OFFICE OF SPECIAL MASTERS

95-0272V Filed: November 13, 1997)

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PATRICIA SHYFACE and JUNE SHYFACE,	*	
as the Legal Representatives of	*	
the Estate of CHEYENNE MICHAEL	*	
SHYFACE,	*	
	*	
Petitioner,	*	
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VS.	*	PUBLISHED
VS.	*	PUBLISHED
vs. SECRETARY OF THE DEPARTMENT		PUBLISHED
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SECRETARY OF THE DEPARTMENT	* *	PUBLISHED
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	* * *	PUBLISHED

Curtis R. Webb, Twin Falls, Idaho for petitioners.

Michael Milmoe, U.S. Department of Justice, Washington, D.C., for respondent.

French, Special Master.

DECISION ON REMAND

This decision is provided pursuant to the September 3, 1997 order of Judge Miller remanding this case for further findings of fact and conclusions of law. On May 30, 1997, a decision was issued in which the undersigned found that, as a result of a diphtheria-pertussis-tetanus (DPT) vaccine administered on the first day of April, 1993, Cheyenne Shyface, a two-month old Native American infant, sustained an encephalopathy and died four days later as the result of that encephalopathy.

On June 30, 1997, respondent filed a Motion for Review and Memorandum of Objections challenging the special master's decision on two grounds. First, respondent argued that the special master failed to address or apply the standards set forth in the revised Vaccine Injury Table (hereinafter Table) and regulations promulgated in relation thereto. Second, respondent objected to the special master's failure to require petitioners to demonstrate that an encephalopathy caused the infant's death, or that the vaccine in

fact, caused his death.

Judge Miller's order requires the following:

- 1) To make factual findings required by the revised Vaccine Injury Table regulations, 42 C.F.R. §100.3 (b)(2)(I)-(A); and,
- 2) To make findings based on petitioners' proof by a preponderance of the evidence with respect to causation by the Injury Table method, the actual causation method, or both.

Judge Miller allowed the undersigned discretion to make such findings based on either the record as it exists, or by receiving additional evidence. During a status conference held on October 20, 1997, counsel for petitioners and respondent indicated that they did not object to the court's preference for making such findings on the record as it presently exists. Unfortunately, in a case that represents for petitioners such tragic circumstances, my review changes the outcome.

FACTUAL BACKGROUND

Certain facts in this case are documented in the medical records, but most of the factual evidence consists of the oral testimony of the infant's grandmother, June Shyface, and his youthful mother, Patricia Shyface, members of the Sioux Indian tribe living on the Fort Peck Indian Reservation. Out of traditional respect for older persons or persons in authority, the witnesses conducted themselves with marked reticence. The grandmother was less reticent, but Cheyenne's mother was unable to respond easily to questioning. A tribal representative explained that in their culture, they would not speak at all until spoken to; nor is it likely that they would talk freely outside their immediate circle of friends. Cheyenne's mother was of few words, most often speaking in monosyllables. Most of the information was provided by the grandmother who, by tradition, is primarily responsible for raising the children of the family. The facts, as I can best determine them to be, will be summarized here.

Cheyenne Shyface was an apparently normal infant, albeit somewhat fragile. Medical notations indicate some concern about weight gain and "poor bonding," and his caregivers were advised to stop smoking. Nonetheless, Cheyenne was considered to be in reasonably stable health when he received his first shots including DPT, at approximately 8:00 a.m. on April 1, 1993. He was just seven weeks old.

Following his shots, Cheyenne was taken home where he slept the rest of the day. The testimony is confusing as to the onset of symptoms. A review of the evidence makes it most likely that the baby began to develop fever on the third day, April 3, 1993. Tr. at 37-38. He seemed quiet, was treated with Tylenol, and was described in the following terms: "He didn't look too good . . . wasn't himself . . . wouldn't smile, drank some, but not much, and just lay there." Tr. at 22, 40, 48, 53, 57. He would stare into space and did not seem to respond normally to his mother or grandmother.

