information they contained. Still, the critical issue for this decision is the symptoms, if any, immediately following Cameron's vaccinations.

2. Persistent Fever.

Dr. Frye also based his medical opinion on the claim that Cameron experienced a persistent fever following his October 10, 2006 vaccinations. He described the fever as occurring within 24 hours of vaccination, reaching 101 degrees, and persisting "until the sudden regression" petitioner claims that Cameron experienced on October 28, 2006 Expert Rep. # 3 at 3. Dr. Frye contends that the medical records show this prolonged fever. Id. at 2.

The medical records do indicate two phone calls on October 13 and 16, 2006 to Pediatric Associates after Cameron received his October 10, 2006 vaccinations. However, the records from the call on October 13, 2006 clearly indicate that it was Cameron's allergies which were discussed during that call and that his allergy medication, Zyrtec, was the purpose of the call. Pet. Ex. 2 at 81. There is no indication in the record of fever. Id. Petitioner testified it was her understanding the call was to discuss Cameron's fever and the dosage of Tylenol, not his allergies. Tr at 62. However, she admits that she was not home at that time and that Cameron's

¹⁸ Having already received three IPV vaccinations, Cameron would not be ready for his fourth and last dose of that vaccination until he was between the ages of four to six years old. Since he received his fourth PCV vaccination, it is unlikely that Cameron would have needed an additional dosage of this vaccine as a fifth dose is only required for certain children ages two to six years old. See Centers for Disease Control and Prevention (CDC), *Recommended Childhood and Adolescent Immunization Schedule –United States, 2006*, Morbidity and Mortality Weekly Report (MMWR) 2005;54 (Nos. 51&52):Q1—Q4. This schedule also can be found at the following website: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5451-immunizational.htm>

father made this phone call. Tr at 61-63. Cameron's father agreed that he placed the phone call to Pediatric Associates and also claims the call was about Cameron's fever and to discuss Tylenol. Tr at 154, 170. However, when asked, he could not recall if he also discussed Cameron's allergies or his allergy medication, Zyrtec. Tr at 171.

With regard to the October 16, 2006 phone call, both of Cameron's parents again testified that Cameron's father placed the call because Cameron had a fever.¹⁹ Tr at 64, 171. Indeed, the medical records indicate "Nurse call – dad calling for Tylenol dosage - info. given." Pet. Ex. at 82. Cameron's current medications also are listed but there is no other information concerning the reason for the call. Id. Based on the inquiry concerning Tylenol, however, it can be reasonably inferred that Cameron was experiencing a fever as Tylenol is a common treatment for fever.

Cameron's parent and grandmother all testified that his fever continued until the morning of October 28, 2006. See, e.g., Tr at 26, 193. However, Cameron's parents do concede that the fever was often a low grade fever of approximately 99 degrees. Tr at 27, 175. Cameron's grandmother described the fever as lasting "[a] couple of weeks, two weeks, three weeks" and claimed that Cameron was lethargic during that same time period. Tr at 193-95. To illustrate the difference in Cameron's behavior she gave the example that Cameron would let his legs go limp when she picked him up instead of wrapping them around her waist as he did prior to that time.²⁰ Unfortunately, Cameron's medical records do not contain evidence that Cameron's parents visited or called Pediatric Associates or any other individual concerning Cameron's fever until ten days later on October 26, 2006.

Cameron's medical records show that his fever either returned or spiked around October 24, 2006. The records indicate that Cameron's father took him to see Dr. Deis at Pediatric Associates on October 26, 2006 because he had been experiencing a fever of 100-101 degrees for two days. Pet. Ex. 2 at 83. The record of that visit also indicates that Cameron vomited twice and was holding his left ear. Id. Dr. Deis diagnosed an ear infection, and prescribed an antibiotic, Augmentin. Id. at 3.

