

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

No. 99-211V

Filed: June 18, 2012

Not to be Published

MOHAMED BABEKIR AHMED,
by his parents and natural guardians,
BABEKIR AHMED AND
NAHLA HASSAN

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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* Findings of Fact; Onset; Autism
* Spectrum Disorder; Contemporaneous
* Medical Records; Subsequent
* Medical Histories and Testimony;
* Lack of Factual Predicate for a Table
* Injury Claim.
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RULING ON FACTS PERTAINING TO ONSET¹

Vowell, Special Master:

On April 7, 1999, Babekir Ahmed and Nahla Hassan [“Mr. Ahmed,” “Ms. Hassan,” or “petitioners”] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² [the “Vaccine Act” or “Program”], on behalf of their minor son, Mohamed Babekir Ahmed [“Mohamed”]. The original petition alleged that vaccines Mohamed received on April 16 and 24, 1996, caused seizures, vomiting, lethargy, and unspecified sequelae. Original Petition, ¶¶ 5-7. An amended petition was filed on October 26, 2000. A second amended petition, which now constitutes the operative petition for petitioners’ vaccine injury claim on behalf of Mohamed, was filed on June 5, 2011. This petition identifies the polio and measles, mumps, and rubella [“MMR”] vaccines administered on April 16, 1996 and the

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims’ website, in accordance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), petitioners have 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

diphtheria, pertussis, and tetanus [“DPT”] and haemophilus influenzae type b [“Hib”] vaccines administered on April 23, 1996, as the vaccines claimed to be causal. Second Amended Petition, ¶¶ 5-6.³ This petition indicates that Mohamed had a severe reaction to all of these vaccines, manifesting on April 24-25, 1996 as seizures,⁴ fever, vomiting, diarrhea, and lethargy. *Id.*, ¶¶ 7-10. The petition further asserts “that Mohamed was an entirely different child in that he would not speak appropriately, would not play with others appropriately, and in every way began exhibiting the symptoms of autistic behavior” after these vaccinations. *Id.*, ¶ 11. Petitioners also assert the Table injury claim of encephalopathy as to both the MMR vaccination administered on April 16, and the DTP and Hib⁵ vaccinations administered on April 23, as well as a cause in fact claim for all the vaccinations received. *Id.*, ¶ 13.

Medical records were filed at various times in 1999 (Pet. Exs. 1-16), 2000 (Pet. Exs. 17-18), 2008 (Pet. Exs. 19-20), 2009 (Pet. Exs. 21-24),⁶ and 2011 (Pet. Exs. 26-27).⁷

The parties requested a hearing to resolve factual conflicts. See Order, filed July 1, 2011. The hearing was conducted in Washington, DC, on January 31, 2012. My factual findings are set forth in Section III below.

³ Hereinafter, unless the context clearly indicates otherwise, any references to “petition” are to this Second Amended Petition.

⁴ None of the medical records substantiate the claim in the petition that Mohamed suffered from seizures after the allegedly causal vaccinations. Injury claims entirely lacking a factual predicate violate Rule 11. Rules of the Court of Federal Claims [“RCFC”] 11(b)(3). Mohamed had an EEG in 1998, read by Dr. Shafrir as showing a “mild degree of cortical hyperirritability in the left and right frontal areas.” Petitioners’ Exhibit [“Pet. Ex.”] 22, pp. 43-44; see also Pet. Ex. 20, p. 72. Subsequent EEGs were read as normal (Pet. Exs. 18, p. 23; 20, p. 33) and there are no medical records substantiating that he has ever experienced a seizure, much less one in temporal proximity or otherwise connected to the allegedly causal vaccinations.

⁵ There is no table injury associated with the Hib vaccine. 42 C.F.R. § 100.3.

⁶ Petitioners’ Exhibit 25 was a statement of non-availability for medical records from one health care provider.

⁷ The gap in filings between 2000 and 2008 was due to petitioners’ request to “opt into” the Omnibus Autism Program [“OAP”], which had the effect of deferring any further case development, pending resolution of the OAP test cases. During the period between the commencement of the initial hearings in the OAP test cases and the completion of appellate review, petitioners in this case, like others in the OAP, were ordered to complete the filing of medical records to position their case for resolution. After the completion of appellate review in the test cases, petitioners were ordered to inform the court if they intended to continue to pursue their claim that vaccinations were responsible for Mohamed’s autism, and if so, to file an amended petition setting forth their theory of causation. Order, filed May 5, 2011. More recent records have been filed since the fact hearing concluded, but they are not relevant to the factual issues in controversy. Some of the more recent records reflect genetic testing and evaluation for syndromes associated with large stature, certain other physical findings, and behavioral problems. See, e.g., Pet. Ex. 41, pp. 34-38, 81-85.

I. Scope of This Ruling.

The pertinent portions of the record in this case are the medical records (both those prepared contemporaneously to the events in question and later records containing histories of the events in question), petitioners' affidavits, and their hearing testimony. Petitioners' expert, Dr. Yuval Shafir, was also a treating physician, although his treatment of Mohamed did not begin until several years after the events in dispute. Doctor Shafir's opinion, filed as Pet. Ex. 28, includes his assessment of petitioners' ability to observe and accurately recount the events in question. Pet. Ex. 28 at 9-10. I have considered his opinions and the reasons given for arriving at the conclusions he did, but his opinions are not binding on me. § 13(b)(1). I note that Dr. Shafir's summary of his initial evaluation of Mohamed, as contained in a letter to Mohamed's primary care provider, contains several factual assertions regarding Mohamed's medical history that conflict with contemporaneous medical records. See *infra*, Section III (B)(3).

In this ruling I determine the facts of what transpired between Mohamed's birth and March 26, 1998, when he was diagnosed with pervasive developmental disorder. Pet. Ex. 10, p. 4. The nature of the events surrounding Mohamed's illness after the allegedly causal vaccines and when he manifested the symptoms leading to his diagnosis with an autism spectrum disorder⁸ are the primary matters in dispute at this point in these proceedings.

The issue of vaccine causation will require a second hearing at which the parties may present the testimony of their respective experts. At this time, I determine, by preponderant evidence, what symptoms Mohamed manifested and when they occurred. Unless subsequently modified, these facts are those upon which causation opinions must be based.

⁸ "Autism Spectrum Disorder" or "ASD" is an umbrella term for certain developmental disorders, including autism (also referred to as autistic disorder), pervasive developmental disorder - not otherwise specified ["PDD-NOS"], and Asperger's Disorder. See R. Luyster, et al., *Language Assessment and Development in Toddlers with Autism Spectrum Disorders*, J. AUTISM DEV. DISORD. 38: 1426-38, 1426 (2008) ["Luyster"] filed as Respondent's Exhibit ["Res. Ex."] A. "Pervasive developmental disorders" is the umbrella term used in the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69, rather than ASD. I use the term ASD throughout this ruling rather than PDD because of the possible confusion between "PDD" (the umbrella term referring to the general diagnostic category) and "PDD-NOS" (which is a specific diagnosis within the general diagnostic category of PDD or ASD).

II. Resolving Evidentiary Conflicts.

A. The Nature of the Dispute.

The dispute between the parties centers on the sequelae, if any, that Mohamed experienced after a febrile illness when Mohamed was just over one year old. Petitioners allege that this illness was caused by the two sets of vaccinations Mohamed received in the two weeks preceding this illness and that, subsequent to the illness, Mohamed's behavior and health deteriorated, eventually resulting in a diagnosis of autism. Petitioners' expert, Dr. Shafrir, opines that this febrile illness triggered or caused Mohamed's autism. Petitioners rely on their affidavits and testimony, and on the history Dr. Shafrir recorded when he first saw Mohamed at about 39 months of age. This history has been repeated in subsequent medical records, but some of it conflicts with the contemporaneous records.

B. Law Pertinent to Evidentiary Conflicts.

Conflicts between contemporaneous records and testimony given several 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 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.

In general, I did not find sufficient indicia of reliability in the testimony of Mohamed's parents to credit their testimony when it conflicted with the evidence found in the contemporaneous records. Their accounts at the hearing of the events of 1995-1997 were, quite understandably, less detailed than the accounts in the medical records themselves. Their testimony took place over 15 years after most of the events at issue, and they had difficulty in discussing specific events without reference to the medical records. When questioned about matters that would logically flow from the medical records, they had no memories upon which to answer. For example, Mr. Ahmed seemed unsure about which febrile illness triggered Mohamed's decline—the illness experienced at about eight or nine months of age, or the one that occurred when Mohamed was one year old.⁹ Tr. at 84. Ms. Hassan had before her a chronology of events prepared by her attorney (see Tr. at 26-27), and frequently referred to this timeline when testifying.

I emphasize that I do not doubt Ms. Hassan's or Mr. Ahmed's sincerity or truthfulness. I believe their account that Dr. Shafrir was the first health care provider who spent considerable time with them and listened to their concerns about Mohamed's health and symptoms. However, I cannot accept that the information Dr. Shafrir elicited was entirely accurate, particularly when it deviated from contemporaneously recorded observations in other records. Furthermore, the history Dr. Shafrir elicited at his initial evaluation of Mohamed appears to reflect, consciously or not, Dr. Shafrir's awareness of the recent news that the MMR vaccine had been linked to the development of gastrointestinal problems and autism spectrum disorders. Pet. Exs. 14, pp. 1-5; 18, pp. 29-32; 22, pp. 32-42;¹⁰ see also Pet. Ex. 28 at 8-9 (Dr. Shafrir's expert report, acknowledging the Wakefield study was "hot news" when he first saw Mohamed). Although this purported link has since been thoroughly discredited,¹¹ I do not fault Dr.

