

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 01-14V
Filed: June 30, 2011

ROBERT DEL MONTE and EVA DEL MONTE, as Parents, Natural Guardians and Legal Representatives of their Minor Child, Matthew Del Monte,	*	
	*	Factual Findings; MMR Vaccine;
	*	Autism; Encephalopathy;
Petitioners,	*	Medical Records; Video Records
V.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
	*	
Respondent.	*	
	*	

ORDER SETTING FORTH FACTUAL FINDINGS¹

Vowell, Special Master:

On January 8, 2001, Robert and Eva Del Monte ["petitioners" or "Mr. and Mrs. Del Monte"] 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, Matthew ["Matthew"]. The most recent amended petition,³ filed on January 4, 2002 ["Amend. Pet."], alleges that a measles,

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² 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).

³ The original petition alleged that a measles, mumps, and rubella ["MMR"] vaccine that Matthew received on January 5, 1998, caused him to develop the Table injury known as residual seizure disorder resulting in an autism diagnosis. Petition, filed Jan. 8, 2001, ¶¶ 3, 10, 12. Because residual seizure disorder was removed from the Vaccine Injury Table in 1997 as an injury presumptively caused by the MMR vaccine,

mumps, rubella [“MMR”] vaccination Matthew received on January 5, 1998, caused an encephalopathy and “resulting neurological sequela.” Amend. Pet., ¶¶ 3, 12. The petition also alleges that Matthew has been diagnosed with autism. *Id.*, ¶ 10.

Although originally represented by counsel, petitioners filed a motion to proceed *pro se* on February 21, 2003. Petitioners subsequently secured representation by their current attorney on May 27, 2003. At petitioners’ request, this case became part of the Omnibus Autism Proceeding [“OAP”] on March 10, 2004.⁴

This case was reassigned to me on April 2, 2007. While the OAP test cases were being heard, decided, and appealed, I ordered petitioners to file missing and updated medical records to position the case for resolution at the conclusion of the appellate process in the test cases. Petitioners notified the court that the records were complete in December 2010. As the Federal Circuit had decided the final appeal in the OAP Theory 1 (MMR) test cases in September 2010, I ordered respondent to prepare a supplemental Vaccine Rule 4 report, and advised the parties to prepare for a hearing on the merits. At a December 2, 2010 status conference, respondent indicated that resolution of some factual conflicts would be helpful before obtaining expert opinions. Petitioners concurred. See Joint Status Report, filed Jan. 3, 2011.

The hearing was conducted in Newark, NJ, on February 23, 2011, with both Mr. and Mrs. Del Monte testifying in person. At the conclusion of the hearing, pursuant to my order, petitioners filed a video (Petitioners’ Exhibit [“Pet. Ex.”] 54), documenting a number of events in the life of Matthew and his family from the celebration of his first birthday through the celebration of his second birthday. I have viewed this video in its entirety. My factual findings, which are based primarily on Matthew’s medical records, other exhibits, the hearing testimony, and the filed video, are set forth in Sections II and III below.

the special master then presiding ordered petitioners to file an amended petition clearly setting forth their legal theory. See Order, filed Feb. 6, 2001. The first amended petition was filed on November 30, 2001. The second amended petition, filed on January 4, 2002, is the operative claim for compensation in this case.

⁴ 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” or “autism.” To meet the burden of establishing vaccine causation of autism spectrum disorders [“ASDs”], six “test cases” were tried under the two theories presented by the Petitioners’ Steering Committee [“PSC”]. The first three test cases presented the theory that a combination of the MMR vaccine and thimerosal-containing vaccines caused ASDs [“Theory 1”]. The second group of three test cases presented the theory that thimerosal-containing vaccines alone can cause ASDs [“Theory 2”]. The three special masters assigned to hear the test cases ruled that there was no reliable evidence that the vaccines caused ASDs. The courts that heard the appeals in the test cases all agreed with the special masters that there was no reliable evidence supporting vaccine causation.

I. Resolving Evidentiary Conflicts.

A. The Nature of the Dispute.

The primary matters in dispute are (1) Matthew's condition after his January 5, 1998 MMR vaccination, and (2) when symptoms of his autism manifested and what those symptoms were.⁵ Petitioners contend that Matthew suffered an encephalopathy, with marked behavioral changes beginning approximately two weeks after the MMR vaccination. They rely on their testimony and on the affidavits executed by them and other family members sometime before January 8, 2001.⁶ The contemporaneous medical records, medical histories provided around the time of Matthew's diagnosis with autism, and the video record of Matthew between his first and second birthdays do not support their claims that Matthew experienced a sharp decline within a few weeks of his MMR vaccination.

Determining precisely what behaviors constitute symptoms of autism may require expert opinions. Thus, I make conclusions regarding whether or when certain behaviors manifested, leaving it to experts to interpret their diagnostic significance.

B. Law Pertinent to Evidentiary Conflicts.

Conflicts between contemporaneous records and testimony given years later at a hearing are common in Vaccine Act cases, and this case is no exception. Two general legal principles guide the resolution of conflicts between contemporaneous records and later-adduced evidence. The first is that the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame. See, e.g., *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." (citation omitted)).