On April 4, 1993, he was still not well, but seemed a little better. He was "all right" and sleeping when his grandmother left for work, and when she returned from work at about 2:00 in the afternoon, in her own words, "[he looked all right. Seemed like we'd talk to him and he would start moving a little bit." Tr. at 27. He was never described, however, as back to his normal self. By the afternoon and evening of April 4, 1993, according to the testimony, Cheyenne's eyes moved a little more and he could focus. Tr. at 41.

THE WITNESS(Grandmother): "[He wasn't that sick that night because I was the one that was holding him. . . he had a little fever. . . . " Tr. at 27.

THE COURT: "Was he back to his usual self on the 4th?"

THE WITNESS: Usual, yeah. He was -- I mean he wasn't like he was." Tr. at 42.

When the baby awoke the next morning, he began suddenly to cry and could not be consoled. The grandmother recalls: "His eyes -- just by looking at his eyes I knew there was something wrong with them." Tr. at 38. They rushed to the emergency room where the baby's fever was found to be hovering between 109 and 110 degrees Fahrenheit. He was pronounced dead at 6:38 that same morning, April 5, 1993. The immediate cause of death was reported to be high fever. Cultures grown from tests revealed the presence of a bacterial infection including a moderate growth of E-coli and, "possibly" Branhamella Catarrhalis. Autopsy findings confirmed the presence of infection, pneumonia of uncertain severity, bladder infection, and dehydration.

What caused the extraordinary high fever is the subject of debate. Petitioners' expert, a well qualified pediatric neurologist, is of the opinion that although one cannot discount the possible effect of the infection, Cheyenne was in an encephalopathic state prior to his death and that the encephalopathy and/or the febrile effect of the vaccine led to his death. Respondent's experts, equally qualified, relate death to an overwhelming fulminating infection.

STATUTORY BACKGROUND

In February 1995, the Department of Health and Human Services exercised its statutory authority to revise the Vaccine Injury Table contained in §14 of the Vaccine Act and promulgated new regulations for proving an encephalopathy. Those changes became effective on March 10, 1995. Petitioners filed their claim on April 4, 1995, just three weeks later. In effect, the March 10, 1995 amendments made proof of encephalopathy more stringent. (2)

For cases filed after March 10, 1995, petitioners must prove a Table encephalopathy by establishing that, within three days following vaccination, the injured individual demonstrated a significantly decreased level of consciousness that persisted for at least 24 hours and could not be attributed to a postictal state (seizure) or medication. A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours:

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
- (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).
- 42 C.F.R §100.3 (b)(2)(I)(A) and (D).

Petitioners must establish also that the encephalopathy was sufficiently severe to require hospitalization. 42 C.F.R. §100.3(b)(2)(I). In other words, to establish such injury by the Table-case method, petitioners must provide evidence of a more dramatic and more catastrophic event than had been previously required. Many cases decided under the old standards for a Table encephalopathy would not have withstood the current guidelines.

Respondent included a brief note in its July 3, 1995 "Rule 4" report calling attention to one portion of the new guidelines, specifically, the elimination of residual seizure disorder as a DPT Table injury.

Respondent's Report, filed July 3, 1995 at n.3. Respondent's note should have prompted me to review the revisions in their entirety. I simply failed to note the changes; the issue of a new level of proof for an encephalopathy was never raised, and no other reference to the new regulations was made by either party. My decision of May 30, 1997, that an on-Table encephalopathy had been established, therefore, was based erroneously on the law as it existed prior to the amendments. (3) For reasons set forth hereafter, the undersigned reverses its opinion and concludes that an on-Table encephalopathy consistent with recent guidelines has not been established in this case. That finding affects profoundly the analysis of the entire case.

