

OFFICE OF SPECIAL MASTERS

November 25, 2003

EARL DIXON AND JOY DIXON, *
parents of NOAH MATTHEW DIXON, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES *

Respondent. *

No. 01-0605V
PUBLISHED

James E. Baker, Seattle, Washington Attorney for Petitioners.

Catherine Reeves, United States Department of Justice, Washington, D.C. for Respondent.

ENTITLEMENT DECISION

FRENCH, *Special Master.*

On October 10, 2001, Petitioners, Earl Dixon and Joy Dixon, filed their claim in the above captioned matter for compensation under the National Childhood Vaccine Injury Act of 1986, as amended (“Vaccine Program” or the “Program”).¹ Petitioners allege that their son, Noah Matthew Dixon (Noah), sustained an injury (encephalopathy) as a result of the Measles-Mumps-Rubella (“MMR”) vaccine, the Hib influenza vaccine, and the Varicella vaccine, all of which were administered on the same day, May 14, 1999. See Petition (hereinafter “Pet.”) at 2.

¹The National Vaccine Injury Compensation Program comprises Part 2 of the National Vaccine Injury Act of 1986 (hereinafter “the Vaccine Act” or “the Act”), as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1999 & Supp. 2000). Hereinafter, individual section (§) references will be to 42 U.S.C.A. § 300aa of the Act.

I. PROCEDURAL BACKGROUND

After reviewing the evidence, the Department of Health and Human Services concluded that the nature of the evidence provided was insufficient to support Petitioner's claim for vaccine- injury compensation. Petitioners filed a Supplemental Petition on March 12, 2002, and on May 3, 2002, Respondent filed her responsive report pursuant to Vaccine Rule 4(b) denying Petitioner's claim for lack of evidence. Reports of the medical experts and affidavits of the eyewitnesses were filed during the ensuing months of December and January 2003, and a date was set for hearing in January. As is often the problem in vaccine cases, missing records delayed the hearing, and the case was finally heard on March 20, 2003, in Washington, D.C.

At the evidentiary hearing, Petitioners presented the testimony of Mrs. Dixon and their medical experts, Dr. F. Edward Yazbak, Dr. Thomas A. Schweller, and Dr. Mark Geier. Respondent presented the testimony of Dr. Lawrence Moulton and Dr. Yuvak Shafir.

Thereafter, on July 25, 2003, the parties filed post-hearing briefs. Thus, the record is complete and the case is ripe for decision. After considering the entire record in this case and for the reasons stated below, the court finds that Petitioners are not entitled to compensation.

II. THE LEGAL REQUIREMENTS

In order to prevail in a vaccine-related case, Petitioners can prove they are entitled to compensation in one of two ways: through a statutorily prescribed presumption of causation or by proving causation-in-fact. Causation is presumed if Petitioners can prove that Noah sustained an injury or condition set forth in the Vaccine Injury Table ("the Table"). The injury must have been observed or manifested within a prescribed time period following the immunization alleged to have caused the injury. §11 (c)(1)(C)(I). If Petitioners are able to establish these criteria by a preponderance of the evidence, they are entitled to a presumption of causation. §13 (a)(1)(A). If Noah qualifies under this presumption, he will be said to have suffered a "Table injury." Once Petitioners show that they are entitled to a presumption of causation, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." §13 (a)(1)(B).

In the event Petitioners fail to satisfy the requirements under the Act for demonstrating a Table injury, they may prove by a preponderance of the evidence that the vaccination in question, more likely than not, caused the alleged injury. §§11 (c)(1)(C)(ii)(I) and (II); *See Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992). This standard is the same one required in traditional tort litigation, proving a case by a preponderance of the evidence. This causation-in-fact standard, according to the Federal Circuit, requires proof of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant*, 956 F. 2d 1144. If Petitioners are successful in establishing such proof, the burden

shifts to respondent to prove that the injury or condition “is due to factors unrelated to the administration of the vaccine described in the petition.” § 3(a)(1)(B).