The second principle addresses the degree of reliance commonly accorded to contemporaneous records. 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. at 733 (citation omitted); see also *Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy)

⁵ There is no statute of limitations issue in this case, but determining when symptoms of autism manifested is relevant to petitioners' claim that Matthew experienced an encephalopathy after the MMR vaccination. See Respondent's Statement Regarding Jurisdiction and Appropriateness of Proceeding within the Omnibus Autism Proceeding, filed Nov. 19, 2008.

⁶ The affidavits were filed with the original petition on January 8, 2001, but they are undated.

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. *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). The following medical history and the conclusions drawn therefrom are presented with these legal principles in mind.

C. Credibility Determinations.

Mr. and Mrs. Del Monte are caring and loving parents who are a part of an equally caring and loving extended family. The video (Pet. Ex. 54) and Matthew's baby book (Pet. Ex. 3) paint a picture of parents, grandparents, aunts, uncles, and cousins devoted to one another and the welfare of Matthew and the other children fortunate to be a part of such a family. I am confident that the testimony and affidavits in this case contained sincere accounts of what petitioners and other family members remembered of the events between Matthew's MMR vaccination and his diagnosis with autism shortly after his second birthday.

Unfortunately, their accounts are somewhat contradicted by Matthew's medical records, his baby book, and by the video record of events between January and August, 1998. After considering the testimony given by both Mr. and Mrs. Del Monte, I placed more weight on the contemporaneous medical records and the video record than on their testimony or affidavits as support for the facts found herein. I emphasize that I do not find the petitioners to be deceptive or untruthful, merely that memories are fragile and their conflation of events appears to be a consequence of their search for a cause for Matthew's condition.

D. Scope of Ruling.

These factual findings are not intended to encompass all of Matthew's medical history to date. Because the disputes between the parties center on when Matthew's autistic behaviors began to manifest and what those manifestations were, most findings are limited to the period between Matthew's birth and his diagnosis with an autism spectrum disorder. I placed the most reliance on the contemporaneous medical records and the histories taken closest in time to the events being described. I found the video record pertaining to the period between Matthew's first and second birthdays to be particularly valuable in determining what behaviors Matthew could and did manifest.

As petitioners' counsel indicated at the hearing, the reason for conducting the fact hearing was to determine “whether or not an encephalopathy occurred” and the onset of certain symptoms Matthew displayed in relation to his MMR vaccination on January 5, 1998. Transcript [“Tr.”] at 6.

II. Undisputed Medical History.

A. Matthew's General Health.

Matthew was born on August 27, 1996, via repeat cesarean section performed due to signs of fetal distress and oligohydramnios.⁷ Pet. Ex. 4, pp. 40, 52.⁸ Nevertheless, Matthew was healthy at birth, with Apgar scores of 9 at one minute and 9 at five minutes.⁹ Pet. Ex. 4, p. 51; see also Tr. at 13.

Matthew's earliest well child visit records are unavailable.¹⁰ He was hospitalized for pneumonia in December 1996, when he was about four months old. Tr. at 13; Pet. Ex. 38. Mr. Del Monte testified that Matthew had a rectal temperature of 103° and was moaning in his sleep, so they called the doctor, who advised taking Matthew to the emergency room. Tr. at 59. The earliest available well child record, dated January 9, 1997, refers to a follow up for his pneumonia. Pet. Ex. 6, p. 132.

During the following 12 months, Matthew had numerous visits with his pediatrician, Dr. Pelliccia, for otitis media, croup, fever, and pharyngitis. See Pet. Ex. 6, pp. 132, 134-40; Pet. Ex. 7, pp. 150-64.¹¹ He was diagnosed with chronic nasopharyngitis on September 16, 1997. Pet. Ex. 6, p. 136; Pet. Ex. 7, p. 162. Although both Mr. and Mrs. Del Monte testified that Matthew had only two to three ear

⁷ Mrs. Del Monte testified that Matthew's birth was simply a repeat cesarean section and did not reference the late and variable decelerations and oligohydramnios. Tr. at 12-13. Oligohydramnios is "the presence of less than the normal amount of amniotic fluid." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (31th ed. 2007) ["DORLAND'S"] at 1338.

⁸ The exhibit pages in this case were consecutively numbered, rather than each exhibit being independently numbered.

⁹ The Apgar score is a numerical assessment of a newborn's condition, 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 at 1707.

¹⁰ Some of Matthew's early medical records from Dr. Frances Pelliccia, his pediatrician, were destroyed by a fire. See Pet. Ex. 5 (attorney affidavit describing reason for unavailability).