Cameron's medical records do not support the conclusion that Cameron's October 10, 2006 vaccinations caused a fever within 24 hours which persisted and ultimately reached 101 degrees. Although it is conceivable that Cameron had a fever when his father called Pediatrics Associates on October 13, 2006 to obtain a refill for Cameron's allergy medication, if he had discussed the fever during this first call there should have been an entry in the medical records

¹⁹ Note that Cameron's father also testified that Cameron was prescribed an antibiotic during the October 16, 2006 phone call. Tr at 155, 170-71. That claim is not supported by the medical records which indicate that Dr. Deis prescribed the antibiotic cited by Cameron's father, Augmentin, during an office visit ten days later. See Pet. Ex. 2 at 84.

²⁰ It is clear that Cameron's grandmother spent time with Cameron and was familiar with his behavior as she gave very detailed examples of it. See, e.g., Tr at 188-89. However, there is some confusion as to whether she is remembering Cameron's behavior during the alleged two week period of fever or after the sudden regression petitioner is claiming Cameron experienced on October 28, 2006. Compare Tr at 194-95 with Affidavit of Patricia Favalora at 1-2 (this affidavit was filed December 9, 2011 as an attachment to Petitioner's Prehearing Submission with Witness and Exhibit Lists).

concerning that discussion. In addition, Cameron's father testified that Cameron was prescribed an antibiotic, Augmentin, during the second phone call on October 16, 2006, a fact clearly not supported by the medical records. See supra note 19. A plausible explanation for this error is that Cameron's father remembers calling Pediatric Associates once on October 16, 2006 because Cameron had a fever, and Cameron was prescribed an antibiotic the next time he saw or spoke to one of Cameron's doctors, in this case Dr. Deis on October 26, 2006. Because Cameron's father now recalls asking about a fever on October 13, 2006, he has moved Dr. Deis' act of prescribing the antibiotic to the October 16, 2006 phone call. This confusion highlights the faulty nature of a person's memory when recalling matters which occurred five years earlier and emphasizes the logic of awarding greater credibility and weight to information contained in contemporaneous medical records.

In contrast, the medical records from the October 16, 2006 phone call do indicate that Cameron had a fever six days after vaccination. It does make sense that Cameron could have been experiencing a fever on October 16, 2006 but not necessarily earlier. One of the vaccines Cameron received on October 10, 2006 was the MMR vaccination which is known to cause fever during the period five until fifteen days following vaccination. For Cameron this period would have been from October 15 – 25, thus explaining his fever on October 16, 2006. See 42 C.F.R. § 100.3 (2010) (a Table Injury of acute encephalopathy caused by the MMR vaccination is noted to occur within that time period). However, there is no notation that the fever was extremely high and certainly none that it is was high enough to warrant a visit to the doctor's office. The phone call on October 16, 2006 appears to constitute a simple inquiry as to the appropriate Tylenol dosage. Since there is no follow up call or visit for ten days, it appears that the Tylenol was sufficient to at least control if not eliminate any fever. Cameron's father reinforces this conclusion when he told Dr. Deis on October 26, 2006 that Cameron's fever had been occurring for only two days.

Although Cameron's parents and grandmother testified that his fever began within 24 hours of receiving his vaccinations on October 10, 2006 and continued until October 28, 2006, there is no evidence in the medical records that he was experiencing a fever from October 16, 2006 until October 24, 2006.²¹ After the phone call on October 16, 2006, Cameron's parents did not call or visit Pediatric Associates until October 26, 2006. In contrast, there are numerous entries indicating that Cameron's parents called or visited Pediatric Associates at other times for numerous other illnesses. Furthermore, Cameron's father testified that he was told to contact Cameron's doctor if his fever lasted more than 72 hours. Tr at 151. He cited these instructions in an effort to show that he placed the October 13, 2006 phone call to discuss fever and not just Cameron's allergies. Tr at 153-55. Unfortunately, this testimony then raises the question of why he did not call or visit Pediatric Associates again until October 26, 2006. Since Cameron's parents were very proactive about obtaining medical care any time he was ill, it is incongruous that they did not call or visit the doctor during this time if Cameron was in fact experiencing a persistent fever during those 10 days.

