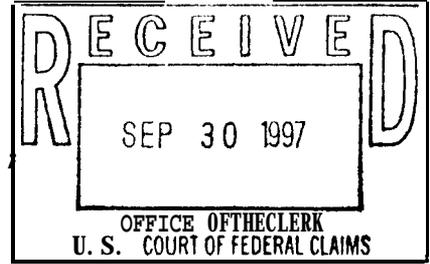


In the United States Court of Federal Claims



OFFICE OF THE SPECIAL MASTER:

(No. 94-0015V)

(Filed September 30, 1997)

* * * * *

LAUREN CROCKETT, by her parents
and guardians, MICHAEL CROCKETT
and REBECCA CROCKETT,

Petitioners,

PUBLISH

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Respondent.

* * * * *

Ronald C. Homer, Boston, Massachusetts, for petitioners.

Gabrielle Manqaniello, U.S. Department of Justice, Washington,
D.C., for respondent.

DECISION

WRIGHT, Special Master.

On January 10, 1994, petitioners filed a claim on behalf of
Lauren Crockett ("Lauren") under the National Vaccine Injury
Compensation Program (hereinafter "Vaccine Act" or the "Act").¹
Petitioners claim that as a direct result of a diphtheria-

¹ The National Vaccine Injury Compensation Program
comprises Part 2 of the National Childhood Vaccine Injury Act of
1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42
U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1997)).
References shall be to the relevant subsection of 42 U.S.C.A. §
300aa.

pertussis-tetanus ("DPT") vaccine administered on January 9, 1991, Lauren suffered a hypotonic-hyporesponsive episode ("HHE"), or shock collapse, as defined by the Vaccine Act, or, in the alternative, that Lauren suffered the significant aggravation of an off-Table underlying condition, myocarditis.

I.

PROCEDURAL BACKGROUND

On March 13, 1995, respondent filed a report in this matter recommending compensation be denied based upon a lack of medical evidence to support petitioners' claim. An evidentiary hearing was held on November 8, 1995, in Boston, Massachusetts. Petitioners presented the testimony of Dr. Thomas Connor and Lauren's parents, Michael and Rebecca Crockett. Respondent offered the testimony of Dr. Joel Brenner and Dr. Martha Lepow. Prior to the hearing, the parties filed a joint stipulation of fact ("Stip.") on November 1, 1995. A second evidentiary hearing was held telephonically on July 15, 1996. During this hearing, respondent presented the testimony of Dr. Wolfgang Mergner and Dr. Brenner. Petitioners presented further testimony from Dr. Connor. The parties subsequently filed post-hearing briefs.²

II.

FACTUAL BACKGROUND

The following evidence is contained in the record in this matter:³

² Respondent filed her initial post-hearing brief on September 30, 1996. (Hereinafter, "R. brief"). On November 4, 1996, petitioners filed their post-hearing brief. ("P. brief") Respondent filed a supplemental brief on November 21, 1996, ("R. supp. brief"), and petitioners filed a reply on December 12, 1996. ("P. reply brief").

³ The evidence in the record consists primarily of exhibits submitted as part of the petition filed in this case ("P. Ex. _____"), respondent's exhibits filed in this matter ("R. Ex. _____"), evidence taken at the evidentiary hearing in this matter ("Tr.: at _____"), as well as the joint stipulation of fact filed by the parties.

Lauren was born on July 13, 1989, with APGAR scores of nine and ten, at one and five minutes, respectively.⁴ P. Ex. 3 at 12. The pregnancy and delivery were uncomplicated. P. Ex. 3.

At two weeks of age, Lauren had a normal well-baby examination. P. Ex. 5 at 6. On September 3, 1989, Lauren was seen at the emergency room for vomiting. A diagnosis of gastroesophageal reflux was made. P. Ex. 7 at 2. On September 12, 1989, at eight weeks of age, Lauren was "doing well," and it was noted that she would receive her first DPT and OPV vaccinations that day.⁵ P. Ex. 5 at 5. Lauren was seen for fever and congestion on November 5, 1989, at the Newport Naval Hospital - Emergency Care and Clinic. P. Ex. 7 at 8. On November 14, 1989, Lauren had her four month well-baby visit, which was normal, and received her second DPT and OPV vaccinations. P. Ex. 5 at 4; P. Ex. 4 at 1; P. Ex. 7 at 7.

On January 5, 1990, Lauren received her third DPT vaccination, apparently without incident. P. Ex. 5 at 4; P. Ex. 4 at 1; P. Ex. 7 at 7. In September 1990, Lauren was diagnosed with pneumonia. P. Ex. 8 at 36-37. Other than normal childhood illnesses, such as upper respiratory infections and bouts of otitis media, Lauren was otherwise healthy and developing normally. P. Ex. 5 at 2; P. Ex. 8 at 40-43.

On January 9, 1991, Lauren was taken to Dr. Donald Hurley for her 18 month check-up. P. Ex. 5 at 1-2. The appointment was at approximately 9:00 a.m. Id. The doctor noted that she had a temperature of 99.9° F, but her physical examination was within normal limits. Id. The pediatrician noted accomplishment of only two of four growth and development criteria and recommended developmental follow-up. Id. Lauren received her DPT and OPV booster vaccinations that day. P. Ex. 4 at 1.

Mrs. Crockett testified that following the vaccination, Lauren cried and was miserable. Tr. at 31. At approximately 3:20 p.m., Lauren was brought back to the clinic with complaints of decreased

⁴ An APGAR test measures heart rate, respiration, 'muscle tone, responsiveness to stimulation, and skin color. Generally, two tests are performed at exactly one and five minutes after birth. The maximum score is ten. The Merck Manual 1858 (15th ed. 1987). The score taken at one minute is an index of asphyxia, while the five minute score is an index of the likelihood of death or neurological residua. Nelson Textbook of Pediatrics 362 (13th ed. 1983). The accuracy of the score for the prediction of long-term outcome, however, is inconsistent. R. Summitt, Comprehensive Pediatrics 370 (1990).