¹¹ Doctor Pelliccia's records are filed as Pet. Ex. 6 (containing nursing notes, vital signs, and principal complaint) and Pet. Ex. 7 (containing dictation of physical examination findings, assessment, and treatment plan). Entries on Pet. Ex. 6 are followed by a note reflecting "Dict," referring to "dictation," followed by a date, or, in later entries, a stamped date, apparently reflecting the date the notes were dictated. Entries on Pet. Ex. 7 reflect a date in the heading, the date of service (abbreviated "DOS") in the third line, and on the bottom left corner, the date of dictation and the date of transcription. In most cases, a record in Pet. Ex. 6 has a corresponding record in Pet. Ex. 7. For example, the January 9, 1997 visit is reflected on Pet. Ex. 6, p. 132 and on Pet. Ex. 7, p. 149. The dictated notes in Pet. Ex. 7, p. 149 are dated February 25, 1997, which is the date of transcription, but the record reflects that the notes were dictated on January 22, 1997.

infections during the period between his hospitalization for pneumonia and his MMR vaccination in January 1998 (Tr. at 43, 59), their recollection was flawed. There were at least seven visits for ear infections during this period,¹² in addition to those for other upper respiratory illnesses. There was at least one emergency room visit for fever and croup between Matthew's hospitalization for pneumonia and his MMR vaccination. See Pet. Ex. 7, p. 157 (discussing an emergency room visit the prior evening, June 11, 1997).

B. Matthew's Development.

Doctor Pelliccia's records do not contain any references to developmental milestones such as sitting, walking, and acquisition of language. Thus, for records of Matthew's development, I rely primarily on medical histories provided by petitioners to other health care providers, Matthew's baby book (Pet. Ex. 3), and, for the period from his first birthday through his MMR vaccination, the video record.

Matthew rolled over at five months, sat up at seven months, crawled between nine and eleven months, and walked at 14 months of age. See Pet. Ex. 3 at 17-18, 23. The baby book describes Matthew's crawl as sitting up with one leg crooked underneath him (see Pet. Ex. 3 at 17), which he displays in Titles 5 and 6 of the video. See Pet. Ex. 54, Title 5 filmed Oct. 31, 1997, Title 6 filmed Nov. 2, 1997.

He had a social smile by two-three months of age. Pet. Ex. 3 at 21. Matthew began babbling "da-da" at eight months, but was not using it in a meaningful way at that point. Pet. Ex. 3 at 25. He began sleeping through the night in mid-May, 1997, when he was almost nine months old. Pet. Ex. 3 at 26.

At his first birthday party, Matthew repeatedly said "Hap Hap Ba" or "Hap Bir" in response to people singing the "Happy Birthday" song. Pet. Ex. 54, Title 1 filmed Aug. 27, 1997, Title 3 filmed Aug. 31, 1997; Pet. Ex. 3 at 30. The baby book notation indicated that Matthew's chanting of "Hap bir day" began to fall off in the week after his birthday, and that he vocalized "go-goo-gaa ga," "mama," and "dee dee dee da," but the baby book did not describe the use of any purposeful words. Pet. Ex. 3 at 30. In the October 18, 1997 video, Matthew made "ba" sounds (Pet. Ex. 54, Title 4), and made similar sounds, plus "hap hap," on the Halloween, 1997 video (Pet. Ex. 54, Title 5).

¹² Matthew had suppurative otitis media on January 9; inflamed and draining ears (otitis externa) on January 20; otitis externa on March 22; coughing and pulling on his right ear on April 1; suppurative otitis media and purulent drainage on April 15, which was not entirely healed on April 24; otitis externa on June 12; otitis media on July 24; and an earache and tugging on his ear on August 9, 1997. See Pet. Ex. 7, pp. 149-161; Pet. Ex. 6, pp. 134, 137.

The November 2, 1997 video of Matthew walking showed him squealing, but not using words. Pet. Ex. 54, Titles 6-7.¹³ In the video of his first haircut, Matthew was mostly quiet, with a brief period of crying. Pet. Ex. 54, Title 8 filmed Nov. 15, 1997. In the Christmas videos, Matthew giggled and laughed, but did not talk. Pet. Ex. 54, Titles 9-14 filmed Dec. 24-25, 1997.

C. Uncontested Evidence Concerning Matthew's MMR Vaccination and Chickenpox.¹⁴

On January 5, 1998, Matthew, then about 15 months old, saw his physician for another ear problem. He received an MMR vaccination at this visit.¹⁵ Pet. Ex. 6, p. 140. Mrs. Del Monte testified that Matthew's older brother had chickenpox at the time Matthew was vaccinated and that Matthew's physician was aware that Matthew had been exposed. Tr. at 15, 17-18. Although Matthew's baby book indicates that his chickenpox began on January 7, 1998 and his father so testified (see Pet. Ex. 3 at 35; Tr. at 62), Mrs. Del Monte testified that he woke up with chickenpox on January 8, 1998 (Tr. at 18). There is a telephone record from Dr. Pelliccia's office on January 8, 1998, reporting that Matthew had developed chickenpox, and seeking advice. Most of the telephone record is illegible. Pet. Ex. 8, p. 170. A brief video segment of Matthew on January 8, 1998, shows his chickenpox eruptions, during which Matthew says "da dee" or "daddy." Pet. Ex. 54, Title 15; see also Tr. at 62-63.

