# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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| SHERRY LERWICK, legal representative of a minor child, BRADEN C. LERWICK, | * | No. 06-847V |
| | * | Special Master Christian J. Moran |
| Petitioner, | * | |
| | * | |
| v. | * | |
| | * | Filed: September 8, 2011 |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | entitlement, DTaP, acute disseminated encephalomyelitis, (ADEM), Sandifer's syndrome |
| Respondent. | * | |
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Curtis Webb, Webb, Webb & Guerry, Twin Falls, ID, for petitioner;
Michael P. Milmoe, United States Department of Justice, Washington, DC, for respondent.

RULING FINDING ENTITLEMENT TO COMPENSATION[1]

[1] Because this published ruling contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

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 is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

Sherry Lerwick alleges that the diphtheria-tetanus-acellular pertussis (DTaP) vaccine and/or the hepatitis B vaccine caused her son, Braden, to suffer a neurological problem known as acute disseminated encephalomyelitis (ADEM). She seeks compensation in the Vaccine Program. See 42 U.S.C. § 300aa—10 et seq. (2006).

The primary dispute between the parties is Braden's neurological development before he received the vaccines. The basis of the dispute is that before vaccination, Braden's treating doctor noted that he was making unusual movements. The Secretary argues that these unusual movements were the first manifestation of a neurological disorder that evolved and became fulminant after the vaccination. In contrast, Ms. Lerwick contends that the unusual movements were actually a manifestation of a gastrointestinal condition, Sandifer's syndrome, that mimics a neurological problem. For the reasons explained in section II.B. below, the evidence preponderates in Ms. Lerwick's favor.

Once the facts about Braden's health are found, the remainder of the case is straightforward. Ms. Lerwick has established the elements to find that the DTaP vaccine caused Braden's ADEM. See section IV. below. Thus, Ms. Lerwick is entitled to compensation.

## I. Procedural History

Represented by attorney Andrew Dodd, Ms. Lerwick filed her petition in December 2006.[2] It was accompanied by two volumes of medical records. Additional medical records were filed shortly thereafter.

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[2] Ms. Lerwick's position regarding a claim based upon the Vaccine Injury Table has varied. Ms. Lerwick filed an amended petition in June 2009, alleging, for the first time, that Braden suffered an on-Table encephalopathy. However, Ms. Lerwick's second amended petition, filed in October 2009, does not assert a table claim. She again argues a Table claim in her post-hearing brief, filed May 17, 2010. See Pet'r Post-Hearing Br. at 35-37.

The Secretary reviewed those records in her report filed pursuant to Vaccine Rule 4. The Secretary's report mentioned that the handwritten records from Dr. Akins, Braden's pediatrician, for visits on August 3, 2004 and August 11, 2004 were difficult to read. The Secretary also maintained that Ms. Lerwick "has provided no credible or reliable evidence to support a cause in fact case." Resp't Rep't, filed March 12, 2007, at 7.

The Secretary also filed a report from Michael Kohrman and his curriculum vitae. Dr. Kohrman is an associate professor of pediatrics and neurology at the University of Chicago. He spends approximately 80 percent of his time on clinical duties during which he sees approximately 2,000 patients in a year. Tr. 104-07; exhibit B (curriculum vitae).

Dr. Kohrman summarized Braden's medical history. Based upon those records, Dr. Kohrman stated that "Braden began having symptoms of irritability, arching, and abnormal eye movements approximately two weeks prior to his vaccination." Exhibit A at 4. Dr. Kohrman also noted that various tests that could identify other causes of Braden's neurological problems had not been performed.

Dr. Kohrman expanded his discussion of tests that could explain the genesis of Braden's problems. See exhibit C (Dr. Kohrman's supplemental report). Ms. Lerwick had Braden tested and filed the results of those tests. Broadly speaking, they rule out other potential causes for Braden's neurological problem such as a mitochondrial disorder. Exhibits 31-32; see also Pet'r Brief at 29, quoting Stipulation of Fact ¶ 29 (discussing the testing requested by Dr. Kohrman); Resp't Brief at 9 n.7 (discussing the testing requested by Dr. Kohrman).