²¹ Because Cameron's father took him to Pediatric Associates on October 26, 2006 and told Dr. Deis that Cameron had been experiencing a fever for 2 days, the medical records do indicate that Cameron experienced a fever on October 24, 2006. The medical records do not indicate that Cameron experienced a fever from October 16, 2006 until October 24, 2006 and show no contact from Cameron's parents from October 16, 2006 until October 26, 2006.

The undersigned finds that it is likely Cameron experienced a fever on October 16, 2006 which was caused by his October 10, 2006 vaccinations but that this fever was not significantly high and appeared to respond to the Tylenol Cameron was receiving. The undersigned believes that although the fever may have continued for the next few days as a low grade fever of 99 degrees, it is extremely unlikely that it continued unabated for the next ten days. Instead, the undersigned finds that Cameron most likely began experiencing a fever again on or around October 24, 2006 caused not by his October 10, 2006 vaccinations but by the ear infection which was diagnosed on October 26, 2006. It is important to note that both petitioner and Dr. Frye fail to address Cameron's ear infection and any effect it may have had on his fever.

The undersigned concludes that in formulating his expert opinion, Dr. Frye again has ignored the information contained in Cameron's contemporaneous medical records and instead, has relied solely upon a description of Cameron's fever as relayed to him by petitioner.²²

3. Sudden Regression.

However, the biggest discrepancy between petitioner's allegations and the medical records exists with regard to the sudden regression which Cameron's parents claim that he experienced on October 28, 2006. In giving his medical opinion, Dr. Frye clearly indicated that he relied on "Mrs. Ridge's credible description of a **sudden and profound** loss of communication and relational skills." Expert Rep. # 2 at 9 (emphasis added). Dr. Frye explains that "[d]uring this time, Cameron **suddenly and dramatically regressed**, losing a **significant** amount of vocabulary and ... eye contact." *Id.* Dr. Frye claims that the "records indicate a **profound regression** beginning suddenly on October 28, 2006." Expert Rep. # 3 at 3 (emphasis added).

Indeed, both Cameron's parents and his grandmother testified to this sudden regression. Petitioner asserted that on the morning of October 28, 2006 Cameron would no longer raise his arms when she went to pick him up, would not respond to either of his parents or even loud noises. Tr at 28-29. She claimed that Cameron lost all of his words and would not say even mama for a year and a half but would take his hand and show them what he wanted. Tr at 30-31. She said that he would not play with his toys in the same manner. Tr at 32. In his testimony, Cameron's father indicated the same, adding that Cameron was "withdrawn" and that "you couldn't comfort him." Tr at 159-62. In her testimony, Cameron's grandmother agreed, explaining that Cameron no longer laughed and danced to the Wiggles and would not play the games they used to play together. Tr at 195-201. All three witnesses gave detailed and consistent testimony, most especially Cameron's grandmother. Unfortunately, there is no other evidence in the record to support their claims.

²² It also appears that, Dr. Frye may have even exaggerated petitioner's version of events. In both his second and third expert reports, Dr. Frye indicates that he is relying on similarities that he finds between this case and a study involving other children with mitochondrial dysfunction as well as cases where causation has been found to exist. Expert Rep. # 2 at 8-9; Expert Rep. # 3 at 3. However, even Dr. Frye notes the fever those children experienced was at least 101 degrees, lasted 3 or more days, and "occurred **immediately** following routine vaccination." Expert Rep. # 3 at 3 (emphasis added). Dr. Frye seems to be basing his medical opinion on a persistent fever which is not supported in the medical records or even the testimony taken at the fact hearing.