III. FINDINGS OF FACT ACCORDING TO THE DOCUMENTED MEDICAL RECORDS

The following facts are documented in Noah’s medical records and are not challenged. Noah was born on January 22, 1998 by repeat cesarean section after a pregnancy of 39 weeks. His Apgar scores were 8 and 9 and he weighed just above 10 pounds. His head circumference was 14.5 inches; his length was 21 inches, large for his gestational age. The infant had bruising on his ear lobes and face, and had a floppy left ear, as well as periorbital edema. The nursing assessment at birth noted a “smallish jaw, and scrotal skin peeling.” He was discharged with his mother on January 25, three days after birth. Pet. Supp. Petition at 72-85. The infant was seen for pediatric care by Dr. Hugh Alexander at the Children’s Clinic beginning on February 5, 1998, and was found to be a well infant. *Id.* at 100-102. At the Children’s Clinic, he was given a hepatitis B vaccination, was seen again on February 22, 1998, and then on April 6, 1998 when it was noted on that visit that he had seborrhea² and a small prominence in the parietal region. *Id.* at 101-104. Thereafter, he was given Diphtheria-Tetanus-acellular Pertussis (DTaP), Hib, Hep B and inactivated Polio (IPV) vaccinations. *Id.* at 101. No adverse reaction to these vaccinations is recorded. On February 2, 1998, Noah was seen again for pediatric care by Dr. Hugh Alexander. On July 14, 1998, Dr. Alexander noted that his development was normal. He was rolling and pulling to sit, using hand transfers and vocalizing. *Id.* at 105. According to the records, it does not appear that Noah was ever seen again by Dr. Alexander after the July 14, 1998 visit, but in the meantime he was given more vaccines, namely, DTaP, Hib and IPV vaccinations. *Id.* at 101.

On October 4, 1998, Noah was brought to the emergency room at Providence St. Vincent Medical Center for difficulty with breathing. His symptoms were considered “most likely consistent with an asthma exacerbation.” Pneumonia or aspiration of a foreign body were considered, but a chest x-ray ruled out those possibilities. He had no evidence of wheezing and his reactions resolved after treatment with an albuterol nebulizer and Prelone syrup. Pet. Ex. D at 173. The diagnosis was bronchospasm. He was discharged approximately one and one-half hours later.

No further pediatric care is recorded until January 29, 1999, when he was seen by Dr. William Pollard at Evergreen Children’s Clinic. It was noted that Noah was walking, playing pat-a-cake, grasping fingers, waving bye-bye, releasing objects, and was going from sitting to standing. No other signs or symptoms were recorded, and his parents maintain that at that time, he was a normal well baby. Pet. Supp. Petition at 133, 134, 137.

²Seborrhea is an excessive secretion of sebum; a semi-fluid substance composed of fat and epithelial debris secreted by the sebaceous glands. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1500 (27th Ed. 1988).

The record indicates that Noah was next seen on February 16, 1999. At that time, Dr. Pollard documented that Noah had mild RAD (believed to be an abbreviation for reactive airway disease). He was treated with a refill prescription for albuterol. Thereafter, for the next four months, no medical records are available until May 14, 1999. Noah received the following vaccines on May 14, 1999, at the Evergreen Children's Clinic: MMR, Hib, and Varicella. *Id.* There are no documented medical records for the five months following the May 14, 1999 inoculations. Adam missed his 18-month appointment, which was to be the next scheduled appointment. His next visit to a doctor was on October 27, 1999. There is no evidence that Adam returned to the Children's Clinic in the interim, or to any other medical facility until the visit on October 27, 1999, approximately five months after his May 14 vaccinations.

At the Children's Clinic visit of October 27, Noah was seen to have "goopy eyes," a runny nose and a cough. In addition, the examining physician documented disturbing signs and noted on the medical records his concerns regarding Noah's behavior. Noah was drooling excessively, making repetitive noises, and was grunting and reaching for objects. The doctor found that his language was abnormal for his age, as was his behavior. The doctor diagnosed possible URI, viral conjunctivitis, probable language delay, and he suspected other possible developmental delay. The doctor strongly recommended a referral for neuro-developmental testing and speech therapy. He recommended that Ms. Dixon schedule a well-baby exam as soon as possible.

A few days later, on November 3, 1999, Noah was taken to Evergreen Children's Clinic for a well-baby examination. He was given DTaP and oral polio vaccinations. Noah was no longer walking and did not talk; he was eating wood and paper. He could run stiffly, but could not walk up stairs or sit on chairs normally. He could not make two-word sentences, but could feed himself finger foods. The medical chart dictated by Dr. Pollard at that visit revealed that Noah had an older sibling who had been diagnosed with Aspergers syndrome ("high functioning autism") and that Noah's father had been diagnosed with Attention Deficit Hyperactivity Disorder ("ADHD"). *Id.* at 151. The doctor observed that Noah seemed to be "in his own little world." The child ignored the emotions of others, and had a somewhat limited emotional repertory, although he would hug others. He had a very high pain tolerance, and would deliberately and repeatedly burn himself. He had no language and a limited use of gestures. He made eye contact only occasionally. He was diagnosed as having pica, a condition in which non-food items, including rocks, sand, wood and paper, are eaten. At this appointment, the doctor diagnosed possible ADHD, or possible autism spectrum disorder. *Id.* at 133.