On June 27, 2007, Ms. Lerwick filed a transcription of Dr. Akins's notes for his evaluation of Braden on August 3 and August 11, 2004. Exhibit 27. As discussed below, these records are very important to this case because they present information concerning Braden's condition on the day he was vaccinated and eight days after vaccination.

Dr. Kohrman reviewed the transcription of Dr. Akins's notes and the laboratory testing. To Dr. Kohrman, the "onset of Braden's encephalopathy [was] prior to the vaccination on 8/03/04." One basis for this opinion was that Dr. Akins observed that Braden was crying intermittently with extensor posturing. According to Dr. Kohrman, Dr. Akins wrote on August 3, 2004, that he "will consider head CT." Based upon the information in the record, Dr. Kohrman stated

that "Braden's history is consistent with a progressive encephalopathy caused by virus such as EBV [Epstein-Barr virus]." Exhibit D.

In January 2008, after some early attempts to settle this case were not successful, Ms. Lerwick stated that she would seek a report from an expert. Ms. Lerwick submitted the report of Marcel Kinsbourne in August 2008. Exhibit 35.

Dr. Kinsbourne currently teaches courses in psychology at the New School. Between 1964 and 1980, Dr. Kinsbourne had a distinguished career in the field of pediatric neurology. He has written more than 400 articles and several chapters in neurology textbooks. Tr. 37-41; exhibit 36; exhibit 53 (curriculum vitae).

Dr. Kinsbourne's report begins with a review of Braden's medical records. Next, Dr. Kinsbourne states that Braden has ADEM. Dr. Kinsbourne proposes that either the tetanus toxoid or the hepatitis B vaccine can cause ADEM. Dr. Kinsbourne also responded to Dr. Kohrman's various reports. Dr. Kinsbourne concludes that Braden's "ADEM was caused by the vaccinations that he received on August 3, 2004." Exhibit 35.

In November 2008, Ms. Lerwick requested an opportunity to serve interrogatories requesting clarification of Dr. Kohrman's opinion. Ms. Lerwick's request was discussed during a status conference and, thereafter, the Secretary was ordered to file a status report addressing one particular question. The Secretary stated that "Respondent's position is that Braden C. Lerwick has a progressive encephalopathy and the onset of Braden's neurological disorder preceded the vaccination in question." Resp't Status Rep't, filed Dec. 5, 2008, at 1.

In March 2009, Curtiss Webb became counsel of record for Ms. Lerwick because Ms. Lerwick's initial attorney, Mr. Dodd, had died. After Mr. Webb had a chance to review the records and consult with Dr. Kinsbourne, a schedule for the remainder of the case was set.

The parties filed a joint stipulation of facts on January 6, 2010. In the days leading to the hearing, Ms. Lerwick filed a pre-hearing brief. Ms. Lerwick also filed several medical articles, many of which discussed Sandifer syndrome. A hearing was held on January 29, 2010, during which Ms. Lerwick, Dr. Kinsbourne, and Dr. Kohrman testified.

After the hearing, Ms. Lerwick filed a motion for an award of attorneys' fees and costs on an interim basis. This motion led to a decision awarding attorneys' fees and costs on May 26, 2010.

In addition to the work on the attorneys' fees, the parties submitted briefs.[3] Ms. Lerwick also submitted material demonstrating that Dr. Akins had transcribed his notes for Braden's August 3, 2004 and August 11, 2004 visits. Exhibit 54.

In February 2011, the parties expressed interest in exploring a settlement. To assess the extent of Braden's injuries (hence his potential damages), the parties required updated medical records. Ms. Lerwick filed those in the spring 2011. On July 13, 2011, the parties reported that settlement discussions were not successful and requested a decision.

## II. Findings of Fact

The critical dispute between the parties focuses on Braden's condition from when he was approximately three months old to when he was approximately four months old. This period encompasses the date, August 3, 2004, when Braden received a set of vaccinations. Braden's health (or lack thereof) is a question of fact. Thus, the standards for determining facts are set forth preliminarily. Thereafter, the findings of fact regarding Braden's health are made.

