

**OFFICE OF THE SPECIAL MASTERS**

June 27, 1997

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MILES McMURRY and REBECCA  
McMURRY, as Legal Representatives of  
LAUREN O. McMURRY, a Minor,

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Petitioner,

\* No. 95-682V

\* PUBLISHED

vs.

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SECRETARY OF THE DEPARTMENT  
OF HEALTH AND HUMAN SERVICES,

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Respondent.

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Sherry K. Drew, Chicago, IL, for petitioners.

Eleanor Barry, Washington, DC, for respondent.

**DECISION AND ORDER**

**MILLMAN, Special Master**

Miles A. McMurry and Rebecca L. McMurry filed a petition on behalf of their daughter Lauren O. McMurry (hereinafter, "Lauren") on October 13, 1995 for compensation under the National Childhood Vaccine Injury Act of 1986<sup>(1)</sup> (hereinafter, the "Vaccine Act" or the "Act"). Petitioners have satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, that the DPT vaccination was administered to Lauren in the United States, and that they have incurred \$1,000.00 in unreimbursable medical expenses prior to filing the petition.

Petitioners allege a causation-in-fact seizure disorder following DPT. 42 U.S.C. § 300aa-11(c)(1)(C)(ii) (I).<sup>(2)</sup> Respondent denies that DPT caused in fact Lauren's onset of seizures or seizure disorder.

The court held a hearing in this case on April 17, 1997. Testifying for petitioners were Rebecca McMurry and Dr. Marcel Kinsbourne. Testifying for respondent was Dr. Gerald M. Fenichel.

## FACTS

Lauren was born on March 7, 1992. She received her first DPT vaccination on May 19, 1992 when she was two and one-half months old. She received her second DPT vaccination on September 2, 1992 when she was six months old. She received her third DPT vaccination on October 30, 1992 when she was eight months old. Med. recs. at Ex. 4, p. 2. Five hours after her third DPT, Lauren had a seizure.

Mrs. McMurry called the doctor at Capitol Pediatrics to tell him that Lauren had a temperature and that her arm was twitching. Mrs. McMurry was very upset and the doctor told her to bring Lauren in, which she did. Lauren was in status epilepticus when she appeared at the doctor's office. She had a fever of 101.7 degrees on arrival and had been seizing for ten minutes. The doctor identified her seizure on arrival as a tonic-clonic generalized seizure. He administered oxygen and used suction. He used an intravenous with Phenobarbital. Lauren had an increase of cyanosis and was bagged for ten minutes and suctioned numerous times. The doctor inserted a nasogastric tube. Air was removed multiple times. Lauren stopped seizing after a total of forty minutes. Her color was good. She was transferred via ambulance to Wake Medical Center in stable condition. Med. recs. at Ex. 4, p. 23.

Lauren's immunization record states she had a DPT seizure on October 30, 1992 and was to receive no more DPT. Id. at p. 2.

Lauren was diagnosed during her hospital stay at Wake Medical Center from October 30 to November 2, 1992 as having seizures of unknown etiology. The history was that Lauren had finished antibiotics two weeks previously for otitis media. She continued to have some congestion, but no fever. She received DPT that morning, and at approximately 3:30 p.m., her right arm stiffened and she became unresponsive. Lauren's mother took her to the pediatrician and her entire body was stiff and she was progressively less responsive. She had a normal CT scan and a normal spinal fluid study. Med. recs. at Ex. 6, p. 5. Mrs. McMurry was at the mall with Lauren when the event first occurred. Med. recs. at Ex. 5, p. 3.

On physical examination at Wake, Lauren had symmetrical deep tendon reflexes, good tone, and moved all extremities well. Her problem was non-focal. An EEG performed on October 31, 1992 showed some quick beta activity, which was probably due to sedation. Otherwise, it was normal. Med. recs. at Ex. 6, pp. 6-7. The history that a consulting neurologist, Dr. Kapil Rawal, took was that Lauren went into a generalized convulsive seizure with drooling, eyes rolling back, and shaking all over. Mrs. McMurry stated that Lauren had felt extremely hot when the seizure activity started. Med. recs. at Ex. 7, p. 48.