⁹ This was not the first time that Mr. Ahmed attributed Mohamed's developmental problems to the illness at eight to nine months of age. See Dr. Shafrir's report of July 30, 1999 ("Dad says [Mohamed] developed normally until 8 or 9 months, and after a year stopped developing completely.") Pet. Ex. 18, p. 23.

¹⁰ Several copies and at least two versions of Dr. Shafrir's report from this initial visit exist. Because it is unclear which one represents his final report, in this ruling I include citations to all filed copies of the report.

¹¹ See *Snyder v. Sec'y, HHS*, No. 03-654V, 2009 WL 33204 at *137-147 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) ("Section VII. Analysis of Evidence Regarding MMR Causation of Autism"). Since the OAP Theory 1 test case decisions were issued, the medical journal that published the research paper that launched the MMR-autistic enterocolitis theory withdrew the paper from publication, and two of the paper's authors have lost their medical licenses in the wake of evidence of misconduct connected with the research upon which the theory was based. R. Horton, *A Statement by the Editors of The Lancet*, *Lancet* 363(9411): 820-821 (2004); UK General Medical Council, *Determinations on Serious Professional Misconduct and Sanction Regarding Andrew Wakefield and Simon Murch* (May 24, 2010), available at http://www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf and http://www.gmc-uk.org/Professor_MURCH_determination.pdf_32597633.pdf (last visited June 14, 2012).

Shafir's reliance on it at the time. However, it focused petitioners' attention on the illness following the MMR vaccination, and their subsequent accounts of when symptoms first arose reflected that focus, when earlier and more contemporaneous accounts did not.

I also note that histories provided by petitioners to some health care providers other than Dr. Shafir also deviate from those contained in contemporaneous records. Their recounting of dates when events occurred are often significantly inaccurate, and their characterizations of the frequency and severity of symptoms differ markedly in some histories from those contained in records created at or near the time of the events. In some cases, their accounts in the same record are internally inconsistent. I emphasize that I do not consider these inconsistencies as any indication of untruthfulness or exaggeration. Rather, they reflect petitioners' best efforts to recount what happened as they remember it. Also, the discrepancies may reflect some degree of difficulty in communicating in English.¹² After carefully considering the testimony given by petitioners, I placed more weight on the observations found in the contemporaneous medical records as support for the facts found herein.

III. Factual Findings.

A. Facts Not Reasonably Subject to Dispute.

1. Mohamed was born on April 14, 1995. Pet. Exs. 3, p. 14; 19, p. 3.¹³ He was several weeks preterm. Pet. Ex. 3, pp. 19-20. Labor was induced for preeclampsia, decreased amniotic fluid, and a decreased biophysical profile of the fetus. His mother was positive for group B streptococcus, which was treated with antibiotics prior to delivery. *Id.*, pp. 14, 18. The placenta showed chronic chorioamnionitis.¹⁴ *Id.*, pp. 15-17. In spite of his preterm birth and the evidence of infection in his mother and the placenta, Mohamed appeared to be a healthy newborn, with Apgar scores of 9 and 9.¹⁵

¹² For example, the January 6, 1996 call note from Mohamed's first pediatricians noted a "language barrier" existed. Pet. Ex. 4, p. 7. Additionally, Ms. Hassan testified that her English skills have improved over the years, since Mohamed was born. Tr. at 25.

¹³ Petitioners' Exhibit 3 also contains records pertaining to a subsequent pregnancy. See, e.g., p. 20, which reflects a fetal ultrasound on 12/23/1996, a date after Mohamed's date of birth.

¹⁴ Chorioamnionitis refers to inflammation of the chorion, the outermost membrane surrounding the embryo, and the amnion, the membrane lining the inside of the chorion. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"], at 65, 354. It often results from bacterial invasion of the amniotic fluid. NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S"], at 630.

¹⁵ The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S at 1682.

Id., p. 14. He received his initial hepatitis B vaccination on April 14, 1995, without any apparent ill effects. Pet. Ex. 4, p. 1.

2. Mohamed received his early pediatric care in Pittsburgh, PA. See *generally*, Pet. Ex. 4. His parents were proactive in seeking health care treatment and advice, with the records reflecting both sick and well child visits. Several medical histories taken in 1997 and 1998 describe Mohamed as a baby who cried a great deal and had difficulties with self-regulation. See, e.g., Pet. Exs. 14, pp. 1-2; 16, p. 10. Those descriptions are largely substantiated by Mohamed's early pediatric records and Ms. Hassan's testimony. See Pet. Ex. 4; Tr. at 9, 11-12.

3. In his first seven months of life, Mohamed had nine pediatric visits, with problems such as excessive crying, gas, refusal to nurse, constipation, fever, coughing, and poor sleeping discussed at five of them. See *generally*, Pet. Ex. 4, pp. 16-23. In addition, there were numerous telephone calls to his pediatrician's office for similar complaints.

a. He was first seen at his pediatrician's office on April 22, 1995, for a well child visit. He was breastfeeding well, but had not gained any weight. Pet. Ex. 4, p. 23.

b. On April 29, 1995, in a telephone call to his pediatrician's office, his parents reported that Mohamed cried all the previous night and might have a fever. His parents were advised to get a thermometer and to check his temperature. Pet. Ex. 4, p. 22.

c. On May 4, 1995, he was brought to the pediatrician's office with similar complaints. Mohamed was gassy, had a slight temperature, decreased appetite, refused to nurse for two days, had decreased bowel movements, and was spitting up with each feeding. He was diagnosed with "gassy colic,"¹⁶ diaper rash, and a possible urinary tract infection. Pet. Ex. 4, p. 22.

d. At his one month well child visit on May 18, 1995, Ms. Hassan indicated that he cried all the time and was gassy. He was nursing well. He received his second hepatitis B vaccination at this visit without any reported ill effects. Pet. Ex. 4, p. 21.

e. Mohamed's two month well child visit took place on June 15, 1995. Mohamed had nasal congestion, and was reported to have bowel movements every four to five days. Breastfeeding was going well, and the physician's impression was that Mohamed was a well child. He received his initial DTP, Hib, and oral polio vaccines at this visit. Pet. Ex. 4, pp. 1, 20.

¹⁶ Infantile colic is defined as "a benign paroxysmal abdominal pain during the first three months of life." DORLAND'S at 383.

f. Eleven days later, the pediatrician's office notes reflect a telephone call indicating that Mohamed had not had a bowel movement in 10 days. Pet. Ex. 4, p. 20.

g. Mohamed received his second DTP and Hib vaccines on July 31, 1995, but there is no record of any office visit on this date. Pet. Ex. 4, p. 1.

h. On August 8, 1995, Mohamed visited his doctor with a complaint of a cough for two days, shortness of breath, and a slightly elevated temperature (99.2° rectally) the previous evening. His appetite was fine, and he had not had any vomiting or other symptoms of illness. His pediatrician indicated that he had an upper respiratory infection. Pet. Ex. 4, p. 19.

i. No problems were noted at his four-month well child checkup on August 31, 1995. His mother reported that Mohamed was beginning solid foods.¹⁷ Pet. Ex. 4, p. 18.

j. Mohamed had another upper respiratory infection in September, 1995, prompting an office visit and a telephone call. Pet. Ex. 4, p. 18.

k. A telephone message on October 13, 1995, reflected that Mohamed was ill with cough, runny nose, vomiting, loose stools, and a temperature. He was breastfeeding well, and crying. His mother was told to continue to observe him, and in a telephone contact later that same day, she reported that he had not had any additional vomiting or diarrhea. She was told to call back if the symptoms returned. Pet. Ex. 4, p. 17.

l. Mohamed had his six-month check up on October 20, 1995, and was assessed as a well child. He received his third Hib and DTP vaccinations at this visit. Pet. Ex. 4, pp. 1, 17.

m. Six days later, he returned to his pediatrician with a complaint of a cough for four days. Mohamed was fussy, had a runny nose, seemed warm, and was not eating or sleeping well. The impression was an upper respiratory infection. Pet. Ex. 4, p. 16.

n. During a telephone consultation on November 3, 1995, Mohamed was reported to have been coughing for more than a week. Pet. Ex. 4, p. 16. The note reflects that the caller was told to call back if he was not better in the morning. *Id.*

¹⁷ This record conflicts with a history taken on May 30, 1998, when Mohamed was hospitalized for abdominal pain. That history reflects that Mohamed was "exclusively breastfed" for nine months. Pet. Ex. 23, p. 11. Because Ms. Hassan indicated in her testimony that Mohamed did eat solid foods and took formula (Tr. at 71), I do not consider this a matter in dispute.