### A. Standards for Finding Facts

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C.

[3] Because Ms. Lerwick's initial (March 30, 2010) brief contained typographical errors, her attorney requested an opportunity to file a corrected brief. Ms. Lerwick filed the corrected brief on May 17, 2010.

§ 300aa–11(c)(2). Medical records that are created contemporaneously with the events that they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the problems of the patient. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all of their problems to the doctor. Third, having heard about the symptoms, the doctor records what he (or she) was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter, Nicole, began to have seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. Cucuras, 993 F.3d at 1527. A judge reviewing the special master's decision stated that "In light of [the parents'] concern for Nicole's treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred." Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

Decisions by judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. E.g. Doe/70 v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598 (2010); Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec'y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder v. Sec'y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating "The special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete, however, is rebuttable. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete.

In weighing divergent pieces of evidence, contemporaneously written medical records are usually more significant than oral testimony. Cucuras, 993 F.2d at 1528. However, compelling oral testimony may be more persuasive than written records. Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

The relative strength or weakness of the testimony of a fact witness affects whether this testimony is more probative than medical records. An assessment of a fact witness's credibility usually involves consideration of the person's demeanor while testifying. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

## B. Braden's Early Medical History

### 1. History through Day of Vaccination

Braden was born on April 15, 2004, in United States Naval Hospital in Okinawa, Japan. His first day was complicated by some minor respiratory problems but these did not persist beyond the first 24 hours. Stip. ¶ 1.

Beginning when he was approximately three months old, Braden sometimes arched his back when nursing. The arching occurred only in the context of nursing, that is, when he was being held horizontally. When Ms. Lerwick placed

Braden in a vertical position, such as in a bouncy seat, Braden did not arch his back. Stip. ¶ 4; tr. 24-25.

There is no dispute that Braden arched his back. There is, however, a slight dispute about when the arching began. The finding that places the arching as starting in mid-July is supported by Dr. Akins's August 3, 2004 note and a history obtained by Dr. Volquartsen on August 21, 2004. Exhibit 4 at 94 (handwritten notes); exhibit 27 at 7-9 (transcription); exhibit 7 at 274. The mid-July onset is also supported by the parties' stipulation of facts that states that Ms. Lerwick "would testify that she first noted occasional episodes in which Braden would arch his back when she held him in mid-July." Stip. ¶ 4. Although Ms. Lerwick testified that Braden's arching began one or two days before she saw Dr. Akins on August 3, 2004, tr. 24, this testimony is not credited because it is inconsistent with the records created in August 2004. Similarly, although one record places the onset of arching at two months of age, exhibit 7 at 272, this one date lies outside the range of other dates contained in the various histories. Consequently, a mid-June onset is rejected as not in accord with the record as a whole.

Arching is the only abnormal behavior that Braden displayed before his August 3, 2004 vaccinations. Another possible unusual behavior is Braden's bicycling his arms in conjunction with arching his back. Bicycling is mentioned in one set of histories taken in San Diego. Exhibit 7 at 274 & 276. This report is not credited. Dr. Akins's August 3, 2004 notes do not report bicycling, although he mentions arching. Similarly, Dr. Akins's report from August 11, 2004, when there was more concern about Braden's well-being, does not mention bicycling. Finally, Ms. Lerwick denied observing Braden bicycling before the vaccination. Tr. 26.

If Braden had been bicycling his arms before August 3, 2004, then it is likely that Ms. Lerwick would have mentioned this to Dr. Akins and Dr. Akins would have memorialized her observations in either the August 3, 2004 or August 11, 2004 report. The absence of notation suggests that Braden, in fact, was not bicycling his arms. See Doe/70, 95 Fed. Cl. at 607; Doe/17, 84 Fed. Cl. at 711; Ryman, 65 Fed. Cl. at 41-42; Snyder, 36 Fed. Cl. at 465. Consequently, a preponderance of evidence supports the finding that Braden was only occasionally arching his back and not bicycling his arms before the August 3, 2004 vaccination.[4]

[4] The finding that Braden was not bicycling his arms does not affect Dr. Kohrman's opinion. Tr. 152.