Matthew's bout with chickenpox was much worse than his brother's was. According to both Mr. and Mrs. Del Monte, Matthew was very cranky. Tr. at 18, 66. Mrs. Del Monte also described him as more feverish and sickly. Tr. at 19. Mr. Del Monte described him as very listless and babbling. Tr. at 65.

¹³ Matthew's speaking ability is difficult to determine based on this video, as he has a pacifier in his mouth.

¹⁴ Chickenpox (varicella) is a disease caused by the varicella-zoster virus. Before introduction of the varicella vaccine, chickenpox was widespread, with 90% of cases occurring in children under age 13. The incubation period is 10-20 days. The presenting symptoms include rash, fever, and malaise. Temperatures of 100°-103° Fahrenheit for three to five days are common. 2 Gerald L. Mandell, et al., PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES 1964 (7th ed. 2010); DORLAND'S at 348.

¹⁵ There are no dictated notes from Dr. Pelliccia for this visit in any of the exhibits.

III. Evidence Concerning Contested Matters.

A. Evidence Pertaining to Matthew's Condition on January 9, 1998.

1. Mr. and Mrs. Del Monte's Accounts.

Mrs. Del Monte testified that on January 9, 1998, Matthew was inconsolable, and had a fever of 104° taken rectally,¹⁶ after being given Advil. Tr. at 21-22. Because his fever was so high, Mrs. Del Monte contacted Dr. Pelliccia's office and was told to bring him in. Tr. at 23.

According to Mrs. Del Monte, while dressing Matthew to take him to the doctor's office, Matthew had what she called a seizure, with his body rigid and flailing¹⁷ and the whites of his eyes showing. She became hysterical and called the doctor's office again. She was told to bring Matthew in to the office. Tr. at 23-24. Mrs. Del Monte testified that she did not think Matthew would "make it," and told Dr. Pelliccia that she wanted to bring him to the hospital, but Dr. Pelliccia insisted that she bring him to the office. Tr. at 25. There are no records from Dr. Pelliccia of either telephone call on January 9, 1998, although there is a record of the call on January 8th, reporting that Matthew had chickenpox. Pet. Ex. 8, p. 170.

Mrs. Del Monte could not explain why she didn't call 911, but instead called her husband, reporting to him that Matthew had a seizure. Mr. Del Monte described his wife as "hysterically crying" when she called him that morning. He attempted to calm her down. Tr. at 25-26, 67-68. Mrs. Del Monte told her husband that Matthew was "not going to make it," and told him that Matthew's eyes rolled back into his head and his arms went stiff. Tr. at 67-68.

Mr. Del Monte arranged for Mrs. Del Monte's father to take them to the doctor. Tr. at 26, 69. Matthew was listless and lethargic when they arrived. Tr. at 27.

Mrs. Del Monte could not recall how long she waited at Dr. Pelliccia's office. She reported that Dr. Pelliccia said Matthew looked really bad, and that the chickenpox looked almost like an "allergic reaction." According to Mrs. Del Monte, Dr. Pelliccia attributed the "allergic reaction" to the vaccination. Tr. at 28. Mrs. Del Monte also

¹⁶ A rectal temperature is about one-half to one degree higher than an oral temperature. See *Holmes v. Sec'y, HHS*, No.08-185V, slip op. at n.17 (Fed. Cl. Spec. Mstr. Apr. 26, 2011), *mot. for rev. docketed* (Fed. Cl. May 26, 2011).

¹⁷ I note that these two descriptions ("rigid" and "flailing") conflict. An account made about nine months after the event described Matthew as "limp," but did not mention any rigidity or flailing. Pet. Ex. 12, p. 183k.

testified that she told Dr. Pelliccia that Matthew had experienced a seizure. Doctor Pelliccia indicated that she would try “to stabilize his fever” and would “keep him for observation.” Tr. at 28.

With the help of her attorney, Mrs. Del Monte explained why the contemporaneous medical record indicated that Matthew’s temperature was 99.3° (see Pet. Ex. 6, p. 141). This involved a timeline of 90-120 minutes between her taking Matthew’s 104° temperature rectally and his 99.3° temperature at Dr. Pelliccia’s office. Tr. at 30. Although there was no record of another temperature reading at the doctor’s office, Mrs. Del Monte appeared confident that Matthew’s temperature was taken more than once. Tr. at 40.

Mr. Del Monte met Mrs. Del Monte at Dr. Pelliccia’s office about an hour after their telephone conversation. Tr. at 31, 69. When he arrived, Matthew was still listless and unresponsive, lying on the table, with Dr. Pelliccia present in the room. Tr. at 31, 70. Matthew was glassy-eyed and did not appear to recognize his father. Tr. at 70. In contrast to his wife’s testimony, Mr. Del Monte indicated that Dr. Pelliccia described the chickenpox as looking like an allergic reaction, but that she did not say it was a reaction to the vaccination. Tr. at 70.