⁵ Lauren's vaccination card records these vaccinations as occurring on September 13, 1989. P. Ex. 4 at 1; P. Ex. 7 at 7.

appetite, coughing, and irregular breathing. P. Ex. 8 at 4. She had a temperature of 100.8° F. Id. The examining physician noted evidence of an ear infection, some respiratory grunting, and fussiness. Lauren was diagnosed with otitis media and possible febrile reaction to DPT and sent home on Amoxicillin, Benedryl, and Tylenol. Id. Mrs. Crockett testified that once home, Lauren began vomiting water, would not eat, and was having trouble breathing. Tr. at 32. According to Mrs. Crockett, Lauren "didn't want to do anything She just wasn't doing well at all." Id. Mrs. Crockett testified that Lauren's lips and areas around her face appeared to be blue. Mrs. Crockett stated, "She may have slept ten or fifteen minutes at a time, but she was just crying and blue, and not a happy child."⁶ Tr. at 32. When asked whether she recalled Lauren being limp, Mrs. Crockett replied that she did not remember a specific period of limpness. Tr. at 34. According to Mrs. Crockett, Lauren would not respond to her name and her breathing sounded as if she were grunting. Id.

The next morning, according to Mrs. Crockett, Lauren would not take any food or fluids and would throw up the little water that was given to her. Tr. at 32. Lauren's parents took her back to the clinic with a temperature of 101.4° F and complaints of an increase in her breathing rate, lethargy, and vomiting.⁷ P. Ex. 8 at 5. Lauren was referred for a pediatric consultation. Id. Lauren's parents provided a history of her illness, which included vomiting, foul smelling stools that morning, and slightly abnormal breathing without apnea or cyanosis. P. Ex. 8 at 48. Dr. Chellappa, the examining physician, noted slightly abnormal breathing, slight grunting and nasal flaring. Id. Dr. Chellappa further observed that Lauren was alert, moving her neck and noted "no bulging, no fluid. ..." Id. Dr. Chellappa reported a gallop rhythm in Lauren's heartbeat. Id. Lauren's temperature at the time was 101.3° F. P. Ex. 8 at 48. She was referred to the Medical University of South Carolina (MUSC) after being diagnosed with viral myocarditis. P. Ex. 8 at 48.

An x-ray of Lauren's heart revealed her heart size was enlarged when compared with a previous x-ray of her heart from September 24, 1990. P. Ex. 8 at 58. An electrocardiogram (ECG) was done and

⁶ Mr. Crockett recalled that throughout the night, when he was watching Lauren, she slept most of the time, and he did not recall that she cried very often. Tr. at 154. According to Mr. Crockett, while she slept, Lauren's breathing sounded constricted and labored. Tr. at 155-156.

⁷ Petitioners and respondent differed in their interpretation of the handwritten notes on this medical record. Petitioners aver that the note states, "pale, crying, limp." Tr. at 57. However, respondent asserts that the note should be interpreted as stating, "pale, grunting resp." Tr. at 152.

interpreted as remarkable for low voltage but otherwise normal. P. Ex. 8 at 54. Lauren was referred to the pediatric cardiology department at MUSC with the questionable diagnosis of viral myocarditis and cardiomyopathy. P. Ex. 8 at 6.

Upon admission at MUSC, Lauren was pale, crying, and in mild respiratory distress and was noted to have a temperature of 101.7° F. P. Ex. 18 at 189. Her skin was warm and dry and her lips were slightly cyanotic. Id. She was fussy but alert, moving all four extremities. Id. During an admitting examination, Lauren was further noted to have good perfusion with symmetric pulses, bilaterally coarse breath sounds, and a gallop rhythm without a murmur. P. Ex. 18 at 194. The assessment upon admission was dilated cardiomyopathy by ECHO and bilateral otitis media with a history of pneumonia and otitis media. P. Ex. 18 at 190, 267. A complete workup was recommended. P. Ex. 18 at 190, 194. Over the next two days, Lauren's respiratory rate decreased. P. Ex. 18 at 182. On January 15, 1991, Lauren was increasingly fussy and was started on Augmentin for otitis media. P. Ex. 18 at 183, 201. On January 23, 1991, catheterization of the heart with myocardial biopsy was performed and was interpreted as showing evidence of myocarditis. P. Ex. 11 at 3. Lauren was started on a month-long tapering dose of Prednisone. P. Ex. 18 at 183. At that time, a consulting rheumatologist felt that Lauren's condition was secondary to viral myocarditis. P. Ex. 18 at 183.

On the second day of her hospitalization, January 12, 1991, Lauren began exhibiting right-sided weakness, aphasia, and drooling from the right side of her mouth. P. Ex. 18 at 195. A CT scan of the brain revealed an infarction (stroke) of the left middle cerebral artery, which was confirmed by MRI on January 21, 1991. P. Ex. 18 at 269-270. On January 14, 1991, Lauren was alert, smiling spontaneously and appeared to be doing better. P. Ex. 18 at 200. She was discharged on January 25, 1991, with a diagnosis of: 1) dilated cardiomyopathy secondary to myocarditis of unknown etiology, and 2) status post left middle cerebral artery infarction with residual right sided weakness. P. Ex. 18 at 184. At the time of her discharge, Lauren was receiving speech, occupational and physical therapy. P. Ex. 18 at 183, 256.