Noah was referred to the Mary Bridge Neurodevelopmental Team for evaluation. He was seen there by Glenn Tripp, M.D. On February 2, 2000 and later, on March 30, 2000, Noah underwent a series of transdisciplinary evaluations. The evaluations resulted in a diagnosis of autism, moderate developmental delay, and pica. *Id.* at 176-178.

The foregoing facts are documented in the medical records. The following constitutes the eyewitness testimony presented by Noah's Parents.

IV. THE PARENTS' WRITTEN and ORAL TESTIMONY

Noah's parents claim that they had been concerned about their son's development after the administration of his MMR vaccine on May 14, 1999, but neither parent is able to date the first manifestations or otherwise time the onset of Noah's symptoms except to say that it began after the May 14 vaccinations. Petitioners have no other supporting evidence of the child's condition or behavior other than their own testimony, with the exception of Ms. Dixon's mother who observed the child during June of 1999. No medical doctor observed Noah for a significant period of time following the MMR vaccination. As stated earlier, Noah missed his 18-month appointment, and did not see the doctor again until October 27, 1999, approximately five months after the vaccination.

Ms. Dixon believes that her first concerns regarding Noah's development were after the May 14 vaccinations, when he was at approximately 15 or 16 months of age. She claims that by that time, his eating skills had regressed dramatically. Pet. 2nd Sworn Statement of Parents Tr. at 12-17.

Ms. Dixon states that on the morning of May 15, the day following the child's inoculations, she found him crying with severe projectile vomiting followed by a lengthy period of severe diarrhea that continued for at least 10 days or more after his inoculations.³ *Id.* at 9. Noah's grandmother, Uldine M. James, testified by sworn affidavit that she observed the child during a brief visit shortly after the vaccinations, witnessed the severe diarrhea and other symptoms claimed, and insists that "he was not the same baby." She described a drastic change in her grandson who would not eat his favorite foods but was eating paper and chewing wood. A call to the doctor's office to report these problems resulted in advice that Noah's mother should discontinue milk and that pica is "somewhat normal." But Noah continued to act differently, with strange and dangerous behaviors. Petitioners maintain that these symptoms, beginning with the vomiting and diarrhea, were the first manifestation of an encephalopathic event.

V. THE ISSUES

³ Respondent argues that the vomiting and diarrhea could not have been caused by the MMR as alleged by Petitioners in this case. That challenge was, however, successfully rebutted by further evidence supplied by Dr. Yazback, one of Petitioner's experts. It appears that these very symptoms are a possible side-effect of MMR, and a known complication acknowledged by the manufacturer. Tr. at 187. Dr. Yazback states further that diarrhea and vomiting following MMR were noted in a study of five million cases in Finland -- and that the onset of symptoms occurred within hours. The court finds that Mrs Dixon's testimony regarding Noah's vomiting and diarrhea is credible.

Petitioners take the position that the MMR vaccine administered on May 14, 1999, caused brain injury to this child, manifested in “autistic-like” symptoms. Petitioners acknowledge that the encephalopathic event claimed in this case does not comport with the very restrictive definition of “encephalopathy” required for a “Table case,” but argue, correctly, that the restrictive definition does not apply to the causation-in-fact method of proof that Petitioners pursue in this case. They do not claim that the MMR vaccine caused autism in Noah Dixon’s case. That issue, however, cannot be fully ignored and was addressed by the experts. Nonetheless, the central issue is whether the MMR vaccine resulted in a vaccine-related encephalopathic event caused by one or more of the “attenuated viruses,” weakened but still live viruses, administered to Noah on May 14, 1999.

Respondent maintains that Petitioners have established no evidence of a vaccine-related encephalopathy, and that Noah’s condition is clearly autism, an injury not recognized as a Table injury for any vaccine listed on the Vaccine Injury Table. Respondent maintains that Noah’s symptoms are, in fact, evidence of autism. Respondent argues that the child’s symptoms clearly demonstrate a case of regressive or “late appearing” autism, and that the evidence does not support the presence of an encephalopathy. Respondent expressed its intent to establish a factor unrelated to the vaccine as being responsible for Noah’s present condition.