There is no record of any additional follow up for this illness. Mohamed was seven months old at the time of this telephone call. *Id.*

4. In late December 1995, when Mohamed was eight and one half months of age, he developed an upper respiratory infection that prompted numerous telephone consultations and office visits, and one emergency room visit. Although a medical history taken by Dr. Shafir in July, 1998 (discussed in section B below) indicates otherwise, Mohamed received no vaccinations within the two months preceding this visit.

a. On December 28, 1995, Ms. Hassan took Mohamed to his pediatrician's office. Pet. Ex. 4, p. 14. This visit followed a telephone consultation the day before, indicating that Mohamed's temperature was 104° by axillary measurement. *Id.*, p. 15. His mother had reported eye drainage, but no diarrhea or vomiting. *Id.* At the office visit, his mother gave a history of fevers since the prior day, with temperatures as high as 103°¹⁸ for which she gave him Tylenol. Both of his tympanic membranes (ear drums) were red, and the pediatrician diagnosed bilateral otitis media. Mohamed was prescribed an antibiotic and his parents were to return in two days for reevaluation. *Id.*

b. In a late evening telephone consultation on December 29, 1995, Mohamed's parents reported that he had developed diarrhea the previous evening. His rectal temperature remained 102°, in spite of Tylenol. The call was prompted by Mohamed's irritability, reddened eyes, and some dizziness, in addition to the persistent fever. When the call nurse inquired about the Tylenol dosage, there appeared to be some language difficulty in ascertaining how much he had been given. His mother reported that he was refusing solids and possibly liquids, not crying tears, and had not had any wet diapers. Pet. Ex. 4, p. 13.

c. Mr. Ahmed called back two hours later to report that they were at the emergency room but had not yet been seen. He indicated that Mohamed had taken four ounces of milk and that his temperature was down, so he was taking him home. Pet. Ex. 4, p. 13.

d. At around 11:00 AM on December 30, 1995, Mr. Ahmed telephoned to say that Mohamed had not had any further vomiting or diarrhea, but still had a

¹⁸ This is not necessarily inconsistent with the telephone report, in that temperatures taken at the same time will vary depending on where they are measured. An axillary (armpit) temperature is about one-half to one-degree lower than an oral one, and rectal and tympanic (ear) temperatures are about one-half to one-degree higher than an oral one. See *Fever-First Aid*, MAYO CLINIC, <http://www.mayoclinic.com/health/first-aid-fever/FA00063>; *Temperature Comparison*, WEBMD, <http://www.webmd.com/parenting/rectal-ear-oral-and-axillary-temperature-comparison>; (last visited June 14, 2012). See also *Bricker v. Sec'y, HHS*, No. 90-1297V, 1995 WL 325792, *5-9 (Fed. Cl. Spec. Mstr. May 15, 1995)(discussing the differences in oral, axilla, and rectal temperature readings).

temperature of 101°. Mohamed had more energy and was smiling and standing up. Pet. Ex. 4, p. 12. Notes from an office visit that same day indicated that the fever was intermittent, that Mohamed was cranky, and suffered from some diarrhea and gas. The office visit notes reflected his visit two days earlier for otitis media and some current problems with liquid stools without associated vomiting. They also reflect a possible diagnosis of roseola.¹⁹ *Id.*

e. Mohamed continued to suffer from this illness for several more days. In a telephone call at 6:30 AM on December 31, 1995, Mohamed was reported to have been crying since 3:00 AM. He was afebrile and had not been vomiting, but was refusing fluids. He was still wetting diapers. Mr. Ahmed was initially advised to give Mohamed water and to rock him. Pet. Ex. 4, p. 11. The pediatrician's office attempted to contact Mohamed's parents later that morning. At 11:20 AM, Mr. Ahmed reported that Mohamed slept from 7:00 AM until 10:30 AM and had taken two ounces of milk. *Id.* At 11:30 AM, there was another telephone consultation that reflected that Mohamed had been diagnosed with the flu the previous day and had been given a prescription for antibiotics. Mr. Ahmed indicated that Mohamed was irritable and cried frequently the previous evening and through the night, but was better in the morning. Mohamed had a slight fever (99°), runny nose and mild congestion, but appeared alert. Mr. Ahmed was advised to push fluids and to give Mohamed Tylenol. Pet. Ex. 4, p. 9.

f. Over the next six days, there were three telephone consultations. On January 1, 1996, a parent reported that Mohamed had gas. Pet. Ex. 4, p. 8. A similar telephone report was made on January 3, 1996, but in addition to gas, Mohamed was not eating or taking fluids, and had a fever of 103°. His parents were advised to give him Pedialyte for several feedings, before beginning formula at half strength and then 3/4 strength. *Id.*, p. 10. On January 6, 1996, Mr. Ahmed called the pediatric clinic office to report that Mohamed had a fever for a couple of days, accompanied by a rash that was more prominent than before. His temperature had been up to 104° but he did not have a fever at the time of the call. He had a decreased appetite, but was taking fluids and urinating. *Id.*, p. 7. Mr. Ahmed was instructed to hold off on any medications until morning and to evaluate Mohamed then. *Id.* There is no record of any other visit for this illness.

g. Mohamed likely quit breast feeding after this illness. His mother's medical records reflect a visit on March 3, 1996, in which she reported that she had quit breastfeeding "3-4 months ago," a time frame that would roughly coincide with this illness. Pet. Ex. 3, p. 12.

5. Mohamed was assessed as well at his nine-month well child visit on January 16, 1996. He was refusing some foods, but liked yogurt. Pet. Ex. 4, p. 6. He received his third hepatitis B vaccination at this visit. Pet. Ex. 4, pp. 1, 6.

¹⁹ Roseola is a type of rose-colored rash seen frequently with infectious diseases. DORLAND'S at 1654.

6. Apparently Mohamed did not see any health care providers for either sick or well visits between his nine-month well-child visit and his first birthday on April 12, 1996. He received his third oral polio vaccination and his MMR vaccination on April 16, 1996, and his fourth DPT and Hib vaccinations on April 23, 1996. Unlike his earlier vaccinations, these were administered at the health department in Alexandria, VA. Pet. Ex. 5, p. 1. Ms. Hassan testified that an examination was performed before the vaccinations were administered (Tr. at 42-44), but there are no records reflecting anything other than the vaccinations themselves.

7. Mohamed experienced a second febrile illness shortly after receiving the April 23, 1996 vaccinations, prompting two emergency room visits, a call to his pediatrician's office in Pittsburgh, and an office visit to the public health clinic in Alexandria, VA. It is this illness, and the vaccinations that preceded it that petitioners claim caused Mohamed's autism spectrum disorder.

a. At about 3:30 PM on April 24, 1996, Ms. Hassan took Mohamed to the Alexandria Hospital Emergency Room ["Alex. ER"] because he had vomited and had three bouts of diarrhea. The triage nurse took his vital signs at 3:45 PM, recording that his temperature was 104°. Pet. Ex. 8, p. 24. Tylenol was administered at around the same time. *Id.* (medications section of the nursing record). Mohamed was examined by a physician at 3:55 PM, who recorded that the injection site on the left thigh for the DPT vaccination he had received the day before had an area three inches in diameter of erythema around an indurated central area, which was very tender.²⁰ Mohamed's lungs, throat, and ears were all normal in appearance. The physician described him as alert, somewhat irritable, and with no abnormal movements. His temperature had declined with the administration of Tylenol, and Mohamed was vocalizing and drinking. His hydration status was described as "good." A complete blood count and blood cultures were ordered, and a urine sample was obtained.²¹ *Id.*, p. 23. By 4:55 PM, Mohamed was sleeping in his mother's arms, but was easily aroused. At the time of discharge at 6:15 PM, Mohamed was alert, active, and drinking water. *Id.*, p. 24. Ms. Hassan was directed to have Mohamed reexamined in two days if he was not better, and to return to the emergency room if he experienced seizures, severe vomiting, or lethargy. *Id.*, p. 22. She was to administer Tylenol every four hours, beginning at 8:00 PM, PediaProfen²² every six hours beginning at 10 PM, and to push fluids. *Id.*

²⁰ Erythema means redness of the skin. DORLAND'S at 643. Indurated means hardened. *Id.* at 933.

²¹ The urine sample was subsequently reported as normal. Pet. Ex. 8, p. 26. The blood test results are illegible. *Id.*, p. 25.

²² PediaProfen is the proprietary name for a formulation of ibuprofen for pediatric use. *Pedia-Profen Oral*, WEBMD, <http://www.webmd.com/drugs/drug-57949-Pedia-Profen+Oral.aspx?drugid=57949&drugname=Pedia-Profen+Oral> (last visited June 14, 2012).

b. Early in the morning of April 25, 1996,²³ Mohamed's parents contacted the office of the Pittsburgh pediatricians who had cared for Mohamed since his birth.²⁴ They reported that since receiving the Hib and DTP vaccines, Mohamed had vomited ten times, was having diarrhea, and had a temperature of 105°. Ms. Hassan explained that she had taken him to the emergency room the previous afternoon. She reported that the doctor who examined Mohamed there thought this might be a vaccine reaction and recommended contacting his pediatrician. Pet. Ex. 4, p. 5. Ms. Hassan also reported that Mohamed was very lethargic, producing only a small amount of tears, and that there was a small amount of blood in his emesis. He had not urinated in the last five hours. The after-hours staffer at the pediatric practice contacted the on call doctor, who recommended that petitioners take Mohamed to an emergency room. *Id.*

c. The triage records from the return visit to the Alex. ER reflect an arrival at 1:38 AM on April 25, 1996. Pet. Ex. 8, p. 21. Mohamed's temperature was 101.3°. The intake form noted his ER visit the previous afternoon and indicated that Mohamed was vomiting with blood and would not eat or drink anything. The triage nurse recorded that Mohamed was alert, looked good, and that his lungs were clear. *Id.* Mohamed saw a physician at 1:45 AM. During the physician's examination, Mohamed vomited, but there was no blood in the emesis. Mohamed was alert and non-toxic in appearance. He had no diarrhea; his neck was supple; his eyes and chest were clear, and his throat was slightly red. His abdomen was soft and not tender, and he was producing tears. *Id.*, p. 20. Mohamed was discharged with a diagnosis of gastroenteritis. *Id.*, p. 19.

d. There were no records pertaining to any follow up visits for this illness.

8. The next record of any medical treatment was at the Alexandria Health Department's Casey Health Center²⁵ on June 26, 1996, when Mohamed was 14 months

²³ Although the date on this telephone record appears to be April 23, 1996, at 12:05 AM, the body of the message indicates that Mohamed received vaccinations on the day before, a Tuesday. The vaccination record clearly reflects that the vaccines were received on April 23, 1996, which was a Tuesday, according to two websites that display perpetual calendars.