On August 3, 2004, Braden saw Dr. Akins. Ms. Lerwick informed Dr. Akins that Braden was a very interactive baby, smiled responsively, and tracked appropriately. Stip. ¶ 3; exhibit 4 at 94 (handwritten notes); exhibit 27 at 7-9 (transcription). Ms. Lerwick's later reports of Braden's status when he was vaccinated are consistent about describing Braden as interactive, cooing, and smiling. E.g. exhibit 7 at 272. Although given years after these events, Ms. Lerwick's trial testimony is also consistent. Tr. 22-28; tr. 34-35. Ms. Lerwick also told Dr. Akins that Braden was arching his back. Stip. ¶ 5-6; exhibit 4 at 94 (handwritten notes); exhibit 27 at 7-9 (transcription).

In addition to obtaining this history, Dr. Akins performed a "comprehensive neurologic exam." (Dr. Kinsbourne and Dr. Kohrman, helpfully, explained the process by which a pediatrician assesses the neurological development of a child approximately three and one-half months old. Tr. 98; tr. 152.) Dr. Akins found "no focal deficit," "normal tone" in both lower extremities and upper extremities, "no head lag," and no fisting. Dr. Akins also found that Braden had retained his Moro/fencer reflex. Stip. ¶ 6; exhibit 4 at 94 (handwritten notes); exhibit 27 at 7-9 (transcription).

Dr. Akins's conclusion was that Braden was a "3 month old male with some likely behavioral neck extension. . . . No findings in comprehensive neurologic exam. Still this behavior is unusual and will consider head CT. . . . Will follow up 7 days." Stip. ¶ 6; exhibit 4 at 94 (handwritten notes); exhibit 27 at 7-9 (transcription).[5] Dr. Akins gave Braden a series of vaccinations, including the DTaP vaccine. Stip. ¶ 7; exhibit 4 at 95-96.

The crux of the case is the significance of the arching. Ms. Lerwick and Dr. Kinsbourne maintain that arching was a symptom of a non-neurological condition known as Sandifer's syndrome. In contrast, the Secretary and Dr. Kohrman see the arching as part of a neurological problem that worsened in the days after vaccination. A preponderance of the evidence supports a finding in accord with Ms. Lerwick's position that Braden suffered from Sandifer's syndrome. The reasons for this conclusion follow.

Arching in an infant is presumably a neurological problem, according to Dr. Kohrman. Tr. 113. Dr. Kinsbourne testified that arching can be evidence of a

[5] There was some confusion as to whether Dr. Akins wrote "will consider head CT" or "will order head CT." Further exploration showed that Dr. Akins wrote "consider."

neurological problem. Tr. 71. To Dr. Kinsbourne, arching would be associated with two types of neurological problems. The first example is a tonic seizure in which an infant stretches unpredictably at various times. The second is opisthotonus in which the infant has a very damaged brain. Tr. 65; see also Dorland's Illustrated Medical Dictionary (31st ed.) at 1351 (defining opisthotonos).

Other than an injury in the neurological system, another cause for an infant's arching of his (or her) back is Sandifer's syndrome. "Sandifer's syndrome is a combination of gastro-oesophageal reflux disease or hiatal hernia with spastic torticollis and dystonic body movements. It is hypothesized that such a positioning of the head and upper extremities provides relief from the abdominal discomfort caused by acid reflux." Exhibit 49 (N. Lehwald et al., "Sandifer Syndrome – A Multidisciplinary and Therapeutic Challenge," 17 Eur J Pediatr Surg 203 (2007)) at 203.[6] The unusual movements are often mistaken for seizures. Id. at 204; tr. 72-73. One way to distinguish Sandifer's syndrome from seizures is that in Sandifer's syndrome, the movements will usually occur during or shortly after feeding. Exhibit 49 at 204.

Because Braden's arching happened when he was nursing, his presentation is consistent with Sandifer's syndrome. This was the opinion expressed by Dr. Kinsbourne. Tr. 66-67. Importantly, one of Braden's doctors also indicated that Braden suffered from Sandifer's syndrome. Dr. Volquartsen reached this conclusion after observing Braden during an arching episode. Exhibit 6 at 158.

