

OFFICE OF SPECIAL MASTERS

No. 99-538V

(Filed: December 14, 2004)

WILLIAM NOEL, as Administrator of the Estate of RACHEL NOEL, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

TO BE PUBLISHED

Clifford J. Shoemaker, J. Bradley Horn, Vienna, VA, for petitioner.
Traci R. Patton, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

Statement of the Case

On July 29, 1999, petitioner¹ filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that DPaT and HiB vaccinations that Rachel Anne Noel (hereinafter, “Rachel”) received on March 12, 1997 caused her an unspecified adverse reaction.

¹ At that time, Rachel was still alive and her mother Martha was a petitioner as well as Rachel’s father.

Rachel died on December 13, 2000 due to a seizure disorder. Death Certificate (P. Ex. 15, p. 58) and Supplemental Report of Cause of Death (P. Ex. 16, p. 2).²

Petitioner's counsel filed a report on December 9, 1999, claiming that this case should be included under the hepatitis B cases he was filing under the Vaccine Program which were consolidated before the chief special master and he moved to consolidate the cases ("Motion to Designate Master File"). The chief special master, on February 14, 2000, denied petitioner's motion for discovery in the hepatitis B cases since medical records had not been filed.

On February 15, 2000, petitioner's counsel filed a status report stating that he was continuing to gather all relevant documentation in this case "to complete the record." He anticipated extensive discovery would be required. On March 13, 2000, the chief special master issued an Order suspending for a period of 180 days proceedings in the amassed hepatitis B cases, including this case. On May 16, 2000, two months later, petitioner's counsel filed another status report stating he was still collecting records. Petitioner's counsel referred to the process of filing status reports in his hepatitis B cases.

On September 26, 2000, the chief special master assigned this case to the undersigned. The undersigned, with consent of the counsel for both parties as to date and time, set a status conference for November 3, 2000, which petitioner's counsel cancelled a half-hour beforehand. On November

² Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

3, 2000, the undersigned issued an Order to Show Cause by December 1, 2000 why the case should not be dismissed both for failure to file medical records and an expert report, noting that petitioner's counsel had wrongly classified the case as a hepatitis B case when Rachel had not received hepatitis B vaccine, but instead acellular DPT and HiB vaccine. Petitioner still had not specified his allegations.

On January 8, 2001, one month after the deadline for responding to the undersigned's Order to Show Cause, petitioner's counsel filed a status report and response to Order to Show Cause, apologizing for the failure to respond to previous orders and deadlines, stating he had stopped taking new cases, and was in the process of trying to find other counsel to take some of his pending cases. He requested time to find other counsel to take over this case and "give it the attention that it deserves."

On January 25, 2001, the undersigned held a telephonic status conference with petitioner's counsel, a partner of petitioner's counsel who proceeded to take over the case, and respondent's counsel. This was followed by an Order that petitioner file P. Ex. 1-10 by February 8, 2001. On February 20, 2001, the undersigned held another status conference, followed by an Order that petitioner file the autopsy report, death certificate, most recent medical records, an expert report, and petitioner's affidavit. On May 16, 2001, the undersigned held a status conference during which petitioner's counsel said he was seeking the death certificate and had to set up an estate in North Carolina. This was followed by an Order that petitioner file an affidavit and a medical expert report by July 13, 2001. Petitioner filed a motion for an enlargement of time on June 15, 2001, which was granted until July 20, 2001.

On August 7, 2001, the undersigned held another status conference, during which petitioner's counsel stated there was a draft affidavit from Mrs. Noel and he was looking for an expert to give him a report. This was followed by an Order that petitioner file a medical expert report by September 21, 2001. On October 2, 2001, the undersigned held a status conference, during which petitioner's counsel said he had a meeting with his expert, Dr. Carlo Tornatore, coming up. This was followed by an Order that petitioner file a medical expert report by November 16, 2001.

On December 6, 2001, the undersigned held a status conference, during which petitioner's counsel said Dr. Tornatore had not completed his expert report yet. This was followed by an Order that petitioner file a medical expert report from Dr. Tornatore as soon as possible. On February 7, 2002, the undersigned had another status conference, during which petitioner's counsel said he was still waiting for Dr. Tornatore's report and needed to change the caption to reflect Rachel's death. He also stated he was no longer a partner of petitioner's original counsel. On March 12, 2002, the undersigned held a status conference, during which petitioner's counsel stated Dr. Tornatore would provide an expert report by April 5, 2002. On March 14, 2002, the undersigned issued an Order that petitioner file a medical expert report no later than April 11, 2002.

On July 10, 2002, the undersigned held another status conference, during which petitioner's counsel stated he had not talked to Dr. Tornatore. This was followed by an Order that petitioner file a medical expert report from Dr. Tornatore by August 8, 2002. On August 8, 2002, the undersigned held another status conference, during which petitioner's counsel stated that Dr. Tornatore would provide an expert report within 30 days. This was followed by an Order that petitioner file a medical expert report from Dr. Tornatore by September 16, 2002.

On September 23, 2002, the undersigned held a status conference, during which petitioner's original counsel, having resumed control of the case, said he needed to contact Dr. Tornatore. This was followed by an Order that petitioner update the caption in this case. Status conferences twice scheduled were rescheduled at request of counsel. On November 26, 2002, the undersigned issued an Order that petitioner file a medical expert report by December 20, 2002. On January 31, 2003, petitioner's counsel moved for a 60-day extension of time within which to file a medical expert report. On February 10, 2003, the undersigned issued an Order granting petitioner's motion, and ordered petitioner to file a medical expert report by March 31, 2003. On May 21, 2003, the undersigned issued an Order that petitioner file a medical expert report by July 3, 2003.

On July 3, 2003, petitioner's counsel instead filed a status report stating that his expert Dr. Tornatore was out of town and requested a 30-day extension of time. On July 11, 2003, the undersigned held a status conference, during which petitioner's counsel stated he forgot to change the caption but will, and that Dr. Tornatore e-mailed him that the expert report was almost finished, and counsel expected to file it by the end of the day. This was followed by an Order that petitioner amend the caption to reflect the demise of Rachel and file an expert medical report by July 31, 2003.