EVIDENCE OF ENCEPHALOPATHY

I. Table Injury Method.

Upon review, and applying the same facts to the current guidelines in effect since March 30, 1995, I conclude that the evidence does not support the existence of a Table encephalopathy prior to the child's death. Nothing out of the ordinary is described during the first two days following vaccination. Cheyenne began to show symptoms of fever and lethargy on April 3, 1993, and remained ill throughout the remainder of his brief life. The severity and characterization of that illness, however, is subject to interpretation, and remains inconclusive. He seemed ill and less responsive than normal during third day, April 3, 1993, but is described as a bit better on the fourth day, April 4, 1993. When she left for work on April 4, 1992, his grandmother testified that he was sleeping and looked "okay," and was "a little better" when she returned from work that afternoon. That evening of April 4, 1993, "he wasn't that sick," but still had fever and did not play. Tr. at 27,38, 39, 41-43. Whether or not these signs represent a measure of recovery is unclear, but he was clearly "not like he was." Tr. at 42. His mother recalls that at some unspecified period he would stare, would not cuddle, smile, take his bottle, or vocalize. By process of elimination, those symptoms must have been observed on April 3, 1993 but no conclusions can be drawn as to their severity or duration. (4) Tr. at 42.

Dr. Torch, for petitioners, concluded that the symptoms described an encephalopathic condition beginning on the second day. Despite his medical expert opinion, the eyewitness descriptions of symptoms do not comport with the new guidelines for finding a Table encephalopathy. It is impossible to piece together from the testimony enough factual evidence to support a "significantly decreased level of consciousness" lasting 24 hours or symptoms with the level of severity to require hospitalization. The oral testimony describes a sick child beginning on the third day, April 3, 1993. A clear picture of an encephalopathic state, as specified in the new regulations, on any one of the second, third, or fourth days following vaccination simply does not emerge. Cheyenne died in the early morning of the fifth day.

For cases filed after March 10, 1995, the new regulations limit severely the signs that can be considered for an on-Table encephalopathy. The court's discretion in determining whether clinical symptoms demonstrate a Table encephalopathy has been significantly curtailed and makes recovery in death cases more difficult because the time between vaccination and death may be too brief to discern the signs required. Congress may or may not have intended such a result, but the imposition of stringent regulatory guidelines requires such an outcome. For these reasons, petitioners' claim of a Table injury within Table time cannot be sustained. (5)

II. Causation in Fact Method.

The next inquiry is whether petitioners' evidence is sufficient to establish the existence of an acute encephalopathy by the causation in fact method. Petitioners in vaccine cases may present an off-Table

claim utilizing the same standard of proof that obtains in traditional tort law. This method is referred to as "actual causation," or "causation in fact." The amendments and regulatory changes of March 10, 1995 do not affect actual causation cases but apply to Table cases only.

Proof of causation in fact is more burdensome than in Table cases because petitioners do not enjoy the statutory presumption available for on-Table injuries. The Federal Circuit addressed the issue of actual causation as follows: "The [Vaccine] Act relaxes proof of causation for injuries satisfying the Table in §300aa-14, but does not relax proof of causation in fact for non-Table Injuries." Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992). In Munn v. Secretary of HHS, 970 F.2d 863 (Fed. Cir. 1992), the court held similarly: "The claimant must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury." Id. at 865. Actual causation cases require the court to determine, as well, that there is not a preponderance of evidence that the injury was caused by alternative etiologies. Grant, at 1144.

Petitioners' Expert: Dr. William C. Torch, a board certified pediatric neurologist and a diplomate of the National Board of Medical Examiners, relies on the constellation of signs, beginning on the third day after vaccination, to support his opinion that Cheyenne was in an encephalopathic condition prior to death. Dr. Torch characterizes Cheyenne's symptoms as evidence of "an abrupt change in mental status suggesting a depression in higher levels of mental functioning." Dr. Torch listed the following factors he considers to be indicative of encephalopathy in Cheyenne's case: Failure to recognize his caregivers; failure to respond in his usual manner; failure of eye contact; staring off into space; inability or failure to move his head or his eyes; disinterest in his bottle; and failure to grasp, vocalize, smile, or cuddle as usual. Tr. at 68. Dr. Torch's opinion is that these symptoms persisted from the third to the 5th of April. Tr. at 69. Dr. Torch does not believe the signs of improvement on the 4th day require a conclusion that the infant was recovering from his encephalopathy: "I think as with any kind of encephalopathy there can be fluctuating changes in mental status. And a person who has an encephalopathy can change from one hour to the next and one day to the next, and there can be different degrees of responsiveness." Tr. at 104.

