

OFFICE OF SPECIAL MASTERS

No. 01-61V

Filed: September 28, 2005

(Reissued for Publication December 1, 2005)<sup>1</sup>

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JAMES ENGLISH and SHARON ENGLISH, \*
as parents and natural guardians of \*
JAMES JONES ENGLISH, \*

Petitioners, \*

v. \*

SECRETARY OF HEALTH AND \*
HUMAN SERVICES, \*

Respondent. \*

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TO BE PUBLISHED

Anne C. Toale, with whom was Altom M. Maglio, Maglio Law Firm, Sarasota, Florida, for
Petitioners.

Michael P. Milmo, United States Department of Justice, Washington, D.C., for Respondent.

DECISION<sup>2</sup>

GOLKIEWICZ, Chief Special Master

<sup>1</sup>This Decision was originally entered by the court on September 28, 2005 as an unpublished
decision. This reissuance as a published decision follows in response to respondent’s written request
for publication, which the court granted on December 1, 2005. The reissuance of this decision shall
not affect the time for filing a motion for review pursuant to Vaccine Rule 23.

<sup>2</sup>Because this decision contains a reasoned explanation for the undersigned’s action in this
case, the undersigned intends to post this decision 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). As provided by Vaccine Rule 18(b), each party has 14 days within which to
request redaction “of any information furnished by that party (1) that is trade secret or commercial
or financial information and is privileged or confidential, or (2) that are medical files and similar
files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine
Rule 18(b). Otherwise, “the entire” decision will be available to the public. Id.

## **I. PROCEDURAL BACKGROUND**

On January 30, 2001, petitioners, James and Sharon English, as parents and natural guardians of their son, James Jones English (“Jake”), filed a petition pursuant to the National Vaccine Injury Compensation Program<sup>3</sup> (“the Act” or “the Program”) alleging that James suffered a seizure disorder as a result of one or more of the vaccinations he received on September 12, 1998. Petition (“Pet.”) at 2. Tragically, Jake died on November 28, 2002.<sup>4</sup> On March 31, 2004, respondent filed a Rule 4(b) Report contesting the sufficiency of the evidence and recommending that compensation be denied. Respondent’s Report (“R. Report”), filed Mar. 31, 2004.

\_\_\_\_\_ To resolve outstanding factual questions and elicit expert testimony, a hearing was held on March 11, 2005. Petitioners, James and Sharon English, and Jake’s grandmother, Van Palmer English, testified as fact witnesses. Petitioners also presented Anne E. Dickison, M.D., and Paul Richard Carney, M.D., as expert witnesses. Respondent presented John T. MacDonald, M.D., as an expert witness.

Following the hearing, the undersigned issued an order on March 17, 2005, in which observations were offered based on the hearing testimony and evidence presented to that date, without benefit of the transcript, to focus any further discussions or proceedings in the case. See Order, filed Mar. 17, 2005. The undersigned noted that the key issue in the case is whether Jake’s seizures on September 13, 1998, were caused by the vaccinations, which were administered on September 12, 1998. However, complicating this issue beyond the arguable relationships of vaccines and seizures is the fact that Jake suffered a seizure one month earlier on August 12, 1998, which respondent contended established that Jake’s seizure disorder pre-dated his immunization.

On April 21, 2005, petitioners filed Dr. Carney’s supplemental report along with peer-reviewed literature and textbook excerpts regarding the issues discussed in the March 17, 2005 order. See Notice of Filing (“P. Response”), filed Apr. 21, 2005. On April 26, 2005, respondent filed a response to the March 17, 2005 Order. See Respondent’s Response to the Chief Special Master’s Order of March 17, 2005 (“R. Response”), filed Apr. 26, 2005.

