

**OFFICE OF SPECIAL MASTERS**

96-0783 V

Filed: December 13, 2000  
(Reissued for Publication January 29, 2001)

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AARON and ANGELA HILL, as the Legal	*	
Representatives of their Minor Daughter,	*	
ARIELLE HILL,	*	
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	*	<b>PUBLISHED</b>
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Petitioners,	*	
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
	*	
Respondent.	*	
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Curtis Webb, Twin Falls, Idaho for Petitioner.

Glenn A. MacLeod, U.S. Department of Justice, Washington, D.C., for Respondent.

**French**, Special Master.

**DECISION**

**PROCEDURAL MATTERS**

This matter arises under 42 U.S.C. §300aa-1 et seq., the National Vaccine Injury Compensation Act. Petitioners Aaron and Angela Hill filed their petition on December 13, 1996 as the legal representatives of their minor daughter, Arielle. Petitioners claim that Arielle suffered the onset of a serious neurological illness, namely an intractable seizure disorder, as a direct and proximate result of a diphtheria-pertussis-tetanus (DPT) immunization administered on December 20, 1993. Petitioners allege further that Arielle's current developmental delay is the sequela of that injury. On March 13, 1997, Respondent filed its defense required by Rule 4 of the Vaccine Program rules. Respondent's Rule 4 Report denies Petitioners' claim, arguing that Petitioners have failed to demonstrate the occurrence of a Table injury and have failed also to prove actual causation under the causation-in-fact method of proof.

An evidentiary hearing was held on May 16, 2000 at the U.S. Courthouse in Miami, Florida. All factual issues are well documented in medical records, and no dispute exists as to any material fact. The hearing of May 16, 2000 was limited to the testimony of expert witnesses. Petitioners called, as witness, Dr. Robert F. Cullen, Jr. of Miami, Florida. Dr. Cullen is a child neurologist and is board certified in pediatrics and in neuro rehabilitation; he is also board eligible in neurology. Dr. Cullen has teaching responsibilities at Children's Hospital in Miami, Florida and has administrative responsibilities as well. Since 1974, he has been the Director of Child Neurology at Miami Children's Hospital.

Respondent presented the testimony of Dr. Robert J. Baumann. Dr. Baumann is board certified in pediatrics and is certified by the American Board of Psychiatry and Neurology with special competence in child neurology. He is certified also in epidemiology and is a professor of Pediatrics and Neurology at the University of Kentucky in Lexington, Kentucky. The court found both experts to be highly qualified.

### **STATUTORY PROVISIONS**

Table Case Method of Proof: A Petitioner who files a claim under the Vaccine Act may establish causation in one of two ways. Petitioner may establish a Table case by proving that the individual sustained an injury set forth in the Vaccine Injury Table (§14 of the Act), or sustained a significant aggravation of a preexisting injury set forth in the Table, and that the first manifestation or onset of symptoms of injury or significant aggravation occurred within a prescribed period of time -- in the case of DPT vaccine, that time period is 72 hours. If successful, Petitioner enjoys a rebuttable presumption that the injury or significant aggravation was caused by the vaccine.

Causation-in-Fact Method of Proof: If Petitioner is unable to establish a Table case, for example, if the claimed injury is not listed in the Vaccine Injury Table, or if the onset did not occur within the 72-hour Table time, an alternate method is available. Petitioner may pursue an off-Table claim by establishing that the vaccine "in fact" caused the injury. This method, commonly referred to as "actual causation" or "causation-in-fact," is analogous to the method by which traditional tort claims are proved. The statutory presumption of causation does not apply in causation-in-fact cases. The standard of proof, in causation-in-fact cases, as in traditional tort claims, is a simple preponderance of the evidence.

Petitioners here, must pursue the actual causation method of proof for two reasons: First, the initial manifestation of onset of the claimed injuries did not occur within the requisite Table time; second, an amendment to the Vaccine Injury Table became effective on March 10, 1995 that removed residual seizure disorders from the list of injuries that may be presumed subject to vaccine injuries.<sup>1</sup> Petitioners, therefore, are required to prove

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<sup>1</sup> The amendment took effect in March of 1995. All cases filed after that date, as in this case, are subject to the amendment. The amendment affects the Table case (continued...)

affirmatively that, more likely than not, it was the vaccine, more than any other factor, that caused Arielle's neurological disorder.

### **FINDINGS OF FACT**

Arielle Hill was born on August 20, 1993. She was the product of an uncomplicated pregnancy; her neonatal APGAR scores were 9 and 10 at one and five minutes, respectively. To all appearances, Arielle was a normal newborn. She and her mother were discharged home shortly after delivery. She followed a normal clinical course without apparent problems for the first four months of life.