According to Mrs. Del Monte, they remained at Dr. Pelliccia’s office about three to four hours, during which time Dr. Pelliccia checked on Matthew three to four times. Tr. at 39, 47; see also Pet. Ex. 27 at 285 (Mrs. Del Monte’s affidavit, explaining she remained at the doctor’s office for three to four hours). Mr. Del Monte did not testify that Dr. Pelliccia checked on Matthew repeatedly, but testified that a nurse checked on him once. Tr. at 83. Matthew did not have any other episodes of “seizure” activity.¹⁸ Tr. at 32-33. Dr. Pelliccia wanted to avoid hospitalization and was confident that Matthew would be better off at home. Tr. at 41. When Mrs. Del Monte left the office, Dr. Pelliccia provided instructions to watch Matthew, keep him hydrated, and to give him Tylenol or Advil for fever. Tr. at 30. Once at home, Matthew was more interactive with his father. Tr. at 72.

Mr. Del Monte testified that he arrived at the doctor’s office about an hour after his wife called him, and then he went back to work after the doctor’s office visit. Tr. at 88. In his affidavit, he explained that he remained at the doctor’s office for 1.5 hours, and then had to return to work. Pet. Ex. 26 at 280; see also Tr. at 71 (Mr. Delmonte’s testimony that he waited at the doctor’s office for “an hour and a half”). He further explained that his wife remained with Matthew at the doctor and later went home. Pet. Ex. 26 at 280.

¹⁸ None of the medical records filed in this case indicate that Matthew currently (or has ever) suffered from a seizure disorder.

Although Mrs. Del Monte was not certain what time they left the office, she estimated they arrived about 1:00-2:00 PM, and returned home before her older son got home from school. Tr. at 31, 40. Mr. Del Monte testified that Christopher typically returned home from school between 4:00 and 5:00 PM. Tr. at 88. Mr. Del Monte testified that typically Mrs. Del Monte would pick up both Christopher and Mr. Del Monte at the end of the day. He testified that when he returned home on January 9, 1998, his wife, Christopher, and Matthew were all at home. He could not recall how he got home that day. Tr. at 88. Neither witness explained how Christopher got home that day.

2. The Contemporaneous Medical Records for January 1998.

The medical records regarding the January 9, 1998 visit are very brief, consisting only of the nursing notes. Pet. Ex. 6, p. 141. They reflect that Matthew "has chickenpox [with] allergic reaction," but as the rest of the entries are made in the same handwriting, and the note is illegibly signed, with "BSN" following the signature, this entry was likely made by a nurse with a bachelor of science degree in nursing, rather than Dr. Pelliccia. No dictated notes from Dr. Pelliccia were filed as a part of Pet. Ex. 7 for this visit and the nursing notes do not contain any indication that a dictation was made. There are no entries that reflect Mrs. Del Monte's urgency, possible seizure activity, or the listlessness Mrs. Del Monte described. There are no records for the two telephone calls Mrs. Del Monte reported making to Dr. Pelliccia's office prior to taking Matthew there.

Matthew was seen again on January 14, 1998, with complaints of fever and pulling at his ear. Pet. Ex. 6, p. 141. He still had chickenpox; the records reflect that part of the physical examination was curtailed because "pt is still infected." *Id.* Although the progress report of the visit contains a notation regarding dictated notes (see last entry on the left of Pet. Ex. 6, p. 141, which is consistent with other entries in Pet. Ex. 6 reflecting notes dictated by Dr. Pelliccia and providing an identifying number (12298)), no dictated notes from this visit were filed. There are no references at this visit to the events of January 9, 1998.

3. Later History of the January 1998 Illness.

In October 1998, Matthew was seen by Dr. Beverly Fischer, a pediatric neurologist, who diagnosed Matthew with autism. Pet. Ex. 12, pp. 183, 183j.¹⁹ In a history dated October 2, 1998, Dr. Fischer's notes reflected "severe case varicella [temperature] 104° not hospitalized eyes rolled back [several illegible words] went limp had swelling around lesions on face but recovered [illegible] few days." *Id.*, p. 183k.

¹⁹ Initially, only a brief letter from Dr. Fischer was filed as Pet. Ex. 12, p. 183. When the rest of her records were filed, the additional pages kept the designation of Pet. Ex. 12, p. 183, with letters assigned to each newly filed page.

B. Matthew's Condition through September 1998.

1. Physical Health.

Mrs. Del Monte testified that from January through September 1998, Matthew was "constantly sick" with ear infections. Tr. at 33, 48. Mr. Del Monte provided similar testimony. Tr. at 72-73.

In contrast, the medical records reflect four visits for ear infections: January 14, 1998, about one week after his MMR vaccination; March 23, April 8, and August 31, 1998. Pet. Ex. 6, pp. 141-48. The January 14, 1998 visit is described above. A telephone record from February 27, 1998, reflected that Matthew had been coughing for three days and had a runny nose. Pet. Ex. 8, p. 171. Matthew's next visit was on March 3, 1998, which was described as "follow up chickenpox" in the nursing notes. Pet. Ex. 6, p. 142. Doctor Pelliccia's notes indicate that the "parents offers (sic) no complaints." Pet. Ex. 7, p. 165. Once again, however, Matthew had pharyngitis. Pet. Ex. 7, p. 165.

