OFFICE OF SPECIAL MASTERS

No. 95-0785V

(Filed: June 11, 1999)

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NINA OETTING and JOHN OETTING	*	
Parents and Guardians of	*	
KATHERINE ELIZABETH OETTING,	*	
	*	
	*	
Petitioners,	*	**TO BE PUBLISHED**
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

William J. Pauzauskie, Topeka, Kansas, for Petitioners.

Glenn A. MacLeod, United States Department of Justice, Washington, D.C., for Respondent.

DECISION

French, Special Master.

This case concerns the eligibility of Katherine Elizabeth Oetting (hereinafter Katherine or "Katie") for compensation under the National Childhood Vaccine Injury Compensation Act (hereinafter Vaccine Act, Act, or Program).[(1)] Petitioners claim that as a direct result of a diphtheria-pertussis-tetanus (DPT) vaccination administered on April 11, 1994, Katherine suffered a residual seizure disorder which has resulted in diminished mental capacity.

Procedural Background

Petitioners filed a petition on behalf of their minor daughter on December 4, 1995. On March 15, 1996, Respondent filed her Rule 4 Report denying Petitioners' entitlement to compensation. An evidentiary hearing was held on the issue of causation on February 10, 1999, in Kansas City, Missouri. Petitioners presented the testimony of Nina Oetting, Katherine's biological mother, Dr. Jerome Murphy, a pediatric neurologist, and Dr. Mark Geier, a medical geneticist. Respondent presented the testimony of Dr. Walter J. Molofsky, a pediatric neurologist.

Summary of Facts

The following are the facts as supported by a preponderance of the evidence. Katherine was born on October 6, 1993, the product of a premature delivery complicated by Intrauterine Growth Retardation (hereinafter IUGR). (2) Katherine delivered at 36 weeks gestational age and weighed three pounds, three ounces at birth. Her APGAR scores were 7 and 8 at one and five minutes, respectively. Medical records (hereinafter Med. Rec.) at 336. After approximately three weeks in the hospital, Katherine was discharged home with a weight of four pounds, nine ounces.(3) Pediatrician visits document that she was developing well prior to January 24, 1994.

On January 24, 1994, Katherine received her first administration of the DPT vaccine. According to Mrs. Nina Oetting, for a period of four days following the vaccination, Katherine exhibited a high fever accompanied by a constant, grating, moaning cry. She was unable to maintain normal eye contact and did not demonstrate her normal alertness or responsiveness. Mrs. Oetting described one incident during that period in which Katherine became limp and unresponsive "just a rag doll."(4) This episode lasted for approximately 15 minutes. Finally, on January 26, 1994, Katherine was taken to a physician at the Warrensburg Family Clinic. The clinic notes were remarkable only for the notation of fever due to the recent immunization. Katherine was found to be alert, and had a soft, flat fontanelle. Her neurological examination was unremarkable.(5) Med. Rec. at 242.

Despite the above history of an adverse reaction, and despite her mother's misgivings, Katherine was given a second DPT vaccination on April 11, 1994. Before the inoculation, Mrs. Oetting reported Katherine's reaction to the first DPT, but was advised by the nurse administering the vaccine that "everyone has a reaction to some degree."(6) Katherine was given Tylenol prophylactically before the DPT vaccination and throughout the afternoon and evening of that day. No fever was noted and the only discomfort Katherine suffered was tenderness at the injection site.

In the early morning hours of April 12, 1994, Katherine developed unusual breathing--as if struggling for breath. Again, Mrs. Oetting observed an episode in which the child became unresponsive and limp. While Mrs. Oetting phoned the physician, Mr. Oetting held the infant, and reports that Katherine became very stiff, began to stare off into space and continued the unusual breathing. As the Oettings prepared to bring Katherine to the Emergency Room (ER), Katherine began making patterned movements with her arms.(7) En route to the hospital, the Oettings stopped at the EMT dispatch station, where an emergency medical technician advised the Oettings that Katherine was undergoing seizures, and because she was "going in

and out and in and out of them," she should go by ambulance so oxygen would be available. Transcript of February 10, 1999 (hereinafter Tr.) at 31. Katherine was transported via ambulance to the ER. Throughout the entire journey to the ER, Mrs. Oetting noted continuing seizure activity and breathing difficulties. She described the infant's condition as vacillating between stiffness and limpness throughout the trip to the ER. The EMT team was in communication with the emergency room by radio, and an IV was administered in the ambulance itself. Tr. at 33. The child's symptoms resolved shortly before presenting to the ER.(8)

Upon arrival at the ER, the Oettings were advised that Katherine must have had a reaction to the DPT vaccination. The child was released later that morning and Katherine became more alert, her cry was normal, "with a normal tone."(9) The ER note confirms that this was the second such reaction, recording that Katherine had suffered a similar episode with the previous vaccination but that the reaction was "not as severe." In Mrs. Oetting's own words, "the second one was just an exploded version of the first." Tr. at 61. Katherine was released from the ER with a diagnosis of "Immunization Reaction."