On November 2, 1992, Capitol Pediatrics telephoned the North Carolina Department of Environment, Health, and Natural Resources Office of Public Health Nursing to report that Lauren had had a severe reaction to DPT administered on October 30, 1992. They diagnosed atypical febrile seizure. Med. recs. at Ex. 5, p. 2.

On November 11, 1992, Mrs. McMurry took Lauren to Dr. Rawal, who opined that she had a reaction to DPT which caused a fever to spike, causing a seizure that lasted forty-five minutes. Med. recs. at Ex. 7, p. 51.

On December 18, 1992, the pediatrician received a phone call from Mrs. McMurry that Lauren had seizure activity. Med. recs. at Ex. 4, p. 18. From December 18 to 20, 1992, Lauren was in Wake Medical Center. She was discharged with a diagnosis of status epilepticus and bilateral otitis media. The Phenobarbital which she had been taking since her first seizure in November was presumed to be subtherapeutic. Med. recs. at Ex. 10, pp. 2-3.

On February 25, 1993, Mrs. McMurry telephoned the pediatrician to report that Lauren had had a seizure on February 21, 1993. Med. recs. at Ex. 4, p. 16. From March 17 to 23, 1993, Lauren was in Wake Medical Center. The history states she had had a fifty-minute generalized tonic-clonic seizure that initially began as stiffening of her right upper extremity. She had received her third DPT shot earlier that day but without history of fever. She was being admitted after her fourth prolonged (more than one hour) generalized seizure with tonic-clonic movements. Med. recs. at Ex. 7, pp. 31-32.

On March 25, 1993, Mrs. McMurry telephoned the pediatrician to report that Lauren had a fever of 101.7 degrees and had had a seizure that morning. Med. recs. at Ex. 4, p. 15.

On June 25, 1993, the pediatrician received a call from Mrs. McMurry that Lauren had had a seizure the day before. Med. recs. at Ex. 4, p. 12. The doctor wrote a lengthy note on September 28, 1993 that Lauren had a temperature of 100.5 degrees and was having seizures. She had a long history of recurrent status epilepticus associated with intercurrent infections, i.e., bilateral otitis media, purulent rhinitis, bronchitis, and fever. An MRI of her brain was negative. She was neurodevelopmentally within normal limits. Med. recs. at Ex. 4, p. 10.

On October 22, 1993, the pediatrician received a phone call from the Wake Medical Center Emergency Room. Lauren was febrile and in status epilepticus. She required intubation secondary to respiratory depression in the pediatric intensive care unit. Med. recs. at Ex. 4, p. 9.

On December 16, 1993, the pediatrician noted that Lauren had had a seizure the previous night. Med. recs. at Ex. 4, p. 8. At 5:30 p.m. on December 24, 1993, the pediatrician noted that Lauren had a febrile seizure without sequelae which lasted one minute. Med. recs. at Ex. 4, p. 7.

The pediatrician had a phone follow-up on March 13, 1994 that Lauren had had status epilepticus on March 11, 1994 with a possible diagnosis of pneumonia in her left upper lobe. Med. recs. at Ex. 4, p. 6. On March 14, 1994, she was admitted to New Hanover Regional Medical Center for seizures. Med. recs. at Ex. 4, p. 6.

On March 25, 1994, Mrs. McMurry informed the pediatrician that Lauren had had a seizure the prior Thursday lasting less than five minutes. Med. recs. at Ex. 4, p. 5.

On April 29, 1994, the doctor called Mrs. McMurry, who reported that Lauren had continued to have seizures (some of which were grand mal) every four to six weeks for the last eighteen months. Med. recs. at Ex. 5, p. 4.