As stated above, the burden of proof in a causation-in-fact case rests with the Petitioner who is required to provide affirmative evidence, in this case of encephalopathy, of what caused Noah’s condition, or, in the alternative, must prove that the MMR can cause autism, and did so in this case. To date, the issue of whether the MMR vaccine can, in fact, cause autism has yet to be resolved. An answer has not been agreed upon to the satisfaction of the medical community. Some qualified and well respected individuals in that community believe that the vaccine can, and does, cause autism, while others reject the theory as speculation. That issue is being addressed now, in Omnibus hearings, and is being discussed and researched throughout the United States and in several other countries.

Whether the MMR can cause autism is, however, not at issue in this case. Petitioners have chosen to pursue their case by establishing that the MMR, more likely than not, caused an encephalopathic event. That causation issue was addressed by the expert opinion testimony in this case, a discussion of which will follow. Whether the MMR vaccine can and does cause autism will not and cannot be decided in this case because the research and evidence is still inconclusive, according to those who are studying the issue.

VI. THE EVIDENCE

It is difficult for the court to parse the evidence that will provide the key clues to decide a case that means so much to Petitioners. To begin, the experts all agree that the viruses contained in the MMR vaccine are reactogenic, that is, attenuated but still alive, and clearly capable of causing brain damage. According to some experts, it is most likely that the measles component of the MMR is responsible,

although the mumps and rubella viruses are also capable of causing damage to the central nervous system. The cause of injury is an issue to be decided in this case and one of the major problems presented is that the signs and symptoms of encephalopathy are frequently similar to the signs and symptoms of autism.

Opinions of the Medical Experts

The testimony of Dr. F. Edward Yazbak M.D for Petitioner

Dr. Yazbak, of Falmouth Massachusetts, is board licensed as a pediatrician. He is an Academic Appointee of Brown University, Providence, Rhode Island, a Member of the Institute of Health Sciences, and Deputy Director for Pediatrics, Child Development Study, and of the Collaborative Project of National Institutions of Neurological Diseases and Blindness. He has numerous affiliations and appointments with other hospitals and has published many articles regarding autism. He has studied the research and the medical articles, and is of the opinion that the MMR vaccine probably does, or at least can, cause autism on occasion. Dr. Yazbak maintains that sufficient evidence exists to support the likelihood of an association between the MMR vaccine and autism. He admits that he has a personal interest in the burgeoning increase in autism inasmuch as his grandson was diagnosed as autistic. Tr. at 220. Dr. Yazbak states that since 1998, he has done nothing but look at the connection between the MMR vaccine and autism, at both the incidence of autism and all studies that examine the relationship of autism to vaccines.

In this particular case, Dr. Yazbak maintains that it is more probable than not that Noah Dixon was injured by the MMR (the measles vaccine being the most likely cause) and thereby sustained a neurological problem. Dr. Yazbak begins his testimonial presentation by revealing two clear and disturbing trends relating to autism. The first is that the incidence of autism has remarkably increased lately to a veritable explosion. The second, and particularly relevant to this case, is that a distinct shift exists in the time of onset of autistic symptoms. In early years, parents almost always noticed symptoms of autistic behavior shortly after birth and in infancy. Since 1980, 66 % report their children's symptoms started at or after 18 months of age. In his opinion, that shift constitutes evidence of "late-onset, or regressive autism." *Id.* at 287.

Dr. Yazback describes recent studies in the medical literature. For example, a recent study of children in South London demonstrated that 4 out of 5 children subsequently diagnosed as having an autistic disorder, appeared normal at the age of 18 months, were exhibiting good eye contact and were engaged in imaginary play. This suggests that the previously rare regressive onset pattern of autism is now the most common presentation of the condition. Pet. Ex. A at 2.

He maintains that parents, in ever increasing numbers, are reporting shockingly similar stories. A child, most often a boy who is developing socially and verbally on par for his age, suddenly stops acquiring new words and skills in the second year of life (often after his MMR vaccination) and then regresses into the abyss of autism, losing speech, losing his cognitive abilities, and losing his social dexterity. The scenario

described in the South London study is consistent with the facts in the present case; the signs and symptoms of Noah Dixon's condition are similar to the South London study in almost every way.