Upon examination just ten days later, April 22, 1994, Dr. Dyer examined the child and advised that the pertussis component of the DPT vaccination should be removed from all subsequent immunizations. A second opinion by Dr. Mozer confirmed Dr. Dyer's recommendation. During the period between April and July the only medical problem was a blotchy rash that lasted approximately five days.(10)

Petitioners described the period between April and July as "a flurry of activity" which included moving, working, caring for their older son, and participating in Church activities. Mr. and Mrs. Oetting explained that Katherine may have been experiencing seizures during this time period, but they were not trained to notice subtle seizures and did not, at the time, recognize any seizure activity--until a major event that occurred on July 7, 1994. On July 7, 1994, Katherine developed a fever accompanied by fussiness. After administration of Tylenol, she fell asleep and slept through her supper time. But upon awakening at around 6:00 p.m., the child began to cry and to exhibit unusual behavior--jumping at slight noises and acting as if she had no balance. She became unresponsive and began to "stare off into space." Mrs. Oetting phoned the doctor and was told to bring Katherine to the ER. At this time, Katherine began to twitch--this twitching involved various parts of her body and finally involved her entire body. During the trip to the ER, Katherine developed breathing difficulties and circumoral cyanosis, and her body became rigid. This episode continued for about 45 minutes and ceased without intervention.(11) Med. Rec. at 121. Mr. and Mrs. Oetting recognized that this event on July 7, 1994 constituted major seizure activity. Mrs. Oetting testified that although she can recognize now that Katherine experiences small 10-20 second seizures, she was unable to recognize the nature of such signs prior to the July 7 event. She believes it likely that they had been occurring during the above-mentioned time period.

As a result of the July 7, 1994 episode, Katherine was transferred to Children's Mercy Hospital; a CT scan found no abnormalities, but an EEG showed spontaneous epileptiform discharges. The admission history of this hospitalization notes that Katherine was "just sitting up alone, rolling over, smiles, appropriate socially; [but that] Mother notes that she is behind 2 y.o. [year old] brother's developmental milestones." Med. Rec. at 177. See also Med. Rec. at 110. Developmental delay was reported in July of 1994, but Mrs. Oetting, in denial, did not begin to fully realize the extent of Katherine's delays until the Fall of 1994, most notably after Katherine's first birthday in October of 1994.

STATUTORY REQUIREMENTS

To establish a claim under the Vaccine Act, Petitioners must follow one of two methods of proof. If Petitioners can establish the occurrence of a covered injury, that is, an injury listed on the Vaccine Injury Table (§14 of the statute), and if the first manifestation of onset of that injury occurred within the requisite time frame (for DPT that time frame is 72 hours), Petitioners enjoy a statutory presumption that the injury was caused by the vaccine in question. That presumption may be rebutted by proof that the injury was caused, more likely than not, by a factor unrelated to the vaccine. Respondent has the burden of proving a factor unrelated by a preponderance of evidence. The term "factor unrelated," however, may not include an injury or condition that is idiopathic, unexplained, hypothetical, unknown, undocumentable, or unidentifiable. §13(a)(2).(12) This first method of proof is referred to as "a Table case."

If Petitioners cannot establish a Table case, Petitioners may still prevail by demonstrating actual causation. Petitioners are not entitled to the statutory presumption and must establish "causation in fact" by traditional tort litigation standards, that is, by a preponderance of all the evidence.

Amendments to § 14 of the Act, the Vaccine Injury Table, affect all cases filed after March 10, 1995, of which this case is one. The two changes relevant to this case, the removal of "residual seizure disorder" as a "Table" injury and a revised definition of encephalopathy will be addressed in the discussion section of this decision.(13)

Petitioners propose to pursue their case by arguing that the onset of seizures was the first manifestation of an encephalopathy. Because the factual description of Katherine's signs and symptoms are not fully consistent with the revised definition of encephalopathy contained in the new regulations, petitioners must prove their case by the causation-in-fact method.

EXPERT OPINION

DR. JEROME MURPHY, for Petitioners. Dr. Jerome Murphy is of the opinion that the infant, Katherine Oetting, sustained an encephalopathy as a result of the DPT vaccination. The first of Dr. Murphy's two reports concludes that her vaccine-related injury was first manifested by the onset of seizures within 24 hours of the April 11, 1994 vaccination and that the unusually serious nature of her seizure disorder, its resistance to medical therapy, and the subsequent evidence of serious developmental delays that became increasingly apparent as she matured, in his opinion, are fully consistent with a finding of an encephalopathy. No evidence exists of any alternative cause, leading Dr. Murphy to conclude that her injuries were, in fact, secondary to the pertussis vaccine. May 23, 1995 letter of Dr. Jerome V. Murphy, Med. Rec. filed December 4, 1995, at 247.

Dr. Murphy's second report, filed on July 23, 1996, supplements his reasoning as follows: The constellation of neurological symptoms, epilepsy, developmental delay, and hypotonia, constitute neurological signs and symptoms that identify an encephalopathic condition that persists to the present day. No evidence of such condition was apparent prior to the DPT vaccination of April 11, 1994.

In order to determine the etiology, or cause, one has to look at events preceding the first evidence of neurologic symptoms. On April 12, 1994, Elizabeth [Katherine] Oetting, previously not exhibiting any signs of neurologic abnormality, suffered her first seizures . . .[with] no evident illness that would produce seizures, . . . no head trauma or illness involving the central nervous system, [and subsequent studies . . . have not revealed an etiology of her illness [other than the vaccine].

Petitioners' Exhibit (hereinafter P. Ex.) 1 at 1.

Dr. Murphy supports his opinion by reference to the science of epidemiology suggesting that the DPT vaccine is capable of causing neurological injury. He notes that the now famous British Encephalopathy Study, (NCES), has demonstrated a statistically significant rate of risk of permanent neurologic disability, such as encephalopathy, in those children whose symptoms are first manifested within 72 hours of immunization. Although much controversy has ensued since its publication, the NCES epidemiological evidence has never been successfully refuted.(14) The NCES remains the largest, most comprehensive study to date and is considered valid by a significant group of experts although not all subscribe to its conclusions. Dr. Murphy cites the 1994 report of the Institute of Medicine in support of his reliance on the NCES. After reviewing all available evidence, the Institute of Medicine (hereinafter IOM) concluded that there is a risk of encephalopathy following pertussis vaccine immunization and that some individuals would go on to demonstrate permanent sequelae. The only alternate explanation of Katherine Oetting's condition, (one which Dr. Murphy rejects as unlikely,) is that her encephalopathy is idiopathic, that is, without explanation, and that the two events, immunization and subsequent encephalopathy were merely coincidental. Dr. Murphy explains: "One cannot prove a 'nul' hypothesis (that the two events are unassociated) but, in medicine, when two events occur, and these have been shown to be related, one assumes a cause and effect relationship." Id. at 1-2.