In opposing the diagnosis of Sandifer's syndrome, Dr. Kohrman seems to rely upon two facts. The most important reason for Dr. Kohrman to discount Sandifer's syndrome is that the August 13, 2004 CT scan revealed that Braden's brain was not normal. For Dr. Kohrman, as a matter of "logic," Braden's arching was the first sign of a neurological disorder that was visualized on the CT scan. Tr. 111-16.

A problem with Dr. Kohrman's logic is that the CT scan occurred after Braden's vaccination. According to Dr. Kinbourne's theory, the DTaP vaccination caused Braden's neurologic disorder. Thus, it is difficult to use the CT scan to

[6] The first person to report cases of Sandifer's syndrome was Dr. Kinsbourne. Exhibit 49 (Lehwald) at 203; exhibit 52 (Marcel Kinsbourne and D.M. Oxon, "Hiatus Hernia with Contortions of the Neck," 13 Lancet 1058 (1964)). Dr. Kinsbourne explained how he made this discovery. Tr. 42-45.

determine whether Braden was neurologically healthy when he received the vaccinations. See tr. 165; see also Pet'r Post Hearing Br. at 10-12 (making this argument).

Because the August 13, 2004 CT scan is not persuasive, the more probative evidence comes before Braden was vaccinated, and the best source of information on this topic is Dr. Akins. Dr. Akins's work is the second reason offered by Dr. Kohrman for finding that Braden did not suffer Sandifer's syndrome. Dr. Kohrman interprets Dr. Akins's long narrative about Braden's condition, including a note that he will consider ordering a CT scan, as indicating that Dr. Akins was concerned that Braden was already displaying symptoms of a neurological disorder. Tr. 110; tr. 129. Further, Dr. Kohrman also indicates that if Dr. Akins thought that Sandifer's syndrome was a likely cause of Braden's arching, then Dr. Akins would have prescribed some medication to treat the Sandifer's syndrome. Tr. 171.

Dr. Kohrman's interpretation of Dr. Akins's work is not persuasive. First, Dr. Akins's decision on how to treat Braden offers little clear insight into Dr. Akins's thinking. Dr. Akins requested that Ms. Lerwick return with Braden in seven days (or immediately if his symptoms worsened). Essentially, this is a "wait-and-see" approach. Dr. Akins neither immediately ordered a CT scan nor immediately prescribed a medication for reflux. It does not appear that Dr. Akins's action is necessarily more consistent with an underlying belief that Braden was showing signs of a neurological disorder or Sandifer's syndrome. See tr. 79 (Dr. Kinsbourne's discussion of Dr. Akins's treatment).

Second, Dr. Akins performed what he described as a "comprehensive neurologic exam." He noted "no findings," and specifically documented no focal deficit, no head lag, and no fisting in Braden. Dr. Akins stated that Braden's tone was normal. Braden had also achieved normal developmental milestones, such as being able to lift his head. Exhibit 4 at 94; exhibit 27 at 7-9.

As noted, except for the arching, Braden did not exhibit any signs of a neurological disorder. Although Dr. Kinsbourne acknowledged that arching may be a sign of a neurological disorder, Dr. Kinsbourne stated that he was not familiar with any neurological diseases in which the first sign is arching. Tr. 71. Dr. Kohrman did not persuasively rebut this point by, for example, explaining how a neurological problem would start with approximately 15 days of arching alone and then worsen. See tr. 148; see also Resp't Brief at 18.

Finally, Dr. Kohrman's opinion that the CT scan means that Braden cannot have been suffering from Sandifer's syndrome is undermined by the report of Dr. Volquartsen. Dr. Volquartsen examined Braden and listed both Sandifer's syndrome and a brain injury as possible diagnoses for Braden. Exhibit 6 at 158-59. His firsthand observations enhances the persuasiveness of his opinion. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Additionally, Dr. Volquartsen's signature line indicates that he had attained the rank of Lieutenant Colonel and was the commander of the maternal-child flight at Kadena airbase in Japan. This position suggests that Dr. Volquartsen had many years of experience, giving further confidence in the conclusion that Braden could have suffered from both Sandifer's syndrome and a brain disorder.