Dr. Yazbak refers to other reports that support his opinion. Drs. Rimland and Lingham's study released in 2002 rejects genetics and heredity altogether as the sole cause of such a sudden and exponential increase in autistic disorder reports. Another example documents a 273% increase in autism in the State of California from 1987 through 1999 --- and the trend is accelerating. Tr. At 191. Nationwide, increasing numbers of U.S. school children at age 6 are also documented, and statistics reveal that the number of autistic children in U.S. schools rose steadily and drastically, and the trend is likely to continue. *Id.*

Dr. Yazbak testified that he has personally experienced the danger in the measles virus vaccine component of the MMR. He looks forward to a new vaccine, now in research, that is likely to benefit and better protect children than does the attenuated vaccine. Dr. Yazback cites the danger of injuring the immune system by inserting the live measles virus into the body by injection as is presently done. *Id.*

Although he is of the opinion that the MMR can, at times, either cause or trigger autism, he explains that in this particular case, there is reason to believe that an encephalopathy "could very well be the cause of Noah's condition." He considers it likely that the MMR caused an encephalopathy. He believes that it was not the MMR that caused Noah's autism, but that the child sustained an encephalopathy due to the antigens in the MMR vaccine. His support is based on the fact that the MMR can cause the symptoms described, and the fact that the manufacturer has acknowledged that such injury can be caused within a 30-day time frame from the date of inoculation. Thus, he speculated that Noah may, in fact, meet the temporal guidelines for a vaccine-related injury considering the fact that the Merck company itself, the company that manufactures the vaccine, acknowledges that significant central nervous system reactions such as encephalitis and encephalopathy can be temporally associated with the measles vaccine within 30 days after vaccination. The vaccine maker has stated that "experience with more than 80 million doses of all live measles given in the U.S. through 1975 indicates that significant central nervous system reactions, such as encephalitis and encephalopathy, can occur within 30 days after vaccination and may have been temporally associated with the measles vaccine." Tr. at 181-182. The Merck company does not associate injury with their vaccine, of course, but maintains that other studies and reports suggest the need for further study

The recent Singh study findings, released in 2002, leads Dr. Yazback to believe that a measles and/or MMR- triggered auto-immune response to myelin may indeed play a role in autism. Pet. Ex. 13. Thus, Dr. Yazback not only acknowledges the possibility that a MMR encephalopathy can, indeed, cause the type of injury demonstrated in this case, but that it is more likely than not that it did. Further, inasmuch as the 30 day timing of onset is acknowledged by Merck, he believes there is evidence for that possibility and that Noah could meet the Vaccine Program's guidelines criteria for a vaccine-related injury.

Opinion Testimony of Dr. Yuvak Shafir for Respondent

Respondent presented the expert opinion of Dr. Shafir. Dr. Shafir is a board-certified neurologist, is board certified in pediatrics, and also in electroencephalopathy. The main focus in his professional life is treating children with autism. He has treated “probably” 400 patients with autism. Tr. at Dr. Shafir agrees with Dr. Yazbak that “there is a horrible, severe autism epidemic in this country for the last 10 years.” He relates that he sees two new autistic children every week. Tr. at 285. He states that he has no clue as to the cause of the autism epidemic. He is of the opinion, however, that there is no question that in this case, Noah’s condition fits the profile described by Dr. Yazbak in the London study, and that Noah’s condition is symptomatic of autism. He believes that Noah has a genetic propensity for the neurological problems that he suffers today. His brother, Benjamin, is autistic. Noah’s genetic propensity gives him a 50 % risk to develop autism.

But the more persuasive position is that nothing in the evidence serves to prove the presence of encephalopathy. Dr. Shafir’s analysis is based on the lack of evidence of any identifiable neurological reaction to the MMR. Certainly, there was none observed and documented by any physician during the 30 day period following Noah’s inoculations. Furthermore, there is a failure to provide a credible causal relationship between vaccination and onset of symptoms.

The basis for any claim for a causal relationship with the vaccine, Dr. Shafir maintains, is the temporal relationship, evidence of which is missing in this case. Moreover, he continues, if one takes what the mother says in the medical records and the affidavits, there is still no fit. Noah’s parents have been unable to provide evidence of the timing and onset of the signs and symptoms. According to Dr. Shafir,

It is enough to say that we simply do not know the timing of signs and symptoms in Noah’s case, and symptoms of encephalopathy and autism are often similar. The medical records present absolutely no evidence that relates Noah’s condition to the vaccine, and there is no credible evidence that suggests a link between autistic regression and the MMR other than speculation. Furthermore, there is no credible evidence from the parent’s testimony. Resp. Ex. C.