Dr. Murphy notes also that the child's treating physicians believed she had had an adverse reaction to the vaccine. Numerous notations appear in the medical records that relate the child's adverse reaction to her DPT shot, citing abnormal responsiveness, grunting mewing noises, poor head control, vacant stare, limpness, rigid posturing with arms, and seizures as neurological signs. See, e.g. Med. Rec. pages: 27, 60, 61, 100, 118, 119, 121, 241. For example, the following note appears on April 22, 1994:

IMPRESSION: Immunization reaction with probable seizure, most likely due to the Pertussis. "Pertussus [sic]-prob cause of Sz disorder." Med. Rec. at 24,572.

In summary, Dr. Murphy contends that although nearly two months elapsed between the first and the second major seizure events, and although the child made a few small gains in the interim, her development had slowed abruptly, making clear that the April event was not a benign event. In retrospect, the severity of her subsequent clinical course and significant neurological deficits are evidence that the injury was serious enough to leave permanent sequelae. Going back, the injury to Katherine's brain had to occur before the first evidence [of symptoms]. One need look no further for an alternate explanation. Dr. Murphy is convinced that the DPT vaccine was its probable cause. Tr. at 126-127.

DR. MARK R. GEIER, for Petitioners: Dr. Geier appeared as a witness by telephone conference call. Dr.

Geier has made a study of the medical literature on the adverse effects of pertussis vaccine. His affidavit dated July 18, 1996 states that his notebooks of published literature contain voluminous articles and represent only a fraction of the available literature that supports the view to which Dr. Murphy also subscribes, that the pertussis vaccine is capable of causing permanent neurological injury.(15) It is his opinion that the case of Katherine Oetting is an obvious and well documented example of a DPT reaction that resulted in a seizure disorder/encephalopathy that occurred within one day of her second DPT. He notes further that, according to the medical record, it is clear that her treating physicians recognized a causal relationship between the shot and her reaction. He concludes that Katherine's second DPT shot is the cause of her current neurological problems.(16)

Sworn Affidavit of Dr. Mark R. Geier, dated July 18, 1996, at 18-19.

DR. WALTER J. MOLOFSKY, for Respondent. Dr. Molofsky, a board certified pediatric neurologist, submitted an expert report and testified in person at the hearing of February 10, 1999. Dr. Molofsky is of the opinion that Katherine Oetting's seizure disorder and subsequent neurological impairments are unrelated to her DPT vaccination. Dr. Molofsky acknowledges that prior to the April 11, 1994 DPT shot,(17) the child's development appeared normal. Tr. at 177. He notes however, that even after the shot, her second, the medical records report normal development; abnormal development was not reported until after a second seizure episode of July 7, 1994. Following that date, states Dr. Molofsky, it is clear that her seizure disorder was on-going, uncontrollable, and was accompanied by developmental impairments.

Dr. Molofsky attributes Katherine's problem to "an underlying congenital multifocal seizure disorder" related probably to a metabolic abnormality. He contends that the encephalopathic symptoms following the second DPT shot were simply not severe enough to cause her subsequent seizure disorder, so one must look elsewhere for probable cause. The episode of April 11, 1994, and even more particularly the seizure episode of July 7, 1994, he argues, merely "unmasked her underlying seizure disorder." Expert Report of Walter J. Molofsky, M.D., R. Ex. A at 7. This, he believes is further supported by "normal" intercurrent growth and development between the first and second DPT vaccinations and between the second vaccination and what he considers to be the true onset of her subsequent seizure disorder which he places after the July 7, 1994 flurry of seizures. Id.

Dr. Molofsky argues further that her seizure disorder is "compatible with a congenital epileptic disorder, and is not of the type that might be expected to occur secondary to the DPT reaction."(18) Dr. Molofsky aligns himself with those who criticize the NCES conclusions.(19) He declines to consider a vaccine-related cause based, in part, on the troubling fact that there is no way to literally prove that DPT can cause serious acute neurological illness "because there is no specific syndrome or symptom that we can use *per se* [to prove it does]." Tr. at 188.

SUMMARY OF ISSUES

Both parties agree that Katherine Oetting suffers from an encephalopathic condition manifested by severe seizures, cognitive delay, speech dysfunction, and motoric dysfunctions. Petitioners claim that the seizures observed just 12 hours after her April DPT shot constituted the first manifestation of her encephalopathy and that the vaccine is its likely cause, not simply because of its close temporal relationship, although that factor must be taken into consideration, but because the severe neurological dysfunctions that followed constitute substantial, relevant, and persuasive evidence of brain damage. Her present deficits, it is argued, more likely than not, resulted from the same

injury that caused her seizures.

Respondent's view is that an underlying congenital seizure disorder, constitutes a factor unrelated to the vaccine and is the more likely cause of Katherine's neurological dysfunctions. The April and the July seizure events "merely unmasked the child's underlying seizure disorder in association with her febrile response to DPT" because she had "a propensity--a congenital seizure disorder and the fever may have irritated her in a way that provided the first . . . seizure." Tr. at 190-191. Dr. Molofsky does not consider "unmasking" to be the same as "causing" Katherine's condition. Id.