On August 1, 2003, the undersigned held another status conference, during which petitioner's counsel stated he sent the records to another neurologist, Dr. Mary Elizabeth Latimer, because Dr. Tornatore was unresponsive. He said he would meet with Dr. Latimer in a week or two. This was followed by an Order that petitioner amend the caption and file an expert report from Dr. Latimer by August 29, 2003.

On September 5, 2003, petitioner filed Dr. Tornatore's expert opinion (P. Ex. 19), which stated that Rachel had an acute encephalopathy and a possible seizure after vaccination which

became a chronic seizure disorder from which she died. On September 12, 2003, the undersigned held a status conference, during which counsel discussed what were Dr. Tornatore's theories and the literature upon which he relied. This was followed by an Order that petitioner file an amended caption, file medical literature upon which Dr. Tornatore relied, and explain the theories petitioner was asserting, i.e., a Table encephalopathy, a non-Table encephalopathy, causation in fact.

Petitioner's motion to amend the caption was granted on September 16, 2003.³ On October 23, 2003, the undersigned held another status conference, during which petitioner's counsel stated he had sent Dr. Tornatore the prior Order asking for an explanation of his opinion. This was followed by an Order for Dr. Tornatore to supplement his report by discussing the bases of his opinions that Rachel had an on-Table encephalopathy and a causation-in-fact encephalopathy. On November 24, 2003, the undersigned held a status conference and informed the parties of dates from which they could choose a date for a hearing in this case. The undersigned considered it a waste of time to wait for Dr. Tornatore's supplemental report and decided, instead, to query him about the bases of his opinion at the hearing, giving respondent enough time to review the transcript and then have a portion of the hearing later on during which respondent's expert would testify.

It most certainly occurred to the undersigned during the extraordinary delay of petitioner's two counsel in this case that the undersigned should dismiss for failure to prosecute. However, the undersigned, having read the medical records, viewed the case as one in which petitioner might prevail since Rachel seemed to have reacted adversely to her acellular DPT and the interpretation

³ At that time, Martha was still considered a representative of Rachel's estate. However, P. Ex. 18, Letters of Administration, show that only William Noel is the administrator of Rachel's estate. At the first part of the hearing in this case, on February 24, 2004, petitioner moved orally to change the caption of the case to reflect his being appointed administrator, which the undersigned granted (tr. at 170) and memorialized in an Order dated February 25, 2004.

of that reaction and its effect were matters requiring a hearing. In light of the unfairness of punishing petitioner for the dysfunctional behavior of his counsel, the undersigned did not order this case dismissed for failure to prosecute.⁴

By Order of January 13, 2004, the undersigned set a hearing in this case on February 24, 2004. Petitioner filed Dr. Latimer's report as Ex. 21 on January 30, 2004 and Dr. Tornatore's supplemental report as Ex. 22 on February 11, 2004.

Witnesses during the first part of the hearing, held on February 24, 2004, were William Noel and Dr. Carlo Tornatore. Respondent's expert, Dr. Yuval Shafir, testified during the second part, held on October 1, 2004, after petitioner finally filed requested records for the Sarah Barker School.

FACTS

Rachel was born on September 8, 1996. She received her first acellular DPT and HiB vaccines on March 12, 1997, when she was six months old. Med. recs. at Ex. 2, p. 14. A call was placed to the University of North Carolina Hospitals, Chapel Hill, at 3:22 a.m. on March 13, 1997. The history given was that she had received her shots on March 12, 1997 and was doing some strange things. The nurse could hear a gurgly cat-like crying in the background, very high-pitched and bizarre. Rachel's temperature was 100.9° by forehead strip, but she felt as if she were burning up. She had a high-pitched, eerie, cat-like cry but it was less wet and gurgly. This was a severe, unusual reaction. The parents felt that Rachel was having trouble breathing, but she was not blue. Med. recs. at Ex. 2, p. 55.

⁴ However, when petitioner's counsel submits a request for fees and costs, the undersigned intends to evaluate carefully how much time petitioner's counsel asserts he worked on this case. The undersigned doubts that petitioner's counsel should receive compensation for saying, in effect, he was not ready to proceed on two dozen occasions.

A note in the records of Regional Pediatric Associates for a phone call at 3:30 a.m. on March 13, 1997 states that the recorder tried to call the Noels twice, but there was no answer. Later, he or she inscribes this was a 6-month-old who developed a fever of 101°, was moderately fussy, did not vomit, but had shallow breathing, and no real responsiveness. The inscriber referred the Noels to the ER at Durham Regional Hospital. Med. recs. at Ex. 28, p. 108.

Rachel was taken to Durham Regional Hospital on March 13, 1997, at 3:50 p.m. The history given was that Rachel had fever and inconsolable crying for the prior 30 minutes to one hour. She had received her six-month immunizations (DPT, polio, and Hib). The parents described her crying onset at 3:30 that morning with some shallow breathing. They denied any decreased oral intake or decreased activity. Rachel had been in her normal state of health until 3:30 that morning. They denied a cough, runny nose, diarrhea, or vomiting. On physical examination, she was crying but consolable. Her temperature was 100.9°. The doctor suspected this was vaccine-related. Med. recs. at Ex. 3, p. 11.

On April 26, 1997, Rachel was taken back to Durham where she saw Dr. Gordon S. Hardenbergh. She had had a generalized tonic-clonic seizure. She did not have a recent illness or fever and no altered mental status. Her past history was a reaction to DPT which consisted of an unresponsive episode, possibly a seizure, but was related to fever. Med. recs. at Ex. 3, p. 24.

A CT scan of Rachel's head was done on April 26, 1997, showing right frontal and temporal atrophy which Dr. Julia R. Crim wrote could be related to perinatal anoxia. Med. recs. at Ex. 3, p. 27.