Arrielle's first visit to the doctor was on September 3, 1993. She was two weeks of age and was immunized at that time with Hepatitis B vaccine without apparent reaction. On October 22, 1993, at eight weeks of age, Arielle received her first DPT immunization. Again, she had no reported adverse reactions. At four months of age, however, Arielle received her second DPT vaccination, "Tetrammune," which is a combination of DPT and Hib (hemophilus influenza influenza type b). The date was December 20, 1993. She had a slight upper respiratory infection and congestion at the time and had possibly a slight fever, although that factor was not documented. Petitioners' Exhibit (hereinafter P. Ex) 6 at 1-4. On December 22, 1993, just two days later, Arielle returned to her doctor because of congestion and a fever of 101 degrees F. She was treated with an antibiotic for an ear infection and a decongestant for her cold symptoms. She was noted to be alert, active and responsive.

At 7:30 p.m. on December 23, 1993, just 80 hours after the administration of the DPT (Tetrammune) vaccine, Arielle had a seizure of approximately 1 minute duration and was postictal for an additional 30 minutes. There was no documented fever. While in the emergency room (ER), she appeared alert, and playful. But while still in the emergency room Arielle had a second seizure. An EEG of the brain showed focal seizure activity despite receiving anticonvulsant therapy. Her mother states that she was "irritable" in the days that followed. On the second day following, she was diagnosed with a cold and an ear infection. Three days after the immunization she had another brief focal seizure; this seizure lasted only 30 seconds, again, without fever. Arielle's seizures were brief, but they persisted. Between seizures, she appeared appropriately responsive, "awake, active, responsive and smiling."

The child continued to have daily seizures throughout the Spring and was followed by Dr. Harry Abram, a pediatric neurologist. Based on the facts that no evidence of diffuse encephalopathy was observed, no evidence of inflammation in the cerebral spinal fluid

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<sup>1</sup>(...continued)

method of proof, but does not apply to causation-in-fact cases. In other words, the amendment does not affect Petitioners' right to argue that a causal relationship between Arielle's seizures and the DPT vaccination exists in Petitioners' case. The burden of proof, however is an onerous one, and rests with the Petitioner.

(CSF) was observed, and there was no apparent evidence of a metabolic condition, Dr. Abram concluded that she had not sustained a serious neurologic illness that could be attributed to the DPT. Her seizures eventually evolved into infantile spasms, a type of seizure disorder observed in some infants and often of unknown origin. The typical pattern of hypsarrhythmia commonly observed with infantile spasms never materialized. Respondent's expert characterizes her condition as infantile myoclonic seizures that ultimately evolved into focal partial seizures. Her seizures did not abate and were most notable during periods of sleep. Treatment with ACTH was successful in arresting her seizures for a period of months only.

On May 17, 1995, Arielle returned to Dr. Abram because she had suffered a recurrence of her seizures. Her developmental progress had not suffered apparently. Her milestones, according to medical notations between March, 1994 and October 10, 1994 indicate that she was developmentally within normal limits. That condition would change but at a much later time. On August 16, 1996, she was still described as being developmentally normal, although she was still experiencing morning focal seizures. P. Ex. 8 at 41-55. Arielle's condition, however, began to worsen thereafter; she became severely delayed and has remained so to the present day.

### **THE ISSUE**

The issue before the court is whether the vaccine is the cause of her present condition. At present, Arielle's condition is clearly encephalopathic. She demonstrates global delay with cognitive deficits and intractable seizures. To summarize the controversy, the court must determine whether Petitioners have established evidence sufficient to conclude that the December 20, 1993 vaccination caused a severe encephalopathic condition that did not manifest itself until late in 1996. Petitioners are of the opinion that the treating physicians, of whom there were many, simply missed a diagnosis of emerging neurological delays; the vaccine caused the initial seizures, Petitioners argue, and the child's uncontrolled seizures, over the years, caused further brain damage. Respondent argues conversely, that more likely than not, Arielle was simply following the expected clinical course that frequently characterizes an epileptic condition. According to Respondent's expert, Arielle's disorder, which he characterizes as Lennox-Gastaut Syndrome, is a disorder that is known to evolve from infantile spasms. Although this case is deeply involved in the medical issues, counsel for both parties agree that the issue in this case is primarily a legal one and depends upon proof of a single issue to be discussed hereafter.