Matthew was seen again on March 23, 1998, for ear drainage and diarrhea.²⁰ Pet. Ex. 6, p. 143. A hearing test was performed on April 9, 1998, after another bout of otitis media diagnosed on April 8, 1998. *Id.* pp. 144-45. There is a reference in Dr. Fischer's history, taken on October 2, 1998, that likely refers to this April 1998 illness. In commenting on a febrile illness in April 1998, Dr. Fischer wrote: "mom noted jerking of body and eye rolling [temperature] was 102° had [otitis media]." Pet. Ex. 12, p. 183k.

In mid-May 1998, Matthew had a fever for 4 days, and had a cough on June 3, 1998. Pet. Ex. 6, p. 147. On June 24, 1998, Matthew was seen for a fever of 104° Fahrenheit and vomiting. Pet. Ex. 6, p. 146; Pet. Ex. 8, p. 167.

2. Personality Changes.

Mrs. Del Monte testified that after the vaccination, Matthew wasn't the same "sweet, sociable" child he had been before. Tr. at 33. He was cranky and isolated himself. Tr. at 34. She explained that there were no reports in the medical records of a developmental problem or changes in Matthew's awareness level because they were focused on his many physical illnesses and thought the behavior problems were the result of the illnesses. Tr. at 34. She also indicated that her work schedule was more erratic as the result of a job change and that Matthew may have been reacting to that. Tr. at 34.

²⁰ The handwritten date for this visit is difficult to read, and could be either March 23 or March 27. See Pet. Ex. 6, p. 143. There are no corresponding dictated notes filed in Pet. Ex. 7 for this visit.

In contrast, the video reflects that Matthew was smiling and interactive at his mother's birthday party on February 14, 1998. Pet. Ex. 54, Title 16; see also *id.* at Title 17 (brief clips of February 15, 1998, and Feb. 22, 1998). There are several other videos from March-April 1998, in which Matthew smiles and appears to enjoy playing in the snow, sledding, participating in an Easter egg hunt with his older brother, and playing with a toy phone with an adult, his cousin, and his older brother. See Pet. Ex. 54, Titles 17-22.

3. Loss of Verbal Skills.

The extent of Matthew's verbal skills prior to and after the MMR vaccine also demonstrates a conflict between contemporaneous records and petitioners' testimony. Mrs. Del Monte testified that Matthew could identify things such as cat, dog, car, and house at 15 months of age, and could use two or three words together. Tr. at 45. Mr. Del Monte testified that Matthew had 25 words at the time of his MMR vaccination. Tr. at 65-66; see also *id.* at 76 (noting he had 25 words at some point before August 1998). Both parents pinpointed Matthew's loss of words to April 1998. Tr. at 50, 85. However, Mr. Del Monte thought that Matthew was talking during a video scene he identified as occurring in June 1998 (Tr. at 74), but which appears on the video with date/time stamps reflecting May 27 and 28, 1998. Matthew and his older brother are in the bathtub, and Matthew appears to be saying "Pa-pe" or "Ba-pe" and "Dee." He is clearly vocalizing, but no other words are used, in spite of his father's encouragement. See Pet. Ex. 54, Title 23.

However, in most of the video clips, Matthew rarely used words. None of the medical histories taken at around the time of his autism diagnosis reflect anything more than the use of one or two words.

On the videos, Matthew makes noises, but rarely babbles (the clip on May 30, 1998 with Matthew and his brother in tubs of water outside is an exception (see Pet. Ex. 54, Title 24)), and there is no indication of the use of phrases or single words, other than what may have been "daddy," "hap," "dee" and "ba" or "ba-be" on the videos, either before or after the bout with chickenpox. I note that on the May 30, 1998 video, Matthew is happy, babbling, and quite interactive. Pet. Ex. 54, Title 24.

Doctor Fischer's medical history taken in October 1998 indicates that Matthew used "mama" and "dada" at eight months of age, but marginal notes indicate that he was imitating words. Pet. Ex. 12, p. 183k. Her notes indicate that Matthew "lost eye contact" and "stopped all [illegible] words ~ 3 wks ago." *Id.* They also indicate that Matthew never used three word phrases or sentences. *Id.* At Matthew's two year check up, the pediatrician recorded "no speech," but also noted two words, "papi" and what could either be "mommy" or "nanny." Pet. Ex. 6, p. 148.

4. The August 1998 Family Vacation.

Mrs. Del Monte testified that in August 1998, during a family visit to a zoo in Virginia, she told her husband that Matthew was not right. She described him as "not looking well," "not interacting with what's going on," and "blankly staring out into space" during the zoo visit. Tr. at 49. Mr. Del Monte testified that Matthew was listless in the stroller and that his condition was one of numerous reasons the trip was cut short. Tr. at 75.