<http://www.timeanddate.com/calendar/?year=1996&country=1>;
<http://www.calendardate.com/?Month=4&Year=1996&SUBMIT=GO> (last visited June 14, 2012). The Alexandria Hospital records reflect that Mohamed was first seen in the afternoon of April 24, 1996, and then again on the morning of April 25, 1996. I thus conclude that this entry was actually made shortly after midnight on April 25, 1996.

²⁴ During the telephone call, petitioners indicated that they were in Virginia and might not be returning to Pittsburgh. Pet. Ex. 4, p. 5.

²⁵ The Casey Health Center records are filed as Pet. Ex. 9. The Casey Health Center appears to be part of the Alexandria Health Department. See <http://alexandriava.gov/CaseyHealthCenter> (Last visited June 14, 2012). Petitioners' Exhibit 7 also contains records from the Alexandria Health Department, but from a different clinic. The records in Pet. Ex. 7 appear to be well-child visits, and those from the Casey Health Center appear to be sick child visits. Ms. Hassan addressed this issue in her testimony. See Tr. at 21-22.

of age. Pet. Ex. 9, p. 33. He had been coughing and had a runny nose for two days, and had mild congestion on examination. The notes reflected that he had been last seen by a physician two months earlier. Mohamed was walking alone, and, although the handwriting is not entirely clear, it appears to indicate that he was “talking to Mom” and that he had “4-5 words.” *Id.* The notation that Mohamed spoke four or five words would indicate that he was talking at this point in his development. The treatment section is largely illegible, but the last entry reflects a referral to the “WIC Program.”²⁶ *Id.* In testimony, Ms. Hassan described this visit as a very abbreviated one, with the physician spending five minutes or less with Mohamed. Tr. at 19-20.

9. Mohamed was seen again at the Alexandria Health Clinic on July 24, 1996, when he was 15 months old. Pet. Ex. 7, p. 4. Some of what transpired at this visit is contested and is thus addressed in Part B, below. Much of the visit focused on his diet. Mohamed was noted to sleep with a bottle, had poor appetite, and on some days he didn’t want to eat. The only mention of a recent illness was for a stomach virus, but he was “ok now.” Most of the physical examination section is difficult to read. The neurology portion of the physical examination section indicates that Mohamed’s reflexes were ok, and that he walked at nine months of age, but other entries are too faint to decipher. *Id.* He was certified for the WIC program, and his parents were advised to discontinue his bottle, and were given “extensive feeding advice.” *Id.*, p. 3.

10. Mohamed next visited the Casey Health Center on August 19, 1996, when he was 16 months old. He was again noted to have had a poor appetite. Although the duration of the poor appetite is difficult to decipher, the record appears to indicate a two-month duration, placing onset in June. Mohamed was also having hard black and green stools, which had been “pellet-like” for the last several days. He had a fever “since Friday,”²⁷ had continued to have wet diapers, and would accept formula or milk in a bottle even when he was refusing table foods. He was alert and crying, but consolable, and had some raised papules on his cheeks. His height and weight were in the 25th percentile and were described as “appropriate for age.” He was prescribed juice for constipation and a cream for his face for possible eczema. His parents were counseled about normal appetite fluctuations in toddlers. They requested that he receive a varicella vaccine, but were advised that they would have to see a private pediatrician to obtain it. He was given a prescription for iron and vitamins. Pet. Ex. 9, p. 32.

²⁶ The Special Supplemental Nutrition Program for Women, Infants, and Children (“WIC Program”) is a federally funded program that provides food vouchers and offers educational programs regarding proper nutrition to pregnant, post-partum, and breastfeeding women and children under the age of 5. *Alexandria Health Department*, <http://alexandriava.gov/health/info/default.aspx?id=11444#nutrition>; *About WIC*, <http://www.fns.usda.gov/wic/aboutwic> (Last visited June 14, 2012).

²⁷ According to two websites that display perpetual calendars, August 19, 1996 was a Tuesday, so at the time of the appointment Mohamed had been febrile for five days. See *supra* n. 23.

11. In early October 1996, Mohamed was seen at the Casey Health Center for a cough and sore throat the previous three-four days. He had a purulent nasal discharge and was placed on antibiotics. Pet. Ex. 9, p. 31.

12. Mohamed's 18 month well child visit took place on October 23, 1996, at the Alexandria Health Clinic. He was reported to have problems with constipation and eating. His most recent illness was a cold, for which he had been treated at the Casey Health Center. His physical exam was notable for large tonsils. The neurologic portion of the exam noted that he walked at nine months of age, but that his speech was delayed, and that he should have a speech and hearing evaluation. Pet. Ex. 7, p. 4. This is the first mention of delayed speech in Mohamed's medical records. Mohamed was referred to the Alexandria Parent Infant Education ["PIE"] early intervention program, and the record reflects that he and his mother were taken to the PIE office on the date of this visit. *Id.*, p. 3.

13. The recommended speech therapy evaluation took place on November 8, 1996. Mohamed scored most consistently in the range of 9-12 months. He used Arabic words for mom and dad, and used vocalizations and crying to protest and request things. Mohamed was capable of imitating sounds when requested to do so, but primarily communicated with crying. He was able to follow very simple (one step) commands in Arabic, the primary language spoken at home. Pet. Ex. 16, pp. 21-22. Weekly speech therapy was recommended. *Id.*, p. 21.

14. The speech therapy evaluation was followed a week later by an early intervention evaluation on November 14, 1996.²⁸ Mohamed was evaluated in his home, with his parents and the PIE social worker present. At the time of the referral, "Mohamed had no intelligible language." Pet. Ex. 16, p. 8. He was noted to have "had only common colds since birth." *Id.* His mother was concerned about his eating habits, reporting that he preferred fried foods, but had begun to accept other foods so long as he did not have to touch them. *Id.* His cognitive skills were assessed at the 13 month level, with some skills at the 14-16 month level. Although some problems with transitions were noted, Mohamed was interested, enthusiastic, and made many attempts to engage with his parents. He was responsive to and cooperative with the examiner about 50% of the time. Early intervention services were recommended "to address cognitive delays." *Id.*, p. 9.

15. Mohamed had a sensory integration evaluation on January 3, 1997. His mother described him as a difficult infant who cried constantly. She also reported that he was sensitive to textures. In contrast to other records that reflected that Arabic was the primary spoken language in the home, the evaluator indicated that English was the

²⁸ Although the date of the visit was recorded as 11-14-1995, I conclude that the visit occurred on November 14, 1996, as Mohamed was listed as 19 months old at the time of the evaluation. Additionally, the report references his November 8, 1996 speech/language evaluation.

primary language.²⁹ The evaluator also indicated that Mohamed was doing well in speech therapy, but was having problems adjusting to the PIE play group in which he was enrolled. He had difficulty in adapting to new settings, prompting inconsolable crying. During the evaluation, he became so distressed at a move to a different room that he vomited. He would not engage in imitative play with cars and he displayed repetitive movements. The evaluator found deficits in self-regulation, interactive play skills, and motor planning. Pet. Ex. 16, pp. 10-11.

16. On January 24, 1997, Mohamed was taken to Alex. ER for fever, cough, and vomiting. He was fussy and crying during the examination. Ms. Hassan provided a history of one day of fever and cough, and vomiting the previous evening. He had a temperature of 101.4° in triage. Pet. Ex. 8, pp. 16-17. A chest x-ray was read as negative. *Id.*, p. 18. The assessment was an acute febrile illness. *Id.*, p. 16.

17. Mohamed went to the Alexandria Health Clinic on January 31, 1997, for his 18 month well child assessment. Mohamed was coughing, and his recent emergency room visit for the “flu” was noted. Mohamed’s history of delayed speech and sensory integration problems were also reflected. A hearing evaluation was ordered³⁰ and Mohamed was referred for a neurologic examination. Pet. Ex. 7, pp. 5-6. The hearing evaluation, a brainstem auditory evoked potential study, was performed on March 19, 1997, and was normal. Pet. Ex. 21, p. 24.

18. In March 1997, Mohamed had two medical visits to the Casey Clinic for otitis media and an upper respiratory infection. His temperature was 101° at one point in the illness. Pet. Ex. 9, pp. 28-29.

19. On April 7, 1997, just a few days before his second birthday, Mohamed was seen at the Casey Health Center. The principal complaints were yellow mucus in his stools for four days, followed by one day of black stool and vomiting. Pet. Ex. 9, p. 27. A stool culture was ordered at this visit, and submitted on April 10, 1997. No ova, toxins, or parasites were found. *Id.*, pp. 18, 27.

20. Mohamed received a varicella vaccination on April 8, 1997, without apparent ill effects. Pet. Ex. 5, p. 1.

²⁹ Ms. Hassan explained during her testimony that, at the recommendation of the speech therapy evaluator who conducted the initial evaluation, she and her husband began speaking only English at home in order to assist Mohamed’s speech development. Tr. at 72-73.

³⁰ Although Ms. Hassan testified that a hearing evaluation had been ordered in July, 1996 (see Tr. at 57), there is no July medical record containing such an order and no record of any hearing evaluation prior to March 19, 1997. The October 1996 well child evaluation does reflect that Mohamed “need[ed] S & H eval,” and the speech evaluation took place the next month. Pet. Ex. 7, p. 4. At the speech evaluation Ms. Hassan indicated that she had no concerns about Mohamed’s hearing, suggesting a possible reason that no hearing evaluation had been performed. Pet. Ex. 16, p. 22.