### **PETITIONERS' EVIDENCE**

#### **Dr. Robert F. Cullen for Petitioners:**

Dr. Cullen testified that the DPT propensity to cause seizure disorders and developmental delays is well established. That factor has been presented by medical experts in countless cases under the Vaccine Program. Respondent does not challenge

Dr. Cullen's statement. Dr. Cullen is of the opinion that the circumstances and nature of Arielle's seizure disorder suggest strongly that the vaccine did, in fact, cause her illness. In short, Dr. Cullen believes that her serial seizures have caused damage to her brain, resulting in her present neurological deficits. He is confident that the vaccine initiated the seizures and argues that those seizures are the proximate cause of her neurological condition.

Dr. Cullen relies on the following factors: 1) Arielle was neurologically intact prior to her December 20, 1993 DPT vaccination. Until that time, she appeared to be normal; 2) It is known that the DPT is capable of causing the symptoms observed; 3) It is his opinion that Arielle's symptoms would satisfy the criteria described in the 1994 Report of the Institute of Medicine (IOM) that acknowledges the possible existence of a causal connection between the DPT vaccine and subsequent dysfunctions;<sup>2</sup> 4) Dr. Cullen believes her injuries would have qualified her for inclusion in the renowned epidemiological study (NCES) that found a probable link between neurological injury and the DPT vaccine; and finally, 5) no other cause for her problem has been identified. Petitioners' Exhibit (hereinafter P. Ex) 14 at 4. He explains:

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<sup>2</sup> The IOM Report of 1994 relied upon the data and conclusions of the National Childhood Encephalopathy Study (NCES). If Arielle sustained a condition described as a "serious neurological event" that is, if she sustained the type of injury described in the National Childhood Encephalopathy Study, she could have qualified as one of the "case" children and would come under the egis of NCES findings and conclusions. The National Childhood Encephalopathy Study is considered the most comprehensive and reliable epidemiological study of the rate of risk of neurological injury following DPT vaccination. The NCES concluded that their study demonstrated a significant statistical increase in the rate of risk of neurological injury within seven (7) days following the DPT vaccinations in cases studied. The majority of injuries were observed within the first 72 hours. That study led the Institute of Medicine to conclude that the balance of evidence is consistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a "serious acute neurologic illness" within seven days after receiving the DPT vaccine. The 1994 Report of the IOM concluded further that the evidence remains insufficient to indicate the presence or absence of a causal relation between DPT and chronic [permanent] nervous system dysfunction under any other circumstances. The IOM clearly indicates that unless the child sustained a "serious acute neurologic illness" within the 7 day period, a statistical likelihood of a DPT the relationship between the vaccination and the injury found by the NCES would not apply. The NCES defined "serious acute neurological injury" as encephalopathies, complicated seizures, or prolonged seizures (30 minutes or more duration). If the individual did not meet those criteria, no presumption of a causal relationship could be established. If the individual did not meet those criteria, the rate of risk would be identical to the background rate in the general population and would be considered a random occurrence -- mere coincidence.

Arielle remained in the hospital from December 23 until January 1, 1994 and during that time she had over 30 seizures. She had at least eight other seizures in the interim before the next follow-up neurological visit. Dr. Cullen believes those seizures, in the aggregate, although brief, (often lasting only seconds) would qualify as “an acute event,” a “severe neurological injury,” as defined by the NCES. He believes that she would have been included in the study based on the number of seizures. In other words, he theorizes, the NCES conclusions, that is, the NCES finding of a causal link to the vaccine, would apply in Arielle’s case. Further evidence of brain damage, he argues, would be consistent with the observed falling off in head circumference from the 40<sup>th</sup> percentile in December, dropping to about the third percentile in March. A falling off in head circumference is considered evidence that the brain is no longer growing. Under these circumstance, he states, there had to have been an insult to the brain of such significance that it continued to disrupt the nerve cells, was not transient, and was of a serious nature. Transcript of proceedings of May 16, 2000 (hereinafter Tr. ) at 28-29.

Petitioners’ case rests primarily upon whether her observed symptoms, that is, her clinical course, can qualify as an “encephalopathy,” or a “complicated seizure,” or a seizure of more than 30 minutes duration. These factors would then be accepted, in fact, as constituting “a severe acute neurologic illness” as that phrase is defined in the NCES. If so, she would then then have met the qualifications for inclusion in the NCES study. Petitioner’s expert argues that her subsequent course resulted in encephalopathy, even though that encephalopathic condition was not temporally related to the initial event.

### **RESPONDENT’S EVIDENCE**

#### **Dr. Robert J. Baumann for Respondent:**

Dr. Baumann points out that Arielle Hill’s clinical course is not compatible with an acute encephalopathy and that without symptoms compatible with that condition [encephalopathy], her injury cannot be so characterized. Nor, he posits, is any evidence available to link her present condition with the vaccine. Her development, according to the medical records, continued along normal and expected paths for many months long after her vaccination. His explanation is that Arielle was following the expected evolution of an underlying condition, a factor unrelated to the vaccine. Tr. at 144-145.