A neurological encephalological reaction to the MMR vaccine is not impossible, according to Dr. Shafir, but the sad diagnosis of autism is more likely. “Nothing points to encephalopathy. We do not know the timing of the onset or of the beginning of Noah’s developmental regression.” *Id.* There is simply no evidence that would meet the requisite affirmative evidence of an encephalopathic etiology. Dr. Shafir concludes that Noah’s condition is due to autism, consistent with a diagnosis of regressive autism, not encephalopathy. In his opinion, there is no question that Noah’s condition fits the profile described by Dr. Yazbak in the London study. There is no evidence that an encephalopathy led to the autism. A preponderance of the evidence points instead to regressive autism, not encephalopathy. Tr. at 255, 256, 257, 258, 259, 260. In short, Dr. Shafir found no evidence of a neurological reaction to Noah Dixon’s MMR vaccination.

The Opinion Statement of Dr.Schweller for Petitioners

Dr. Schweller practices in San Diego, California. He is board certified in pediatric neurology, specializing in child neurology, and is board certified in electroencephalography. Dr. Schweller examined Noah when the child was 4 years and 8 months, long after Noah's vaccinations. He noted multiple areas of brain dysfunction. The constellation of symptoms and findings displayed malfunctioning in the language and cognitive areas and in the motor areas, suggesting that there had been damage to those areas of the central nervous system. He found no alternative causes capable of causing such damage and found no genetic or metabolic cause. Alternative causes having been appropriately ruled out, Dr. Schweller believes that Noah could have sustained an encephalopathy. His testimony is based solely on the medical records, and upon what Ms. Dixon could recall. In hearing her history, however, he found her narrations unclear. He states that he was having trouble pinpointing the onset. Tr. at 34, 35, 37.

What is an Encephalopathy?

In response to Respondent's question, Dr. Schweller explained what is meant by encephalopathy and what is meant by "brain damage." He explains that encephalopathy is basically an impairment of various parts of the brain. In other words, it is a regression or a change in some mental function. This may be a loss of attention; it can be a loss of consciousness, and it can be a loss of motor skills. It can be a problem with memory. It can even be manifested by seizures. There is a disturbance of function of the brain. If the onset is relatively sudden, this would be called an acute or sudden encephalopathy. It differs from brain damage, in that one who has one of these insults, or disturbance of the brain, may recover completely and have no evidence of any residual brain injury. Other individuals may continue to have a smoldering or ongoing progression of deterioration of the brain. This would then be called a chronic encephalopathy, but sometimes will continue to cause a progressive deterioration of the brain. Tr. at 29-30.

In response to questioning, Dr. Schweller agreed that an individual could have a vaccination and later have a diagnosis of autism. Significantly, however, he repeats that he was unable to get some type of a sequence of events because Ms. Dixon was unable to identify the timing of the onset of various conditions and symptoms and had difficulty describing Noah's history. Dr. Schweller found it difficult to define clearly the things that Ms. Dixon was trying to describe. In other words, he states, "I was trying to get some type of a sequence of events of when she noticed that...and I believe that ...I'm trying to look at...to get more specific[sic] of what I got in the history from the mother. That's - you know, I'm having trouble pinpointing that." Tr. at 34. "If you understand what I was trying to say was, I had trouble pinpointing the onset." Tr. at 37.

The Testimony of Dr. Mark Geier for Petitioner:

Petitioners presented the testimony of Dr. Geier. Dr. Geier is not a neurologist, but is a board certified geneticist who has been deeply involved in the field of vaccine epidemiology. He ranks high among

those who have studied vaccine issues through the medical literature on vaccines, databases, studies, articles and information on vaccine safety and efficacy in vaccine policy. He has published many articles involving vaccine matters. The tenor of his testimony in this case addressed the importance of statistical databases in providing statistical reliability and validity in interpreting the epidemiology and issues relating to autism and various vaccines. His testimony, however, does not address directly the core issue in this case, i.e., the presence or absence of an encephalopathy. The import of his testimony is primarily related to causes of autism. His expertise relates more to the large issues related to autism but does not inform the court in its decision about the cause of Noah Dixon's present condition.

Dr. Geier has recently proposed a data-sharing process that would improve the reliability of present statistical data that would include the present VAERS statistical database. It would be helpful in interpreting the epidemiology and issues relating to the autism controversy. He is not alone. Dr. Yazback is of the same opinion, according to his testimony.

Testimony of Dr. Laurence Moulton, for Respondent

Respondent presented the expertise of Dr. Moulton who is an associate professor in the Department of International Health, and has a joint appointment in the Department of Biostatistics. This institute is relatively new and serves as an objective source of information and research about adverse events following an immunization. This independent academic center hopes to provide a safety board for vaccines. It is an independent group assessing the "built-in conflict of interest regarding vaccine safety" inasmuch as there is an industry out there selling the vaccines.