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<sup>3</sup> 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, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

<sup>4</sup>Petitioners argue that the vaccinations caused Jake’s seizure disorder, which led to sepsis and ultimately death. See Tr. 70-74. As stated by petitioners’ expert witness, Dr. Dickison, “Ultimately, his death was a sequela of his seizure disorder. But for his seizure disorder, and complications arising from treatment thereof, he would not have died.” Affidavit of Anne E. Dickison, M.D., filed Oct. 1, 2004.

In an order dated May 4, 2005, the undersigned directed respondent to file Dr. MacDonald's response to Dr. Carney's supplemental report, specifically addressing Dr. Carney's definition of status epilepticus. See Order, filed May 5, 2005. On June 6, 2005, respondent filed Exhibit I, the supplemental report of Dr. MacDonald, and Exhibits J through P, articles referenced in Dr. MacDonald's report. See Respondent's Notice of Filing Exhibits I Through P, filed June 6, 2005.

The record is now closed and the case is ripe for decision. After reviewing the entire record, and for the reasons set forth below, the court finds petitioners have failed to carry the burden of proof required under the Act, and thus are not entitled to compensation. A full discussion follows.

## II. FACTUAL BACKGROUND

The following is a condensed version of the facts as they appear in the medical records. The facts in this case are generally undisputed.

Jake English was born on February 10, 1998. On August 12, 1998, Jake took a long morning nap and around 5:30 p.m. appeared tired and vomited. Petitioners' Exhibit ("P. Ex.")12 at 635. A rectal temperature taken at 7:00 p.m. read 99.2 degrees Fahrenheit ("° F") and at 8:00 p.m. rose to 99.4° F. Id. Around 9:00 p.m., Jake began experiencing generalized, three to four minute clonic seizures and was taken to the Lee Memorial Hospital. Id. Upon arrival to the emergency room, Jake experienced a seven minute seizure. A temperature of 100.5° F was recorded upon admission and subsequently increased to 101.9° F. Id. at 633. Later that night after being admitted to the hospital, James experienced another forty second generalized clonic seizure. Id. at 635. Jake was discharged on August 13, 1998. Id. at 637. A neurology follow-up was ordered on an as needed basis should Jake develop a recurrence of seizures. Id.

On September 12, 1998, Jake visited his pediatrician, who noted Jake's previous seizures. P. Ex. 5 at 280. Jake received the DT, Hib and hepatitis B vaccinations. Id. The pertussis component was not given. Id. On September 13, 1998, Jake's mother reported that he took a nap for slightly longer than normal and refused to eat when he awoke. P. Ex. 12 at 630. She noticed that Jake looked like he was about to cry, his eyes deviated to the side, and his extremities were stiff. Id. Jake was taken to the emergency room and continued to have seizures for ten to fifteen minutes, for a total of twenty to twenty-five minutes of seizure activity. Id. His temperature upon admission was 100.6° F. Id. at 631. Jake was discharged the same day, with instructions to be monitored from home. Id. at 632.

On September 19, 1998, Jake underwent another hospitalization for seizures. P. Ex. 12 at 623. He was evaluated by many physicians over the next few years and numerous diagnostic test and treatments were performed. However, the cause of Jake's seizures was never identified. The seizures continued. On November 27, 2002, Jake was admitted to the hospital after a visit to his pediatrician's office, where Jake was found to be "obtunded, clammy, hypotensive, and with a dilated left pupil." P. Ex. Volume 1, Tab 4 at 1005. At the hospital, Jake was found to have a low

platelet count of 6,000, scattered petechiae, hydrocephalus and a valproic acid level of 172. *Id.* Jake died on November 28, 2002. The death certificate lists the immediate cause of death as septic shock and respiratory failure from pneumonia. Certificate of Death of James Jones English.