21. Mohamed's two year well child check up was performed at the Alexandria Health Clinic on April 18, 1997. His elimination and sleep patterns were described as good. He was assessed as having developmental delay, speech delay, and low weight. He was referred for nutritional counseling, and was pending a neurological assessment. Pet. Ex. 7, pp. 7-8.

22. On April 24, 1997, Mohamed was seen again at the Casey Health Center for a complaint regarding poor appetite for the prior two weeks, flatulence, and black and malodorous stools. He was described as being much less active than usual for the prior 10 days. Pet. Ex. 9, p. 26. Blood tests were performed that day. *Id.*, pp. 11, 26. Although some individual results were listed as low or high, the physician who reviewed the test indicated it was within normal limits. Pet. Ex. 9, pp. 11, 25. Mohamed was seen for follow up two weeks later. At that point, he had normal activity and appetite, and had not experienced any vomiting. The physician thought that the stool problems might be related to a multivitamin he was taking. *Id.*, p. 25.

23. From May through early June 1997, Mohamed was seen several times for problems with his stools, fever, vomiting, a throat infection and decreased appetite. Pet. Ex. 9, pp. 6-8, 20-25. He had one visit to the Alex. ER on May 18, 1997, for fever and vomiting, and was treated with an antibiotic (Rocephin) and an anti-emetic (Phrenegan). Pet. Ex. 8, pp. 13-14. He had no reported diarrhea in conjunction with this illness. *Id.*

24. Mohamed's initial neurological evaluation, performed by Dr. Philip Sheridan, took place on June 10, 1997, when he was 26 months of age. By history, Mohamed had "only routine minor illnesses such as ear infections." Pet. Ex. 12, p. 4. He walked at nine months of age, and began scribbling at 21 months of age. His receptive language skills appeared good, and he was able to follow directions. He had been able to point to body parts since about 21-22 months of age, and tried to imitate songs. However, he babbled, rather than using words. His mother was reported to have been "slow to speak." *Id.* The neurologist assessed Mohamed as having normal development, other than a speech delay, and recommended a follow up in 6 months. *Id.*, p. 5.

25. There were no medical records filed for the remainder of the summer, but Mohamed was seen several times in September through November 1997, for various stooling problems (possible parasites, diarrhea, and gas), stomach ache, a urinary infection, and a viral illness. Pet. Exs. 9, p. 19; 8, pp. 7-9; 11, p. 1; 18, p. 3.

26. At some point, Mohamed was referred to Dr. A.R. Colon, a gastroenterologist at Georgetown University Medical Center, where Mohamed was first seen on November 5, 1997. The complaint was chronic recurrent diarrhea for one year. Pet. Ex. 18, p. 44. The problems were described as starting after a bout of stomach flu

and persisting in a cyclic fashion thereafter.³¹ Doctor Colon's impression was a "post-enteritis syndrome," but he ordered a number of tests to rule out other causes *Id.* Mohamed had a barium enema on December 8, 1997, which showed a large amount of stool, but no structural abnormalities. Pet. Ex. 11, p. 10. Mohamed tested positive for clostridium difficile toxin B³² in December 1997. *Id.*, p. 11.

27. Mohamed was evaluated by his preschool special education teacher in December 1997. She provided a detailed assessment of Mohamed's activities, strengths, and limitations. Pet. Ex. 16, pp. 15-16. She described Mohamed as a bright child who could not sit still, but who could focus on activities of his own choosing. He had difficulty with transitions between activities, and would throw tantrums to protest routine activities such as hanging up his coat. He rearranged classroom chairs so that the same colors were always in the same order. *Id.*, p. 15. He could not take turns or share with other children, but would play in a group if the activity did not require sharing. He mouthed objects, avoided touching certain textures, and would use only a few single words inconsistently without prompting. He would occasionally use sign language. She described his tantrums and ability to manage novel situations as improved since beginning the program in September, and concluded that Mohamed presented a "complex picture of atypical development." *Id.*, p. 16.

28. Doctor Sheridan, the health department neurologist, reviewed this letter in making his six month reassessment of Mohamed. He noted considerable developmental and language progress in the preceding six months, and commented again that the delayed speech could be a familial pattern, in view of Ms. Hassan's history of not speaking until two years of age. Pet. Ex. 12, p. 2.

29. Mohamed was evaluated by a British physician during a family visit to England in February 1998. By history, Mohamed had an acute illness with fever, diarrhea, and vomiting 18 months earlier, which would have placed the illness as occurring in August 1996.³³ Since that illness, his parents indicated that he had

³¹ There are no medical records reflecting chronic or recurrent diarrhea in the year preceding this visit. Likewise, there are no records reflecting a bout of stomach flu a year before this visit. The illness which followed the allegedly causal vaccinations was characterized as gastroenteritis, which is commonly known as the stomach flu, but that illness occurred more than 18 months prior to Dr. Colon's evaluation. The only illness occurring about a year prior to this evaluation was an upper respiratory problem in October 1996. See Pet. Ex. 9, p. 31. The two medical visits bracketing this October upper respiratory infection both reference problems with constipation, not diarrhea. See *id.*, pp. 27, 32.

³² The toxin produced by this species of bacteria is known to produce diarrhea in children, particularly in those undergoing antibiotic therapy. DORLAND'S at 374, 625.

³³ There are no records pertaining to a gastrointestinal illness during July, August, or September 1996, although there was a reference at a July 1996 visit to a "recent" bout of stomach flu. See Pet. Ex. 7, pp. 3-4. The allegedly causal vaccinations and subsequent gastrointestinal illness took place in April 1996. However, in August 1996, Mohamed was seen for a fever, rash, and problems with his stools, which were reported as hard and pellet-like for several days before the August 19, 1996 visit. See Pet. Ex. 9, p. 32.

intermittent diarrhea with abdominal pain and flatulence.³⁴ No other family member was affected and treatment for the clostridium difficile infection did not relieve Mohamed's symptoms. This physician "concurred with the specialists" that Mohamed had a "post enteritis syndrome." Pet. Exs. 11, pp. 14-15; 18, pp. 38-39.

30. Mohamed was referred to Georgetown University by his pediatrician for an evaluation of his development in March 1998. Testing showed that Mohamed, then almost three years of age, had cognitive development at the 16 month level, but the evaluator indicated that this might be an underestimate. His language skills were scattered at the 12 month level. Mohamed's score on the Childhood Autism Rating Scale was 37, reflecting mild to moderate autism. Pet. Ex. 10, pp. 1-4.

31. A follow up visit at the neurology service of the Alexandria Health Clinic in April 1998 did not reference the Georgetown University developmental evaluation conducted just a month earlier. Doctor Sheridan noted Mohamed's distractibility and impulsiveness, and indicated that he might need medication. He wanted to see Mohamed again in five months to ensure his school placement was "optimal." Pet. Ex. 9, p. 4

32. Mohamed was hospitalized for three days in late May and early June, 1998, leading to a diagnosis of lymphonodular hyperplasia.

a. Ear pain was diagnosed as right otitis media at an emergency room visit on May 23, 1998, and treated with amoxicillin. Pet. Ex. 8, pp. 3-4. By the time of a follow up visit on May 27, Mohamed had developed nasal congestion. Pet. Ex. 18, p. 8. A stool sample was tested for clostridium difficile, suggesting that Mohamed was experiencing stooling problems. Pet. Ex. 11, p. 1.

b. Two days later, he was seen at another emergency room for abdominal pain and pain on defecation. His parents reported blood in his stools and diarrhea, but a stool sample tested negative for blood. Mohamed was sent home with advice to use mineral oil and increase his fiber intake. Pet. Ex. 21, pp. 17-21.

c. On May 30, 1998, Mohamed was admitted to Georgetown University Hospital, where he stayed for three days. The history taken initially indicated that

³⁴ Between August 1996 and the date of this evaluation, Mohamed was seen for constipation in October, 1996 (Pet. Ex. 7, pp. 3-4); fever and vomiting in January 1997, with a follow up visit on January 31, 1997, where his elimination was reported as "ok" (Pet. Exs. 7, pp. 5-6; 8, pp. 15-17); otitis media in March 1997 (Pet. Ex. 9, pp. 28-29); flatulence, and black, malodorous and mucus stools in April 1997 (Pet. Ex. 9, pp. 25-27); diarrhea during a febrile illness in May, 1997 (Pet. Ex. 9, p. 24); stomach aches and poor appetite in June 1997 (Pet. Ex. 9, p. 21); diarrhea in conjunction with a febrile illness in September 1997 (Pet. Exs. 8, pp. 7-9; 11, pp. 1,3); and diarrhea without any accompanying illness in October 1997 (Pet. Ex. 11, p. 1; 18, pp. 3-4). At the initial visit to Dr. Colon in November, 1997, Mohamed was first reported to have had "chronic diarrhea." (Pet. Ex. 11, pp. 8-9).

Mohamed had chronic diarrhea since birth, but later noted chronic diarrhea between birth and three months of age, followed by intermittent diarrhea, and also indicated that Mohamed alternated between constipation and diarrhea. Pet. Ex. 23, p. 11.³⁵ Mohamed was difficult to examine, but was in no apparent distress. *Id.*, p. 16. Mohamed appeared playful through the day of May 31, but became hysterical and complained that his “belly hurts” when staff attempted to take vital signs. *Id.*, pp. 30, 33. He had no diarrhea during his hospitalization. *Id.*, p. 14. An endoscopy performed during the hospitalization showed lymphonodular hyperplasia of the terminal ileum. *Id.*, p. 12. Mohamed was discharged on June 1, 1998.

33. Mohamed was first evaluated by Dr. Shafrir on July 17, 1998. There are several copies and at least two different versions of Dr. Shafrir’s report in the records filed.³⁶ Because much of the history included in his evaluation is in controversy, I address this evaluation in Part B, below.