Pediatric neurology and pediatric cardiology reports from February 1991, indicate that Lauren was showing gradual improvement. P. Ex. 9 at 1-3, P. Ex. 18 at 83, 504. On February 26, 1991, Mrs. Crockett reported that Lauren could sit alone, recognized her parents, was back to speaking most of the words and phrases she knew before her stroke, and could take some steps while holding on. P. Ex. 18 at 83. In March 1991, Lauren was readmitted to MUSC for a follow-up biopsy. P. Ex. 18 at 484. The results of the biopsy showed active but resolving myocarditis. P. Ex. 18 at 486, 499-500. In June 1991, Lauren was evaluated for increased drooling, mood swings, and falling spells. P. Ex. 9 at 12. An electroencephalogram (EEG) and MRI failed to reveal an etiology for

her symptoms. P. Ex. 9 at 21. By August 1991, Lauren's mother reported marked improvement in Lauren's falling spells. Id.

By February 24, 1992, Lauren's myocardial dysfunction had resolved, and she had normal cardiac function. P. Ex. 18 at 50. In February 1993, Lauren was progressing well overall but still did not use her right arm and hand well. P. Ex. 9 at 28. She had been receiving physical and occupational therapy at school. Id. Lauren spoke clearly in sentences and said her alphabet. Id. In November 1993, Lauren was seen by a new pediatric cardiologist when the family moved to Rhode Island. She had a normal cardiac examination. P. Ex. 14 at 1. She also had a neurology evaluation. The neurologist noted that she stuttered and walked with a hemiparetic gait. P. Ex. 15 at 1. It was recommended that she continue to receive physical, occupational, and speech therapy in school for her speech delay and right sided weakness. Id.

Expert Testimony

Petitioners presented the testimony of Dr. Thomas Connor.⁸ Dr. Connor believes Lauren suffered the first stage of an HHE, or shock collapse, within 72 hours of her DPT inoculation on January 9, 1991. Tr. at 14-15, 72. Dr. Connor opined that within one to two hours after Lauren's DPT vaccination, an antibody antigen reaction took place in her myocardial tissue which resulted in an inflammatory response. Tr. at 14, 15, 36, 65. According to Dr. Connor, this response causes a disruption of the delivery of blood and oxygen to the cell, creating a dysfunction of that cell and leading to a shock process. Tr. at 14-15.

Dr. Connor believes that Lauren's previous DPT vaccinations sensitized her, setting up her immune system for an antibody antigen reaction. Tr. at 14. Dr. Connor opined that on January 10, 1991, Lauren was in the early to mid-portion phase of shock based upon Lauren's increased heart rate, coughing, irritability, and labored breathing following the DPT inoculation. Tr. at 16-17, 61-63. Also significant to Dr. Connor was that Lauren was limp, lethargic, and pale.⁹ Tr. at 17. It is Dr. Connor's belief that

⁸ Dr. Connor is board certified in pediatrics and cardiology and is the director of pediatric cardiology at St. Joseph's Hospital and Medical Center. P. Ex. 31.

⁹ Dr. Connor also addressed the list of symptoms for HHE described in the Act's Aids to Interpretation. He testified that Lauren had decrease or loss of muscle tone, loss of color, turning pale and blue, lethargy, which denoted that she was unresponsive, and irritability. Tr. at 29, 35, 57. Dr. Connor stated that Lauren did not experience hemiparesis, depression or loss of consciousness, or cardiovascular or respiratory arrest. Tr. at 30-
(continued...)

Lauren's shock process began simultaneously with her cardiac involvement. Tr. at 24-25. Dr. Connor opined that Lauren was in cardiac failure, the beginning of cardiogenic shock. Tr. at 253. Dr. Connor further believes that if Lauren had not received medical attention, she would have exhibited additional shock symptoms, which may have culminated in cardiovascular and respiratory arrest. Tr. at 76, 239-40.

In the alternative, Dr. Connor opined that Lauren's DPT vaccination significantly aggravated her underlying viral myocarditis, causing fever and an increased cardiac output.¹⁰ Tr. at 71, 75, 228. Dr. Connor believes that Lauren's pre-existing myocarditis began around October or November 1990, but went undetected by her doctors. Tr. at 225. At her January 9, 1991, doctor visit, Lauren was described as a well child with no evidence of heart murmurs, lung problems, or otitis media. Tr. at 225-26. Following her DPT vaccination, Lauren then began to have a febrile illness and vomiting. Tr. at 238. By the next day, Lauren had an enlarged heart and was hospitalized for congestive heart failure. Tr. at 239. "Approximately 72 hours later, a clot from the left side of the heart entered into the circulatory system injuring the child's nervous system, causing a cerebral infarction." Tr. at 239.

Dr. Connor explained that the DPT vaccination triggered Lauren's fever which unmasked her underlying myocarditis. It is Dr. Connor's belief that fever alone can be a stressor that would turn a subclinical myocarditis into a more fulminant myocarditis.¹¹ Tr. at 72, 254. Dr. Connor opined that the mechanism for exacerbation is the increased oxygen demand on the injured myocardial cells in the ventricles, causing those cells to function at less than full capacity. Tr. at 254.

⁹(...continued)

31.

¹⁰ Initially, petitioners' expert was not aware of biopsies of Lauren's heart showing that she had an underlying myocarditis. During the first evidentiary hearing in this case, evidence was adduced revealing cell death and scarring on Lauren's heart biopsies. These findings were significant because they indicated a more chronic, rather than acute, process. Subsequently, Dr. Connor opined that Lauren's myocarditis was significantly aggravated by the DPT vaccination and a second evidentiary hearing was held on that issue.

¹¹ According to Dr. Connor, the fever which can trigger a myocarditis may vary from child to child, but a temperature of 102° to 105° F could be a stressor. Tr. at 255. Dr. Brenner, respondent's expert, agreed that a fever can unmask an underlying myocarditis. Tr. at 109.