DISCUSSION

As an initial matter, the court finds that Respondent's claim of an underlying congenital multifocal seizure disorder of probable metabolic origin must be discarded as conjecture. Very simply, no evidence exists to support that hypothesis. The infant was considerably premature with the attendant problems associated with prematurity, but both parties acknowledge that on April 11, 1994, prior to her DPT shot, she appeared normal neurologically. Respondent argues that evidence of elevated lactate, pyruvate, and alanine levels noted after the April 11 event are suggestive of an underlying metabolic disorder. That argument carries little weight because those abnormalities resolved and did not recur. Elevated levels of these organic and amino acids, according to Dr. Murphy, can be explained as "breakdown products" of the antiepileptic drugs she was being given at the time and do not constitute reliable evidence of an underlying metabolic disorder. Tr. at 91-93. Had they persisted, such levels might cause one to suspect a metabolic disorder, but no such reports are found in the medical records. The treating physicians found no reason to suspect a metabolic disorder. Tr. at 92. Medical testimony that states merely that symptoms are "consistent" with a specific injury, as Respondent claims, is legally insufficient. to establish a factor unrelated. See, Lacour v. Secretary of HHS, No. 90-316V 199WL66579, slip op. at 8 (Cl. Ct. Spec. Mstr. April 15, 1991).

Can the DPT cause permanent Neurological Injury?

The Vaccine Act is based on the premise that on rare occasions, the DPT vaccine can cause neurological damage. This court accepts that premise based upon evidence presented in this and in countless other vaccine cases over the past decade. Respondent's expert is unwilling to concede this premise outright, and certainly not under the facts presented in this case. Tr. at 255. A brief summary of the controversy that continues to rage over the issue of causation may be instructive.

In 1991, the Institute of Medicine (IOM) Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines filed its Report, Adverse Effects of Pertussis and Rubella Vaccines.[(20)] Their findings were based on a review of the medical literature, including the British National Childhood Encephalopathy Study, (NCES), of the relationship between DPT and encephalopathy, seizures, and other neurological manifestations. The IOM concluded that the evidence of a statistically significant elevated rate of risk of neurological injury following vaccination within a seven day period was sufficient to establish a causal relationship between the vaccine and acute injury. In its 1991 report, the IOM concluded that the evidence at that time was insufficient to establish a causal relationship between the vaccine and chronic (permanent) damage. That conclusion was not intended to indicate that the vaccine does not cause chronic neurological damage, but only that the evidence was insufficient to prove one way or the other.

A ten-year follow up to the NCES, however, provided new information that led the IOM to revise its conclusion. A closer examination of children included in the earlier study demonstrated broad areas of neurological dysfunction ten years later, including neurological motor, sensory, educational, behavioral, and self care dysfunctions. Some children had died.[(21)] In 1994, based on the new evidence, the IOM Committee to Study New Research on Vaccines concluded that the vaccine can cause, not only an acute injury, but also permanent neurological sequelae.[(22)] This court gives considerable weight to the reliability of the IOM.

Did The DPT Vaccine Cause Permanent Damage in This Case?

The more difficult issue is not whether the vaccine can cause injury to the central nervous system causing neurological deficits (encephalopathy), but whether the signs and symptoms in a particular case constitute evidence of such injury. The burden of proof falls on petitioners to establish either an on-Table case, which provides a presumption of causation, or to establish actual causation by the traditional methods required in tort litigation. Proof of causation by either method has become far more difficult since March 10, 1995 due to Department of Health and Human Services (HHS) revisions to the Vaccine Injury Table. [(23)]

Prior to March 10, 1995, a residual seizure disorder was considered a Table injury. If Petitioners could demonstrate the onset of a residual seizure disorder within Table time frame (three days) they were entitled to a rebuttable presumption in favor of compensation. Residual seizure disorder was removed from the Table for all cases filed after March 10, 1995. Removal from the Table, however, does not eliminate consideration of seizures as a possible sign of neurological injury for the following reasons. Although Dr. Molofsky acknowledges the relevance of seizures in his testimony, he is of the opinion that seizures in this case were due, not to the vaccine, but to an unidentified past problem.

Seizures are generally a very dramatic event. They reflect the fact that the brain is not functioning normal. They are an indicator that the brain is not--it has been damaged and is not working well or is not functioning well to either a recent problem or a past problem. Tr. at 108.

Complicated seizures, or seizures of 30 minutes or more duration were considered by the NCES as "serious acute neurological events," on a par with "encephalopathy" and/or "encephalitis." Under the provisions of the revised Table, a seizure disorder can still be characterized as "a serious neurological event" for purposes of an on-Table injury but only if accompanied by clinical manifestations of encephalopathy. Many experts have testified in vaccine cases that some seizures may in fact indicate a serious dysfunction of the brain, or, in other words, a sign of encephalopathy. The revisions to the Table do not change that possibility. The following is quoted from the Department of Health and Human Services discussion of its 1995 revisions to the Table:

While febrile seizures are by their very nature benign, and therefore not associated with permanent damage, not all seizures contemporaneous with fever are "febrile seizures." . . . Alternatively, one can have an acute encephalopathy which presents itself as fever and seizures [example omitted]. In such a case, the other requisite clinical manifestations of clinical encephalopathy should be present (i.e., diminished consciousness and/or focal or generalized neurological signs).

60 Fed. Reg. 26, 7690 (1995).

Prior to the March 1995 revisions, no distinction was made between various types of seizures for which Petitioners could be compensated. Petitioners who established the onset of seizures within the three day period were entitled to a presumption of causation irrespective of the type of seizure disorder manifested. In its discussion of the March revisions to the Rules and Regulations, the Department of Health and Human Services (hereinafter the Department) states that simple febrile seizures constitute a common occurrence in infants and children, and, the Department argues, such seizures constitute "a benign condition known to be triggered by DTP vaccine, yet never proven to have lasting effects unless signs of acute encephalopathy accompanied such seizures." Id. Removal of residual seizure disorder from the Table, therefore, was not intended to eliminate seizures as a possible sign of a neurological injury, but to prevent an automatic presumption of vaccine-related injury in the event that the seizures were benign and did not meet the criteria for a "serious acute neurological event," as set forth in the NCES epidemiological study.