B. Facts in Dispute Resolved in this Order.

The primary matters in dispute concern onset and severity of various symptoms. Unlike many cases, the onset does not have statute of limitations implications, as this petition was filed within three years of receipt of the allegedly causal vaccinations. To summarize the findings below, after a very careful review of the medical records, I find no evidence supportive of a Table encephalopathy and I do not find evidence of onset of most of the symptoms complained of within close temporal proximity to Mohamed’s April 1996 vaccinations.

I accept petitioners’ assertions that many of the physicians who saw Mohamed, other than Dr. Shafrir, did not spend much time with him or listen carefully to their concerns. It is not surprising that a public health clinic physician, or even one in private practice, might not have the time that Dr. Shafrir devoted in his initial assessment of Mohamed. The records reflect that Dr. Shafrir was the first physician who recorded a possible cause for Mohamed’s difficulties. However, the affirmative physical and developmental findings recorded in the primary care records do not support petitioners’

³⁵ The records for this history are scattered throughout Pet. Ex. 23, beginning on p. 11, jumping to p. 23, and then to p. 28.

³⁶ See Pet. Ex. 20, p. 70 and Pet. Ex. 22, p. 10 (office notes, initial draft of report); Pet. Ex. 18, pp. 29-32 (incomplete, signed copy of first version in the form of a letter, printed on letterhead, to Mohamed’s pediatrician, Dr. Nora Jose) and Pet. Ex. 22, pp. 38-42 (complete, signed copy of first version in the form of a letter, printed on letterhead, to Mohamed’s pediatrician, Dr. Jose); Pet. Ex. 22, pp. 13-14 (Telephone messages from Mr. Ahmed requesting Dr. Shafrir call him and noting that “something has changed.”); Pet. Ex. 22, p. 48 (one page draft with hand written edits and comment regarding “changes on consult per father”); Pet. Ex. 14, pp. 1-5 (signed second version, in the form of a letter, printed on paper without letterhead, to Dr. Jose); Pet. Ex. 22, pp. 32-37 (unsigned second version, in the form of a letter, printed on letterhead, to Dr. Jose). I note that the signed version of the report found in petitioners’ exhibit 14 appears to have been signed by someone else on behalf of Dr. Shafrir, while the signed versions found in petitioners’ exhibits 18 and 22 seem to have been signed by Dr. Shafrir himself.

claims of a Table encephalopathy or of onset of symptoms attributed to autism shortly after receipt of the allegedly causal vaccines.

I address first the facts as related to the Table injury claim, followed by the facts as related to the claims in the petition and in Ms. Hassan's testimony.

1. Table Encephalopathy.

a. Definition.

A person is considered to have suffered a table encephalopathy if the individual manifests an injury encompassed in the definition of an acute encephalopathy, within the appropriate time period, and if a chronic encephalopathy is present for more than 6 months after the immunization. Vaccine Injury Table's Qualifications and Aids to Interpretation ["QAI"], 42 C.F.R. § 100.3(b)(2).

The QAI defines an acute encephalopathy as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i). For a child younger than 18 months, presenting without an associated seizure event, an acute encephalopathy is indicated "by a significantly decreased level of consciousness . . . lasting for at least 24 hours." § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is indicated by the presence of one of three clinical signs for a period of at least 24 hours: "(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)." § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are not alone, or in combination, a demonstration of an acute encephalopathy. § 100.3(b)(2)(E).

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination." § 100.3(b)(2)(ii).

b. Factual Findings Regarding an Acute Encephalopathy.

Based on the QAI definition, it is clear that, although Mohamed was obviously ill following the DTP and Hib vaccinations on April 23, 1996, he did not experience symptoms consistent with an acute Table encephalopathy. There is no evidence that Mohamed had a "significantly decreased level of consciousness" for more than 24 hours. Mohamed was seen twice by physicians at the Alexandria Hospital emergency room. He was described as alert and somewhat irritable on April 24 (Pet. Ex. 8, p. 23), and alert and non-toxic in appearance on April 25 (*id.*, p. 20). None of the physicians who actually examined him characterized him as lethargic, although he was described that way in the record of a telephone consultation with his Pittsburgh pediatrician's office

before the second emergency room visit. Pet. Ex. 4, p. 5. Even if accurate, lethargy alone does not constitute a Table encephalopathy.

Mohamed responded to his environment during both hospital visits. He was described as sleeping in his mother's arms, but easily arousable during the April 24 visit. He was alert and active and drinking water at the time of his discharge from the emergency department. Pet. Ex. 8, p. 24. At the April 25 visit, the triage nurse reported that Mohamed was alert and "looked good." *Id.*, p. 21.

It is also significant that Mohamed was not admitted to the pediatric ward or any intensive care unit at either of these two visits, and that the discharge diagnosis from the final visit was gastroenteritis, not encephalopathy or any other neurological diagnosis. See Pet. Ex. 8, p. 19.

c. Factual Findings Regarding Chronic Encephalopathy.

There is no reliable evidence that Mohamed experienced a chronic encephalopathy for the six months following his two April 1996 emergency room visits.

Mohamed was not seen again by any health care provider for two months after these emergency room visits. The reason for his next physician's visit was a cough and runny nose. Although I accept Ms. Hassan's testimony (Tr. at 53-54) that the physician did not spend much time with Mohamed during this visit, the records do reflect that Mohamed received a physical examination that included his eyes, ears, and abdomen, and included the observations that he was walking alone and talking to his mother using "four to five words." Pet. Ex. 9, p. 33. This interaction with his mother is also inconsistent with a persistent Table encephalopathy.

The remainder of Mohamed's medical records also fails to support the existence of a persistent Table encephalopathy in the six months following his initial illness after the allegedly causal vaccinations. Mohamed was seen by physicians in July, August, and October, 1996. None of the records from these visits suggest that Mohamed had a decreased or absent response to his environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli. In August, he was described as alert and crying, but consolable, an affirmative indication that he was responsive to his environment. Pet. Ex. 9, p. 32.

I thus conclude that the factual predicate for a Table encephalopathy is lacking in this case.

2. Mohamed's Health and Behavior after the April 1996 Vaccinations.

The petition asserts “that Mohamed was an entirely different child in that he would not speak appropriately, would not play with others appropriately, and in every way began exhibiting the symptoms of autistic behavior” after these vaccinations. Second Amended Petition, ¶ 11. Ms. Hassan testified that after the two April, 1996 emergency room visits, Mohamed “wasn’t eating at all,” vomited everything he ate, and cried almost constantly. His stools changed, becoming dark and loose, and he had a poor appetite. Tr. at 17. He did not sleep well, stopped talking and babbling, and began communicating by pointing. He did not respond to his name. Tr. at 17. He stopped playing with his toys and would not play with other children. Tr. at 18.

The medical records establish that Mohamed experienced speech delay, problems in interacting with peers, and other symptoms of autistic behaviors at various times, but I conclude that these behaviors did not manifest soon after his vaccinations. While it is nearly impossible to determine precisely when Mohamed’s speech was delayed, I conclude that he was using four to five words two months after his vaccinations, but had lost words by the time of his speech and language evaluation in November, 1996.

Mohamed’s social interactions were observed and discussed at the November 1996 speech and developmental evaluations. Mohamed appeared to have limited opportunities to interact with peers until he joined the PIE playgroup at some point around the time of his developmental evaluation. Thereafter, his difficulties in interacting with peers became apparent.

Mohamed did, at various points, display other symptoms of autistic behavior, including picky eating and poor appetite, a rigid adherence to routines, and inappropriate play activities. There is little evidence, however, that most of these behavioral symptoms began in close proximity to the allegedly causal 12 month vaccinations. Mohamed certainly had gastrointestinal problems, but these began much earlier in life. It does appear that his gastrointestinal problems significantly worsened by August 1996. I draw these conclusions largely from the contemporaneous medical records, and to a lesser extent from histories recorded close in time to the events described.

a. Speech and Language Development.

If the pediatric practice where Mohamed received his first nine months of pediatric care did developmental assessments, any such assessments were not in the records filed. Likewise, the forms used by the public health clinic where Mohamed received his 12 month vaccinations, and where his 15 and 18 month well child visits were conducted, do not contain any specific sections for developmental evaluations.

Thus, contemporaneous information from medical records concerning his speech and language milestones is quite sparse, but not entirely non-existent.

At the first emergency room visit after receipt of the allegedly causal vaccines, Mohamed was observed to vocalize, but there was no further indication that he was using words. Pet. Ex. 8, p. 23. Mohamed was 12 months old at the time of this visit. Parental histories reflect that Mohamed used words for mother and father by 12 months of age. See, e.g., Pet. Ex. 23, p. 57.

The next mention of his speech in a contemporaneous medical record was in June, 1996, when he was 14 months old. In what Ms. Hassan described as a very quick examination, Mohamed was observed talking to his mother, and using four or five words. Pet. Ex. 9, p. 33.

Ms. Hassan testified that at the July 24, 1996 visit to the health department (Mohamed's 15 month well child visit), the doctor raised issues about Mohamed's response to his name, lack of eye contact, and language regression. Tr. at 20. She reported that he had changes in his behavior, and had stopped talking. In response, the doctor referred Mohamed for speech and hearing evaluations. Tr. at 20-21. With regard to these specific concerns and symptoms, it is clear that a health department doctor had concerns about Mohamed's language development, but not at the July 1996 well child visit. Rather, the medical records support that these concerns about Mohamed's behavior arose instead at the 18 month well child visit in October 1996. I base this finding on the contemporaneous medical records. Although a portion of the July 1996 record (Pet. Ex. 7, p. 4) is poorly reproduced, and is thus illegible, the October record clearly reflects the concern about speech delay, the referrals for further evaluation made, and the escorting of Ms. Hassan to the early intervention program office the same day as the visit. The records also reflect that the evaluations occurred within a few weeks of this referral. I thus conclude that Ms. Hassan was simply in error about the date of these events. Based on the prompt referral for evaluation in October and the lack of any referral notation at the July visit (in a portion of the July record that is legible), and the other actions taken when delay was noted in October, I find it unlikely that the physician found speech delay in July, 1996.