As support for his opinion, Dr. Connor relied chiefly upon a case study describing a three-month-old infant who was admitted to the hospital 24 hours after receiving his second DPT vaccination with complaints of severe respiratory distress and cyanosis. Amsel, et al., Myocarditis After Triple Immunisation, 61 Archives of Disease in Childhood (1986); P. Ex. 25. In that report, the child was diagnosed with myocarditis which was believed to be a reaction to the vaccine. Although the authors of the article noted that myocardial damage after a DPT vaccination is rare, they concluded that the myocardial reaction of the child in that instance was associated with the vaccine. The authors also noted that although there was a possibility that a viral infection was the cause of the myocarditis, the child did not present with any viral symptoms and all the viral serology and cultures were negative, **making the possibility unlikely in their view.**

Dr. Connor asserted that, similarly, Lauren did not have a viral illness at the time of her DPT vaccination since she was not experiencing an upper respiratory infection.¹² Tr. at 229. Lauren received her DPT vaccination and six hours later was brought into the clinic and noted to have some injection in her ear. Tr. at 226. According to Dr. Connor, although the doctors saw redness of the tympanic membrane shortly following Lauren's immunization, these symptoms did not evolve into acute otitis media. Tr. at 231, 243. Dr. Connor opined that when Lauren presented at the hospital on January 10, 1991, she was experiencing congestive heart failure.¹³ Tr. at 232, 256.

¹² Dr. Connor testified that upper respiratory infections are associated with otitis media in approximately seventy-five to eighty five percent of all cases. Tr. at 229-230. Dr. Brenner agreed that approximately 90 percent of those children who present with otitis media also have an associated upper respiratory infection. Tr. at 198.

¹³ Dr. Connor testified,

The symptoms of congestive heart failure tend to be an increase in the heart rate, an increase in the respiratory rate, the patient has the heart fail, begins to lose fluid into the interstitial spaces in the lungs, which can cause ... difficulty breathing or grunting type of respirations. The activity level can go down, and basically the children can become more irritable, and they will have decreased feeding.

Tr. at 256. Dr. Connor testified that viral illnesses involving the upper respiratory tract and ears, such as otitis media, generally do not cause grunting respirations. Tr. at 236. Dr. Connor also noted that Lauren did not experience vomiting with any
(continued...)

Dr. Wolfgang Mersner

Respondent presented the testimony of Dr. Wolfgang Mergner, an anatomical pathologist. Tr. at 175; R. Ex. D. Dr. Mergner examined the microscopic slides from Lauren's biopsies on January 23, 1991, and March 14, 1991. Tr. at 176. From the first biopsy, Biopsy A performed on January 23, 1991, Dr. Mergner found evidence of myocarditis. Tr. at 177. Specifically, Dr. Mergner testified that he found inflammatory cells which infiltrate and stain the cells as well as evidence of some necrosis (cell death). Tr. at 177. According to Dr. Mergner, the second biopsy, Biopsy B conducted on March 14, 1991, only showed evidence of probable myocarditis due to the fact that the necrosis was not as clear. Tr. at 177-178. In both biopsies, Dr. Mergner found the presence of fibrosis (scarring). Tr. at 179. Dr. Mergner testified that the presence of fibrosis in combination with the acute cell necrosis is evidence of a chronic process that had been going on for some time.¹⁴ Tr. at 180, 189-190.

Dr. Mergner also testified that if Lauren had experienced shock then he would have seen evidence of a significant ischemic injury on the biopsies, which he did not. Tr. at 181.

Dr. Joel Brenner

Respondent also presented the testimony of Dr. Joel Brenner, a pediatric cardiologist.¹⁵ Dr. Brenner believes that Lauren had an underlying chronic myocarditis and then a viral illness which triggered the underlying condition, making it fulminant. Tr. at 86, 88, 213. Dr. Brenner studied the biopsy material from Lauren's heart taken in January and March 1991. Tr. at 90. He found evidence of cell death and fibrosis, indicating a chronic condition. Tr. at 91-92, 94, 95, 99. Although he could not pinpoint the exact time of onset of the myocarditis, Dr. Brenner testified that it could take several weeks for fibrosis to begin to form. Tr. at 99. He opined the onset of her myocarditis was probably in November or December 1990. Tr. at 192, 207-208. Dr.

¹³ (...continued)
of her prior episodes of otitis media. Tr. at 233.

¹⁴ Although Dr. Mergner could not offer an opinion as to exactly how long the myocarditis had been present, he testified one would expect to see fibrosis in a matter of weeks after an acute myocarditis. Tr. at 183. He testified that, although the fibrosis he saw in Lauren's biopsies was "small," it looked mature, indicating a more chronic process. Tr. at 190.

¹⁵ Dr. Brenner is the Director of Pediatric Cardiology at the University of Maryland Medical Systems. R. Ex. B.

Brenner did not believe that Lauren's illness on January 9, 1991, played any role in her underlying myocarditis. Tr. at 212-213.

Dr. Brenner further does not believe that Lauren suffered shock collapse following her DPT vaccination. Tr. at 79. He bases his opinion on the lack of evidence that Lauren had decrease or loss of muscle 'tone, paralysis, depression or loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest. Tr. at 79-80. Although Dr. Brenner noted that the medical records described Lauren as pale, he attributed this to her being anemic. Tr. at 80, 81-82, 83. Dr. Brenner also noted that Lauren was described with altered color, which could also be an explanation for her paleness.¹⁶ Tr. at 83-84.