### III. 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. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.<sup>5</sup>

For presumptive causation claims, 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. 42 U.S.C. §300aa-14(a). Seizure disorder is not an injury listed on the Vaccine Injury Table and thus does not benefit from the Act's presumed causation. *Id.* Thus, petitioners must prove that the vaccines in-fact caused Jake's injury, a so-called "off-Table" case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. *See, e.g., Bunting v. Secretary of HHS*, 931 F.2d 867, 872 (Fed. Cir. 1991); *Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Grant v. Secretary of HHS*, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). *See also* §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, "[petitioners must] show a medical theory causally connecting the vaccination and the injury." *Grant*, 956 F.2d at 1148 (citations omitted); *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Hines*, 940 F.2d at 1525; *Grant*, 956 F.2d at 1148; *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Hodges v. Secretary of HHS*, 9 F.3d 958, 961 (Fed. Cir. 1993); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." *Grant*, 956 F.2d at 1148; *Jay*, 998 F.2d at 984; *Hodges*, 9 F.3d at 960.<sup>6</sup>

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<sup>5</sup>A 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 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 (1984).

<sup>6</sup>The general acceptance of a theory within the scientific community 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.*, 509 U.S. 579, 594

See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods.

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(1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication “does *not* necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” Daubert, 509 U.S. at 594. However, the Supreme Court’s only guidance to lower courts in determining the reliability of a novel proposition is that

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Gall v. Secretary of HHS, No. 91-1642V, 1999 WL 1179611, at \*8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

Recently, in Althen v. Secretary of HHS, 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioner’s burden is to produce “preponderant evidence” demonstrating: “(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 the vaccination and injury.” The Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)). Moreover, the Federal Circuit stated, “The purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” Id.

However, the Federal Circuit’s finding does not preclude the use of medical literature in evaluating expert testimony. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993), the Supreme Court stated that whether a theory or technique has been subjected to peer review and publication is a “pertinent consideration.” The Court continued, “[t]he fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.” Id. at 594. In Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000), the Federal Circuit approved of the special master’s use of Daubert as “a tool or framework for conducting the inquiry into the reliability of evidence” and affirmed the special master’s rejection of a proposed theory that did not meet Daubert standards. Thus, petitioners’ proposed causation theory must be supported by a “sound and reliable medical or scientific explanation.” Knudsen, 35 F.3d 543, 548 (Fed. Cir. 1994).

The factual issues in this case in relevant part are undisputed. The family’s testimony was

very credible and consistent with the contemporaneous medical records. In addition, Dr. Dickison testified to the agonal events at the time of death. To the extent that those issues become critical to the outcome of this case, the undersigned will rely on Dr. Dickison's testimony.<sup>7</sup> Dr. Dickison was in all respects a very persuasive witness. Thus, the decisive issue in this case is whether the vaccinations Jake received on September 12, 1998 caused him to experience seizures on September 13, 1998. A complete discussion follows.

A. **The Experts' Opinions**

1. The Experts' Reports

*Dr. Carney*<sup>8</sup>

In petitioners' expert report, Dr. Carney opines that Jake suffered from a severe seizure disorder, which ultimately led to his death. Affidavit of Paul Richard Carney, M.D. ("P. Expert Report"), filed Nov. 19, 2003, at 6. Dr. Carney states that Jake was a normal child prior to the initial seizure on September 13, 1998. *Id.* at 7. Dr. Carney avers that the initial prolonged seizure suffered on September 13 damaged Jake's brain and resulted in a neurological developmental delay. *Id.* at 6-7. Dr. Carney contends that the initial seizure was more likely than not caused by the DT and hepatitis B vaccines that Jake received on September 12, 1998. *Id.* at 7. Dr. Carney also notes that "James had a febrile seizure, accompanied by temperatures up to 101.9, on August 12, 1998. All evaluations performed at that time, including a CT and EEG, were found to be normal." *Id.* at 1 n.1.