As was true with the testimony of Dr. Geier, Dr. Moulton's testimony is largely tangential and irrelevant to the issue of Noah Dixon's injuries. He did not express an opinion and the institute's intention to flag signals for other studies is not designed for assessing actual relationships in particular cases. The testimony was interesting and may prove valuable in the future, but not in this particular case. It did not provide the evidence sought by this court.

The Wakefield study

Dr. Shafir provided two arguments that I believe to be helpful in deciding this case. Both considerations are associated with the Wakefield study.⁴ The study was first referenced by Dr. Yazbak, but also by Dr. Geier, and finally by Dr. Shafir who claims to be in accord with Dr. Yazbak and "takes

⁴ Wakefield et al., *Enterocolitis in Children with Developmental Disorders*, 95 American J. of Gastroenterology 2285-95 (Sept. 2000).

the Wakefield study data very seriously.” Dr. Shafir bolsters his own analysis with two other considerations, one of which is associated with the Wakefield study. First, Dr. Shafir found no evidence of a neurological reaction to the MMR, and more significantly, he found no evidence of autistic enterocolitis syndrome in Noah’s injuries which, according to the Wakefield study, “would have suggested a causal link, considered by the medical community as a possible link between MMR and autism.”

The Wakefield study has caused a stir across the world, beginning in England by publishing the observation that there is an association between MMR vaccine and severe gastrointestinal disorders and autistic-like syndromes. Dr. Wakefield is a gastroenterologist. His findings suggest new information by biopsying children who had autism, had received the MMR, and were demonstrating the presence of live measles vaccine strain in the gut [sic] (intestine). Others are now finding some of the measles vaccine in the central nervous system’s cerebral spinal fluid. This research is still controversial, but is hopeful and relevant to autism cases. It is irrelevant in Noah’s case, however, because no live measles enterocolitis was identified in the child’s intestinal tract. The presence of live measles was not found and no evidence of autistic enterocolitis syndrome was demonstrated in Noah’s case. Tr. at 48. Dr. Shafir considers the absence of the live measles in this case, as evidence contrary to presence of an encephalopathy. “We do not have the Wakefield syndrome to fit MMR encephalopathy or any relationship to the MMR..” Tr. at

In fairness to Petitioners, the court notes that pica was not the sole sign of changed behavior as Dr. Shafir may have suggested in his testimony. In fact, the court acknowledges that other strange and worrisome symptoms were described by his parents and are described elsewhere as evidence in this case. By October, when the child returned to the doctor, disturbing signs were already in evidence. Those symptoms cannot be considered as positive evidence on behalf of Petitioners, because we cannot determine their onset. Moreover, Dr. Shafir argues that one cannot establish any sort of causal relationship on such flimsy evidence. One must have something more specific than just saying that he was normal at 15 months, and that later, in October, he’s obviously became autistic.

VII. Analysis

It became clear very early in this case that Petitioners would have difficulty prevailing in their claim. The evidence was too sketchy, and too speculative to establish the presence of an encephalopathy. Without better evidence, the court cannot conclude that the child’s injuries were vaccine-related with any degree of certainty.

In this case, as discussed above, Petitioner’s experts established that encephalopathy could be caused by the MMR vaccine. It is generally agreed that an encephalopathic event is possible, but, in this case, the court finds that it was not proved. The evidence presented by Respondent is more persuasive that Noah’s symptoms, more likely than not, were manifestations of autism with no proven link to the vaccine. The court agrees that there is simply no convincing evidence and no reliable evidence of a

temporal relationship. Temporal association of the onset of the injury with the vaccination, although probative, is not sufficient in and of itself to establish causation-in-fact. *Grant v. Secretary of HHS*, 956 F.2d at 1144, 1148 (Fed. Cir. 1992); *Strother v. Secretary of Dep't of Health and Human Servs.*, 21 Cl. Ct. 365, 369 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). Moreover, showing the absence of an alternative cause of injury does not meet Petitioner's affirmative duty to show causation. Although lack of alternative causation is probative, it does not meet Petitioner's affirmative duty to show causation. A preponderance of evidence of encephalopathy has not been established.