On April 28, 1997, Rachel saw Dr. Tadeusz F. Poplawski, a pediatric neurologist. The history was that, six weeks ago, the day she had DPT, she had a temperature of 101° at night, and

30 minutes of grinding, staring off, and being unresponsive. She recovered satisfactorily without significant problems and just this past Saturday, at 6:00 p.m., she stared to the left and her eyes fluttered for four to five minutes. This evolved into a generalized tonic/clonic seizure lasting about 30 minutes without fever. She was rushed to the emergency room where she received Ativan and Phenobarbital. She had a temperature of 101°. A CT scan was abnormal, showing selective atrophy of her frontal lobes. A spinal tap was normal. She was transferred to Duke for 23 hours of observation. She finished a dose of IV Phenobarbital and was discharged the day after. Since then, Rachel had been doing fine. She was a little bit irritable and somnolent.

On physical examination, she had a normal head. She was awake, alert, and interested in her surroundings. She did not have hypotonia. Her mother's description of the first episode was very suspicious and could be an epileptic seizure at that time definitely related to a high fever. Dr. Poplawski was very skeptical about the CT head scan, which most likely represented a benign hygroma, a common finding at that age. Med. recs. at Ex. 4, p. 1.

From April 26 to 27, 1997, Rachel was at Duke University Medical Center where Dr. Susan B. Boutilier wrote that she had a history of having had another episode of "seizure activity" the day she had her DPT. This was described as being quite different from this most recent episode in that she seemed to be staring, had no fixed gaze deviation, and was moaning and somewhat less responsive than usual for about 30 minutes. On physical examination, Rachel was alert to voice, opened her eyes, and fixed and followed appropriately.

She was quite reactive to touch and purposefully grasped toys which were placed in her hand. She also transferred from hand to hand. Med. recs. at Ex. 7, p. 3. See also Ex. 2, p. 37, which reflects in the admission history and physical on April 26, 1997 that Rachel's past history included

a reaction to DPT, a seizure lasting about 30 minutes during which she was non-responsive and had fever and from which she came out by herself.

EEGs done on May 1, 1997 and July 15, 1997 were normal. Med. recs. at Ex. 4, p. 30, and Ex. 3, p. 62. An MRI done on May 9, 1997 questioned if there were very subtle periventricular leukomalacia and noted a somewhat atrophic appearance. Med. recs. at Ex. 4, p. 24.

From April 6-8, 1998, Rachel underwent a video EEG. Med. recs. at Ex. 8, pp. 2-5. Eleven seizures were described. All the seizures were different and included symptoms such as: eye fluttering, upward gaze, fixed right gaze preference, cessation of movement, fixed tonic posture (seizure #1); no clinical change (seizure #2); vocalization (seizure #3); vocalization, moaning, jerking of lower left limb (seizure #4); quiet lying (seizure #5); head deviation, right gaze preference (seizure #6); fixed tonic flexed posture (seizure #7); becomes quiet, right head deviation, motor arrest (seizure #8); becomes quiet (seizure #9); right head deviation (seizure #10); turning blue; head deviation, decrease in activity (seizure #11). The attending electroencephalographer Dr. O'Neill D'Cruz stated the seizures were consistent with partial complex seizures with independent onset in the left and right temporal regions, three starting in the right temporal region and 8 starting in the left temporal region. Med. recs. at Ex. 8, p. 5.

On December 13, 2000, at 7:00 a.m., Mr. Noel went to check on Rachel and found her limp, pale, not breathing, with no pulse, and with a small amount of bloody secretions in her mouth. He started CPR and called 911. Med. recs. at Ex. 15, p. 63. Her prior seizure had been on October 18, 2000. Id. Rachel arrived at the Duke University Medical Center Emergency Department in full cardiopulmonary arrest, still warm to touch but pale. Med. recs. at Ex. 15, pp. 45, 63. She died due to her seizure disorder. Med. recs. at Ex. 13, pp. 1, 4.

Additional Submissions

On January 30, 2004, petitioner filed an expert report from Dr. Mary Elizabeth Latimer. dated January 22, 2004 (P. Ex. 21), and Dr. Latimer's curriculum vitae (P. Ex. 22). Dr. Latimer, a pediatric neurologist, states that the triage nurse who received a phone call from Rachel's mother and father at 3:22 a.m. on March 13, 1997, put in her notes "Immunization reaction (pediatric)." Rachel was seen in the ER that night, evaluated, diagnosed with a presumptive vaccine-related adverse reaction, and discharged home. P. Ex. 21, pp. 1, 2.

Dr. Latimer states Rachel returned to the ER on April 26, 1997, at seven months of age, "with another seizure that was a generalized tonic clonic seizure." P. Ex. 21, p. 2. This was a prolonged seizure and required a transfer to Duke University. Two days after her release, she saw Dr. Poplawski, who became her primary treating neurologist. He noted in his records Rachel's reaction to acellular DPT vaccine. He diagnosed Rachel with intractable epilepsy. She returned to the ER on June 2, June 7, June 27, July 15, September 4, September 10, October 4, and December 31, 1997. A 48-hour video EEG performed April 1998 showed seizures. Many types of anticonvulsants which Rachel used did not control her seizures. She died on December 13, 2000 as a result of her intractable epilepsy. Id. Dr. Latimer's opinion is that Rachel developed a chronic intractable seizure disorder as a direct result of the vaccination she received in March 1997 and that she had a severe reaction within several hours of that vaccination. Id.

Dr. Latimer's CV shows that she was Chief of Child Neurology from September 1995 to January 1999 at Georgetown University Children's Medical Center. She was also Chief of Outpatient Child Neurology from July 1993 to June 1994 at Walter Reed Army Medical Center. She

is board-certified in both pediatrics and neurology with special qualifications in child neurology.
P. Ex. 22.

Petitioner filed chapter 7, “Neurologic Complications of Immunizations. Postvaccinal Encephalomyelitis,” from Child Neurology, 6th ed., ed. J.H. Menkes and H.B. Sarnat (2000) 678-91 (P. Ex. 23). The authors discuss only whole-cell pertussis vaccine encephalopathy, stating, at page 680, “No major neurologic reactions to acellular pertussis vaccine have been reported to date.”