*Dr. MacDonald*<sup>9</sup>

In respondent's expert report, Dr. MacDonald opines that the onset of Jake's seizure disorder was on August 12, 1998, one month prior to the September 12, 1998 immunizations. R. Ex. A (Expert Report of John T. MacDonald, M.D.), filed Mar. 31, 2004, at 2. Dr. MacDonald contends that "[i]t is clear from Dr. Osterman's note on August 12, 1998, that he [Jake] had a cluster of generalized seizures in August and there was no clear relationship to fever." *Id.* Dr. MacDonald observes that Jake's September 13, 1998 hospitalization was only for four hours, was not associated with severe encephalopathy, the seizures resolved with Valium, and he was not started on anticonvulsants. *Id.* Dr. MacDonald also notes that in a September 19, 1998 record, Dr. Osterman stated, "The child has normal neurological developmental history and no abnormalities on examination." *Id.* (quoting P. Ex. 12 at 625). Dr. MacDonald further points out

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<sup>7</sup>Only if it is determined that the vaccinations caused Jake's seizure disorder, does whether the vaccinations also caused Jake's death become a relevant issue.

<sup>8</sup>Dr. Carney's curriculum vitae is found at the "Curriculum Vitae of Paul Richard Carney," M.D., filed Nov. 19, 2003.

<sup>9</sup>Dr. MacDonald's curriculum vitae is found at R. Ex. B.

that developmental delays were noted later, but it was unclear if there was a progressive disease and later notes from a geneticist specifically ruled out any regression. Id. at 2-3. Moreover, although a MRI scan in 2002 suggested some atrophy, the initial scans done in 1998 were unremarkable. Id. Thus, Dr. MacDonald concludes that Jake's case does not appear to be a Table injury and the records clearly show the onset approximately one month prior to the immunizations. Id. Dr. MacDonald believes that Jake's death was due to severe infection with sepsis and not directly related to his seizure disorder. Id.

## 2. The Hearing Testimony

### *Dr. Carney*

At the March 11, 2005 hearing, Dr. Carney opined that based on a review of the medical records and various opinions, Jake was normal until September 13, 1998. Transcript ("Tr.") at 107. Dr. Carney testified that Jake did have "a series of febrile seizures one month prior, in August of that same year, but he completely returned to normal during the month prior to his DT and hepatitis vaccine." Id. As for the seizures Jake experienced in August 1998, Dr. Carney concluded that these were "simple febrile seizures in the setting of fever and which was self-limited." Id. Dr. Carney explained that on September 12, 1998, Jake visited his pediatrician and was assessed as being "completely normal." Id. at 109. Dr. Carney noted that with the DT vaccine Jake received at this visit, the pertussis component was not given. Id. Based on his interpretation of the chart, Dr. Carney opined that the rationale for not giving the pertussis was because Jake had a history of a simple, febrile seizure. Id. Dr. Carney further testified that the notes indicate that the following day, Jake became lethargic, was hard to arouse and was sleeping; he was described as "statute-like," his eyes went off to one side and he was unresponsive. Id. Dr. Carney interpreted this event as a seizure, which according to the record, lasted about 10 minutes. Id. Jake was then taken to the hospital, where he had what appeared to be a full-blown seizure, which lasted about 15 minutes. Id. at 109-10. Thus, Dr. Carney felt the total duration of the seizure was approximately 25 minutes. Id. at 110. Dr. Carney stated that the records did not indicate that Jake had a fever the day prior to the immunization, but that "he did have fever at the time of the seizure or at least he had some elevated temperature at the time of the seizure." Id. Jake returned to normal and a subsequent MRI was interpreted as normal. Id.