As the Table stands now, Petitioners must prove that a seizure disorder, in fact, is causally related to the vaccine, and, for the most part, according to this court's analysis of the statute and its revised regulations, Petitioners may do so by establishing that the seizures are part and parcel of an encephalopathy. Id. If Petitioners can thus establish the initial event as a serious neurological event, the seizure disorder becomes subsumed in the encephalopathy and entitles a Petitioner to the favorable statutory presumption of causation. It is the experience of this court, however, that such cases have become now few and far between for the reason that the definition of "encephalopathy" was revised also for cases filed after March 10, 1995. Proof of an encephalopathy is now significantly more difficult. Petitioners in this case argue that Katherine's subsequent clinical course, including seizures of severe nature and other neurological deficits, constitute proof in fact of an encephalopathy notwithstanding the change in the definition of that particular injury.

Encephalopathy

The revised definition of "encephalopathy" for purposes of establishing a "Table" injury requires proof that the encephalopathy was "sufficiently severe to require medical intervention or hospitalization;" 42 CFR Part 100.3(b)(2)(I). If accompanied by seizures, a child may be viewed as having an acute encephalopathy only if the child has a significantly decreased level of consciousness that persists beyond 24 hours and cannot be attributed to a postictal [post-seizure] state or medication. Id. "Significantly decreased level of consciousness is explained:

A significantly decreased level of consciousness is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . : (1) Decreased or absent response to environment . . . ; (2) Decreased or absent eye contact . . ; or (3) Inconsistent or absent responses to external stimuli. . . .

60 Fed. Reg. 26, 7695 (1995).

Seizures alone, in the absence of other evidence of an acute encephalopathy, are not sufficient to constitute a diagnosis of encephalopathy.[(24)] Id. at (E).

It must be noted that the new guidelines relate to Table cases only. Id. at 7680. Few cases, in the court's experience, are able to qualify as Table cases under the revised guidelines. As stated earlier, the majority of DPT cases are now being pursued by the causation-in-fact method, as in the present case.

How, then, may a Petitioner establish actual causation? First, the court retains broad authority to assess the testimony in vaccine cases and to make its findings and draw its conclusions based on the record as a whole. The Department acknowledges that the March 10, 1995 revisions were not intended to alter the role of the Special Master in considering all information and weighing the evidence "including oral testimony, medical records and medical opinion." Id. at 7680. Second, in pursuing the causation in fact method of proof, Petitioners are not necessarily limited to the narrowed definition of encephalopathy, although they, and the court, may, indeed consider the new guidelines which are intended to place a measure of control on presumptive causation only.

Absent the favorable presumptions which the pre-revision Table permitted, proof of causation in DPT cases may be difficult, but not impossible. The level of difficulty arises from the fact that medical science can find no markers that differentiate between an encephalopathy caused by the pertussis vaccine and any other encephalopathy. DPT leaves no footprints. One is unlikely to find empirical evidence of any sort that is pathognomonic of a vaccine-related encephalopathy, and, we are told, no markers that science can identify as a DPT vaccine injury can be found--even on autopsy--particularly in very young infants; diagnosis of encephalopathy is dependent largely upon clinical observations, that is, on the treating physician's evaluation based on the patient's clinical course and behavior.

Epidemiology

Petitioners rely in part upon epidemiology to establish their claim that Katherine's injury, more likely than not was vaccine related. Epidemiology is defined as follows:

[T]he science of studying factors determining and influencing the frequency and distribution of disease, and other health-related events and their causes in a defined human population for the purpose of establishing programs to prevent and control their development and spread. Also, the sum of knowledge gained in such a study. (Emphasis supplied.)

Dorland's Illustrated Medical Dictionary, 27th Ed. at 566.

The role of epidemiological studies, such as the NCES and others, in establishing evidence of causation in an individual case, is problematical. Petitioners' reliance upon an epidemiological study, however, is not misplaced. Epidemiological evidence has been considered valuable as scientific evidence in many cases where there is no direct evidence of causation. Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir. 1989) at 311. (Epidemiology attempts to define a relationship between a disease and a factor suspected of causing it[.] An odds ratio or relative risk greater than two can demonstrate a causal relationship); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 959 (3rd Cir. 1990) ([A] relative risk greater than "2" means that the disease more likely than not was caused by the event.); In re Joint Eastern and Southern District Asbestos Litigation, 52 F.3d 1124, 1138 (2nd Cir. 1995) (without "direct proof

of causation," the preponderance of evidence standard can be met where the relative risk exceeds two); See also, Manko v. U.S., 636 F. Supp. 1419, 1434 (W.D. Mo. 1986); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1092 (D. Md. 1986) aff'd 814 F.2d 655 (4th Cir. 1987). ([I]n epidemiological terms, a two-fold increased risk is an important showing for plaintiffs to make because it is the equivalent of the required legal burden of proof--a showing of causation by the preponderance of evidence or in other words, a probability greater than 50%).

In Knudsen v. Secretary of HHS, 35 F.3d 543 (Fed. Cir. 1994), the U. S. Court of Appeals for the Federal Circuit held that although bare statistical facts alone are insufficient to establish causation in a particular case, causation may be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child. (25)

Against this background, then, following the Knudsen and Grant courts, and other cases cited above, the court must weight the evidence. As stated earlier, the court gives credence to the position taken by the IOM that the NCES is a valid epidemiological study which found risk ratios at and above those required to prove causation by the relative preponderance standard. If this court finds that Katherine's injury was "a serious neurological event," Petitioners' proof meets the standard required for finding a DPT related cause of her condition.