Numerous experts in vaccine cases have described these signs as being consistent with an encephalopathy. Dr. Torch clearly identifies them as such (Tr. at 67-69), and Dr. McDonald, testifying for respondent, admits that they <u>might</u> be signs of encephalopathy (Tr. at 171, 185, and 188-189), although he believes there is another, more likely, diagnosis.

<u>Respondent's Experts</u>: Respondent's two experts argue that Cheyenne's condition prior to death is fully consistent with a developing infection (Tr. at 187-188), a condition unrelated to an encephalopathy and unrelated as well to the vaccine by any other mechanism. Dr. John McDonald argues that the same signs of altered mental status invoked to support petitioners' claim of encephalopathy are more likely evidence of sepsis. (7) Tr. at 172. He argues that the E. coli infection Cheyenne sustained, in particular, is extremely dangerous in neonates. (8) <u>Id</u>. at 172, 173, 178.

Evidence of sepsis in this case is documented. Dr. Torch not only does not challenge its presence, but, on the contrary, acknowledges it was most likely a contributing factor to the infant's condition. In other words, Dr. Torch's position is that the infant sustained both encephalopathy and an infection, and that both factors must be considered to explain his death.

Proving an encephalopathy is more difficult than proving the presence of an infection because infection can be identified by empirical evidence. Encephalopathy, on the other hand, often leaves no footprints. Not surprisingly, the autopsy does not assist petitioners' claim, although neither does it rule out the existence of an encephalopathy. The undersigned has heard many experts testify that one is unlikely to

observe evidence of encephalopathy on autopsy, particularly when death occurs relatively quickly after the onset of symptoms. (9) Vaccine cases are replete with evidence that diagnosis of encephalopathy is defined in terms of altered brain function and is based primarily on clinical presentation -- observation of alterations in behavior and response. Dr. Lucy Rorke, board certified in anatomical pathology and neuropathology, testified that she is in agreement with that statement in this very case. Tr. at 142-143.

The undersigned is hard pressed to decide whether an encephalopathic process occurred in this case. Both Dr. Torch and Dr. McDonald, are equally qualified to testify in the field of pediatric neurology. To prevail in actual causation cases, petitioners have an affirmative burden to provide evidence sufficient to tip the scales. That level of proof is not apparent here. The following statement suggests, possibly, that Dr. Torch knew his case requires stronger evidence:

DR. TORCH: "Again, I think one would be of a stronger opinion that the DPT caused the encephalopathy if symptoms were present during the first and second day following the vaccination." Tr. at 106.

It is the court's opinion that the evidence is in equipoise. Petitioners have established that Cheyenne's clinical presentation could possibly have been due to an encephalopathy, but I cannot equate the evidence with the "more likely than not" standard.

CAUSE OF DEATH

The fact that the evidence supports neither a Table encephalopathy nor an encephalopathy in fact, is not fatal to petitioners' claim if a preponderance of the evidence establishes that Cheyenne's death was caused by the DPT vaccine by another mechanism. This section will address that claim.

Death, in and of itself, is not a compensable injury. Section 14 of the statute requires proof that death was --

[An] acute complication or sequela . . . of an illness, disability, injury, or condition referred to [on the Table] which illness, disability, injury, or condition arose within the time prescribed (10)

Section 300aa-14(a)(I)(E).

Because petitioners failed to establish a Table injury, they may not show that death was the result of a Table injury. Petitioners must prove that Cheyenne's death, was, in fact, caused by the vaccine. (11)

Dr. Torch proposes another mechanism whereby the vaccine may be implicated as a significant cause of death. (12) His theory is that fever caused by the DPT was significantly exacerbated by the developing sepsis. The DPT vaccine is known to contain pyrogenic properties, and indeed, fever is the most common reaction to the vaccine. Dr. Torch theorizes that toxins and endotoxins, known components of the pertussis vaccine, adversely affected those systems that control body temperatures and caused dehydration. Failure to feed or take liquids compounded the dehydration and elevated the fever even further. The combination of the two sources caused the fever to rage out of control rendering the child incapable of sustaining adequate cardio-vascular support. Septic shock and death resulted. Tr. at 83. But

for the vaccine, Dr. Torch reasons, sepsis alone would not have caused death.