Petitioner filed “Delayed Neurological Deterioration After Anoxia” by F. Plum, et al., 110 *Arch Int Med* 56-63 (1962) (P. Ex. 24). The authors discuss five patients who experienced delayed neurological damage after anoxic coma (lack of oxygen). Most of the patients awakened within 24 hours and resumed full activity in four or five days. A normal interval followed for weeks but usually lasted from two to ten days when they abruptly became irritable, apathetic, and confused. Neurologic deterioration progressed to coma and death or stopped and proceeded to recovery of full health. Id. at 22. The consistent pathologic abnormality was cerebral hemispheric demyelination without significant neuronal damage. Id. at 24.

Petitioner filed “Idiopathic catastrophic epileptic encephalopathy presenting with acute onset intractable status,” by P. Baxter, et al., 12 *Seizure* 379-87 (2003) (P. Ex. 25). The authors discuss six children who had focal or multifocal seizures and a devastating acute epileptic encephalopathy leading to death or severe disability. No cause was identified.

Petitioner filed “Hypoxic-ischaemic encephalopathy after near miss sudden infant death syndrome,” by J.E.C. Constantinou, et al., 64 *Arch Dis Childhood* 703-08 (1989) (P. Ex. 26). The authors studied 14 infants aged three to twenty-six weeks who presented with severe hypoxic

episodes due to “near miss” sudden infant death syndrome. Five of the survivors had an interval of near normality from 36-96 hours after the event before neurological deterioration. Id. at 707.

Respondent filed 13 articles (Exs. D - P) which discuss whole-cell DPT, MMR, and tetanus vaccine, experiments with pertussis toxin in rats, and a trial of various types of acellular DPT and whole-cell pertussis vaccines.

In “Symptoms After Primary Immunisation with DTP and with DT Vaccine,” by T.M. Pollock, et al., *Lancet* 146-49 (July 21, 1984), the authors note that after each dose of either DTP or DT vaccine, vaccinees had attacks of high-pitched screaming, fever, episodes of pallor or cyanosis with limpness, convulsions, and local reactions. Id. at 146, 147. (Ex. D.) “Crying or screaming starting within 2 days of vaccination was described as high-pitched or shrill...” Id. at 148. The authors state, “Any vaccine which causes fever may provoke a febrile convulsion in a susceptible child; DTP is potentially more likely to do so than DT, since it causes fever more often.” Id.

The authors in respondent’s Ex. E, “Neurologic Events Following Diphtheria-Tetanus-Pertussis Immunization,” by A.M. Walker, et al., 81 *Ped* 345-49 (1985), describe, inter alia, an 11-month-old girl who had a two-and-one-half hour generalized tonic-clonic seizure on the evening of her third DPT. Her temperature during the seizure was 102.2°. Id. at 348. She was treated with phenobarbital. At six years of age, still under treatment, she had rare focal left-sided seizures in the absence of fever and abnormal EEG readings. Id.

The authors state, “Pertussis immunization induces fever and irritability in a substantial fraction of children, and the occurrence of febrile seizures, including first febrile seizure in children without known predisposition to neurologic disease, may be counted as one of the hazards of DTP

administration. ...Uncomplicated febrile seizures are likely to be taken more seriously when they occur soon after an immunization.” Id. at 349.

The authors in respondent’s Ex. F, “The Risk of Seizures After Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine,” by W.E. Barlow, et al., 345 *New Eng J Med* 9:656-61 (2001), state that DTP vaccine is associated with an increased risk of febrile seizures only on the day of vaccination, with a three times higher risk among infants from 0 to 12 months old than among children 13 to 24 months old. Id. at 659.

The authors in respondent’s Ex. I, “A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines,” by P. Farrington, et al., 345 *Lancet* 567-69 (March 4, 1995), state that their study “confirmed a significant association between DTP vaccination and febrile convulsion resulting in hospital admission in infants less than a year old.” Id. at 568.

The authors in respondent’s Ex. N, “Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children,” by A.L. Cody, et al., 68 *Ped* 5:650-60 (1981), state that unusual or persistent crying was noted occasionally following DTP vaccination. In most cases, parents likened the cry to that of a pain cry, which usually began three to six hours post-vaccination. “An unusual cry was defined as a cry of unusual character, usually described by the parents as a high-pitched scream. It was a cry that the parents claimed they had never heard their child produce before.” Id. at 651.

Children who had convulsions after DTP vaccination were scheduled to receive DT immunizations in place of future DTP immunizations. Id. Convulsions were noted following all three of the DTP vaccinations and occurred within 24 hours of immunization with a median time of

14 hours. Id. at 653. Most of those children who had convulsions also had elevated temperatures. Id. Children who had seizure activity were also noted to be either fussy or irritable or to have other unusual behavior. Id. “Unusual, high-pitched crying has been previously reported after DTP immunization.” Id. at 656.

“Convulsions appear to be the most common more serious reaction observed following pertussis immunization.” Id. “The most severe reactions following pertussis immunization are permanent neurologic damage and death.” Id. at 657. The authors recommend that children who experience convulsions or unusual crying episodes receive a DT immunization in place of future DPT immunizations. Id.

The authors in respondent’s Ex. O, “Longitudinal Study of Adverse Reactions Following Diphtheria-Tetanus-Pertussis Vaccine in Infancy,” by S.S. Long, et al., 85 *Ped* 3:294-302 (1990), state that fever or adverse behavior was described following 89% of DTP vaccinations. Id. at 296. They estimated the probability of a febrile reaction to DPT as 64% following the first vaccination. Id. at 297. The authors state that “Crying that persists for more than 3 hours and crying that has a high-pitched or unusual tone have been defined as contraindication to further pertussis immunization.” Id. at 300.