On August 18, 1994, Mrs. McMurry told the pediatrician that Lauren had just had a seizure, which lasted twelve minutes. Med. recs. at Ex. 4, p. 4.

### **TESTIMONY**

Mrs. Rebecca McMurry, Lauren's mother, testified first for petitioners. Tr. at 8. Lauren has Robertsonian translocation, i.e., whereas most people's genes are paired, Lauren has a threesome and one single gene. Tr. at 10-11. Lauren's father and sister Madeline also have Robertsonian translocation and are normal. Tr. at 11. Mrs. McMurry has a maternal cousin who had seizures as a child, but does not have them anymore and is normal. Tr. at 11-12.

As a neonate, Lauren had viruses, ear infections, and fevers. Tr. at 12-13. She had otitis media and fever just a few weeks before she received her third DPT vaccination. Tr. at 13. Prior to her seizures, her development was normal. Tr. at 14. The first and second DPT vaccinations were not a problem for

Lauren. Id.

Lauren received her third DPT vaccination at 10:00 or 10:30 a.m. on October 20, 1992. Tr. at 15. Afterwards, they went to her husband's office and then home. Id. Lauren took a nap, and then went with her mother to the store. Id. It was there that Mrs. McMurry saw her arm jerk. Id. She called the pediatrician's office from the store. Id. Dr. Mann told her to bring Lauren in, which she did. Id. The trip took twenty to thirty minutes, all of which time Lauren was seizing. Tr. at 15-16.

Lauren did not respond to Mrs. McMurry. Id. She did not look at her. Tr. at 16. Her eyes were blinking. Id. Lauren seized throughout her whole body. Id. Her mouth and eyes twitched and there was saliva coming out of her mouth. Id. The doctor immediately took Lauren and called 911 to transport her to the hospital. Id. Dr. Mann rode with Lauren to the hospital. Tr. at 16-17.

Lauren was white and limp in the hospital. Tr. at 17. Her seizure lasted fifty or more minutes. Id. Mrs. McMurry does not know the degree of Lauren's temperature, but she felt warm during the seizure. Tr. at 18. Lauren was in the hospital for three or four days. Tr. at 17. Afterwards, she seemed all right. Tr. at 17-18.

Lauren's next seizure was on December 18, 1992, and lasted forty-five minutes. Tr. at 18. In the year following her first seizure, Lauren had many seizures; every four to six weeks, she had a seizure for forty-five minutes or so. Tr. at 19. Mrs. McMurry said that one seizure lasted longer because they could not get it under control. Id. After the second seizure, she was given medicine, at first Phenobarbital and then Dilantin, followed by other drugs. Tr. at 20.

After Lauren was on medication, she became clumsy, hyperactive, and had insomnia. Tr. at 23. At day care, she did not participate or talk as other children did. Id. However, she stopped taking anti-convulsants one year and three months before the hearing. Tr. at 24. The McMurrays are controlling Lauren's seizures with a ketogenic diet. Id. She still has some seizures, lasting ten minutes, but they do not occur as frequently as before. Id. Lauren still has brief, gasping seizures. Id.

Developmentally, Lauren is getting ready for kindergarten. Tr. at 25. People are surprised that she does as well as she does. Id. Lauren has some delay, especially with communication sequencing and organization. Id. She is low average mentally. Id. Her sister Madeline is very verbal and expressive, makes conclusions and asks why. Tr. at 26. Lauren does not do these things. Id. Lauren takes more one-on-one attention. Id. She does not interact with other children the way Madeline does. Id.

The types of seizures Lauren had or has are the following. Her first was grand mal. Tr. at 27. Typically her seizures are grand mal and start on the right side and progress throughout the rest of her body. Id. Sometimes the seizures begin with her arms jerking and her mouth pulls to one side. Id. It takes her two to three hours to recover from a grand mal. Id. She also has absence seizures. Id. In addition, she has gasping seizures where she takes a really deep breath and then goes limp. Id. She often drops what is in her hands and her head falls. Id. From this she recovers quickly. Id. The diagnosis is partial complex seizure disorder. Tr. at 27-28. Medication affects the type of seizure Lauren has. Id. No etiology was ever given to Mrs. McMurry. Tr. at 29. She is a college graduate as is her husband. Id.