Dr. Torch thus proposes a medical theory connecting vaccination and death by a logical sequence of cause and effect, satisfying arguably, the requirements set forth in Strother v. Secretary of HHS, for establishing causation in a death case. (13) In the underlying decision of May 30, 1997, I concluded, at that time, that the evidence was sufficient to link death to the vaccine based primarily on evidence that infection alone was insufficiently severe to cause death, on the vaccine's tendency to elevate temperatures (temperature being the putative cause of death), and, significantly, on the assumption that petitioners had established an on-Table injury. That finding, regrettably, was based on invalid law. My decision did not include an analysis of the actual causation standard for establishing that death was actually caused by the vaccine. It was enough at the time to determine that death was the result or "pathological consequence" of the prior Table injury(14) and that Cheyenne's condition was consistent with the standard set forth in Allen v. Secretary of HHS. (15) Based on the court's analysis in Allen, I concluded that the facts were sufficient to support a causal link to the vaccine by the Allen standard of an observable and relatively uninterrupted progression from vaccination through [a Table injury] to death. (16) A different analysis of death as caused by the vaccination without reference to an intervening Table injury, therefore, is now required.

My analysis is focused on whether petitioners have provided affirmative proof, but the analysis must include consideration of the record as a whole. To determine whether a preponderance exists, the evidence from all sources, is to be considered, not that from petitioners alone. Dr. Torch challenges the severity of Cheyenne's infection by arguing that no clinical signs of pneumonia (inflammation in the lungs) were observable prior to death, the autopsy revealed only modest levels of bacteria in the bladder and lungs, and the lungs were not as inflamed as in most cases of fatal pneumonia in children. Finally, Dr. Torch points to the fact that in filing an autopsy report, the pathologist, Dr. McKinley, concluded that autopsy findings were insufficient to explain the outcome.

Respondent argues that both the clinical presentation and the autopsy findings support infection as the more likely etiology. Respondent's experts argue that it is not uncommon for a bacterial pneumonia to be completely clinically silent in a 7-week-old baby. Evidence of pneumonia may not be observed or recognized prior to death if death occurs rapidly, as here. Tr. at 135. Although only moderate levels of organisms were observed on autopsy, Dr. Rorke explained that one can have a very rapidly progressive overwhelming bacterial infection which kills the individual before there is a chance to get really extensive findings in the tissues. She stated that "reaction to the presence of the organism produces this tremendous shock and temperature and the individual dies rapidly, then you don't have a chance to get the full blown changes in the organ that you might see if it had been present for three or four or five days." Tr. at 136, 137. She explained further that in this case, pneumonia was "interstitial," that is, in the lining and connective tissues of the lungs rather than in the air passages, and may be as serious as other types of pneumonia in interfering with oxygenation. Tr. at 140.

On autopsy two types of bacteria were identified in the child's organs. First, E. coli was found, which is known to be capable of causing death and is particularly deadly in infants and small children. Branhamella Catarrhalis, considered generally to be a non-pathogen, was also identified. That bacterium may be a significant organism in pathogenesis of pneumonia in infants and children. Tr. at 121.

Minimal disintegration of lymphocytes in the thymus convinced Dr. Rorke that the onset of disease was acute, probably not more than 24-48 hours which suggests the rapid intensity of a fulminating process. Observed symptoms comport with such diagnosis. The child had a fever on the evening of April fourth, but his care-givers were not alarmed by the degree of fever. By the next morning, however the child was brought to the emergency room with an extremely rapid pulse of 168 and temperature of 109 which

respondent's experts consider manifestation of a severe sepsis. Dr. Rorke adds that although the unusually high temperatures are uncommon, the specific agents present are capable of raising temperatures to those extraordinary levels. According to Dr. McDonald, the baby's rapid decline in physical status, with death occurring within an hour, or hour and a half, is consistent with an overwhelming bacterial illness septic shock syndrome. (17) All of the child's clinical features, respondent argues, are "quite consistent" with a clinical diagnosis of overall sepsis. Tr. at 122.