Instead, the record shows speech delay, which most likely became apparent when Cameron was 15 or 18 months of age. See supra Part I.C. As mentioned earlier this speech delay prompted Cameron's parents to schedule an appointment for a hearing evaluation on October 10, 2006 and a daycare provider to refer Cameron to First Steps on October 4, 2006. Id. In contrast, Cameron's parents claim they initiated contact with First Steps on the Monday following October 28, 2006 because they were extremely concerned by the sudden regression they witnessed. Tr at 29, 33-34, 163, 177-78. However, as discussed earlier, the records from First Steps clearly show that Cameron was referred to them on October 4, 2006 because of a concern that he was exhibiting speech delay and may be autistic. See supra Part I.C. and note 10. This is 6 days prior to his October 10, 2006 immunizations.

The First Steps' records indicate that an appointment for an initial evaluation was scheduled for October 25, 2006 at 11 AM at Cameron's home. First Steps' Records at PL 00001. The records also contain notations that Cameron's father left a message on 10/22/06 at 3 PM that he needed to cancel and reschedule the appointment, that someone from First Steps left messages for Cameron's father on 10/23/06 at 11 AM and 10/24/06 at 2 PM in an attempt to reschedule the appointment, that a letter was sent to the family on 10/25/06, and that the case would be closed by 10/30/06, presumably if First Steps had not heard from Cameron's parents. Id. While Cameron's behavior may have prompted his parents to call First Steps on Monday, October 30, 2006, to reschedule their canceled appointment, the records clearly indicate they had spoken to First Steps prior to that call.

On November 3, 2006, Cameron's parents met with an Initial Service Coordinator, Kathy Rudnick. In the intake documents, she noted that Cameron "is not saying any real words – babbles a lot & says mamama and dadada" and that this concern occurred at 18 months of age. First Steps' Records at PL00005, PL00007. However, there is no mention of any type of regression in the intake documents. Critically for this decision, there is no mention of the sudden regression petitioner claims occurred on October 28, 2006, just 6 days earlier.

On November 4 and 28, 2006, Cameron was evaluated by Kathy Alexander and Julie Roberts, respectively. The records from both evaluations state that the purpose of the evaluation was for speech delay.²³ Pet. Ex. 2 at 136, 141. There is no mention of regression or any indication that Cameron's behavior had changed in any way.

In her report from the evaluation on November 4, 2006, Ms. Alexander did note that she "could not understand any words that Cameron tried to say" and that "[w]hen he wanted something from one of his parents, he would take their hand and lead them to what he wanted." Id. at 137. This information appears to support the testimony of Cameron's parents and grandmother. All testified that he had little or no language at this time. Tr at 30, 161, 195-95. However, since he clearly was experiencing speech delay prior to this time, the fact that Ms. Alexander could not understand what Cameron was trying to say does not necessarily show regression. See supra Part I.C. See also Pet. Ex. 2 at 77 (Cameron was diagnosed with

²³ Note that Kathy Alexander testified that for her evaluation on November 4, 2006, this entry came from the Kathy Rudnick, the Initial Service Coordinator. Tr at 118-19.

dysphasia, dysarthria, other speech disturbance on October 10, 2006). In addition, although both petitioner and Cameron's grandmother testified that Cameron would touch the refrigerator when he wanted something as evidence of regression, Cameron's father testified that he was doing so prior to his second birthday. Compare Tr at 30-33, 195-96 with Tr at 147.