In short, a preponderance of evidence supports a finding that on August 3, 2004, Braden was suffering from Sandifer's syndrome. He was not showing signs or symptoms of a neurological problem.

### 2. History after Day of Vaccination

In the evening of August 3, 2004, Braden cried extensively. Ms. Lerwick could not console him. Stip. ¶ 8; exhibit 39 (Ms. Lerwick's affidavit, filed Dec. 1, 2009). Ms. Lerwick attempted to arrange an appointment for Braden with Dr. Akins but he was not available until August 11, 2004. When Dr. Akins saw Ms. Lerwick and Braden, Dr. Akins wrote that Braden had been "crying all the time for 7 days." Exhibit 4 at 100; exhibit 27 at 9-10.[7]

Compared to Braden's arching, the experts found Braden's inconsolable crying to be less important. Dr. Kinsbourne stated that crying does not evidence a neurological problem, although crying is consistent with a neurological problem. Tr. 59; tr. 72. His testimony is in accord with his testimony in (some) past cases. Winert v. Sec'y of Health & Human Servs., No. 90-2582, 1996 WL 622773, at *4 (Fed. Cl. Spec. Mstr. Oct. 28, 1996); Stevens v. Sec'y of Health & Human Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990). Dr. Kohrman viewed Braden's inconsolable crying as evidence that the neurological process that was first evident as arching was continuing. Tr. 129-30.

[7] Another part of this statement indicates that Braden was "Crying all the time for the last 2 weeks." This entry, if accurate, would place the onset of crying before the August 3, 2004 visit. However, extensive crying was not noted in the records from that visit.

In addition to the notations about Braden's crying, Dr. Akins reported additional information about Braden's history. Braden had not reduced his nursing. Dr. Akins also noted that Braden had "Less arching, but still arching back. . . . denies reflux crying after feeds." As part of Dr. Akins's physical examination, Dr. Akins reported "Mild increase tone both lower extremities." Stip. ¶ 12; exhibit 4 at 100; exhibit 27 at 9-10. The increase in tone, which Dr. Kinsbourne describes as spasticity, is an unmistakable sign of a neurologic problem. Tr. 60 (Dr. Kinsbourne); tr. 169 (Dr. Kohrman).

According to Ms. Lerwick, after Braden saw Dr. Akins, his feeding decreased. Exhibit 39 (affidavit); see also tr. 29-30 (Ms. Lerwick's testimony that Braden nursed less often). Ms. Lerwick places the decline in feeding as between the August 11, 2004 visit with Dr. Akins and the August 13, 2004 CT scan. Her recollection is corroborated by an August 16, 2004 discharge report, stating that Braden's dehydration began three days earlier. Stip. ¶ 19; exhibit 6 at 106. Ms. Lerwick also states that Braden stopped smiling and became non-responsive during this time. Exhibit 39 (affidavit); tr. 29 (referring to babbling, eye contact, level of interaction). The lack of smiling is similarly documented in a note from when he was hospitalized. Exhibit 6 at 153.

On August 12, 2004, Braden was evaluated in the hospital before his CT scan. The doctor describes Braden as a "4 month old male with increased irritability and paroxysmal movements." His neurologic examination showed increased hypertonicity. Stip. ¶ 15; exhibit 6 at 133.

The August 13, 2004 CT scan was "markedly abnormal, with multiple areas of hypodensity" involving several parts of the brain. This CT scan was given without contrast. The radiologist's impression was that there were a "broad" range of items to consider, including anoxic and ischemic events, infection, toxic events, and metabolic abnormalities. Stip. ¶ 16; exhibit 6 at 229-30; tr. 177-79 (Dr. Kohrman discussing lack of contrast). Braden remained in the hospital.

A second CT scan was done on August 14, 2004, approximately 36 hours after the previous CT scan. This CT scan was given with contrast. The contrast could have shown enhancing lesions but none was detected. The lack of enhancement suggested that an infection was less likely, although an infection could not be excluded because the infection could be recent. Stip. ¶ 18; exhibit exhibit 6 at 233-34.