Mrs. McMurry first noticed that Lauren's development was not normal after she had seizures and was put on medication. Tr. at 30. Lauren had normal development through age two, according to the pediatrician. Tr. at 31. She has difficulty running and going downstairs. Id.

The next witness for petitioners was Dr. Marcel Kinsbourne, a pediatric neurologist. Tr. at 34. Five

hours after Lauren's third DPT at seven months and three weeks of age, she went into status epilepticus with a right focal onset. Tr. at 37. She had another attack seven weeks later. Id. Lauren had a variety of partial seizures. Id. It took considerable effort to manage her seizures' frequency and intensity. Id.

Lauren's development continued to be normal and then plateaued. Tr. at 38. She has impaired impulse control, impaired attention, and delay in expression and language. Id. Her IQ is low normal. Id. Dr. Kinsbourne expects it would have been higher without the seizure disorder. Id. In his opinion, the pertussis portion of the third DPT vaccination caused Lauren's seizure disorder. Id. He bases his opinion on case reports in the literature and epidemiological studies. Tr. at 39.

There is an accumulation of case reports of encephalopathy and seizures shortly after the administration of DPT vaccine. Id. He suspects a pattern of toxic effect diminishing in frequency as the period of time increases after vaccination. Id. The temporal relationship between vaccination and onset is critical to Dr. Kinsbourne. Tr. at 40. Seventy-two hours is the cut-off for causation for him. Id. (This would be a different interval, i.e., the second week, for measles vaccine.) Tr. at 39.

Dr. Kinsbourne relies on the National Childhood Encephalopathy Study (NCES)<sup>(3)</sup> and applies its criteria to Lauren. Tr. at 41. The NCES concluded that the relative risk of severe seizures or encephalopathy is significantly greater (beyond 95 percent) following DPT vaccination. Id.

However, Dr. Kinsbourne testified that the NCES was not written to show cause and effect, but just association. Id. There are other epidemiological studies that have sample sizes smaller than the NCES. Tr. at 42. Dr. Kinsbourne stated that there is reasonable biological plausibility, but not scientific certainty, for DPT to cause neurological illness. Tr. at 45. On rare occasions, DPT damages the brain. Tr. at 46.

In close temporal relationship, DPT can cause seizures. Tr. at 46-47. The pertussis element of DPT contains two toxins: pertussis toxin (exotoxin) and endotoxin. Tr. at 48. Pertussis toxin can interfere with the energy metabolism of neurons by binding with proteins that mediate that metabolism. Tr. at 49. Capillaries absorb the pertussis toxin into the bloodstream. Tr. at 50. Endotoxin breaches the walls of the capillaries, making them more permeable. Id. This allows the pertussis toxin to reach the neurons. Tr. at 54. The variable is the amount of endotoxin in the vaccine which varies depending on the lot. Tr. at 52. In addition, hosts differ in susceptibility, a difference not fully understood. Tr. at 52-53.

Lauren had a focal onset with focal features of grand mal, implicating the left side of her brain. Tr. at 55-56. The Institute of Medicine (IOM) stated that DPT can cause serious acute neurological illness and chronic encephalopathy.<sup>(4)</sup> Tr. at 58. Under the NCES, status epilepticus of more than thirty minutes is a serious neurological disorder. Tr. at 59.

Lauren's explosive onset of seizures is not separate from the seizures that followed. Tr. at 60. Clearly, she has a serious case of epilepsy. Tr. at 61. The seriousness was expressed in the long duration of her first seizure and in its being status epilepticus. Id. A first seizure of focal onset and extended duration often leads to further seizures. Tr. at 64. Her developmental delay is a sequela of her seizure disorder. Tr. at 65. Delay developed over time. Id.