Video footage of this zoo visit was filed, reflecting a date of August 2, 1998. Initially, Matthew is seated in his stroller and does not appear to be very interested in what is going on. When taken out of his stroller, he walks to the railings and trots along with his brother. He claps and squeals, clings to the railing and tries to climb it, and babbles. He is not particularly responsive to his name, but he does not appear to be listless. He appears to enjoy being pushed in a swing, and slides down a slide. Pet. Ex. 54, Title 25. Later that same day, Matthew is playing on the beach, after what his mother describes as his worst temper tantrum ever at lunch. *Id.*

5. Matthew's Two Year Check Up.

According to Mrs. Del Monte's testimony, in August or September, 1998, Matthew saw a physician who was covering for Dr. Pelliccia.²¹ This physician asked how Matthew was doing developmentally, and Mrs. Del Monte reported that he had lost language. The physician indicated that this was abnormal and suggested testing. Tr. at 35-36, 49. Although Mrs. Del Monte did not identify a specific date, this visit likely occurred on August 31, 1998. Page 148 of Pet. Ex. 6 is the only record of a visit to the pediatrician's office during this time frame, and it is completed differently from the others, suggesting that a different physician saw Matthew at this visit. Matthew was referred for a hearing evaluation. Pet. Ex. 6, p. 148. According to Mrs. Del Monte, the physician's questions and the experience at the zoo triggered the family's concern about Matthew. Tr. at 49-50.

C. Autism Screening and Diagnosis.

The Del Monte family switched pediatricians, from Dr. Pelliccia to Dr. Melindres Lim, on September 5, 1998. This particular visit was prompted due to "parents' concerns that he might have signs of autism." Pet. Ex. 39, p. 396 (emphasis original). Matthew's parents reported that he had "few spoken words/phrases" by one year of age and that he "used to be a 'happy baby'." Over the past months, he had developed

²¹ Mr. Del Monte testified that Mrs. Del Monte was not present at this visit. Tr. at 86.

evasive behavior and stopped talking, although he continued to express needs through body language. *Id.* Doctor Lim referred him for a formal hearing evaluation and a neurological evaluation, but her assessment was probable early autism and learning disabilities. *Id.*; Tr. at 50-51.

Matthew had a hearing evaluation on September 21 and 23, 1998. His parents reported that about four-five months earlier, Matthew's communication behavior changed. They reported that "he stopped talking, made little to no eye contact, and [did] not always respond[] to his name being called." Pet. Ex. 17, p. 190. Audiometric testing and auditory brainstem response testing were performed, and Matthew's hearing was within normal ranges. *Id.* A speech pathology evaluation was completed on September 28, 1998. Matthew was noted to have fleeting eye contact and only three spontaneous words. Pet. Ex. 12, p. 183i.

Doctor Fischer diagnosed Matthew with autism on October 2, 1998. She reported a history of early onset of speech, use of single words at one year of age, and "ultimate loss of expressive language." She noted normal hearing. Pet. Ex. 12, p. 183j. Additional testing included an EEG,²² which was interpreted as normal. Pet. Ex. 12, p. 183b. A test for Fragile X Syndrome was also normal. Pet. Ex. 12, p. 183c.

An evaluation at Montclair State University in August 1999 provides a history that Matthew was not interested in playing with his brother in May and June of 1998. In August 1998, his parents noticed that he was "fixated on objects, throwing temper tantrums" and that he had "ceased responding to his name." Pet. Ex. 19, p. 215. The history also indicated that his speech developed normally until he was 20 months of age, when he experienced speech and play skills regression. *Id.*

I note that in the video of the August 2, 1998 vacation to Virginia and Maryland, Mrs. Del Monte commented on Matthew's temper tantrum and that in the videos taken at the zoo and on the beach, Matthew was not responding to his name or nickname. Pet. Ex. 54, Title 25.

IV. Resolving Disputed Factual Issues.

The primary matter in dispute is whether Matthew experienced an encephalopathy after his MMR vaccination. A secondary dispute concerns Matthew's speech and when he lost expressive language skills.

²² An EEG or electroencephalogram measures electrical activity of the brain. Fluctuations are seen in the form of waves, which correlate with different neurologic conditions and are used as diagnostic criteria. DORLAND'S at 607.

A. Encephalopathy.

Matthew did not experience an encephalopathy consistent with the definition contained in the Vaccine Injury Table²³ after his MMR vaccination. Matthew did not demonstrate a significantly decreased level of consciousness for at least 24 hours. He was responsive to his environment and related to his parents and brother after his MMR vaccination and in the weeks that followed.

I find that on January 9, 1998, four days after his MMR vaccination,²⁴ Matthew experienced a 104° fever, measured rectally. This converts to a 103° fever, if measured orally. While febrile, Matthew's eyes rolled back into his head and he became limp. Although there are no contemporaneous medical records documenting these symptoms, petitioners' testimony in this regard is buttressed by the history they provided in October 1998 to Dr. Fischer.

²³ Encephalopathy in the Vaccine Injury Table is defined as follows:

(2) Encephalopathy. For purposes of [the Vaccine Injury Table], a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. . . .