Dr. Carney averred that it is medically plausible that the vaccinations of September 12 caused Jake to have a seizure the following day. Tr. at 111. He opined that the lack of underlying infection, no history of trauma or brain disorder, the timing of the seizure's onset, the constellation of signs and symptoms, and the severity of the seizure all demonstrate that the vaccinations caused Jake's neurological disorder. Id. at 111-12. Specifically, Dr. Carney stated that Jake experienced "what we refer to in the epilepsy community as status epilepticus, a prolonged seizure lasting longer than 20 minutes." Id. at 112. Dr. Carney further testified that the medical community recognizes a plausible association between both the DT and hepatitis B vaccines and seizures. Id. at 112-14. Dr. Carney posited that it is plausible that a seizure such as the one experienced by Jake on September 13, 1998, could develop into a seizure disorder. Id. at 114. He explained that Jake was in "status epilepticus...it was a focal prolonged seizure," and that

immunological studies and animal model have demonstrated that status epilepticus is associated with a high risk for subsequent epilepsy. Id. Dr. Carney explicated that by epilepsy, he meant “recurrent seizures that usually persist beyond a certain time duration, say two years.” Id.

Dr. Carney contended that a temperature of 38 to 38.5 degrees Celsius (“° C”) taken rectally meets the criteria for a febrile seizure. Tr. at 115. However, when asked why he considered the August 12, 1998 event a febrile seizure, Dr. Carney answered, “[t]here’s reference to him [Jake] being warm.” Id. at 116. Dr. Carney read from the history and physical at page 640 of the medical records, which noted that “[h]e then had a six- or seven-minute seizure of the same nature and subsequent to that, a temperature of 101.5 was noted after the seizure.” Id. at 117. Dr. Carney stated that the August 12 seizure was assessed as a simple febrile seizure. Id. at 119. However, on further questioning he conceded that the records **do not** assess the seizure as such. Id. Instead, Dr. Carney based his conclusion that Jake suffered a febrile seizure on the fact that he was not started on an anticonvulsant. Id.

The undersigned questioned Dr. Carney concerning his definition of status epilepticus. Tr. at 121. In Dr. Carney’s report and during his testimony, he defined status epilepticus as lasting greater than 20 minutes. Id. However, all of the literature that Dr. Carney submitted defines status epilepticus as greater than 30 minutes. Id. Dr. Carney explained that the 30 minute figure is based on a late-1950s study. Id. However, the more practical definition, which is used by most EMS personnel, is anything more than five minutes. Id. Dr. Carney said that he actually teaches using the five minutes standard. Id.

Dr. Carney proceeded to read from the August 12, 1998 consultation of Dr. Osterman, which indicated that Jake had a rectal temperature of 99.2° F at 7:00 p.m. and 99.4° F at 8:00 p.m. Tr. at 123. The undersigned asked Dr. Carney if those temperatures met the accepted temperature for a febrile seizure. Id. Dr. Carney averred that the “elevated temperatures” indicated that James had a fever and that a temperature above 99 constitutes the textbook definition of a febrile seizure. Id. at 124. Dr. Carney was then directed to page 633 of the record, the discharge summary from August 12, 1998. Tr. at 126. Dr. Carney explained that the discharge summary indicated that Jake “had a borderline temperature to the emergency room.” Id. Further, reading from a page 632 of the record, a history and physical of the September 13, 1998 visit, Dr. Carney related that the note discussed the seizure type and “discussed that because the patient has had a second seizure which *may or may not be a febrile seizure* the patient’s risk of repeated seizures is even higher than previously discussed, but that the antiepileptic medication is not definitely indicated because [the] patient still does not have a good change of not having any more seizures.” Id. (emphasis added).

Consistent with his expert report, Dr. Carney opined that timing of the onset of the September 13, 1998 seizure, one day post-immunization, played a role in his belief that the seizure was caused by the vaccines Jake received on September 12. Tr. at 127. Dr. Carney postulated that the “duration of the seizure...in combination with the underlying cause led to brain damage, if you will, very focal or perhaps even generalized that subsequently kind of fed this ongoing seizure disorder.” Id. Also lending to Dr. Carney’s belief that the vaccines caused Jake’s

seizure was the fact that he found no alternative cause for the seizure. Id.