At the October 1996 well child visit, the physician recorded that Mohamed had delayed speech and referred him for a speech and hearing evaluation and a developmental assessment. Pet. Ex. 7, pp. 3-4. These assessments took place very shortly after the referral. At the November 8, 1996 speech therapy evaluation, Mohamed used Arabic words for "mama" and "dad" and made other vocalizations. He could follow simple one step commands. Pet. Ex. 16, p. 22. At the early intervention evaluation a week later, Mohamed was able to follow two such one-step commands, such as "give it to me" or "come here." *Id.*, p. 8. Although this developmental evaluation indicates that, at the time of the referral, Mohamed had no intelligible speech, Mohamed demonstrated that he could use vowel-consonant combinations, and could imitate sounds. I rely primarily on this evaluation (*Id.*, pp. 8-9) for an assessment of

Mohamed's social interaction and cognitive skills, and place more weight on the speech and language evaluation a week earlier to assess Mohamed's expressive language skills.

Because there are no records of a 12 month well child visit and no references to speech and language development at the 15 month well child visit, the best available medical evidence of Mohamed's speech and language development reflects that he was speaking several words in June 1996, when 14 months of age, but had less expressive language at 18 months of age in October 1996, when he was referred for speech evaluation. When evaluated, his speech was most consistently at the 9-12 month level.

b. Social Interaction.

Once again, the records pertaining to Mohamed's early social development are sparse. Neither the speech evaluation nor the early intervention evaluation reflects any concern about social interactions with his parents. The written evaluation from the early intervention examination noted that he engaged with his parents, and was responsive to and cooperative with the examiner about 50% of the time. Pet. Ex. 16, p. 27. The testing reflected that Mohamed's social/emotional development was at about the 13 month level. *Id.*, p. 30. Mohamed was 19 months old at the time of this evaluation.

Around the time of the early intervention evaluation, Mohamed began attending a play group occasionally. Pet. Ex. 16, p. 29. In January, 1997, Ms. Hassan reported in a sensory integration evaluation of Mohamed that play group participation was difficult, as Mohamed did not adapt well to new settings, and cried inconsolably at the play group. *Id.*, pp. 10-11. This evaluation did not address Mohamed's interactions with his peers, and no goals were set regarding areas other than speech and cognitive development in the early intervention records.

The first reference to interaction with other children involves a summer preschool transition group which Mohamed attended, at least sporadically, in the summer of 1997.³⁷ The notes reflect that on July 8 or 10, Mohamed greeting another child on arrival and engaged with another during table work. Pet. Ex. 16, p. 19. On July 15, Mohamed primarily played independently, but laughed with another boy. *Id.*, p. 14. On August 5, 1997, he was noted to play on the swing with two children. However, on the same day, he was removed from the classroom because of disruptive behavior, including hitting and pulling other children. *Id.*, p. 18.

The first record reflecting peer interactions over a period of time is the 1997 evaluation from Mohamed's pre-school program for September through December. Pet. Ex. 16, pp. 15-17. It paints a different picture of his peer interactions. Mohamed

³⁷ Notes were filed for only a few dates in July and August. See Pet. Ex. 16, pp. 14, 18-19.

was reportedly capable of playing in a group, but only if there were enough materials for all in the group. He did not take turns or share with others. He engaged in parallel play with other children, and sometimes played with them in gross motor and occasionally in “circle time” activities. *Id.*, p. 16.

In his initial evaluation for developmental concerns at Georgetown University in March, 1998, he was noted to have difficulty interacting with peers. It was at this evaluation, when Mohamed was 35 months old, that he received a diagnosis of mild to moderate autism. Pet. Ex. 10, pp. 1, 3.

In contrast, Dr. Shafir's report from his July 1998 evaluation of Mohamed indicates that his social functioning “is quite good.” Mohamed was reported to interact with guests, enjoyed visits from other children and would try to share toys with them, and played well with his younger sister. He was described as very friendly and willing to share with friends in school.³⁸ Pet. Exs. 14, p. 2; 22, pp. 33, 39. Doctor Shafir also reported that Mohamed was “always affectionate towards his parents” and that there had been no regression in this behavior. Pet. Exs. 14, p. 3; 22, pp. 34, 39. At least some of this information appears to have been drawn directly from the questionnaire completed for this pediatric neurology evaluation. Pet. Ex. 22, p. 178.³⁹

Based on the information available, I conclude that Mohamed was socially engaged with his parents at the time of his initial speech and early intervention evaluations in November, 1996, seven months after the allegedly causal vaccinations, and that he remained socially engaged and affectionate with his parents thereafter, at least through the time of Dr. Shafir's initial evaluation, which occurred 27 months after these vaccinations.

There is inadequate evidence to draw a conclusion concerning peer group interactions at the time of his 12 month vaccinations, and conflicting evidence regarding his social interactions with his peers thereafter. I place the most weight on the evaluation of Mohamed's preschool special education teacher, and conclude that between September and December 1997, Mohamed had difficulties in peer group interactions. I cannot, based on this record, determine that Mohamed had problems

³⁸ In a written questionnaire completed for Mohamed's initial evaluation by Dr. Shafir, petitioners reported that he socialized with visitors to the house, played with children his own age, and played with his siblings. They described Mohamed as very friendly with classmates and willing to share with them. This was an improvement in his behavior since starting school. Earlier, Mohamed would grab toys from other children and would not maintain eye contact with them. Pet. Ex. 22, p. 178.

³⁹ All of the pages of this questionnaire do not appear consecutively in Pet. Ex. 22. Although the first four pages are consecutive at pp. 175-78, the fifth through final pages are at pp. 169-74.

with peer group interactions in the period immediately following his 12 month vaccinations.⁴⁰

c. Appetite and Eating Difficulties.

Ms. Hassan's testimony indicated that Mohamed developed eating problems after his 12 month vaccinations. Specifically, she testified that Mohamed "wasn't eating at all," vomited everything he ate, and he had a poor appetite. Tr. at 17. I find that, with the exception of some feeding difficulties in his first months of life and during illnesses, the first indication that Mohamed was a picky eater was in January 1996, when he was reported to be refusing some foods, but eating yogurt. Pet. Ex. 4, p. 6. After the April 1996 vaccines, he refused to eat while he was acutely ill. See, e.g., Pet. Ex. 8, p. 21. Persistent complaints to health care providers of poor appetite began in July 1996, with probable onset in June 1996. See Pet. Exs. 7, pp. 3-4 ("poor appetite"; "some days doesn't want to eat"); 9, p. 32 ("poor appetite x 2 mos"). Complaints about poor appetite persisted in October 1996, and April 1997, with low weight concerns in April 1997, weight loss concerns in May 1997, poor weight gain concerns in June 1997, and a complaint of "picky appetite when ill" but good activity and energy at the gastroenterology consult in November, 1997. Pet. Exs. 7, pp. 3-4, 7-8; 9, pp. 21, 24, 26; 11, pp. 8-9. I thus conclude that Mohamed did experience both poor appetite and picky eating shortly after his April 1996 vaccinations, but had displayed picky eating prior to these vaccinations as well. There is no support in the medical records of persistent vomiting after the April 1996 vaccinations. Vomiting was reported only in the context of febrile illnesses or when upset by change.

d. Sleep Disturbances.

There is no medical evidence to support onset of sleep disturbances in the months after the April 1996 vaccinations. The medical records contain no references to sleep disturbances at any visit in June, July, or August 1996. There are affirmative references to good sleep. In October 1996 when Mohamed's speech delay was first referenced, he was reported to sleep all night. Pet. Ex. 7, p. 4. He was also reported to sleep well in January and April 1997. Pet. Ex. 7, pp. 5-6. The first mention of poor sleep is in the context of a febrile illness in June 1997, when he was reported to have stomach aches and nighttime crying. Pet. Ex. 9, p. 21. In May 1998, when he was hospitalized for three days, the history of his present illness indicated that he was waking up at night in pain and bouncing on his bed, but the in-patient records indicated that he slept well, only complaining of pain when he was woken for vital signs. Pet. Ex. 23, p. 30. I note that the questionnaire Ms. Hassan completed for Dr. Shafrir's initial

⁴⁰ In the questionnaire completed for Dr. Shafrir's evaluation, petitioners indicated that a family friend voiced concerns about Mohamed's behavior when he was two years of age, or approximately one year after the allegedly causal vaccinations. Pet. Ex. 22, p. 171. Petitioners did not elaborate on the nature of the concerns voiced, but I note that on another page of the questionnaire, petitioners reported that a cause of concern (at 24 months) was decreased language and increased activity. *Id.*, p. 176.

evaluation indicated that it was not a struggle to get Mohamed to sleep and that he had broken sleep only during his “GI problem,” presumably referring to Mohamed’s May 1998 hospitalization. Pet. Ex. 22, p. 169. I thus reject Ms. Hassan’s testimony (Tr. at 68) concerning sleep disturbances following the April 1996 vaccines and illness.

e. “Crying Almost Constantly.”