Dr. Baumann argues further that the facts and the evidence surrounding Arielle’s clinical course do not conform to the requirements for a legal finding of a vaccine-related injury – not by the statutory guidelines -- nor by the volume of case law developed over the lifetime of the Vaccine Program -- nor by the criteria required in order to rely on the NCES epidemiological evidence and conclusions. In his opinion, the evidence falls short because there is simply no evidence to support a vaccine injury-- other than speculation. Other possible causes exist, he notes. It is equally possible that the appearance of an epileptic condition was merely coincidental, due to an unidentified alternative cause. The onset of seizures frequently begins to manifest itself in infants about the same time as immunizations are given. And more often than not, the cause of such seizures is never

identified. In summary, Dr. Baumann insists that the child's clinical course is not compatible with an acute encephalopathy, and cannot be characterized as a Table encephalopathy. Petitioners' proof is based on supposition.

### **THE EPIDEMIOLOGICAL EVIDENCE**

U.S. courts have held that epidemiological evidence, although not required, is admissible and may be considered in determining causation when it is otherwise impossible to prove and no other evidence is available. Epidemiology is the science concerned with the study of factors determining and influencing the frequency and distribution of disease, injury, and other health-related events and their causes in a defined human population.<sup>3</sup> NCES epidemiological evidence provides statistical information about the relative risk of injury within temporal association with the vaccine as compared to the random background rate in the general population. The epidemiological evidence supplied by the NCES has been relied upon in many cases under the vaccine program as an aid to determine the likelihood of a cause and effect relationship linking neurological injury to an antecedent event in a given case -- in this case, a reaction to the antecedent DPT vaccination.

It is well known and accepted in medical science that no footprints or objective criteria exist to identify a DPT-related injury as opposed to a similar injury caused by another source. For example, an encephalopathy (dysfunction in the central nervous system) is largely identified by the clinical course, not by observable pathological findings. In other words, there is no way to prove or identify a DPT injury in an individual case. For this reason, in addition to other types of evidence, the court accepts the findings and conclusions of epidemiology (such as the NCES) as valid evidence to assist in determining causation in individual DPT cases. Most scientists agree that the NCES, with its ten-year follow-up study, is the single, most comprehensive and most respected study of relative risk of neurological injury linked to the DPT vaccine.<sup>4</sup>

### **DISCUSSION**

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<sup>3</sup> Dorland's Illustrated Medical Dictionary, 27<sup>th</sup> ed., at 566.

<sup>4</sup> The NCES data indicated that children vaccinated with DPT had a "relative risk of experiencing a "severe neurological illness" in the following seven days that was about 3.3 times as great as the risk that a non-vaccinated child of similar age would have of experiencing such injury within a given seven day period. Liabe v. Secretary of Health and Human Services, No. 98-120v, p. 18, 2000 WL 1517672 (Fed. Cl. Spec. Mstr, Sept 7, 2000)at 18. Where epidemiologic studies have shown a "relative risk" of greater than 2, such studies can support a finding of causal relationship under the "preponderance of the evidence" standard. See, e.g. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1321 (9<sup>th</sup> Cir. 1995) cert. Denied, 516 U.S. 869 (1995).

The parties agree that the court's decision rests on the interpretation of a single issue -- an issue that will prove dispositive. That issue is whether Arielle's observed signs and symptoms meet the the criteria set forth in the NCES for inclusion as a "case child" in that particular study. The Liabe court, discussing the 1994 IOM Report, found that "serious acute neurologic illness" refers to children who suffered neurologic events that would have qualified them as "case children" under the NCES. If Arielle's symptoms meet the criteria for inclusion in the NCES, the epidemiological evidence would provide statistical support for a vaccine related cause in her particular case. If Arielle's symptoms do not qualify as a "severe acute neurological event" consistent with NCES criteria, Petitioners cannot prevail because the supporting evidence provided by the NCES study would not apply. The, evidence would stand, at best, in equipoise. Petitioners carry the burden of presenting affirmative evidence of causation in causation-in-fact cases; without the support of the NCES conclusions, the weight of evidence makes it equally likely that Arielle's injuries could be related to some other factor unrelated to the vaccine, or as Dr. Baumann testified, simply an unfortunate coincidence.