When asked if his opinion would change if the August 12 seizure was found to be afebrile, Dr. Carney testified that it would not. Tr. at 131-32. He reasoned that it would not make a difference because the August 12 seizure also differed from the September 13 seizure in that Jake “had a series of self-limited seizures and he completely returned to normal” following the August event. Id. at 132. Dr. Carney went on to concede that during the August 12 event, “they don’t come out and use the word ‘febrile seizure.’” Id. at 133. Moreover, Dr. Carney conceded that although the textbooks list a prolonged seizure as occurring for 30 minutes, no practitioner will allow a patient to seize for 30 minutes before treating him as a seizure lasting as long as five minutes will damage the brain. Id. at 134.

Dr. Carney seemed reluctant or unwilling to answer questions related to the article found at P. Ex. 10, and repeatedly provided answers which were contradicted by this article.<sup>10</sup> See Tr. at 134-40. Finally, however, Dr. Carney agreed with the article and stated, “If it [the August 12 seizure] was an afebrile seizure then one might conclude or might hypothesize that he [Jake] has an underlying seizure disorder.” Id. at 140. Dr. Carney testified that although the medical records regarding the August 12 seizure do not “come out and say simple febrile seizure,” based on the course of treatment, specifically that they did not treat Jake with seizure-preventing and anticonvulsant medicine, he believes the seizure was a simple febrile seizure. Id. at 141-42. On further questioning, however, it was discovered that anticonvulsants similarly were not administered after the September event. Id. at 143.

On cross-examination, Dr. Carney testified that he is board certified in pediatric neurology, epilepsy and sleep disorders and that he is a member of the Child Neurology Society.<sup>11</sup>

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<sup>10</sup>The article, N. Paul Rosman, Evaluation of the Child Who Convulses with Fever, 5 PEDIATRIC DRUGS 457, 458 (2003), states that “[s]eizures with fever in children who have experienced a previous nonfebrile seizure are excluded” from the definition of febrile seizures. P. Ex. 10 at 458. The article continues,

The definition implies that in order to make the diagnosis of a febrile seizure in a child who presents with a seizure and a fever, one must exclude, meningitis, encephalitis, serious electrolyte imbalance, and other acute neurologic illnesses, as well as prior unprovoked seizures. The diagnostic evaluation is, therefore, aimed at addressing the cause of the fever and deciding whether there are other potential causes for the seizure besides the fever per se.

Id.

<sup>11</sup>Upon investigation by respondent, it was discovered that in fact Dr. Carney is not board certified in pediatric neurology nor a member of the Child Neurology Society. See Respondent’s Response to the Chief Special Master’s Order of March 17, 2005, at 4.

To discuss this matter, a status conference before the undersigned was held with the parties

Tr. at 145-46. Dr. Carney was asked what effect whether the August and September events were afebrile or febrile had on his opinion. Id. at 147. He responded that it only matters from the standpoint of how the child was managed. Id. Dr. Carney testified that in September, Jake was febrile at the time of the seizure, as he was during the August event; however, unlike at the time of the August event, Jake was not suffering from an intercurrent illness in September. Id. at 148. Upon further questioning, however, Dr. Carney **backtracked** and stated that there was potential evidence for intercurrent illness on September 13. Id. at 149. When questioned by respondent's counsel about any difference in the temperatures between August and September, Dr. Carney testified that they were both febrile events. Id. at 150. Further, he indicated that tests performed at the August and September events both yielded normal results. Id. Accordingly, Dr. Carney admitted that the **only difference** between the two events was that Jake experienced an episode of status epilepticus during the second event, which he did not experience during the first event. Id.; But see discussion, infra, at 12-13.

Respondent's counsel asked Dr. Carney whether a child who died or experienced severe brain injury as a result of status epilepticus would be expected to manifest some type of severe brain injury in his behavior and development in the intervening days and weeks. Tr. at 151. Dr. Carney said that it is not uncommon to go into status epilepticus without having recurrent seizures for 10 to 20 years. Id. at 151-52. He stated:

It's actually quite common in adults that they give a child a history of having had a prolonged seizure and they develop epilepsy in their 20s. For example, there is something called mesiotemp[oral] sclerosis, temp[oral] with epilepsy. It's a very common risk factor history.