Ms. Alexander also documented that Cameron "enjoyed playing with his toy cars during the assessment," that "[h]e attempted some of the tasks presented by the examiner," and that if he liked a toy "he did not want to return it" but "was able to move on to other toys and tasks." Pet. Ex. 2 at 137. Under the personal-social area, Ms. Alexander indicated that "Cameron plays peek-a-boo, ... greets familiar adults spontaneously, ... plays with the family dog, ... likes to clap and dance." Id. After evaluating Cameron on November 28, 2006, Ms. Roberts noted that Cameron "eagerly played when ... toys were presented" and "maintains appropriate eye contact" which "was occasionally fleeting when he was interacting with his parents." Id. at 141-143. This information contradicts the testimony of Cameron's parents and grandmother. For example, Cameron's parents testified that on October 28, 2006, one week earlier, Cameron would not respond to or look at his father. Tr at 29, 160. Cameron's father testified that he had no eye contact. Tr at 162. Cameron's father and grandmother both testified that he would no longer play games such as paddy-cake. Tr at 162, 200. Cameron's grandmother testified that he would no longer dance or sing to the Wiggles. Tr at 199.

There is no mention of a regression, sudden or otherwise, in any of the First Steps' records. The fact that some of the information documented during these evaluations originated with Cameron's parents,²⁴ makes it even more likely that there would be some mention of Cameron experiencing a sudden regression on October 28, 2006 if it had occurred as they later remembered. Instead, Cameron's parents were informing Ms. Alexander that he "plays peek-a-boo, ... greets familiar adults spontaneously, ... plays with the family dog, ... likes to clap and dance." Pet. Ex. 2 at 137.

Both Mr. Alexander and Ms. Roberts testified that although they could not recall if Cameron's parents had informed them of any regression he had experienced, they would have included this information in their report had they been told as any change in behavior or skills is important. Tr at 114-17, 138-40. In fact, Ms. Roberts did note that Cameron's parents informed her that Cameron was vocalizing more at school and that Cameron's fussy behavior at one point during the evaluation was atypical. Pet. Ex. 2 at 141-42.

In November and December 2006, Cameron's parents also telephoned or visited Pediatric Associates on two occasions. Each time they failed to mention the sudden regression they claimed he experienced on October 28, 2006. Cameron's medical records show a telephone call on November 15, 2006 for a cough. Pet. Ex. 2 at 85. The medical records even indicate that Cameron's activity level was appropriate at that time. Id. On December 26, 2006, Cameron's father took him to Pediatric Associates because he "started with a barky cough four days ago," seemed to be "having trouble breathing a couple of days ago," and has had a fever of

²⁴ Both Ms. Alexander and Ms. Roberts indicated that parents provide information during the evaluation. Tr at 108, 114, 136. Much of the information appears to be a history which would be communicated to the evaluator by the parents. See, e.g., Pet. Ex. 2 at 137 (Personal-Social Area).

approximately 100 degrees. Id. at 86. Cameron was diagnosed with croup, an ear infection, and bronchiolitis but the medical records make no mention of a regression of any type. Id. at 87. In fact, Cameron continued to receive treatment at Pediatric Associates until September of 2007. There is no mention of regression in the medical records from that time. The last medical record from Pediatric Associates indicates a telephone call on September 6, 2007 concerning Cameron's allergies. Id. at 113.

Cameron continued his therapy with First Steps and was diagnosed with autism on September 11, 2007 by Dr. Susan Wiley at Cincinnati Children's. Pet. Ex. 2 at 170. See supra note 5. He also switched pediatricians and began seeing Dr. Robin Warner. The medical records show that he visited Dr. Warner for his three year old well child check-up on January 24, 2008. Pet. Ex. 3 at 72. Dr. Warner noted that Cameron had been diagnosed with autism, was receiving occupational and speech therapy at school as well as outside speech therapy weekly, and that they were hoping to get outside occupational therapy as well. Id. She added that he "enjoys school, ... answers questions, responds to examiner, makes eye contact, ... uses two word phrase, and "verbalizes wants/needs, though words [are] not always intelligible." Id. Under the examination section, Dr. Warner noted that Cameron interacted with her, made eye contact, and used the "three word phrase – 'I want down'." Id. Dr. Warner indicated that Cameron also was seeing a DAN doctor²⁵ but did not give the doctor's name. Id. There is no mention of any regression in the medical records from Dr. Warner.