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2) (2010).

²⁴ I note that the Table injury of encephalopathy following MMR vaccination requires onset of symptoms 5-15 days following vaccination. See *id.* at § 100.3(a).

There are no medical records indicating that this event constituted a seizure. Doctor Pelliccia's records do not refer to this event as a seizure, either at the time or at any subsequent visit. Doctor Pelliccia did not refer Matthew to a hospital or for an EEG, or recommend fever prevention measures, all actions that a physician would likely take if she suspected febrile seizures.

Although still ill with chickenpox on January 14, 1998, there are no physician's or nurses notes reflecting that Matthew was experiencing anything that could be characterized as a "decreased level of consciousness" within the definition appearing in the Qualifications and Aids to Interpretation ["QAI"] of the Vaccine Injury Table.

The video records of Matthew between his MMR vaccination and his second birthday are inconsistent with the QAI definition of encephalopathy. Matthew was responsive to his environment, engaged in social interaction, played, smiled, and showed affection.

B. Speech and Social Interaction.

Matthew's behavior, including his use of language and his social interactions, did not materially alter between January and April 1998.

The contemporaneous medical records do not reflect any alterations in Matthew's use of language or social interactions between January and April 1998. In March 1998, his parents specifically reported "no complaints" to Dr. Pelliccia. See Pet. Ex. 7, p. 165. The video records show that Matthew's speech and social interactions did not vary much from the Christmas videos to those through Easter. At his mother's birthday party in mid-February 1998, Matthew smiles, plays with a pinwheel, and looks at people much like he did in the Christmas videos.

Matthew's vocabulary was never large, and the evidence does not support the loss of language in April 1998.

Mr. Del Monte's testimony that Matthew was using 25 words at or around the time of his MMR vaccination is unsupported by the medical records, Matthew's baby book, and the video records.²⁵ There is no support for Mrs. Del Monte's testimony that Matthew was using two- and three-word phrases at that point. The histories of language use supplied to both Dr. Fischer and the speech pathologist indicate Matthew

²⁵ A history taken when Matthew was 32 months of age indicated that he once had a vocabulary of 10-15 words. See Pet Ex. 20, p. 224. However, he was reported to have "few spoken words/phrases already by 1 yr of age." Pet. Ex. 39, p. 396. At his two year check up, he had "no speech," although two words were listed. Pet. Ex. 6, p. 148. Another history, taken when Matthew was 33 months old, reflected that Matthew "had a couple of words in the first year." Pet. Ex. 34, p. 300-01. This is consistent with Matthew's baby book entries.

had a very small vocabulary from his first word onward and had only a few words by the time of his MMR vaccination. After his vaccination, Matthew was most verbal during the late May video segments, taken when he was bathing with his older brother, and playing in tubs of water, but even then, he was not using many words, and used no phrases.

Based on the record as a whole, I conclude that Matthew most likely became less verbal between June and August 1998. I do not rule out a gradual decline in his expressive language over the period between April and August 1998, but the video record from the end of May 1998 demonstrates the most use of language in any of the video segments, and thus he was still using language at the end of May 1998.

Matthew had numerous sick child pediatric visits in the twelve months between his bout of pneumonia at four months of age and his MMR vaccination. He also had numerous sick child pediatric visits between the MMR vaccination and his autism diagnosis. There was no increase in the frequency of sick child visits after the MMR vaccination.

Although Matthew was undoubtedly incubating chickenpox at the time of his MMR vaccination, there is no evidence that receipt of the MMR vaccination affected the severity of his bout of chickenpox. The description of his reactions, including his fever and malaise and their duration, tracks with the description of the common symptoms of the disease set forth in *PRINCIPLES AND PRACTICE OF INFECTIOUS DISEASES*, *supra*, n.14. However, I will certainly defer to a medical opinion regarding the severity of Matthew's reaction. I note that there was no reliable evidence adduced in the OAP test cases that demonstrated a causal connection between varicella or measles viruses and autism spectrum disorders.

IV. Orders to the Parties.

The next step in this case is the obtaining of expert reports. In this regard, I note that petitioners appear to be proceeding on the same theory of causation advanced and rejected in the Theory 1 OAP test cases. That is, they contend that the MMR vaccine is responsible for Matthew's condition. Although the parties are not bound by the results obtaining in the Theory 1 test cases, the body of evidence developed in those cases was deemed inadequate to demonstrate that the MMR vaccine can or did cause autism spectrum disorders. Were I to decide this case based on the evidence developed in the test cases and thus far in this case, I would conclude that there is inadequate evidence of causation. In order to prevail on the merits, petitioners must produce evidence of causation not already considered and rejected in the Theory 1 test cases.

The parties are directed to provide a copy of these factual findings to their respective experts, and the experts shall conform their expert opinions to these factual findings. Should an expert disagree with any factual finding herein, 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 causation.

My chambers will contact the parties to schedule a status conference, during which I will establish deadlines for the filings of expert reports.

IT IS SO ORDERED.

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