Id. at 152. Dr. Carney was further questioned about when he would expect the brain damage, which was discussed his report, to manifest. Id.<sup>12</sup> Dr. Carney responded that it depends on the

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on May 4, 2005. Pursuant to this status conference, respondent was directed to file Dr. MacDonald's response to Dr. Carney's supplemental report, specifically addressing Dr. Carney's definition of status epilepticus. See Order, filed May 5, 2005. Petitioner was directed to file a written statement by Dr. Carney, explaining what his credentials have been in the past and are currently, as well as why he testified as he did regarding his board certification in pediatric neurology and his membership in the Child Neurology Society. Id.

\_\_\_\_\_ On June 14, 2005, petitioners filed the letter of Dr. Carney with attachments. See Notice of Filing, filed June 14, 2005. In this letter, Dr. Carney provided his credentials and explained that he did not fully comprehend the question posed to him at hearing. Id. Dr. Carney clarified his experience and training, enclosing copies of certificates which reflect his training in the specialties of pediatrics, child neurology and epilepsy. Id. The undersigned is satisfied with his explanation.

<sup>12</sup>Specifically, Dr. Carney's report states that the records indicate that the initial seizure on September 13, 1998 was prolonged enough to cause substantial brain damage. P. Expert Report at 7.

underlying cause. Id. With a prolonged seizure secondary to a febrile seizure, Dr. Carney testified that it is “much less likely that you’re going to develop recurrent epilepsy within the first year.” Id. at 152-53. In Jake’s case, the records indicate that he was discharged within about four hours of the September event. Id. at 153. Thus, Dr. Carney was asked if he would expect a child whose brain was substantially damaged to be discharged within four hours of admission. Id. Dr. Carney responded that “It’s rather quick, but he apparently bounced back and looked fine, so I understood why they discharged him.” Id. Dr. Carney was questioned about a note dated September 19, 1998, which indicated that Jake’s neurologic developmental history was normal and there were no abnormalities on exam. Id. at 154. Specifically, respondent’s counsel asked Dr. Carney if he would expect abnormalities to appear on exam six days after the event in question. Id. Dr. Carney answered that “It depends. I mean it could go either way.” Id. Respondent’s counsel pointed out a record from October 29, 1998, six weeks after the September 13 event, which indicated that both Jake’s developmental history and exam were normal and, although subtle deficits were noted, they did not warrant therapeutic intervention. Id. at 154-55. Dr. Carney agreed that the exam results appeared normal. Id. at 155.

Respondent’s counsel clarified with Dr. Carney his theory of medical plausibility for the the DT vaccine or hepatitis B vaccinations to cause seizures. Id. at 157-58. Specifically, Dr. Carney based his theory on the fact that everything else was ruled out as the cause of the seizures, the timing of the seizures post-vaccination, and the particular constellation of symptoms. Id. In addition to these factors, Dr. Carney added another reason for his belief that the vaccines caused Jake to experience seizures:

he was really never normal following September 13 and without any obvious cause, if you will. So I really am forced to focus in on the 12th and the 13th and see if there [is] anything in the history that would explain the fact that this was a normal child who suddenly developed difficult to control seizures and loss of milestones, you know, profound objective MRI changes.