The authors in respondent’s Ex. P, “A Controlled Trial of a Two-Component Acellular, a Five-Component Acellular, and a Whole-Cell Pertussis Vaccine,” by L. Gustafsson, et al., 334 *New Eng J Med* 6:349-55 (1996), state that acellular DPT vaccine was much less likely to cause reactions than whole-cell DPT vaccine. Id. at 354.

TESTIMONY

William Noel testified first.⁵ For her first six months, Rachel developed normally. Tr. at 7. On March 12, 1997, she received her first acellular DPT and HiB vaccinations. At 3:00 a.m. on March 13, 1997, she had a high-pitched cry and moaning. Tr. at 11. He and his wife tried to wake her but could not. Id. The light was on in her room. Tr. at 12. Rachel was unresponsive. Id. Mr. Noel held her and she was very warm. Id. She was keening. Id. Keening is a high-pitched moan which was virtually continuous. Tr. at 13-14. He put her face to his and it was hot. Tr. at 15. The fever strip said she had 101° temperature, but he thinks it was 102 or 103°. Tr. at 16, 18. After calling the doctor, he called the doctor's emergency number. The doctor called back and told him to take Rachel to the hospital. They went to Durham Regional Hospital. Tr. at 18-19. Rachel was unresponsive during the first half-hour at the ER. Tr. at 23. Her whining lasted 45 minutes or longer. She had unfocused staring for two to five minutes, then fell into a deep sleep for five hours. Tr. at 26. Mr. Noel has no doubt in retrospect that Rachel was seizing on March 13, 1997, before he and his wife came into her bedroom, and he is surprised she lived through it. Tr. at 32. What they observed was the post-seizure period of a very severe, protracted seizure. Tr. at 33. In her subsequent seizures, she made noises. Id. Typically, after some of her worst seizures, she was unresponsive, and moaned and made other noises associated with being unresponsive. Id.

Rachel had frequent seizures of varying severity. Tr. at 29. On April 26, 1997, he was out on the patio with friends, one of whom was a nurse. She told him Rachel was seizing. Tr. at 35. They took her to the ER. Id. They watched her during her first video EEG and saw that she had

⁵ Martha Noel, Rachel's mother, also answered questions, and her answers were consistent with William Noel's answers.

three seizures that day, but several more subclinically. Tr. at 36. She behaved normally between March 13, 1997 and April 26, 1997. She developed rapidly and began talking. She had a few words at age one year. Tr. at 37.

Rachel had had seizures with and without fever. Tr. at 96. After the seizure of March 13, 1997, Rachel was grinding and staring. Tr. at 108. Mrs. Noel stated that, although Rachel's behavior was normal between March 13, 1997 and April 26, 1997, she would occasionally quirk, shake, or twitch. Tr. at 39. After April 26, 1997, Rachel continued to develop, but she did not walk until she was four years old. Tr. at 40. Her seizures became more frequent after April 26, 1997. Tr. at 46-47. Two to three weeks later, she had another seizure. Tr. at 48. Her next seizure was the first week of June. Tr. at 49. The seizure she had on April 26, 1997 was more than 20-30 minutes long. Tr. at 50. Two to three weeks later, her seizure which consisted of arm shaking, was 20 minutes long. Tr. at 52. Rachel's development slowed when she was 18 months old. Tr. at 58. Rachel's seizures frequently differed from each other. Id. He began to recognize a postictal period because she moaned and was listless and unresponsive. Tr. at 88. He recognized that was the same behavior as after the first time she had been at the hospital. Id.

After her first acellular DPT and Hib vaccines, Rachel never laughed or cried until she was four years old, except for one time when she fell off the bed. Tr. at 58-59. She developed 30 words, but her speaking ability began to decline at 18 months. Tr. at 59. At 2 years of age, she could not speak at all. She had repetitive behavior.

In November 2000, she contracted a virus, had a 103 - 104° fever, and a seizure. Tr. at 67. On December 13, 2000, he put her to bed at 9:00 p.m. He woke in the morning, heard a noise, but

Rachel went back to sleep and he went to sleep. Tr. at 69. He found her with warm phlegm next to her face and she was dead. He gave her CPR and his son called 911. Tr. at 70..

Dr. Carlo Tornatore, a neurologist, testified next for petitioner. Ten percent of his patients have seizure disorders. Tr. at 115. He found the telephone call to the triage nurse striking because she heard a cat-like crying in the background which was very high-pitched and bizarre. It was constant, siren-like, and inhuman-like crying. Tr. at 117. No other entity causes this than vaccination. It does not make any difference that the DPT was acellular. Tr. at 119. Unusual, high-pitched crying is associated with DPT vaccine and an unusual seizure disorder. Tr. at 118. It is a sign of a very unusual cytotoxicity which we do not see anywhere else. Tr. at 120. Acellular DPT can cause seizures. Tr. at 122, 124.

Dr. Tornatore commented on Rachel's video EEG, done from April 6-8, 1998. Tr. at 127. In her first seizure asleep, she was vocalizing and twitching. She had brief vocalizations and moaning sounds in another seizure. In a third seizure, she lay there without motor movements. These are three different kinds of seizures. Tr. at 128-29. In another seizure, she was quiet, but, in still another seizure, she turned blue (associated with hypoxia) for one minute. Tr. at 130. Rachel had multiple seizures in one day and Dr. Tornatore found it profound that she turned blue. Id.

Dr. Tornatore stated that some of the endotoxin remains in the cell membrane. Tr. at 134. The endotoxin binds to a nerve which is excitatory. Tr. at 138. Endotoxins overstimulate the brain, leading to fever and seizures. Id. Fever facilitates seizing by reducing the seizure threshold. Tr. at 139. Dr. Tornatore testified that Rachel had a seizure on March 13th because of her high-pitched wailing and unresponsiveness. Tr. at 140, 141. The unresponsiveness is very important. Tr. at 141.

We can see that on the April 1998 video EEG which showed that Rachel's unresponsiveness is seizure-related. Id.