Repeated status epilepticus causes brain damage by limiting oxygen supply to the brain, especially in the tonic phase. Tr. at 66. Most seizures do not damage the brain, but status epilepticus can. Id. Anti-convulsants dull the child's mentality, a condition which may endure. Id. Lauren did not have any abnormal EEGs. Tr. at 79.

Dr. Kinsbourne admitted he does not know what happened to Lauren's brain but the temporal association, being within the ballpark of causation, and the toxicity of pertussis bacillus convince him. Tr. at 93-94. In his opinion, the initial seizure, Lauren's other seizures, and her anti-convulsants caused her developmental delay. Tr. at 112-13.

Dr. Gerald M. Fenichel testified for respondent. Tr. at 117. He is a pediatric neurologist. Id. He has been chairman of his department for twenty-eight years. Tr. at 118. Dr. Fenichel treats children with seizure disorders. Tr. at 119. His opinion is that Lauren had a fever associated with her third DPT vaccination which triggered a seizure in her because she was susceptible. Tr. at 119-20. A febrile seizure often occurs when the child has 101 degrees or less. Tr. at 120. Lauren has a seizure disorder whose onset was October 30, 1992. Tr. at 121.

Dr. Fenichel stated that DPT was not the cause of Lauren's seizure disorder. Tr. at 122. The basis for his opinion is that anything that would cause a fever would have caused her to seize. Tr. at 121-22. He stated that DPT cannot cause this disorder because she did not have an acute encephalopathy or serious illness with it. Tr. at 122. She had a normal EEG, which is incompatible with encephalopathy. Id.

Lauren quickly recovered. Id. She was seizure-free for seven weeks. Tr. at 124. She is very bright and does not have any frank neurological deficits. Tr. at 125-26. He does not know why Lauren has developmental disability. Tr. at 126. Perhaps her drugs impaired her. Id.

Dr. Fenichel defined "trigger" as follows. Lauren is a child with a tendency to have seizures which the fever provoked. Tr. at 129. This rarely occurs before the age of six months (she was eight months old at the time). Id. All data show that DPT must first produce encephalopathy in order to cause neurological problems. Tr. at 130.

Dr. Fenichel does not find it a credible theory that DPT causes seizures, although endotoxin does produce fever. Tr. at 132. The DPT did not significantly aggravate anything Lauren was born with. Tr. at 133. The result would have been the same without the DPT. Id.

Dr. Fenichel stated children who have focal febrile seizures have a higher chance of developing afebrile seizures. Tr. at 136. Lauren would have had a seizure eventually even without a fever. Tr. at 139. He does not know why Lauren has a seizure tendency. Id. Moreover, there is no evidence that status epilepticus causes brain damage unless the child becomes hypoxic. Tr. at 143. It depends on what causes the status. Id.

Lauren would not have been considered part of the NCES study because she was alert at the hospital. Tr. at 146. The NCES confidence limits are very broad because the sample size was small. Tr. at 147. The authors included children with brain damage due to other than DPT vaccine. Id. Dr. Fenichel was part of the Advisory Commission of the IOM. Tr. at 148. It is not biologically plausible that DPT causes encephalopathy. Tr. at 155.

Although endotoxin causes fever, case studies are not of sufficient magnitude to simulate vaccine practice. Tr. at 156-57. Mice are injected with pertussis toxin in their brains to test effectiveness of the vaccine and they do not have seizures. Tr. at 158. For Dr. Fenichel, the date of onset of seizures does not make a difference in prognosis. Tr. at 172.

Dr. Fenichel testified that DPT cannot cause an afebrile seizure. Tr. at 177. It can cause acute neurological injury. Tr. at 177-78. Lauren was not born with a chronic or static encephalopathy because she did not have a generalized brain problem. Tr. at 202. Her seizure onset was focal. Id.