Contemporaneous medical records are not supportive of Petitioner's claim and, as observed by Dr. Shafir for Respondent, the contemporaneous medical records present the evaluations of at least four developmental specialists, whose main business in life is to find out what actually happened to this child, and what was the source of his developmental problem; none of the specialists supported the notion of encephalopathy. Tr. at 256, 273, 25,75, and 258. Nothing is written in favor of a vaccine-related injury. After the fact, Dr. Yazback, insists that in Noah's case, his doctor should have suspected that he was facing vaccine problems. In short, the evidence points persuasively to the more obvious conclusion that the presence of unexpected onset of early regressive autism described by Dr. Yazbek is the more likely cause of Noah's condition. The court, however, is constrained by the basis upon which Petitioners made their claim, which is that an encephalopathy, not autism, is the alleged injury sustained by Noah as a result of the MMR vaccine he received. Petitioners were unable to prove that onset occurred within a medically appropriate time frame.

The court notes with interest that, according to Dr. Shafir, the average pediatrician is probably not equipped to identify the early onset of autistic symptoms, and certainly the distraught parents could not identify a cause for what was happening to their son. Moreover, Dr. Shafir is of the opinion that many, if not most, pediatricians are unable to identify the early signs of autism, and in kindness to the parents, doctors will use great caution in identifying the presence of autistic behavior in order to assuage the parents' fears until a clear diagnosis is possible. The syndrome is often not identifiable until the passage of many months.

Certainly, Noah's parents are not to be blamed. Presence of an encephalopathy could not be considered likely without verification of a temporal relationship in this case, because the factor of onset could not be retrieved from records or from Petitioner's recollections. The science of medicine has not been able to identify who or what is to blame for autism. Inasmuch as behaviors caused by brain damage and behaviors and symptoms of early autism frequently mirror one another, it is no wonder that determining causation is an agonizing effort.

Petitioners are required to provide affirmative evidence of their claim. The court found Dr. Shafir's testimony in this case most persuasive and in keeping with the facts. It invokes the following reasons for denying Petitioner's claim. Petitioners were unable to provide sufficient evidence of symptoms of, or support for, an encephalopathy. Mrs Dixon admits that she could not identify for certain the timing of their first concerns and the histories were imprecise. Important evidence is missing about what happened and when it happened. The claim that "it was after the May 14 vaccinations" is vague and does not assist the

court as to the onset of developmental regression in relationship to the MMR vaccine. Symptoms observed in Noah's clinical history tend to appear about the same time or at approximately at the age that one may expect to begin seeing evidence of autism. No uniform guidelines seem to be available for experts to identify early autism as opposed to vaccine-related encephalopathy.

Failure to establish onset of symptoms is not uncommon. As a young mother, Mrs. Dixon, beset as she undoubtedly was with the day to day difficulty of facing problems she could not understand, thought her son was merely going through a phase. Tr. at 276. Neither parent could provide evidence of the specific timing of changing conditions. The Dixon family cannot be considered remiss. There was not much they could do in light of the fact that we do not understand autism, which the experts believe to be Noah's condition. The fact that Noah missed his 18 month appointment is irrelevant to the court's decision. Dr. Yazbak maintains that Noah's trouble erupted very quickly and speculates again that the doctor at the clinic should have been looking for serious symptoms and vaccination problems in this case. Further information about onset of symptoms to verify a temporal relationship could not be retrieved from records or from Petitioners' recollections. Both Dr. Schweller and Mrs. Dixon admit that she could not identify with certainty the onset of her first concerns.

Dr. Shafrir found no evidence that would support Petitioner's claim. Dr. Razbak's efforts to demonstrate a temporal relationship is primarily speculative. His supporting testimony is that he believes a causal relationship exists between autism and MMR. He may be right, but the proof is not yet in. Dr. Shafrir addressed also the imprecise histories provided by Noah's parents. At least one medical history supplied to medical personnel by Mrs. Dixon, places the onset of the family's serious concerns in April of 1999. Mrs. Dixon insists that it was an inadvertent error in the records, and that their concerns really began after the May 14 vaccinations. The court's decision, however, is not dependent upon that notation in medical records. Whether the April date is accurate or not is irrelevant and would not change the court's decision. The evidence here is merely insufficient to permit a favorable outcome for Petitioner's claim.

VIII. Conclusions

Congress designed the Program to compensate only those individuals who can demonstrate a causal or temporal link between their injuries and a listed vaccine by a preponderance of the evidence. In this case, the evidence just does not satisfy Petitioner's burden. Based on the foregoing, and based on the entire record in this case, the court finds that Petitioner is not entitled to compensation under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

E. LaVon French
Special Master