Dr. Tornatore related the March 13, 1997 seizure to the April 26, 1997 seizure. Tr. at 142. The March 13th event was profound. A CT scan prompted a query whether Rachel's brain had atrophied. Id. Because of this intense endotoxic event from seizures, nerves are killed and a brain can atrophy. Tr. at 144. In status epilepticus, one does not regain normal consciousness for 30 minutes. Tr. at 147. Rachel had status epilepticus on March 13th. Id. Her January 13, 1998 MRI clearly showed atrophy. Tr. at 149. The May 9, 1997 MRI showed asymmetry of the hippocampal formations, which is exactly from where the seizures were coming. Tr. at 151. A child can have normal behavior even if she has brain atrophy. Tr. at 154. Rachel's death was vaccine-related because it was due to a seizure. Tr. at 161, 162.

Dr. Tornatore testified that Rachel clearly had an acute encephalopathy for a period of time, which led to a chronic encephalopathy and a loss of milestones. Tr. at 163, 164. Her encephalopathy was off-Table. Tr. at 164. She probably had other episodes of subtle seizures between March 13, 1997 and April 26, 1997. Id. The video EEG showed the seizure could be very subtle, and numerous times, she was normal. Tr. at 165, 166, 168-69.

Rachel had partial complex seizures. Tr. at 167. They involved the higher cognitive processes, manifested in behavior like moaning. Tr. at 177. They were sometimes mixed (involving motor and cognitive functions), and sometimes general (involving everything). Id. She was diagnosed with epilepsy in April 1997, but its onset was March 13, 1997, when she had a toxic event to her brain leading to a seizure with an encephalopathic component (screaming, wailing, inhuman cry, and unresponsiveness). Id., 179. The biologic mechanism in the acellular DPT is the same as

in the whole-cell DPT because it has the same protein. Tr. at 182-83. Her reaction occurred within 12 hours of vaccination. Tr. at 184. She had trouble breathing. Tr. at 185. Epilepsy is an intermittent phenomenon. Tr. at 191.

The April 1998 video EEG shows that everything that happened on March 13, 1997 happened on the video EEG, too, such as her vocalizations, head movements to one side, and moaning. Tr. at 194, 196. The eeriness and inhuman quality of the scream and wail tell you that the brain has been affected to cause such bizarre behavior during the March 13th event. Tr. at 198.

The reason the MRI showed asymmetry was because her brain had atrophied. Tr. at 208. The profound effect of the vaccine on her brain plus hypoxia led to a kindling effect. Tr. at 213. Even though Rachel looked good, she had atrophy. Tr. at 215. She met her milestones at nine months, but on July 9, 1997, Dr. Wendy Collins noted that she did not roll over, did not cruise or crawl, and had mild gross motor delays. Tr. at 216, 218, 221. There is a difference between febrile seizures, which are regarded as benign, and seizures, such as partial complex seizures, which may be provoked by fever which lowers the seizure threshold. Tr. at 222. In the hospital on March 13, 1997, Rachel's temperature was 101.3°. Tr. at 224. Pertussis endotoxin can affect the immune system to cause it to release responses that cause fever. Tr. at 225. Rachel experienced a hypotonic, hyporesponsive episode March 13, 1997 when she went limp and was unresponsive. Tr. at 229. She similarly became unresponsive in her April 1998 video EEG. Id. During her high-pitched wailing on March 13th, she probably had some degree of anoxia or hypoxia. Tr. at 231. Rachel made a gurgling noise and had to be suctioned. Tr. at 233. On the day of her death, Rachel had phlegm on her face meaning there must have been a seizure and she asphyxiated. Tr. at 235.

On October 1, 2004, at the second part of the hearing, Dr. Yuval Shafir, a pediatric neurologist, testified for respondent. Interestingly, he had a patient who had an encephalopathic and seizure reaction to acellular DPT and died from her seizures. Tr. at 250, 251, 258. But she would not have qualified under the Vaccine Table for a Table encephalopathy because her encephalopathic symptoms were not severe enough. Tr. at 253. She had decreased responsiveness. Tr. at 255. Her seizures consisted of looking to one side, becoming very quiet, and having a few eye blinkings. Tr. at 256. She died two and one-half years later. Tr. at 258. Dr. Shafir knows this girl had a reaction to her acellular DPT because her symptoms occurred within a time relation to the DPT and she had a mild fever after it (between 100 and 101°). Tr. at 260, 261.

Dr. Shafir testified that Rachel had epilepsy. He stated that the onset of her seizure disorder was April 26, 1997, and the onset of her encephalopathy was at 13 months when she was not walking. Tr. at 264, 294. He stated that the DPT vaccine was not the cause of her seizure disorder or encephalopathy. Tr. at 263-64. He felt strongly that uncontrolled seizures can lead to encephalopathy. Tr. at 265. Rachel had seizures from both sides of her brain. Id.

Rachel's March 13, 1997, episode, during which she was febrile, irritable, had a high-pitched cry, and was lethargic, is a reaction that is described in many case series of pertussis vaccine and fits what these case series describe. Tr. at 267. She was responsive when seen by a doctor and recovered the next day. Her shallow breathing is hard to assess. Id. He attributes her unresponsiveness to a high fever. Id. A temperature of 100.9 degrees could be a high fever. Tr. at 268. He viewed the grinding, staring and unresponsiveness for 30 minutes as a consequence of lethargy due to a pertussis vaccine reaction. These are the described known reactions to pertussis vaccine that occur in a large percentage of vaccinees. Tr. at 269. If one wants to call cases of pertussis vaccine reaction with

lethargy and high-pitched cry a transient encephalopathy, one can do it, but they are quite common and not related to any chronic encephalopathy. Tr. at 270. The term acute transient encephalopathy is never used in the vaccine literature. Tr. at 271.