## DISCUSSION

Because a residual seizure disorder is no longer a Table injury under the Act, petitioners have the burden of proving causation in fact. Petitioners have not alleged that Lauren suffered a DPT-encephalopathy.

To satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." *Grant v. Secretary, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). *Agarwsal v. Secretary, HHS*, 33 Fed. Cl. 482, 487 (1995); *see also, Knudsen v. Secretary, HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

"[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." *Grant, supra*, 956 F.2d at 1149.

The basic difference between the two medical experts is that Dr. Kinsbourne stated that DPT can and does cause seizures and Dr. Fenichel stated DPT can cause fever that triggers seizures, but cannot cause permanent neurological problems absent encephalopathy. Dr. Fenichel dismissed the significance of the trigger of that first seizure on two grounds: (1) Lauren was susceptible to seizures, and (2) she would have seized anyway because she had matured beyond six months so that her brain was ready for a partial seizure.

It is Dr. Fenichel's testimony that DPT triggered the fever which caused the seizure that was the beginning of Lauren's seizure disorder, but DPT did not have permanent injurious effect because she did not have encephalopathy. The real question is whether or not the court is going to grant significance to the difference between "trigger" and "cause."<sup>(5)</sup>

The intent underlying Congress' enactment of the Act was to compensate those whom the Table vaccines injured.<sup>(6)</sup> Congress did not concern itself with whether or not the child was susceptible to the injury unless respondent could prove that a known factor unrelated to the vaccine was the cause in fact of the child's condition.

In Lauren's case, no one knows that she has a factor unrelated to the vaccine. The medical experts did not give any infection, trauma, toxin (other than DPT), or metabolic or genetic reason for her seizure disorder and consequent developmental delay.

In Dr. Fenichel's three editions of his text, he states that whole-cell pertussis vaccine causes seizures, and "febrile seizures are the single most common adverse reaction to pertussis immunization." Clinical Pediatric Neurology. A Signs and Symptoms Approach (3d ed. 1997) at 62; (2d ed. 1993) at 59; (1st ed. 1988) at 57. His statement is in the context of pertussis encephalopathy, but the editions do not state that absent an encephalopathy, DPT cannot cause febrile seizures.

In essence, Dr. Fenichel testified that Lauren seized because she would have had a seizure anyway, and he knows that she would have had a seizure anyway because she seized. Following this logic, the cause of any post-vaccinal non-Table injury would have to be other than the vaccine from its mere occurrence.

Even though there is no burden-shifting to respondent absent a Table injury (that is, petitioners keep their burden of proving causation in fact), respondent still must impeach petitioners' evidence when that evidence rises, as it does here, to a prima facie level. When the condition of Lauren's brain before the third vaccination is unknown (i.e., what disease or injury she had that would result in her onset of

seizures), respondent cannot satisfy its role of impeaching petitioners' evidence when its own witness testifies that DPT triggered the seizure. Impeachment of petitioners' evidence of causation in fact from the vaccine can only take the form of a factor unrelated. Respondent's proof did not establish that a known factor unrelated caused Lauren's seizure disorder even though the DPT triggered her first seizure. Dr. Fenichel stated that the fever occurred just at the right time of Lauren's brain maturation to cause the seizure, but if Lauren had had a fever from some cause other than DPT, she still would have seized. In addition, since she was susceptible to seizures at that point, she may have seized even without a fever. But he did not give a basis for Lauren's susceptibility. It is speculative for the court to assume she would have had a fever anyway. When? This is not sufficient to undermine the testimony of both expert medical witnesses that DPT caused Lauren's seizure, even though Dr. Fenichel termed his linking DPT to her seizure as a trigger.

This uncertainty of diagnosis of a factor unrelated, and dependency on the result (i.e., the seizure) rather than the cause (i.e., a preexisting disease) to explain the onset is the very essence of "an idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" (42 U.S.C. §300aa-13(a)(2)(A)) and is not a factor unrelated defense under the Act.