Dr. Torch does not retreat from his opinion that the vaccine carries the weight of blame for Cheyenne's death. However, his testimony, as a whole, supports both sources as cause:

Is there any way of telling . . . any scientific way of determining which of those two is more responsible for the high temperature. [sic] I don't believe so. I don't know how much you could attribute to each etiology. I cannot go so far [as to say] that one predominated over the other in terms of the death itself. But he [Cheyenne] would not have died without the vaccine.

Tr. at 100-101.

In reading the printed text of the transcript, one does not sense fully the level of conviction with which Dr. Torch presented his opinion that "but for" the vaccine, Cheyenne would not have died. Upon review, however, I now find that Dr. Torch's testimony is insufficiently persuasive to establish that death, in fact, was caused by the vaccine. Petitioners evidence of a vaccine-related cause stands possibly in equipoise, but no better. (18) As even Dr. Torch conceded, it is impossible to know with any degree of confidence, which source is the predominant cause of death. (19)

Respondent's evidence is equally persuasive. Without the benefit of the statutory presumption conferred by the presence of a Table injury, and because petitioners have the burden of affirmatively proving a vaccine-related cause, it is my opinion that petitioners cannot prevail on the record as it stands. (20)

I base my conclusion on my determination that petitioners have failed to carry their burden of proof.

CONCLUSION

It is this court's considered opinion on remand, based on the foregoing analysis, that petitioners are not entitled to compensation for the unfortunate death of the infant Cheyenne Shyface.

If the Judge of the reviewing court requires clarification, I will be happy to provide further explanation or information.

- 1. In my decision of May 30, 1997, I found the onset of illness to have been on the day following vaccination. However, further review and consideration of the evidence led me to find otherwise.
- 2. The amendments also removed the Table injuries "residual seizure disorder" and "shock-collapse or hypotonic-hypresponsive collapse," leaving only "anaphylaxis or anaphylactic shock" and "encephalopathy (or encephalitis)" as DPT Table injuries for which petitioners may seek compensation.
- 3. Petitioners had claimed initially both encephalopathy and residual seizure disorder, but abandoned their claim of residual seizure disorder at an early date. Petitioners' expert testified at the September 16, 1996 hearing that the baby's leg jerks, most likely, were not evidence of seizure activity.
- 4. Both witnesses claim that the child never returned to normal, but they were unable to explain satisfactorily the details or how long the symptoms persisted. Tr. at 62-63. In response to the court's questioning, Patricia Shyface would answer only "yes" and no" or "I can't remember." Tr. at 63-65. Both witnesses became confused as to the days. See for example, Tr. at 38, 65.
- 5. In spite of the confusion of dates and their natural shyness, the witnesses appeared to me to have been completely honest in their responses. I have assessed their demeanor and found no reason to question their efforts to relate events as they recall them. My decision is based on the application of legal requirements as to the significance of those events, not on any lack of credibility on the part of the petitioners.
- 6. Causation in fact in Vaccine cases under the Vaccine Act is "analogous to tort law." <u>Jay v. Secretary of HHS</u>, 998 F.2d 979 (Fed. Cir. 1993).
- 7. "Infection" and "sepsis" are used interchangeably indicating presence of pathogenic microorganisms.
- 8. Dr. McDonald testified that recent studies suggest a 40% to 50% mortality rate from E.coli infection in infants in the first year of life. Tr. at 174.
- 9. Encephalopathy differs from encephalitis in this regard. Encephalitis an infectious process and is usually identifiable by testing. Evidence of encephalopathy is not usually identifiable except by observed behavior.
- 10. "Sequela" has been interpreted to mean that the condition "resulted from" the specific injury. <u>Song v. Secretary of HHS</u>, 31 Fed. Cl. 61 (1994).
- 11. The court in Hossack v. Secretary of HHS, 32 Fed. Cl. 769 (1995) interpreted the term "sequela" to

require petitioner to prove a causal connection between the injury and the subsequent condition. Following <u>Hossack</u>, the court in <u>Greway v. Secretary of HHS</u>, concluded that the standard of proof in determining whether an event qualifies as a sequela is the same standard needed to prove causation in fact. <u>Greway</u>, No. 90-2028V, 1997 WL631871 (Fed. Cl. Spec. Mstr. Oct. 12, 1995).