Dr. Shafir testified that Rachel could have had an epileptic seizure on March 13, 1997, although he doubts it. Tr. at 273-74. Either Rachel did not have a seizure that night or she had status epilepticus. Tr. at 277. The emergency room doctor determined that she was not encephalopathic. Tr. at 278. There is no evidence of hypoxia. She became red, not blue. Id. Dr. Shafir stated there is no relationship between Rachel's reaction to acellular DPT on March 13, 1997 and her seizure on April 26, 1997. Tr. at 279. Rachel's behavior in the two events, March 13, 1997 and April 26, 1997, are described totally differently. Tr. at 280. The appearance of a febrile seizure after a vaccination is not a risk factor for developing any neurological abnormalities later. Tr. at 282. Epidemiological studies do not show any relationship between febrile seizures or other vaccine reactions, such as lethargy, irritability, and high-pitched cry, with long-term neurological effects. Tr. at 293.

Rachel had an immediate reaction to her acellular DPT vaccine, manifested by lethargy, irritability, and high-pitched cry. Id. He does not think there is any evidence that she had a seizure on March 13, 1997. Id. He would not relate her later seizures to her March 13th vaccine reaction. Tr. at 293-94. Pertussis encephalopathy is an immune reaction, not a direct one. Tr. at 351. Anything that can cause severe encephalopathy can cause a mild encephalopathy. Tr. at 353. When Rachel lost functions, she had encephalopathy. Tr. at 359.

Eye deviation is a typical initiation of seizures. Tr. at 318. Whatever caused Rachel's seizure on April 26, 1997, also caused her seizure on June 10, 1997, even though she was normal between the seizures. Tr. at 322, 324. This could be the result of brain damage. Tr. at 322-23.

Eventually, the seizures caused frank encephalopathy due to constant injury to the brain. Tr. at 324, 364.

The April 1997 MRI did not show atrophy of Rachel's brain. Tr. at 294. This was a benign enlargement of the subarachnoid space, a common condition in children with large heads. Tr. at 294, 295. At four months of age, Rachel was in the 75th percentile of head circumference. She had accelerated head growth. Tr. at 298. He thought Dr. Tornatore's testimony was peculiar and against medical logic and experience. Tr. at 300. He also stated Dr. Tornatore, who is an adult neurologist, has no experience to testify as he did. Someone cannot have chronic encephalopathy and behave normally. Tr. at 302.

Dr. Shafir testified that Rachel had a reaction to her acellular DPT, which consisted of lethargy, irritability, and a high-pitched cry. Tr. at 327. He stated that her seizure disorder was independent of her DPT reaction, and that the seizure disorder led to epilepsy, developmental delay, and autism. She died of sudden unexpected death in epilepsy. Id. He admitted that pertussis has been used as a neurotoxin in certain animal models. Tr. at 328. There are very rare cases in which pertussis vaccine causes encephalopathy in people. Id.

In an intermittent seizure disorder, the patient will be perfectly normal between seizures, the MRI will be normal, and that is what happened in Rachel's case. Tr. at 329. If Rachel had a seizure on March 13, 1997, her normalcy between March 13th and her April 26th seizure would be consistent with her having a seizure disorder, just as her April 26th seizure followed by normalcy before her June 10th seizure is consistent with her having a seizure disorder. Tr. at 330. When someone has a febrile seizure after pertussis vaccine followed by other seizures, he thinks there is a relationship.

Tr. at 332. Probably, there is an area of the brain that is more prone to seizure, and the fever and other effects of the pertussis vaccine activate that center, producing a seizure. Id.

The events associated with pertussis (crying, irritability, fever) can activate an epileptic focus that is already there. Tr. at 334. He stated the Barlow article (respondent's exhibit F) shows that DPT does not lead to seizure disorders. Tr. at 333-34. It is not unusual for someone to have seizures that are febrile as part of a seizure disorder and then later have afebrile seizures. Tr. at 341.

One of the reasons Dr. Shafrir gave for not accepting that Rachel had a seizure on March 13, 1997 was that its symptoms were different than those during the seizure she had on April 26, 1997, but all her seizures were different because they came from different parts of her brain. Tr. at 347-48. Rachel had documented seizures on video EEG that did not show up clinically. Tr. at 350.

DISCUSSION

The Vaccine Act affords petitioners two theories of recovery, thereby allowing them to prove causation by showing that either: (1) a Table-injury occurred or (2) the vaccine was the cause-in-fact of the injury. The former theory is governed by Section 14(a) of the Act which contains a Vaccine Injury Table. If the injuries described in this Table occur within the statutorily defined time period, petitioners have proven the existence of a "Table-injury," creating a rebuttable presumption of causation.

Here, petitioner alleges a non-Table acute encephalopathy and seizure disorder that acellular DPT vaccine caused in fact. Petitioner is proceeding on a theory of causation in fact. To satisfy his burden of proving causation in fact, petitioner 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).

Without more, "evidence 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.

Petitioner must not only show that but for the vaccine Rachel would not have had the injury which led to her death, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.

The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

Although the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), listed various criteria for the federal district court judges to follow in their role

as gatekeeper for the admission of scientific and medical evidence, such criteria are merely aides in evaluation, rather than prescriptions, for the Office of Special Masters. Even in federal district courts, “Daubert’s list of specific factors neither necessarily nor exclusively applies . . . in every case . . . [and its] list of factors was meant to be helpful, not definitive.” Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141, 151 (1999).

In the Office of Special Masters, even the Federal Rules of Evidence are not required.⁶ Invariably, consistent with the legislative intent in creating the Vaccine Program, the special masters admit most evidence. But see, Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff’d, (Fed. Cl. May 25, 1999) (unpublished), aff’d, 232 F.3d 912 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist’s testimony for diagnosis of a neuropathy rejected).

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, “Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules.” Thus, the task before the undersigned is not to delineate how petitioner’s evidence of transient encephalopathy and seizure disorder does or does not satisfy the Daubert litany of support in peer-reviewed medical literature, concurrence among a majority of physicians in the field of immunology and/or neurology, and confirmative testing of methodology. Rather, the task is to determine medical probability based on the evidence before the undersigned in this particular case.

⁶ CFC Rules, Vaccine Rule 8(b) Evidence. “In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties.”