Dr. Molofsky would not conclude the existence of an encephalopathic condition in this case because the injury does not adhere to the new regulations provided for on-Table encephalopathies. The court is not constrained to take such a narrow view in a causation-in-fact case. Dr. Murphy, on the other hand, reasons that Katherine's symptoms qualify as an encephalopathic event based on the severity and intractable nature of her seizures, evidence of hypotonia, (a sign of neurologic abnormality) staring, reduced responsiveness, and evidence of significant developmental delays not observed prior to the vaccination in question. These signs and symptoms, he argues, are clear evidence of brain damage of a severe character. The prolonged nature of Katherine's initial seizure, persisting in excess of 30 minutes, followed by other neurological signs not previously present, qualifies as a serious neurological event under the criteria used by the NCES for inclusion in its study of encephalopathy. Her condition constituted a change, and her deficits persisted without resolution to the present day. These factors lead Dr. Murphy to the opinion that Katherine Oetting's condition has a vaccine-related cause.

Did Katherine Return to Normal?

One further issue must be addressed in some detail. Dr. Molofsky argues that the absence of more immediate and dramatic signs of damage indicates an absence of a permanent brain injury. He believes that the medical records demonstrate a return to "normal" after the initial seizure event. A return to "normal," he proposes, would negate any temporal or causal relationship between the vaccine and the child's subsequent course. The court is not convinced that the child returned to normal for a number of reasons. Although a slowed rate of development was neither dramatic nor verified in the child's routine exams until after the September episode, it became gradually apparent to Mrs. Oetting that although the infant was sleeping and feeding, a review of progress or lack thereof as documented in her own records, indicates a change. Whereas Katherine had been closing the gap between where she was and where she ought to be, a slowing began to surface after the April vaccination. Failure of speech development was most notable. Tr. at 73. The evidence confirms Mrs. Oetting's thorough and relentless efforts to convince the doctors thereafter that something was not right with her child. As the child's principal caregiver, she was in the best

position to assess her daughter's change in rate of development.[(26)]

Dr. Molofsky, himself, acknowledges that although there was progress during this time, "[i]t was just slow." Tr. at 193. Dr. Molofsky describes her condition:

She progressed. There was an increasing gap between what you would -- between the time you would expect her to do certain things and the time she did it. Tr. at 234. I should clarify that. Obviously the -- when you compare the developmental milestones, there were delays in which we'd like to see her correcting. So in that sense, she wasn't normal. But she was medically normal. She was not having intercurrent evidence of seizures. She wasn't sick. She was eating. She was sleeping. . . . Seizures can be intermittent. So in between the seizure, you may be normal. Tr. at 245.

This is not the only case in which neurological injury remained initially unidentified. Failure to identify neurological impairment is not uncommon. Many experts have explained to the court that the infant brain has very few ways in which to demonstrate damage. Manifestations of damage may not appear immediately but become apparent only as the brain matures. Respondent's expert acknowledges that it is not always possible to be certain if an infant is neurologically normal. Even trained neurologists and pediatricians may not pick up brain damage. Tr. at 183; R. Ex. 1 at 259. Dr. Molofsky states further:

You don't expect to see it, because a baby's nervous system is not using those kinds of abilities yet. When the time comes and the brain develops to the point that they begin to use those kinds of areas in their brain, then the abnormality emerges from its previous existence. This is a typical problem occurring in neurology. Tr. at 183.

[W]hat I'm saying is that recognition of the difference between normal and observed development in a neurologically-impaired child is much more easily recognized at ten months, 18 months and two years than it is at one month, three months and five months. Tr. at 188.

To further illustrate the difficulty of identifying early neurological impairment , a follow-up assessment, twelve months after the initial NCES study, of a group of children studied by the NCES was unable to identify accurately the rate of permanent damage. In one such study, researchers concluded incorrectly that the subjects studied had recovered fully. As stated earlier, a closer evaluation proved otherwise. The ten-year follow-up of the NCES study identified broad areas of neurological dysfunctions in those same children that had been overlooked by earlier researchers.[(27)] In other words, children can appear normal until time proves otherwise.

The following is quoted from the Department of HHS discussion of its 1995 revisions:

It is expected that any child or adult with a chronic encephalopathy as a result of a vaccine-related acute encephalopathy would show evidence of abnormalities in mental or neurological status in the days to weeks following the vaccination. In the case of an infant or child, these would be seen as a loss or slowing of developmental milestones during this time period. 50 Fed. Reg. 26, 7687 (1995).

Mrs. Oetting claims this precise result. The court believes her. The court was impressed by the clarity and consistency of Mrs. Oetting's recollections, and found her testimony credible. Katherine never returned to a "normal" neurological state. The doctors simply did not identify symptoms of brain damage right away. In hindsight, Mrs. Oetting's growing concerns and fears proved to be well-founded.

The court concludes that Katherine's clinical course is evidence of brain injury of sufficient severity to qualify as an encephalopathy. The initial signs and symptoms were less catastrophic than those criteria required for presumed causation and the sudden change in rate of development was at first, unrecognized. Those facts do not negate the existence of a serious event. Respondent's expert himself characterized her adverse reaction, although brief, as "an acute event--traumatic in many ways" (Tr. at 179) . . . with irritability, change in her alertness, some seizure--some shaking movements." Tr. at 178. Dr. Molofsky simply does not believe that a damaging process was going on, or if so, he attributes it to a prior underlying problem. Tr. at 180. The court has rejected Respondent's claim of an underlying congenital seizure disorder of unknown etiology because it is speculative and hypothetical. Moreover, I am persuaded that she did not return to normal following the onset of her disorder.