Dr. Brenner testified that Lauren's symptoms were consistent with a viral illness. Tr. at 86. He bases his opinion on the fact that Lauren had fever, an ear infection, vomiting, diarrhea, and foul smelling stools.¹⁷ Tr. at 86-87, 113. Dr. Brenner noted that Lauren had a combination of two simultaneous problems: her underlying myocarditis and her fever. Tr. at 115. According to Dr. Brenner, Lauren's fever made her myocarditis become manifest. Tr. at 115-116. Dr. Brenner testified that there is no medical literature to support Dr. Connor's theory regarding an antibody antigen reaction. Tr. at 103, 258. Dr. Brenner further opined that there was no association between the DPT vaccination and Lauren's myocarditis and there is no literature to support such a connection.¹⁸ Tr. at 103.

¹⁶ Dr. Brenner addressed Mrs. Crockett's testimony that Lauren was blue around her lips. Dr. Brenner attributed this to two possibilities: a blueness around the lips could be the result of the blood circulating the lips having a lower oxygen level, or there may have been some compromise in cardiac output. Tr. at 80. Dr. Brenner used the example of jumping into a tub of ice 'water, which would cause the blood vessels in our skin to constrict very tightly, while the skin remained viable by extracting more oxygen, thus giving the appearance of turning blue, but not necessarily paleness. Tr. at 81.

¹⁷ Dr. Brenner also found significant that Lauren's hemoglobin was 9.6 and her hematocrit was normal, which would suggest Lauren had some illness, especially in light of her dehydration. Tr. at 118.

¹⁸ Addressing the Amsel article, Dr. Brenner stated that an isolated case report does not show causality. Tr. at 106-108, 259.

Dr. Martha Lepow

Finally, respondent presented the testimony of Dr. Martha Lepow, a pediatrician with expertise in infectious disease.¹⁹ Tr. at 123. It is Dr. Lepow's opinion that Lauren did not suffer from a shock collapse as defined in the Table. Tr. at 125. Dr. Lepow testified that Lauren did not have decrease or loss of muscle tone, nor did she have paralysis, hemiplegia or hemiparesis. Tr. at 125. Furthermore, Dr. Lepow noted that Lauren was described as having pallor and slightly blue lips,²⁰ but she was not unresponsive to her environment, nor did she have a loss of consciousness or prolonged sleeping. Tr. at 126. Dr. Lepow also noted that Lauren did not experience cardiovascular arrest. Tr. at 126.

Dr. Lepow found no scientific basis for Dr. Connor's opinion that the DPT inoculation created an antibody antigen reaction which caused an inflammatory response leading to myocarditis. Tr. at 128. Dr. Lepow testified that there is no known causal relationship between pertussis vaccine and myocarditis. Tr. at 135. Dr. Lepow further stated that she knew of no medical literature which would support the idea that a DPT vaccination could significantly aggravate an underlying myocarditis.²¹ Tr. at 133-134.

Dr. Lepow opined that Lauren had a pre-existing viral myocarditis which was precipitated by the viral illnesses she experienced in the months prior to the January 1991 event.²² Tr.

¹⁹ Dr. Lepow is the director of the Department of Pediatrics at Albany Medical College, was a member of the Red Book Committee from 1985-1991, and was on the Institute of Medicine Committee. Tr. at 123-124.

²⁰ Dr. Lepow attributed Lauren's blue lips and pallor to her vomiting, dehydration and circulation at the time. Tr. at 126. Dr. Lepow also noted that she was having respiratory difficulty, cardiac in origin, which may have attributed to these symptoms. Id. Dr. Lepow further testified, "I too was struck with the hemoglobin and [hematocrit] on admission to the hospital, where she had not had any fluid for over 24 hours probably, any significant amount of fluid, and there was significant anemia at that time." Tr. at 127.

²¹ Dr. Lepow found the articles relied upon by Dr. Connor do not support a finding of causality. Tr. at 135-137. Dr. Lepow also noted the list of known and presumed etiologies of myocarditis does not include the pertussis vaccine. Tr. at 132.

²² In September 1990, Lauren was diagnosed with pneumonia. In October 1990, she developed otitis media. She was again seen
(continued...)

at 133. Dr. Lepow believes Lauren's acute viral illness in January 1991, manifested by her ear infection, fever, vomiting, and foul smelling stools, unmasked her myocarditis. Tr. at 133. Dr. Lepow testified that vomiting and foul smelling stools are consistent with an acute viral infection, but are not typical symptoms of a DPT vaccine reaction.²³ Tr. at 133, 140.

V.

DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the ACT.²⁴ The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition.²⁵ The presumption may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine.²⁶

²²(...continued)
and treated for otitis media on December 4, 9, and 17, 1990. P. Ex. 8 at 2-3, 36-37, 43-45.

²³ Dr. Lepow did not find it unusual that the doctors were unable to locate a virus in Lauren. Tr. at 137-138. Dr. Lepow testified that one is only able to document approximately twenty percent of all viruses. Tr. at 138.

²⁴ Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring) quoting F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (Cl. Ct. 1984).

²⁵ Section 14(a).

²⁶ Section 13(a)(1)(B). Other prerequisites to compensation include: 1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine. Section 11(c)(1)(D)(i); 2) that the petitioners incurred in excess of \$1000 in unreimbursable vaccine-related expenses. Section 11(c)(1)(D)(i); 3) that the vaccine was
(continued...)

Petitioners claim that Lauren suffered a Table shock collapse (HHE) or in the alternative, that Lauren suffered an off-Table significant aggravation of her underlying myocarditis. The Table lists HHE as a compensable injury which creates a rebuttable presumption of causation if the onset of the HHE occurs within 72 hours of the administration of the vaccine in question.²⁷ The Vaccine Act also allows for compensation when the petitioner successfully proves significant aggravation of injuries which are not listed on the Vaccine Injury Table (off-Table cases).²⁸ In this case, because myocarditis is not an injury listed on the Vaccine Injury Table, petitioners must pursue their significant aggravation claim as an off-Table injury, which means that they must prove that the DPT vaccination actually caused the significant aggravation of her underlying myocarditis.