As for epidemiological support for causation, the Federal Circuit in Knudsen ruled for petitioners even when epidemiological evidence directly opposed causation from a vaccine.

In Knudsen, even though epidemiological evidence supported the opposite conclusion, i.e., that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, the Federal Circuit stated:

The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

So, too, in this case, although the medical literature establishes only that acellular DPT vaccine may cause adverse reactions in a small number of vaccinees, the theory underlying that causation is the same as Dr. Tornatore expressed in this case: an inflammatory response that provokes a fever as well as a transient encephalopathy, the former prompting the beginning of a seizure disorder that would ultimately lead to Rachel's demise.

The timing here of 12 hours is appropriate for an immune response, and consistent with the medical literature that respondent kindly provided, most of which describes exactly the symptoms that Rachel had on March 13, 1997: high-pitched and bizarre, gurgly, cat-like crying, fever, difficulty breathing, unresponsiveness, and staring off. Dr. Tornatore's testimony is consistent with Rachel's contemporaneous medical records which describe this as a seizure episode. He is also consistent with Dr. Latimer's expert report that Rachel's acellular pertussis vaccination caused a seizure disorder which led to her death. Dr. Latimer is a pediatric neurologist

The pathological process described in the medical literature and in Dr. Tornatore's testimony is consistent with what happened to Rachel clinically, and shows a logical sequence of cause and effect. Dr. Shafrir admits Rachel had a reaction to her first acellular DPT. He just thinks it was transient and benign. The undersigned finds Dr. Tornatore more credible than Dr. Shafrir because Dr. Tornatore's testimony that Rachel had a seizure on March 13, 1997 is consistent with both the medical records in this case and the medical literature.

The undersigned finds quite significant that Rachel's April 6-8, 1998 video EEG showed the same symptomatology that Rachel had on March 13, 1997, which the doctor interpreted as seizures on the video EEG: vocalization, moaning, crying, unresponsiveness, staring off.

The only ingredients missing are pathologic certainty and epidemiologic support. Dr. Tornatore testified that some endotoxin, a protein in the cell envelope, still remains in acellular DPT and, rarely, can cause have an excitatory effect on the nerves as well as cause a fever, prompting a seizure, and transient encephalopathic symptoms such as moaning, high-pitched crying, lethargy, anoxia, and unresponsiveness.

As the Federal Circuit held in Knudsen, a definitive understanding of the underlying biological mechanism leading to Rachel's transient encephalopathy and seizure disorder as well as epidemiologic support that acellular DPT can cause both are unnecessary in order for petitioner to prevail. Even when epidemiology leads to a conclusion opposite to vaccine causation, petitioner may still prevail if his expert shows a logical sequence of cause and effect, as well as biologic plausibility.

Dr. Shafrir objected that Rachel's March 13, 1997 episode, which the undersigned holds is her first seizure, was different than her April 26, 1997 seizure (which the undersigned holds is her

second, overt seizure) and concluded that the March 13, 1997 episode, therefore, could not have been a seizure. But he admitted upon further questioning that all of Rachel's seizures differed from each other, depending on where in her brain the seizure originated. That did not mean that all her seizures were not one seizure disorder except that, for Dr. Shafrir, all her seizures started with her April 26, 1997 seizure, not the events of March 13, 1997.

Dr. Shafrir said that Rachel did not have an acute encephalopathy, even if transient, on March 13, 1997 because she was normal after her adverse reaction to acellular DPT until her April 26, 1997 seizure. But, under questioning, he admitted that she was also normal between her April 26, 1997 seizure and her June 10, 1997 seizure, yet he still connected these two seizures as part of her seizure disorder. Thus, Rachel had numerous seizures, all part of one seizure disorder with one (unknown) cause, with periods of normalcy between them.

Yet, Dr. Shafrir would not accept that Rachel's March 13, 1997 seizure was a seizure because she was normal afterward and her seizure was different than some of the other seizures. This does not make sense. If the April 26, 1997 and June 10, 1997 seizures are part of her seizure disorder, even though Rachel was clinically normal between the seizures and they differed from each other, there is no logical reason why the March 13, 1997 and April 26, 1997 seizures are not also part of her seizure disorder, even though she was clinically normal between them and they differed from each other, regardless of whether she had a transient, acute encephalopathy.

Dr. Shafrir testified there is no distinct cry in a DPT reaction, contrary to descriptions of a high-pitched cry, one that the parents have never heard before, described in the medical literature concerning pertussis vaccine that respondent submitted. Dr. Shafrir's testimony is not credible because he contradicts himself, the medical records, and the medical literature.

Dr. Shafrir testified that Rachel's 100.9° temperature on March 13, 1997 was a high fever, high enough to cause a seizure. Dr. Shafrir stated he does not know the cause of Rachel's seizure disorder, and it is not unusual not to know the cause of a seizure disorder. The undersigned finds that the video EEG of April 6-8, 1998, depicting seizures manifesting symptoms similar to those that Rachel experienced on March 13, 1997 (moaning, staring, crying, unresponsiveness) are consistent with Dr. Tornatore's description of her March 13, 1997 episode as a seizure and the beginning of her seizure disorder.

The undersigned holds that acellular DPT caused a fever in Rachel, which prompted a seizure (with symptoms of staring, grinding, lethargy) and transient acute encephalopathy (with symptoms of moaning, high-pitched and eerie crying, and unresponsiveness), leading to a seizure disorder manifested by seizures of every variation interspersed with periods of normalcy until developmental delay was noticed months later, culminating in Rachel's death due to her seizure disorder (epilepsy).

Petitioner has proven through the medical records and his medical expert a logical sequence of cause and effect that acellular DPT caused Rachel's injury and death, and is entitled to the award of \$250,000.00 under 42 U.S.C. § 300aa-15(a)(1)(B)(2).

CONCLUSION

The court awards petitioner the sum of \$250,000.00 in the form of a check payable to petitioner as administrator of the estate of Rachel Noel. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.⁷

⁷ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master