The court respects Dr. Molofsky's expertise, but finds the explanations presented by Petitioners' experts to be better reasoned, more consistent with the facts, more convincing, and consistent with testimony presented in many other vaccine cases of similar nature. The child was closing the gaps caused by her prematurity. Respondent acknowledges that she appeared normal prior to the April DPT shot. As evidence of her prior robust condition, she was able to recover from her first DPT shot given at age two months in spite of an adverse reaction that persisted for four days. She did not recover from her second shot. Failure to identify subtle evidence of early problems is understandable. The severity of her emerging encephalopathy, however, cannot be gainsaid. [(28)]

CONCLUSIONS

A preponderance of evidence supports a finding that Katherine Oetting sustained a vaccine-related injury and that her present deficits are causally related to her vaccine injury. She is entitled to compensation. Respondent's claim of an underlying prenatal neurological injury fails to meet the requisite standard of proof required to prove that a factor unrelated to the vaccine is a more likely cause of her neurological deficits.

The parties are directed to enter into discussions for establishing the appropriate amount of funds required for Katherine's future care and rehabilitation.

IT IS SO ORDERED.

E. LaVon French

Special Master

1. The statutory provisions governing the Vaccine Act are found at 42 U.S.C.A. § 300aa-1 et seq. (West 1998). Hereinafter, for ease of citation, all § references refer to the amended version of 42 U.S.C.A. § 300aa.

2. Intrauterine growth retardation (IUGR) is also referred to as "small for gestational age." IUGR is associated with medical conditions that interfere with the circulation and efficiency of the placenta, with the development or growth of the fetus, or with the general health and nutrition of the mother. Infants with IUGR have a greater morbidity and mortality than appropriately grown gestational age-matched infants. Nelson Textbook of Pediatrics, 441, 442 (14th ed. 1992).

3. Katherine was discharged home with the following diagnoses: asymmetrical growth retardation, transient tachypnea of the newborn (resolved), symptomatic hypoglycemia (resolved), metabolic acidosis (resolved), thrombocytopenia (resolved), bilateral subluxable hips, small aortic thrombus (resolved), and mild biochemical rickets.

4. At the hearing, Mrs. Oetting was unable to recall on which day she found Katherine limp and unresponsive. However, in the petition filed on December 4, 1996, Petitioners place the date of this event on January 25, 1994.

5. When cross-examined by Respondent's attorney regarding why there is no mention of the DPT reaction in the pediatrician's note of this visit, Mrs. Oetting testified that she does not think that the physician wrote down all of her concerns. She would not have taken Katherine to the doctor simply for a fever--she obviously had other concerns about Katherine's condition. Mrs. Oetting is sure that she told the physician about Katherine's unusual moaning, although the moaning ceased before presenting to the physician's office.

6. The Oettings reported this abnormal reaction to the DPT vaccination when Katherine presented to the ER on April 12, 1994. The notation mentions that the Oettings reported this reaction and were told not to worry about it. Med. Rec. at 61.

7. Petitioners' Prehearing Memorandum, describes multiple seizures lasting 2-4 minutes each. Mrs. Oetting's oral testimony presented at the hearing, provided a more detailed description of the seizures. The court concludes and finds that Katherine's seizure activity began at home, continued while her parents contacted the doctor and then drove to the EMT dispatch station, and lasted throughout the 30 minute drive to the ER.

8. According to Respondent's Rule 4 Report, filed on March 15, 1996, this seizure episode lasted only 15 minutes. However, testimony presented at the hearing described the duration of the ambulance ride at about 30 minutes. The hospital in Warrensburg, Missouri was about 30 miles from their home in Higginsville. Mrs. Oetting recalled that the symptoms Katherine was experiencing did not resolve until shortly before presenting to the ER.

9. Katherine did not appear abnormal after this seizure episode, with one exception. Mrs. Oetting kept meticulous notes in a baby calendar comparing Katie's developmental progress with that of her older brother at similar ages. Much later, upon review of her calendar notes, Mrs. Oetting noted that up to the time of the April seizure, Katherine had been slowly closing the gap caused by her prematurity in comparison with progress documented of her older brother. At about the sixth month, shortly after the April vaccination, the chart showed slowing; she was not developing at the same rate as before. Mrs. Oetting did not begin immediately to notice any loss in Katherine's developmental milestones with the exception of speech, after the April episode of seizures. Katherine's slow development became readily apparent thereafter, most notably in speech regression as she matured. Tr. at 71, 74.

10. As neither party addressed the rash, the court assumes that it is not considered relevant to the issue of causation.

11. According to Respondent's Rule 4 Report, filed on March 15, 1996, this seizure episode stopped after about 15 minutes without treatment. The Children's Mercy Hospital record for July 7, 1994, however, records that episode as persisting for 45 minutes. Med. Rec. at 121.

12. The court in Knudsen v. Secretary of HHS, 35 F.3d 543 (Fed. Cir. 1994) carved out one exception to this provision. If it can be established that a viral infection is the likely cause, its precise name is not required. A viral infection is not a factor in the present case.

13. The March 10, 1995 amendments removed also "Shock-collapse or hypotonic-hyporesponsive collapse" (HHE) from the Table of covered injuries for the DPT vaccine. The Table as amended now includes (for DPT) only "Encephalopathy (or encephalitis)" and "Anaphylaxis or anaphylactic shock" as Table injuries. §14. The statutory definition of encephalopathy "any significant acquired abnormality of or injury to, or impairment of function of the brain," was changed substantially as will be discussed hereafter.

14. Many articles have been published, some in support of the NCES conclusions, and others challenging their validity. These articles, both pro and con, have been filed and reviewed by this court.

15. Dr. Geier's claim as to the volume of literature supporting a causal link between pertussis vaccine and subsequent neurological injury is not exaggerated. Copies of Dr. Geier's notebooks have been filed in several vaccine cases. Articles to the contrary, of course, have been filed and considered as well.