Hypotonic-hyporesponsive collapse ("HHE")

As noted, the Vaccine Injury Table lists HHE as a compensable injury if its onset occurs within three days of the administration of a DPT vaccination. Section 14(a) (I) (C). The Act's Aids to Interpretation describe HHE as follows:

A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete[]), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

Section 14(b) (1).

Dr. Connor opined that Lauren had entered the "first phase" of shock, and, without medical intervention, she would have progressed further. His opinion, however, is based upon factors which are not confirmed in the medical records or by Mrs. Crockett's testimony. For example, Dr. Connor opined that Lauren was lethargic. Mrs. Crockett, however, testified that after her DPT vaccination, 'Lauren

²⁶(...continued)
administered in the United States. Section 11(c)(1) (B) (i) (I); 4) that the petitioners did not previously collect a judgment or a settlement in a prior civil action. Section 11(c)(1) (E); and 5) that the action be brought by the injured person's legal representative. Section 11(b) (1) (A).

²⁷ Section 14(a) (I) (C).

²⁸ Section 11(c) (1) (C) (ii).

was crying and fussy. Mrs. Crockett also stated that she could not recall that Lauren was limp at any time. Dr. Connor opined that Lauren was unresponsive to her environment. However, the only evidence of this is Mrs. Crockett's testimony that Lauren would not respond to her name, but would just cry. This description of Lauren does not show that she was unresponsive to her environment, rather that she was crying and fussy.

Furthermore, the medical records at the time of the event do not suggest that Lauren was experiencing a shock collapse. When Lauren was admitted to the hospital on January 10, 1991, she was found to be fussy but alert, moving all four extremities, with good perfusion. She was found to be in mild respiratory arrest, was pale and crying. This description does not comport with Dr. Connor's opinion that Lauren was limp and lethargic.

A shock collapse is a very dramatic event. Proof that Lauren may have suffered some of the symptoms commonly experienced by those who suffer from an HHE does not mean that Lauren experienced an HHE. Particular medical symptoms, such as those listed in the Aids to Interpretation for an HHE, can indicate a variety of medical conditions. Based on the record as a whole, I cannot find that Lauren's symptoms more likely than not constituted a shock collapse. Lauren did not present signs of loss of muscle tone, hemiparesis, depression or loss of consciousness, excessive sleepiness, or cardiovascular or respiratory arrest, nor was there evidence that Lauren was difficult to arouse. Lauren's symptoms simply do not indicate that she was experiencing an HHE by a preponderance of the evidence.

The experts agree that Lauren had an underlying myocarditis. There is also little disagreement that Lauren's infarct was caused by her cardiac function problems. Therefore, the question remains whether Lauren's myocarditis was significantly aggravated by her DPT vaccine.

Off-Table Significant Aggravation

The term "significant aggravation" is defined in the Act as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by a substantial deterioration of health." There is little doubt that Lauren's course within the three days following her DPT immunization fits this description. That does not end the inquiry, however. In order to be entitled to compensation in an off-Table case, petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not

caused the injury alleged.³⁰ Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit in Grant summarized the legal criteria required to prove actual causation under the Vaccine Act. The court held that a petitioner must

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires 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, 956 F.2d at 1148 (citations omitted); see also Strother, 21 Cl. Ct. at 370.

Petitioners do not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. Rather, petitioners must explain how and why the injury occurred. Strother, 21 Cl. Ct. at 370; see also Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1993), cert. denied, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it). If petitioners view the temporal relationship as "key," the claim must fail. Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400, 403 (1991). Nor may petitioners meet their burden by eliminating other potential causes of the injury. Grant, 956 F.2d at 1149.

"[E]vidence in the form of scientific studies or expert medical **testimony** is necessary to demonstrate causation" for petitioners seeking to prove actual causation. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), reprinted in 1986 U.S. Code Cong. and Admin. News 8344, 8356. The general acceptance of a theory within the scientific community of a scientific theory can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2797 (1993).

In an actual causation case, as opposed to a case involving a Table injury, petitioners have the burden of proving that the vaccination is more likely than any other factor to have caused the injury. Under the Act, a petitioner is entitled to compensation only when

the special master or court finds on the record as a whole --

³⁰ Sections 11(c)(1)(C)(ii)(I) and (II).

(A) that the petitioner has demonstrated by a preponderance of the evidence that matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

Section 13(a)(1). Section 11(c)(1) requires petitioners to show the items listed supra at note 26. Among them, and the ones that are relevant to this discussion, are the requirements that petitioners either prove a Table injury (subsection (C)(i)), in which case the vaccination is presumed to have caused the injury, or, alternatively, that petitioners prove that the vaccination actually caused the injury (section (C)(ii)), in which case no such presumption attaches.

Under the Table injury route, after the petitioners have demonstrated the requirements of Section 13(a)(1)(A), the burden shifts to the respondent to prove the injury was caused by a factor unrelated to the vaccination in question pursuant to section 13(a)(1)(B). Matthews v. Secretary of HHS, 18 Cl. Ct. 514, 518 (Cl. Ct. 1989); O'Connor v. Secretary of HHS, 24 Cl. Ct. 428, 429-30, n. 2 (Cl. Ct. 1991), aff'd, 975 F.2d 868. In an actual causation case, however, the inquiry is "collapsed into a single determination: On the record as a whole, has the petitioner proven, by a preponderance of the evidence, that her injury was in fact caused by the administration of a listed vaccine, rather than by some other superseding intervening cause?" Johnson v. Secretary of HHS, 33 Fed. Cl. 712, 722 (1995); aff'd, 99 F.3d 1160 (Fed. Cir. 1996). See also, Bradley v. Secretary of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993); Munn v. Secretary of HHS, 970 F.2d 863, 865 (Fed. Cir. 1992); Wagner v. Secretary of HHS, No. 90-2208V, slip op. (Fed. Cl. Spec. Mstr. Sept. 22, 1997) dec. on remand (awaiting publication).³¹ But see Wagner v. Secretary of HHS, 37 Fed. Cl. 134, 138-139 (1997).