On June 4, 2008, Dr. Michelle Zimmer at The Kelly O'Leary Center for Autism Spectrum Disorders at Cincinnati Children's (The Kelly O'Leary Center) saw Cameron in follow up to his diagnosis of autism by Dr. Wiley. Id. at 38. Dr. Zimmer ordered a "full evaluation of his developmental skills" and "a psychology evaluation" and recommended that he continued his private speech therapy but added private occupational therapy as well. Id. Again there was no mention of any regression. In fact, Dr. Zimmer simply noted that "I found Cameron's parents are concerned with lack of developmental progress." Id.

On September 23, 2008, Cameron returned to The Kelly O'Leary Center where he saw Judy Reinhold, RN. Id. at 47. The medical records from this visit indicated that Cameron was being seen because "there has been increasing concern about staring spells which may represent possible seizure activity" since his last visit. Ms. Reinhold discussed this concern and referred him for a routine electroencephalography (EEG). Id. She also discussed the protocol that Cameron was following under the guidance of Dr. Pelletier in written consultation with Dr. Amy Yasko in Bethel, Maine. Id. She explained that their practice does not recommend this therapy but encouraged Cameron's parents to share the supplements that Cameron was receiving so they could ensure that he is receiving "all dietary nutrients." Id. Cameron had an EEG on October 13, 2008 and a longer, overnight EEG on December 2-3, 2008, both of which were normal. Id. at 51, 60-61.

²⁵ DAN stands for Defeat Autism Now. Although Dr. Warner did not give a name for this doctor, from petitioner's testimony it appears that she probably was referring to Dr. Maureen Pelletier. Tr at 87-88. See also Pet. Ex. 3 at 47 (report from Cincinnati Children's which discusses Dr. Pelletier treatment of Cameron and indicates a copy of the report was sent to Dr. Pelletier as well as Dr. Warner).

On April 2, 2009, Cameron saw Ryan Macks, Ph.D. at Cincinnati Children's for his psychological evaluation. The medical history in the report from that visit, which was given to Dr. Macks by petitioner, contains the first and only mention of any regression. Of note, there is no mention of any regression immediately following vaccination or for the next two and a half years in Cameron's records, including the medical information given by Cameron's parents to Cameron's doctors or therapists at First Steps. According to the report from the visit with Dr. Macks which was sent to Dr. Zimmer, petitioner told Dr. Macks that "[a]fter Cameron's first birthday, he lost eye contact, smiles, and babbling that he demonstrated prior to that point." Pet. Ex. 3 at 62. There is evidence that petitioner either said or meant to say Cameron's second birthday and that she misspoke or the date was erroneously transcribed.²⁶ However, in the final analysis, the issue of whether petitioner said first or second birthday is insignificant. Rather, this entry is important because it is the first and only mention of a regression which was supposed to have occurred over two and a half years earlier.

As petitioner testified, she did not immediately associate Cameron's developmental problems with his vaccinations. Tr at 83. Petitioner testified that she first began doing research, reading books and going online. Tr at 82-83. She explained that she also attended an Autism One conference in Chicago where she heard Dr. Frye speak and give a presentation with Dr. Jon Poling concerning mitochondrial disorder. Tr at 84. Petitioner testified that she had not heard this information before, that it "was all brand new to" her. Id. She added that she "thought maybe that's what happened" to Cameron. Id. To investigate this possibility, petitioner testified that she reached out to Dr. Frye after first speaking to Dr. Zimmer who would not help. Tr at 87-88.

The testimony of Cameron's parents and grandmother is not supported by the record in this case. It is clear that the sudden regression petitioner alleges is not evident in the contemporaneous records, either the medical records or records from First Steps. The only entry concerning any type of regression is given by petitioner herself to Dr. Macks on April 2, 2009, almost two and a half years after the regression was supposed to have occurred, and after petitioner has spent time reading about other cases and speaking to Dr. Frye and Dr. Poling.