16. Dr. Mark Geier is certified by the American Board of Medical Genetics as a "genetics counselor." He describes himself as a specialist in obstetrical genetics. He holds also a Ph.D. in genetics. Respondent points out that the American Board of Medical Genetics (ABMG) no longer certifies genetic counselors. As of 1991, the Board requires additional qualifications beyond those required when Dr. Geier was certified. Respondent's Exhibit (hereinafter R. Ex.) BB at 1. The court takes note also of respondent's caveat as to a possible error on Dr. Geier's CV describing a former faculty position between 1981 and 1984 as an "associate" professor whereas an "adjunct" professor may have been a more appropriate term. R. Ex. CC. The court's decision in this case is not based on Dr. Geier's testimony, but neither will the court discard his testimony as unreliable. The value of Dr. Geier's testimony lies primarily in his unusual knowledge of the medical literature relating to adverse side effects of pertussis vaccine and his own research into the toxins contained in the pertussis vaccine. This court gives Dr. Geier appropriate credibility for his knowledge related to those areas in which he is qualified to opine. The court gives greater weight to the opinions of the pediatric neurologists as to symptomatology in any individual case.

17. Petitioners' claim relies upon symptoms following her April 11, 1994 shot, when the infant was four months of age. The child's reaction to the first DPT shot, given at age two months, was similar to that following the April 11 shot. She apparently was able to recover from the first. According to expert testimony heard in other cases over which the undersigned has presided, as the brain matures, signs and symptoms of injury become more obvious. Petitioners here rely upon the symptoms following the second DPT shot as better evidence of her vaccine-related encephalopathy.

The court notes with interest the following statement of the Department of Health and Human Services, Public Health Service published in the Federal Register relating to the 1995 revisions to the Vaccine Injury Table:

In its analysis, the IOM [Institute of Medicine] suggested that the increasing severity of a reaction following immunization in the same individual *might* indicate a causal link to the vaccine. The Department did not view this hypothesis as strong enough to warrant a presumption of causation. . . . However, any petitioner who can demonstrate evidence of progressive or repetitive adverse effects following vaccination may be eligible for compensation by proving causation in fact. (Italics in the original.)

60 Fed. Reg. 26, 7686 (1995).

18. Dr. Molofsky did not elaborate or further explain his statement, nor did he discuss the type of seizures he would expect of a DPT reaction.

19. Dr. Molofsky cites in support of his opinion, a consensus statement adopted by the Child Neurology Society in

1991 that insufficient evidence exists to establish a causal relationship between DPT and permanent neurological damage. That statement did not have the advantage of the NCES ten-year follow-up study published three years later (1993) which led the IOM to a contrary opinion. This follow-up study will be discussed hereafter.

20. Howson, Howe, and Fineberg, Eds., National Academy Press, Washington, D.C. (1991).

21. Madge et al., 1993; Miller et al., The National Childhood Encephalopathy Study, reported in DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis, IOM, Committee to Study New Research on Vaccines, National Academy Press, Washington, D.C. 1994.

22. Stratton, Howe, and Johnston, Eds., Committee to Study New Research on Vaccines, Division of Health Promotion and Disease Prevention, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis, Institute of Medicine, National Academy Press, Washington, D.C. 1994.

23. In the majority of cases decided prior to March 10, 1995, Petitioners who prevailed would not have prevailed under the revised guidelines.

24. The undersigned special master notes that in the majority of cases before me, those clinicians who are treating physicians testifying on behalf of Petitioners, tend to disagree with the revised definition as inconsistent with the state of medical science as practiced by such clinicians and represents only the most severe and catastrophic of encephalopathic events. Respondent's experts, of course, do not agree.

25. Knudsen, at 549-550. See also, Grant v. Secretary of HHS, 956 F.2d. 1144, at 1148.

26. Mrs. Oetting testified that she did not record negative facts in the baby book itself because she wanted a "happy" book for her child to keep as a memento. Tr. at 41.

27. Stratton, Howe, and Johnston, Eds., Committee to Study New Research on Vaccines, Division of Health Promotion and Disease Prevention, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis, Institute of Medicine, National Academy Press, Washington, D.C. 1994, at 9.

28. The undersigned special master relies upon the foregoing analysis as the basis for this decision. In the event that a reviewing Judge should take a contrary view, an alternative analysis of causation is relevant as well. Respondent's expert suggests that the DPT vaccine merely "unmasked" an underlying prenatal neurological disorder "in association with a febrile response to the DPT." R. Ex. A at 7. The IOM Report of 1994, referenced earlier in this decision, finds no supportable distinction between scenarios in which the DPT "caused an acute neurological illness and subsequent chronic nervous system dysfunction," or one in which the DPT merely "triggered," such illness and subsequent dysfunctions. Specifically, the IOM analysis states that DPT might "trigger" such injury and thereby be an immediate proximate cause, but nevertheless, [is] still a cause. (Emphasis supplied.) Id. at 13-15. Stratton, Howe, & Johnson, Eds., Division of Health Promotion and Disease Prevention: Institute of Medicine: DPT Vaccine & Chronic Nervous System Dysfunction: A New Analysis, National Academy Press, Washington, D.C. 1994, at 13-15. The following cases have found a causal link between DPT and seizures if the experts agree that the DPT caused a fever that "triggered" seizures. McMurry v. Secretary of HHS, No. 95-682V, 1997 WL 402407, (Fed. Cl. Spec. Mstr. June 27, 1997) ; (Court granted no significance to the difference between "trigger" and "cause." Respondent could not impeach petitioners' evidence when its own witness testified that DPT triggered the seizure even though the expert denied that "trigger" meant the same as "cause".); Gall v. Secretary of HHS, 1998 WL * * * (Fed. Cl. Spec. Mstr. October 30, 1998); (Petitioners prevailed on the basis that DPT induced, provoked, or "triggered" the vaccinee's underlying condition which, in fact caused her death.)

In like manner, this court can find no supportable distinction between "causing," "triggering," and/or "unmasking," particularly in this case in which the court finds no evidence of an underlying disorder to unmask.