Also on August 14, 2004, Dr. Volquartsen observed Braden arching his back. Dr. Volquartsen started medications for reflux as a precaution. On the next day, Dr. Volquartsen included Sandifer's syndrome as one diagnosis for Braden. Exhibit 6 at 158-59. Braden was discharged from the hospital at Okinawa on August 16, 2004, with the expectation that he would be flown to San Diego, California for further evaluation. Id. at 144.

On August 20, 2004, Ms. Lerwick and Braden flew from Okinawa to San Diego. Once in San Diego, Braden was admitted to the United States Naval Medical Center. He remained hospitalized until August 26, 2004. Stip. ¶ 22.

During this hospitalization, many doctors saw Braden and obtained histories about his health. The most important histories have been discussed above. Apart from these retrospective narratives, the records from San Diego recount Braden's course while in the hospital.

Braden underwent an MRI on August 21, 2004. The MRI without enhancement showed abnormalities in several parts of Braden's brain. The radiologist's impression was that the MRI was "most consistent with a postinfectious demyelinating process such as ADEM. Less likely would be a primary viral process." Stip. ¶ 29; exhibit 7 at 291-92 (capitalization changed without notation).

A pediatric neurologist, Jacqueline Kovacs, diagnosed Braden as suffering from ADEM. Dr. Kovas prescribed Solumedrol, a medication intended to suppress the body's immune response. Braden improved after receiving Solumedrol. Stip. ¶ 30-32; exhibit 7 at 280.

After discharge, Dr. Kovacs saw Braden as an outpatient. She continued Braden's ADEM diagnosis. Stip. ¶ 36; exhibit 10 at 605-05 (record from Sept. 8, 2004). Another pediatric neurologist, William J. Lewis, also diagnosed Braden as suffering from ADEM in September 2004. Stip. ¶ 37; exhibit 13 at 695-96.

In October 2004, Braden began suffering from infantile spasms. In the following months, the infantile spasms were sometimes controlled when Braden was taking anti-seizure medication, but Braden periodically had more infantile spasms. Stip. ¶ 38, 40; exhibit 10 at 587-88; exhibit 10 at 520-27. Dr. Kinsbourne and Dr. Kohrman testified that the infantile spasms were sequelae to Braden's underlying neurological problem. Tr. 88; tr. 161-62.

In June 2005, Braden began seeing Susan Koh, another pediatric neurologist, at the Mattel's Children's Hospital at the University of California Los Angeles. Dr. Koh also diagnosed Braden as having ADEM. Stip. ¶ 42; exhibit 11 at 654-55. She also stated that Braden's August 3, 2004 DTaP vaccination probably caused his ADEM. Stip. ¶ 43; exhibit 11 at 671.

On June 11, 2009, Ramon Sankar, the chief of pediatric neurology at UCLA, wrote a note describing Braden's condition. (Dr. Kohrman described Dr. Sankar as "a very well-known child neurologist." Tr. 109.) Dr. Sankar stated that Braden suffered from cerebral palsy and a seizure disorder. Exhibit 40. Dr. Kohrman emphasized that Dr. Sankar did not use the term ADEM. Tr. 108; tr. 141.

At the end of 2009, Braden was profoundly delayed in all areas. He has problems taking nourishment. He has little ability to communicate. He cannot sit up or walk. He continues to have seizures. Stip. ¶ 45.

### 3. Summary

The important findings from the preceding sections are restated. Braden's arching was a symptom of Sandifer's syndrome and not a symptom of a neurological disorder. This finding means that Braden's neurological problem was first apparent on August 11, 2004, when Dr. Akins noted that Braden had increased tone in his muscles. These findings are the predicate for determining whether the August 3, 2004 vaccinations caused Braden's neurological problem.