³¹ On remand from the Court of Federal Claims, Special Master Hastings applied the "law of the case" as set forth by Judge Bruggink in Wagner v. Secretary of HHS, 37 Fed. Cl. 134 (1994). Judge Bruggink found it is respondent's burden to prove alternate causation in an off-Table case. In *dicta*, Special Master Hastings set forth his interpretation that in an actual causation case, petitioners must show that it is more likely that the vaccine, rather than any other factor, actually caused the injury. I agree with Special Master Hastings' reasoning.

As **succinctly** stated by the Federal Circuit in Johnson v. Secretary of HHS, 99 F.3d 1160 (Fed. Cir. 1996),

In table cases, vaccine causation is presumed as long as **the** condition begins to manifest itself within the time specified in the table for the vaccine in question. On the other hand, if the condition or injury is not listed on the table or does not occur within the specified time, the petitioner has the burden of proving actual causation by a preponderance of the record evidence. [Petitioner] is correct that in both cases, the Special Master must determine whether a preponderance of the evidence shows that the injury was due to factors unrelated to the vaccination. As a matter of logic, however, a preponderance of the evidence cannot show both actual causation by the vaccine and causation due to factors unrelated to the vaccine. Thus, in a **nontable** case, the single inquiry is whether the petitioner has established by a preponderance of the record evidence that his or her injury or condition was actually caused by the vaccine.

Id., citing Bradley and Munn, supra.

As Special Master Hastings eloquently set forth in **dicta** in his recent decision on remand in Wagner, supra, in an actual causation case the burden does not shift to respondent to prove a factor unrelated to the administration of a vaccine caused the injury. It is petitioners' burden, as it is in non-Program tort proceedings, to show that "the likelihood that the vaccination caused an injury is greater than the likelihood that any other factors caused the injury. In other words, the evidence that the vaccination caused the injury must be weighed **directly against** any evidence indicating that any other factor caused the injury." Wagner, slip op. at 14 (emphasis in original).

Inasmuch as myocarditis is not an injury listed in the Vaccine Table, petitioners' claim that the DPT vaccination significantly aggravated Lauren's underlying myocarditis is one of actual causation. The analysis in case-in-fact cases is two-fold: (1) **can** DPT significantly aggravate an underlying myocarditis? and (2) **did** the DPT inoculation in question in fact cause the significant aggravation of Lauren's underlying myocarditis **in this case?** See Guy v. Secretary of HHS, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995) (two-step cause-in-fact analysis used); Alberdins v. Secretary of HHS, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. March 18, 1994) (two-step cause-in-fact analysis used); Housand v. Secretary of HHS, No. 94-441V, 1996 WL 282882 at *5 (Fed. Cl. Spec. Mstr. May 13, 1996) (two-step cause-in-fact analysis used).

1) Can a DPT vaccination in-fact significantly aggravate an underlying mvocarditis?

As support for their theory, petitioners rely upon the article by Amsel, supra at 8, in which an otherwise healthy infant developed myocarditis after receiving a DPT vaccination. Petitioners also rely upon a case in which the undersigned found that the vaccinee's underlying myocarditis was in fact significantly aggravated by a DPT vaccination, resulting in his death. Leary v. Secretary of HHS, No. 90-1456V, 1994 WL 43395 (Fed. Cl. Spec. Mstr. Jan. 31, 1994). In Leary, the child, who had an undetected subclinical myocarditis at the time of vaccination, died within 72 hours of receiving the inoculation. Id. at *2. The child had been in good health prior to receiving his vaccination, experienced mild irritability the following day, then began experiencing respiratory difficulties. Examining physicians found the child to be ashen and pale, in circulatory collapse, with shallow and gasping respirations. The child went into cardiac arrest and could not be resuscitated. Id. at *2-*3. The coroner attributed the child's death to myocarditis.³² Id. at *3.

In Leary, the undersigned noted the following:

While [petitioners] are not certain of an exact mechanism by which such aggravation actually took place, it must be recognized that because of the exceedingly rare nature of this type of event, a large body of scientific knowledge has not been established regarding the administration of DPT vaccinations and any resulting cardiac damage. The Amsel article involving an infant who developed myocarditis after receiving a DPT vaccination provides evidence that at least one other child may have suffered such consequences

Leary v. Secretary of HHS, No. 90-1456V, 1994 WL 43395 at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 1994).

Respondent, on the other hand, relies on Raspberry v. Secretary of HHS, 33 Fed. Cl. 420 (1995), in which the court affirmed Special Master Hastings' denial of compensation where petitioners alleged a DPT vaccination actually caused myocarditis, reasoning that petitioner's evidence was speculative regarding whether a DPT vaccination can cause myocarditis. In Raspberry, the child was found dead less than two days after receiving a DPT vaccination. Id. at 421. The medical examiner listed myocarditis

³² It should be noted that in Leary, the child had two episodes of vomiting after the vaccination but did not have otitis media, diarrhea or foul smelling stools.

as the cause of death and viremia³³ (the presence of a virus in the blood) as the underlying cause of the myocarditis. Id. It should be noted that Raspberry can be distinguished in a significant way from the instant case in that here, as in Leary, a subclinical undiagnosed myocarditis is alleged to have been significantly aggravated, or made fulminant, by the stress of the DPT vaccination. In Raspberry, petitioner tried to prove the vaccination actually caused the child's death from myocarditis.