Based on the totality of the evidence, the undersigned finds that the medical records set forth the facts to be relied upon in this case. The undersigned finds the medical records are complete, consistent, and reliable. The lay witness testimony, occurring years after the events in question, simply is not credible when measured against the contemporaneous medical records. This is especially so because the medical records contain factual information given by the parents at the time in question.

²⁶ Dr. Macks' report also erroneously indicates that Dr. Wiley diagnosed Cameron with autism when he was two years old rather than the correct age of three. Pet. Ex. 3 at 62. However, the records indicate that petitioner also told Dr. Macks that the regression occurred while Cameron was being treated for nineteen ear infections which she testified occurred between Cameron's first and second birthdays. Tr at 47, 81.

III. Post-Hearing Briefs.

The undersigned has reviewed petitioner's post-hearing briefs and does not find petitioner's arguments persuasive. Petitioner continues to claim that Cameron suffered a persistent fever and sudden regression following his October 10, 2006 vaccinations. She asserts that "on these [factual] issues, medical records and witness testimony are consistent." Petitioner's Post-Hearing Reply Memorandum (Pet. Reply Memo) at 1. As discussed above, the undersigned disagrees.

Agreeing with respondent, petitioner admits that "medical records are reliable evidence *when made contemporaneously* with the events they described" but argues that they are not "infallible." *Id.* at 2 (emphasis in original). To prove this point, petitioner points to an apparent error found in a portion of the medical records. Pet. Reply Memo at 2. *See supra* Part II.B.3. However, this entry involves information given by petitioner as medical history concerning events which she says occurred at least two and a half years earlier. Clearly, this portion of the medical record can not be described as contemporaneous.

Finally, petitioner seems to equate any attempt to discount a witness' testimony with a belief that the witness is lying. *Id.* at 3. The undersigned disagrees with that premise. It is normal for a witness to forget or confuse events as time passes. In addition, events often look different in hindsight and perceptions change. As petitioner herself indicated, seeing Cameron compared to his cousins made his difference in behavior look more significant. Tr at 94-95. It is clear to the undersigned that Cameron's parents and grandmother are loving, caring people who provide the best for Cameron. Their memories are at issue, not their truthfulness.

IV. Conclusion.

The undersigned has considered the lay witness testimony in conjunction with the records in this case. The undersigned finds that the medical records present the factual predicate for any expert opinion. The lay witness testimony is rejected.

As discussed, Dr. Frye relied heavily on petitioner's description of events when formulating his medical opinion, often ignoring information contained in the medical records. The undersigned finds that the facts upon which Dr. Frye based his medical opinion are not valid. As stated above, the Federal Circuit has found that an expert's opinion is only as good as its factual predicate. *Perreira*, 33 F.3d 1377 n. 6. Since Dr. Frye's factual predicate is incorrect, it follows that his opinion fails as well.

The undersigned also finds that Cameron experienced symptoms of speech delay prior to September 11, 2006, mostly likely when he was 15 or 18 months old. As discussed in *White*, speech delay can be the first symptom or manifestation of autism. Thus, there are serious statute of limitations issues in this case; the Petition appears to be untimely filed. Furthermore, the fact that Cameron experienced speech delay prior to his October 10, 2006 vaccinations undermines the theory of causation in this case.

The medical records form the factual predicate for analyzing and resolving this Petition. Thus, the petitioner must either **dismiss this case for lack of proof, or provide a new medical opinion** from Dr. Frye or another medical expert based on the factual information in the medical records in this case. The opinion must address the issue of the first symptom or manifestation of onset of Cameron's autism, which is critical to show that the Petition was timely filed under the Vaccine Act's statute of limitations.

Petitioner shall file within thirty (30) days, by no later than October 11, 2012, a status report informing the court of how petitioner intends to proceed. If petitioner intends to file a supportive medical opinion, petitioner shall state when she anticipates filing the opinion.

IT IS SO ORDERED.

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