Seizures are not uncommon in infants; most are benign. At the outset, Arielle's seizures appeared to be simple brief convulsions. She was described as alert and responsive between episodes, and for many months thereafter. As stated earlier, Petitioners argue that the repetitive series of Arielle's seizures should qualify her injury as a "complicated" seizure. Moreover, Petitioners argue, if added up, in the aggregate, the seizures would likely meet the criteria for seizures of at least 30 minutes' duration, and for this reason alone, would meet the criteria for a "severe neurological event." Respondent argues, to the contrary, that her seizures were too brief. Taken all together, Respondent argues, the total still would not amount to the requisite 30 minutes. No other neurological signs were apparent within temporal relationship(72 hours) of her vaccination; in fact, her encephalopathic signs did not appear until many months later in late 1996, long after the initial event.

The NCES addressed this very scenario, and determined that such cases should be excluded as possibly failing to show a true positive relative risk:

It can be postulated that in some cases a particular dose of vaccine might be followed by one or more short convulsions and then, some months later, a prolonged or complicated convulsion might lead to admission to hospital (which should have prompted notification to the Study). It could be argued that the immunization "triggered" a series of events leading much later to a serious convulsion, and perhaps to brain damage.

The authors of the NCES suggest that in that scenario, the immunization might be considered to be "responsible" for the first short convulsion, but should not be held to account for later convulsions which could have occurred in response to fever or other stimuli. Only in cases where a child had a series of convulsions accompanied with

obvious and continuing evidence of underlying clinical or pathological explanation, could one regard the subsequent condition as part of the previous medical history. Id. No such evidence is apparent in Arielle's case.

The NCES: United Kingdom Department of Health and Social Security, Whooping Cough Reports From the Committee on Safety of Medicines and the Joint Committee on Vaccine and Immunization (London Her Majesty's Stationary Office, 1981. at 146-147.)

Petitioners' counsel raises the possibility that the treating physicians missed or overlooked the potential signs of brain damage in the interim between the vaccination, and the eventual encephalopathic condition. More skilled scrutiny might have revealed ongoing signs of an accompanying underlying encephalopathy. That argument, addressed earlier, is speculative. The medical records state that the child was alert, active, and responsive and developing normally. Without further evidence to the contrary, the court gives greater weight to the medical records which record repeatedly normal developmental status.

The court concludes that Dr. Cullen's theory that the NCES would have included Arielle under its guidelines as a "case" child is overreaching. Petitioners would have the court deviate from accepted interpretations of evidence of injury by expanding the NCES criteria by redefining the definitions of "lengthy or complicated" seizures. The court declines to do so. The evidence is simply too shallow to persuade this court that Arielle's would have been included in the study. The onset of severe symptoms was too remote thereby eliminating the anticipated support that a close temporal relationship would have supplied. Evidence of encephalopathy was temporally separated from the initial event. Without additional evidence, the court cannot conclude a causal link without succumbing to subjective guesswork. Petitioners cannot benefit from the supportive evidence of the NCES in this particular case.

This court has found otherwise in some cases. Evidence of brain damage is not always evident immediately after an event. See, e. g. Almeida v. Secretary of HHS, No. 96-412v, at 7, 1999 WL 1277566 (Fed Cl. Spec. Mstr. Dec. 20, 1999) In such cases, however, something additional was evident to suggest a causal link, first, a clear-cut acute severe neurological event within temporal time frame, and the court was able to discern evidence of temporally related neurological symptoms even though the neurological deficits did not manifest themselves immediately. This case lacks the necessary additional ingredient. The evidence here is simply too sparse and speculative. The court cannot state with any degree of certainty that the vaccine did not have an adverse effect on Arielle's future. But from a legal standpoint, the evidence is not strong enough to persuade the court that it did so. I find Respondent's arguments

in this regard to be the more persuasive.<sup>5</sup> .

### **CONCLUSIONS**

The court concludes that Arielle would not have qualified for inclusion in the NCES as a “case” child. Under these circumstances, the court concludes that Petitioners are not entitled to an award in this case. Petitioners’ however, filed their claim in good faith and had a reasonable basis. They are entitled to compensation for attorney’s fees and costs. The court urges counsel to submit an application for reasonable fees and costs.

**IT IS SO ORDERED.**

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E. LaVon French  
Special Master

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<sup>5</sup> The court cannot and does not conclude that “but for” her vaccination, Arielle would not have sustained her present injuries. Nor is the evidence sufficient to find that the vaccine was a contributing factor consistent with the holding in Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed. Cir. 1999). (The Federal Circuit held that petitioners in Shyface were entitled to compensation because the evidence showed that the DPT was both a “but-for cause of and a substantial factor in the child’s death.) The present case does not so establish.