The undersigned noted in Leary that petitioners' theory was supported by a prominent textbook on infectious diseases. In Richard A. Friedman and Desmond F. Duff, "Myocarditis," Textbook of Pediatric Infectious Diseases, Vol. I (Ralph D. Feigin and James D. Cherry eds., 2d ed. 1987), the authors state that myocarditis is rare in children and "may go unrecognized in a large number of patients whose illness may resolve spontaneously. ..." Further, they report, "Myocarditis may also occur as a manifestation of hypersensitivity or toxic reaction to certain drugs." Id. at 399. In describing the pathophysiology of myocarditis, the authors explain:

In the normal heart, an increase in filling volume leads . . . to an increased force of contraction, ejection fraction, and cardiac output. In the presence of myocarditis, the myocardium is unable to respond in this matter and cardiac output is reduced. Systemic blood flow may, however, be maintained by utilization of the cardiac reserve, mediated by the sympathetic nervous system, leading to vasoconstriction of the skin vessels and an increase in heart rate. With progressive disease, **or any stress such as infection, anemia, or fever**, the heart may be unable to meet the oxygen demands of the tissues, and the clinical picture of congestive cardiac failure may become evident.

Id. (emphasis added).

I found in Learn, as I do here, that this learned treatise gives credence to petitioners' theory that a subclinical myocarditis in which the heart is compensating, may be exacerbated and become fulminant by the introduction of a stress such as a fever. It is well known that DPT vaccinations not infrequently cause mild reactions, including fever. Based on the evidence as a whole, I found in Leary, as I do here, that it is plausible that a DPT vaccination, by virtue of the added stress on the heart produced by fever, could in fact cause an underlying myocarditis to become fulminant, resulting in the "significant aggravation" of an underlying myocarditis.

³³ Viremia is the presence of a virus in the blood. Raspberry at 421.

2. Did the DPT vaccination significantly aggravate the myocarditis in this case?

As to the second prong of the inquiry, however, petitioners have a more difficult task. It is clear in this matter that Lauren's underlying myocarditis became fulminant in temporal association with her DPT vaccination. However, temporal association alone does not prove a causal connection. The question is made more difficult because Lauren presented after her vaccination with otitis media, fever, vomiting and foul smelling stools, as well as her cardiac symptoms. In addition, Lauren was noted to be anemic.

Dr. Connor opined that Lauren's January 9, 1991, DPT inoculation caused Lauren to experience a fever which increased her cardiac output, placing a strain on her heart. Dr. Connor emphasized that Lauren was a healthy child prior to the vaccination in question. Lauren's doctors made no mention of any problems with her heart in any previous examinations. After receiving her DPT vaccination, Lauren began experiencing a febrile illness with vomiting and foul smelling stools. The next day she presented with an enlarged heart. Dr. Connor believes all Lauren's symptoms are related to her myocarditis.

Respondent's experts, on the other hand, believe that Lauren's fever, otitis media, vomiting and foul smelling stools are evidence she had an intercurrent infection of viral origin. Indeed, Lauren's treating doctors shared the opinion that Lauren had viral myocarditis. While Dr. Connor made much of his belief that Lauren did not have an upper respiratory infection, which accompanies otitis media in the vast majority of cases, he did not dispute that otitis media can cause fever. Moreover, I am convinced by respondent's experts that the otitis media, severe vomiting, diarrhea and foul smelling stools Lauren experienced, coupled with her dehydration, also point to an illness that was viral in nature. In sum, while it is certainly true that DPT vaccinations can cause fever, I am unable to state that a preponderance of the evidence shows Lauren's fever was caused by the DPT vaccination rather than by an intercurrent viral illness. Moreover, as noted in the Feigin and Cherry text, anemia is one of the factors listed that can unmask an underlying myocarditis. Lauren was found to be anemic during her hospitalization.

Although, as noted above, I have found here that a DPT vaccination *could* significantly aggravate an underlying myocarditis, petitioners here fail to meet the second prong of an actual causation case. That is, petitioners have failed to show that the vaccination was the culprit *in this particular case*. Other factors were present in Lauren's case which make it impossible for me to find on the record as a whole, that the likelihood that the vaccine caused the significant aggravation is greater than the likelihood that any other factor caused it. After carefully

reviewing and considering all of the contemporaneous medical records and the testimony presented, I find that petitioners have not met their burden of demonstrating, by a preponderance of the evidence, that Lauren's underlying myocarditis was significantly aggravated by the DPT vaccination in question.

IV.

FINDINGS OF FACT

1. As legal representatives of Lauren, petitioners have the requisite capacity to bring this action. Section 11(b)(1)(A).

2. Petitioners have not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Lauren due to the administration of the vaccine in question. Section 11(c)(1)(E); P. Exs. 1 and 17.

3. Lauren was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(B)(i)(I); P. Ex. 5 at 2.

4. Said vaccine was administered in the United States, in Charleston, South Carolina. Section 11(c)(1)(B)(i)(I); Pet. at 2.

5. There is not a preponderance of the evidence that Lauren suffered a Table HHE, or shock collapse.

6. There is not a preponderance of the evidence that the DPT vaccination significantly aggravated Lauren's underlying myocarditis.

7. There is a not a preponderance of the evidence that petitioners expended in excess of \$1000 in unreimbursed medical expenses as a result of a vaccine-related injury.³⁴

V.

CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are not entitled to compensation in this case under the Vaccine Act.

³⁴ Since I conclude that no vaccine-related injury occurred, I cannot conclude that any expenses incurred on Lauren's behalf were vaccine-related.

In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.



Elizabeth E. Wright
Special Master