There is little support in the medical records that would support Ms. Hassan’s testimony of almost constant crying in the months after Mohamed’s 12 month vaccinations. He was a very fussy baby in the first few months after his birth, and he cried during illnesses, both before and after his 12 month vaccinations. The speech and hearing and early intervention records do support her testimony, in as much as they reflect that Mohamed used crying as a form of communication. However, he did not cry constantly during either evaluation,⁴¹ and was described in one as a “curious and enthusiastic 19 month old.” Pet. Ex. 16, p. 8. He cried during attempts to involve him in a play group in the fall of 1996. Pet. Ex. 16, p. 10. I thus conclude that he did not cry “constantly” after his 12 month vaccinations, but that, at some point before November 1996, Mohamed used crying to communicate wants and needs and to express displeasure.

f. Other Symptoms Consistent with Autism Spectrum Disorders.

By the time of the sensory integration evaluation in January 1997, Mohamed was displaying behaviors that are consistent with autism spectrum disorders. *White v. Sec’y, HHS, No. 04-337*, 2011 WL 6176064, *4-9 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (summarizing OAP testimony concerning such behaviors). He was sensitive to textures, had problems adapting to new settings, repetitively opened and closed doors in rooms and in playhouses, did not engage in imitative play, fixated on one activity, and threw new toys in frustration. Pet. Ex. 16, pp. 10-11. Mohamed was handling changes relatively well at the time of his early intervention evaluation in mid-November 1996, and the report from this evaluation (Pet. Ex. 16, pp. 8-9) did not reflect any of the behaviors noted at the January 1997 visit. I thus conclude that, with the exception of problems in adapting to new situations, these behaviors likely manifested during the time between the November and January evaluations. It is possible that they existed prior to the November evaluations, but that would mean that trained observers did not find them significant enough to include in their reports.

g. Gastrointestinal Problems and Their Onset.

Petitioners claim that Mohamed’s gastrointestinal problems are connected to his April 1996 vaccinations. See Pet. Exs. 1 and 2 (Petitioners’ affidavits); Pet. Ex. 28 (Dr. Shafir’s expert report); Tr. at 17. The medical records indicate that Mohamed had

⁴¹ For example, during the November 1995 evaluation Mohamed cried when a TV show was turned off and was soothed within two to three minutes. Pet. Ex. 16, p. 9.

problems with constipation beginning at about three weeks of age. This problem persisted at least until he was three months old. The first complaint of diarrhea occurred when he was about six months old. Pet. Ex. 4, p. 17. There were no further complaints of diarrhea until the febrile illness he experienced between eight and nine months of age.

Mohamed did experience diarrhea in conjunction with his febrile illness after the allegedly causal vaccinations in April, 1996. Pet. Exs. 8, pp. 20, 24; 4, p. 5. However, there were no further complaints about Mohamed's bowel movements until August 1996, when he was reported to have "black and green" stools that were hard and pellet-like for the last several days. Pet. Ex. 9, p. 32. Thereafter, there were a number of medical records substantiating various problems with Mohamed's gastrointestinal functioning.⁴²

I conclude that, although Mohamed suffers from gastrointestinal problems, there is no indication the onset of the problems is associated with his April 1996 vaccines. I base this conclusion on the reports of both constipation and diarrhea suffered prior to April 1996, the four month gap between the vaccinations and a reference to gastrointestinal problems in the medical records, and, after April 1996, the presence of a fever when diarrhea is noted in the records,.

3. Problems with the Medical History Taken by Dr. Shafir.

Doctor Shafir's July 1998 letter to Mohamed's pediatrician included a recitation of Mohamed's medical history. This recitation contains several factual inaccuracies.

a. Mohamed's December 1995 Illness.

Doctor Shafir's letter notes that "at nine months of age, after a third immunization, [Mohamed] had a very high fever." Pet. Exs. 14, p. 1; 18, p. 29; 22, pp.32, 38. Although Mohamed had a febrile illness when he was between eight and nine months of age (December 1995 - January 1996), it did not occur in close temporal proximity to any vaccinations. He received his third set of DTP and Hib vaccines on October 20, 1995. Pet. Ex. 4, p. 1. He experienced cough and congestion and possible fever two days later, which his pediatrician assessed as an upper respiratory infection. Pet. Ex. 4, p. 16. In a telephone consultation on November 3, 1995, Mohamed was

⁴² There was a complaint of constipation in October, 1996 (Pet. Ex. 7, p. 3), but by January 31, 1997, his elimination was described as "ok" (Pet. Ex. 7, p. 5). In April, 1997, he was seen for mucus in his stools, black stools, and constipation, but testing disclosed no ova or parasites. Pet. Ex. 9, pp. 18, 27. He was also seen in April for stools that were black and malodorous for about two weeks, along with complaints of gas and possible stomach aches. Pet. Ex. 9, 26. At a follow up appointment in May, 1997, the physician thought the problem with black stools might be related to a multivitamin Mohamed had recently begun taking. Pet. Ex. 9, p. 25. After developing a fever in mid-May, 1997, he began having diarrhea. Pet. Ex. 9, pp. 22-23.

reported to have been coughing for a week. *Id.* There is no record that he was seen thereafter for this illness. The febrile illness that Mohamed experienced during December 1995 to January 1996 occurred more than two months after these vaccinations.

I note that a hand edited version of Dr. Shafrir's letter reflects a change to "at 1 year of age, after a fourth immunization." Pet. Ex. 22, p. 48. However, it also includes a notation to "keep the nine month info about immunization and add the fourth immunization." *Id.* There are typed copies of the letter that associate fevers with both Mohamed's third and fourth immunizations. Pet. Exs. 22, pp. 32, 38; 14, p. 1.

b. Mohamed's Language Skills.

Doctor Shafrir's history indicates that at the age of one year, Mohamed would point at and use words to describe body parts. Pet. Exs. 14, p. 2; 18, p. 29; 22, pp. 33,38-39. This information likely came from the questionnaire (see Pet. Ex. 22, p. 171) completed for the initial evaluation by Dr. Shafrir. I note, however that the questionnaire does not say that Mohamed pointed to body parts or used words to describe them at the age of one year, just that he could once do so, but had lost that skill. An assertion that Mohamed could name body parts at one year of age conflicts with a response, contained in the same questionnaire, that Mohamed spoke his first word other than mama or dada at the age of 30 months. Pet. Ex. 22, p. 176.

An earlier history, taken at Dr. Sheridan's initial evaluation of Mohamed in June 1997, indicated that Mohamed was first able to point to body parts at 21-22 months of age, but there is no indication that he could name them at that point. Pet. Ex. 12, p. 4. Additionally, the June 1997 evaluation indicated that Mohamed "babble[d] rather than saying words." *Id.* The questionnaire indicated that Mohamed had less than 100 words at this point (July 1998), a point repeated in Dr. Shafrir's history, with the additional comment that Mohamed used words intermittently and inconsistently. Pet. Exs. 14, p.2; 22, pp. 33, 39, 177.

c. Regression.

Doctor Shafrir's history indicates, in an apparent reference to the loss of ability to name body parts, that this regression could not be clearly dated but probably related to the period of high fever after his 12 month immunizations. Pet. Exs. 14, p. 2; 22, pp. 33, 39. However, upon examination of the questionnaire for this initial visit, the loss of ability to point to and name body parts is associated with an illness identified as "GI troubles." Pet. Ex. 22, p. 171. Doctor Shafrir then goes on to indicate that the "beginning of diarrhea was also associated with regression." Pet Exs. 14, p. 2; 22, pp. 33, 39.

The difficulty here is that elsewhere in the questionnaire a reference to "GI problem" appears to refer to Mohamed's hospitalization at Georgetown about a month

earlier, as these “GI problem[s]” were associated on the form with sleep disturbances. Pet. Ex. 22, p. 169. During that late May-early June 1998 hospitalization, Mohamed’s parents reported that he would awake from sleep crying and clutching his belly and saying his “belly hurts,” behavior which was also observed by the hospital staff when they awoke Mohamed to take vital signs. Pet. Ex. 23, p. 30. Also, the questionnaire contains a query about whether there were concerns about Mohamed’s behavior “before the regression occurred.” The answer was that a family friend noticed problems when Mohamed was two years of age. Pet. Ex. 22, p. 171. Thus, any regression Mohamed experienced likely occurred after he was two years of age, and in fairly close proximity to his initial evaluation by Dr. Shafrir.

I base this latter finding on the fact that a March 1998 evaluation indicated that Mohamed scored in the range of mild to moderate autism, with language skills at 14 months of age. Pet. Ex. 10, p. 3. During his hospitalization at the end of May 1998, his mother reported that Mohamed spoke in one to two word sentences and had “good comprehension.” Pet. Ex. 23, p. 16. He was observed by the hospital staff to scream “My belly hurts.” Id., p. 30. However, Dr. Shafrir’s impression about a month and a half later was that Mohamed had a “near complete absence of functional language.” Pet. Exs. 14, p. 5; 18, p. 31; 22, pp. 36, 41. If Dr. Shafrir’s observation is correct, then Mohamed clearly lost ground after his May 1998 hospitalization. Doctor Shafrir’s evaluation of Mohamed as “severely autistic” in July 1998, when an evaluation that included the Childhood Autism Rating Scale scored him in the mild to moderate range four months earlier, coupled with these other indications of declining function, certainly suggests that Mohamed experienced some decline between these two evaluations.

IV. Orders to the Parties.

The next step in this case is for respondent to produce an expert report and a supplemental Rule 4 report. Thereafter, if needed, a causation hearing will be scheduled. 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 in a supplemental report: (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.

Respondent shall file her supplemental Rule 4(c) report, accompanied by her expert report, by no later than Friday, August 17, 2012.

IT IS SO ORDERED.

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