## III. Standards for Determining Entitlement

To receive compensation under the Program, Ms. Lerwick must prove either: (1) that Braden suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the DTaP vaccination, or (2) that he suffered an injury that was actually caused by the DTaP vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano, 440 F.3d at 1320. Here, Ms. Lerwick has successfully established a causation-in-fact claim.[8]

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish three elements. The petitioner's

[8] Thus, it is not necessary to consider Ms. Lerwick's alternative theory that Braden began suffering encephalitis within 72 hours of receiving the DTaP vaccine. See footnote 2, above.

> burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu 569 F.3d at 1379-80 (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty). In this regard, "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280.

## IV. Analysis

### A. *Althen* Prong 1

Through Dr. Kinsbourne, Ms. Lerwick presented a theory that the DTaP vaccine can cause ADEM and a theory that the hepatitis B vaccine can cause ADEM. Pet'r Brief at 18-23. It is not necessary to evaluate the latter theory (based upon the hepatitis B vaccine) because the Secretary has essentially conceded the former theory (based upon the DTaP vaccine).

When asked if the tetanus vaccine can cause ADEM, Dr. Kohrman responded "it's certainly more likely than not." Tr. 139. Additionally, in her brief, the Secretary did not address Ms. Lerwick's evidence regarding prong 1 of Althen. See Resp't Brief. Consequently, a preponderance of the evidence supports a finding that the DTaP vaccine can cause ADEM.

### B. *Althen* Prong 2

The parties' dispute whether Ms. Lerwick has presented a "logical sequence of cause and effect causally connecting" the DTaP vaccine to Braden's injury. The difference in positions is largely based upon different interpretations of Braden's pre-vaccination medical condition. Compare Pet'r Brief at 23-30 with Resp't Brief at 22-23.

As explained above, a preponderance of the evidence supports a finding that Braden was neurologically normal before his vaccinations. This finding supports Ms. Lerwick's argument and undermines much of the Secretary's argument. Additionally, Ms. Lerwick cooperated with the request from the Secretary and Dr. Kohrman that Braden be tested for other possible causes of a neurological disorder. Hence, the evidence that rules out other causes is extremely comprehensive.

Finally, there is affirmative evidence stating that the DTaP vaccine did cause Braden's neurological problem. The primary evidence is, of course, the testimony of Dr. Kinsbourne. Tr. 48-50. Dr. Kinsbourne does not stand alone. His opinion is corroborated by Dr. Koh. She wrote "Based on the timing of the MRI scans as well as the history where he was in good health prior to the DTP immunization, we can narrow the cause of his ADEM to the DTP immunization." Exhibit 11 at 671. This statement is persuasive evidence regarding Althen prong 2. See Capizzano, 440 F.3d at 1326.

For these reasons, a preponderance of the evidence supports a finding that Ms. Lerwick has met her burden regarding Althen prong 2.

### C. *Althen* Prong 3

In regard to the time that the medical community expects ADEM to follow a DTaP vaccination, the opinions of Dr. Kinsbourne and Dr. Kohrman overlap, but not entirely. Relying upon a work by the Institute of Medicine, Dr. Kohrman asserted that the medical community accepts 5-42 days as an interval between

vaccination and onset of symptoms. Tr. 124-25, citing exhibit 37G (Adverse Effects Associated With Childhood Vaccines: Evidence Bearing On Causality 46-50 (Kathleen R. Stratton et al. eds., 1994). Dr. Kinsbourne proposed a broader time, 1-60 days. Tr. 53.

The onset of Braden's ADEM, although not entirely clear, appears to be approximately eight days after vaccination. Thus, even if Dr. Kohrman's narrower period (5-42 days) were credited, Ms. Lerwick satisfies the third prong of Althen.

## V. Conclusion

Ms. Lerwick has established, by a preponderance of the evidence, that Braden was neurologically normal when he received a set of vaccines on August 3, 2004. Within approximately one week, Braden developed neurological problems that several doctors diagnosed as ADEM. Ms. Lerwick has met her burden of establishing each of the Althen prongs. Consequently, she is entitled to compensation.

A status conference will be held on **Tuesday, September 27, 2011 at 11:00 A.M., Eastern Time** to discuss the process for determining the amount of compensation to which Ms. Lerwick is entitled. The parties are encouraged to retain life care planners in advance of this status conference.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master