- 12. Dr. Torch also proposed a mechanism whereby an encephalopathy weakened the child's systems reducing his ability to withstand the stress of infection. Although that theory is a plausible one, and was the basis for the court's prior decision of May 30, 1997, it is not now sustainable because petitioners did not prove the presence of encephalopathy.
- 13. "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." <u>Strother v. Secretary of HHS</u>, 18 Cl. Ct. 816 (1989), <u>subsequent decision</u>, 21 Cl. Ct. 365 (1990), <u>aff'd</u>, 950 F.2d 731 (Fed. Cir. 1991).
- 14. See Abbott v. Secretary of HHS, 27 Fed. Cl. 792, 794 (1993) aff'd in part, rev'd in part and remanded, 19 F.3d 39 (Unpub. Fed. Cir. 1994) (interpreting the terms "complication" and "sequela" as somatic conditions or events recognizable as the pathological sequence or result of an existing disease or disorder. . . of such disease or disorder).
- 15. In determining whether death was a sequela of another Table injury, Judge Bruggink held: "The result in any given case then must depend on whether there is an observable, and relatively uninterrupted progression from vaccination, through [the Table injury] to death." <u>Allen v. Secretary of HHS</u>, 24 Cl. Ct. 295, 296 (1991), <u>appeal dismissed</u>, (No. 92-5028 Feb. 19, 1992).
- 16. Even if Cheyenne seemed a little better on the evening of April 4, 1993, the evidence does not support recovery so as to defeat the "relatively uninterrupted" nature of his condition as it proceeded to his death. Dr. Torch testified that fluctuating changes in mental status with different degrees of responsiveness do not necessarily indicate recovery from encephalopathy. Tr. at 104. I concluded that he did not, at any time, return to a normal nor a "near" normal baseline.
- 17. Dr. McDonald identified the rise in temperature as beginning around the 72nd hour, which increases the likelihood of sepsis as its cause. DPT related fever typically begins shortly after vaccination. Tr. at 157. Fever in the range of 107 to 108 degrees Fahrenheit, in his experience, has infectious causes. Tr. at 154.
- 18. Counsel for petitioners argued that it was not necessary for petitioners to prove that the vaccine was the sole cause of death, but only that it was a significant cause of death. The evidence does not support a finding that the vaccine was a more significant cause than the underlying infection. In my opinion, the evidence cannot be so quantified.
- 19. <u>Bunting v. Secretary of HHS</u>, holds that it is not petitioner's burden to disprove every possible ground of causation suggested by respondent. <u>Bunting</u>, 931 F.2d 867, 873 (Fed. Cir. 1991) (Quoting <u>Tinnerholm v. Parke Davis & Co.</u>, 285 F. Supp. 432, 440 (S.D.N.Y. 1968), <u>aff'd</u>, 441 F.2d 48 (2d Cir. 1969)). The presence of an possible alternative cause can be considered, however, in assessing the relative weight of opposing positions. Determining the weight and credibility of the evidence is the special province of the trier of fact. <u>Inwood Laboratories</u>, <u>Inc. v. Ives Laboratories</u>, <u>Inc.</u>, 456 U.S. 844, 856 (1982).
- 20. See e.g., Gamache v. Secretary of HHS, 27 Fed. Cl. 639, 645 (1993) at 645. (In similar fashion,

Judge Andewelt held that because petitioner never established the pertinent matters by a preponderance of the evidence, the burden never shifted to respondent to establish any alternative cause of [the petitioner's injuries].).