In a case such as the instant one in which respondent's expert agrees that the vaccine triggered the seizure and that he does not know what is the basis of the vaccinee's susceptibility, petitioners do not have to fulfill the standard of showing a reputable scientific or medical explanation for how the vaccine caused the seizure.

In essence, respondent has both conceded and not conceded causation by distinguishing trigger from cause, a distinction without a difference in the context of an idiopathic factor unrelated. Therefore, the court will not discuss Dr. Kinsbourne's theory of endotoxin affecting the metabolism of brain neurons. <sup>(7)</sup>

The "defense" of brain susceptibility is a poor one not only in the context of an idiopathic factor unrelated but also in contemplation of the illogic of the defense. We must assume that all children who suffer vaccine injuries (without factors unrelated that caused them in fact) have susceptible brains else vaccine injuries would be universal, i.e., all vaccinees would have brain injuries after vaccination. But they do not. Only a thankfully small number of children and adults suffer vaccine injuries. It was for these unfortunate vaccinees with susceptible brains that Congress passed the Act. To deny Lauren compensation (if she satisfies the court that she does indeed have sequelae of her vaccine injury) would be to eliminate the *raison d'être* of the Act.

It may be that respondent seeks an intermediate defense in this case of new impression. That is, respondent may be saying it does not have a known factor unrelated defense, but petitioner cannot prove that DPT caused Lauren's seizure disorder because, absent an encephalopathy, it cannot. Therefore, respondent need not prove a factor unrelated. And the court reiterates that respondent need not prove a known factor unrelated in a case in which respondent's expert denies that DPT caused (or triggered) the seizures. But that is not this case. To divorce the initial cause from a putative "primary" cause requires specificity as to the primary or underlying cause, and respondent has not provided it in this case. Moreover, it would be egregious for the court to find that DPT did not cause Lauren's seizure when every medical record that was contemporaneous with the first seizure ascribed its cause to DPT vaccine.

Petitioners have satisfied their burden of proving that DPT vaccine caused in fact Lauren's seizure disorder.

## **CONCLUSION**

Petitioners are entitled to a program award. The court hopes that the parties will be able to settle the

damages portion of this case and will schedule a status conference in aid of determining damages or encouraging settlement.

**IT IS SO ORDERED.**

DATE \_\_\_\_\_

Laura D. Millman

Special Master

1. The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

2. Under the change in the regulations, 42 C.F.R. §100.1-100.3, effective March 10, 1995, residual seizure disorder is no longer considered a Table injury. 42 C.F.R. §100.3. Petitioners filed their petition after the effective date of the regulations.

3. <sup>3</sup> R. Alderslade, M.H. Bellman, N.S.B. Rawson, E.M. Ross, and D.L. Miller, 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 Immunisation, 79-169 (Her Majesty's Stationery Office, 1981). P. Ex. 18.

4. <sup>4</sup> DPT Vaccine and Chronic Nervous System Dysfunction. A New Analysis, Institute of Medicine (Washington, DC: National Academy Press, 1994) at 2-3. P. Ex. 14; R. Ex. D.

5. Dictionary definitions are: "trigger" - "to initiate, set off". The American Heritage Dictionary, 1294 (2nd College ed. 1985); "cause" - "to make happen; bring about; effect". Id. at 249.

6. "While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely foreseeable." ... "A relatively small number of children who receive immunizations each year have serious reactions to them." ... "But for the relatively few who are injured by vaccines -- through no fault of their own -- the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered." H.R.Rep. No. 99-908, 99th Cong., 2d Sess. 6, reprinted in 1986 U.S.C.C.A.N. 6344.

7. <sup>7</sup> However, the court has accepted the endotoxin analysis in a death case. Misenko v. Secretary, HHS, No. 92-0013V, 1995 WL 761436 (Fed. Cl. Spec. Mstr. Dec. 7, 1995).