Id. at 158. The undersigned asked Dr. Carney if his opinion would change if it were determined that the September event was not a status epilepticus. Id. at 159. Dr. Carney said it would not. Id. The undersigned pointed out that this conflicts with Dr. Carney’s report, which was premised on the September 13 event being prolonged enough to cause substantial brain damage. Id. at 159-60. Dr. Carney stated that “[i]t’s really not black and white, okay? It is a prolonged seizure and I guess I wouldn’t focus in on the 30 minutes, but rather that it was prolonged.” Id. at 161. Dr. Carney continued, “Most practitioners agree that any seizure that’s lasting five minutes or longer by all practical definitions meets the criteria of a status. I understand the textbooks say 30 minutes and I understand I wrote that, as well; however, I really wanted to clarify that.” Id. at 162.

Later, Dr. Carney agreed he had testified that status epilepticus can be as short as five minutes in a particular case and that 30 minutes was not a “magic number.” Tr. at 167. He further testified that he believed the August seizures lasted less than 10 minutes, “I think it was six to seven minutes.” Id. at 167. Accordingly, respondent’s counsel questioned Dr. Carney’s

about his assertion that there is a difference between the status epilepticus suffered in the August and September events. Id. at 167-68. Dr. Carney responded that the September event was a “focal status.” Id. at 168. However, the seizures in the August event,

were briefer and there was no focality to it indicating that it was in the setting of a typical febrile seizure, if you will, whereas the one in September had again not only the duration component, but also had the appearance which was totally different indicating a more ominous presentation.

Id.

*Dr. MacDonald*

Dr. MacDonald testified that he found no way to differentiate the events of August and September 1998. Tr. at 175. He stated the following about the two events:

They’re both associated with fever. The second episode was a lot shorter, the child went home after a very short period of time. There was perhaps a clearer relationship of a fever to the seizures on the second occasion. It’s less obvious on the first admission. On both cases there were epileptic seizures and I think this child demonstrated a chronic epilepsy. These were two of the original events with the first event being in August.

Id. Dr. MacDonald also indicated that he defines status epilepticus using the 30-minute criteria. Id. at 175. Dr. MacDonald believed that the 30-minute demarcation is used for most ongoing research studies and teaching programs. Id. Based on his experience, Dr. MacDonald opined that if an episode of status epilepticus causes irreversible and permanent brain damage, he typically sees “some acute signs [of developmental sequela] in the immediate period, the days after, and then almost invariably in the first month of followup parents have severe concerns.” Id. at 176.

On cross-examination, Dr. MacDonald testified that at the time Jake received the September 12 vaccinations, he had an intercurrent illness with a brief fever associated with it. Tr. at 178. He further opined that he would categorize the August 12 seizures as nonfebrile. Id. at 184. Dr. MacDonald explained his reasoning for this and stated that, although there have been endless debates over the years, he follows the definition introduced by Dr. Shinnar, who performed many studies on febrile seizures and wrote a chapter on febrile seizures in the textbook “Neurology.” Id. at 185. This definition requires a fever of 101° F rectally upon admission to the emergency room. Id. Furthermore, the fever should exist before the seizure occurs if it is to be defined as provoking a seizure. Id. Dr. MacDonald stated that the records from Jake’s August 12 emergency room visit indicate that Jake had a temperature of 100.5° F in the emergency room, which then went up and came down. Id. at 186. Thus, Dr. MacDonald believed it did not meet the definition of a febrile seizure. Id. Petitioner’s counsel questioned Dr. MacDonald about the consensus among pediatric neurologists regarding the appropriate definition of febrile seizure. Id. Dr. MacDonald stated that there are many different opinions, and went on to explain the reasoning

behind his definition:

I'm just saying in the current large pediatric neurology textbook Dr. Shin[na]r wrote the chapter and this is what he uses. I find it convenient and scientifically it makes sense. I agree with the treating doctors here. This was not a febrile seizure in my opinion and I think it was basically the beginning of this child's long intractable seizure disorder.

Id. at 186-87. Dr. MacDonald testified that the treating doctors referred to the August 12 seizure as "an unprovoked seizure," which he interpreted as meaning the fever was not the provoking factor in this case. Id. at 187.

Dr. MacDonald opined that Jake's "seizure disorder began on August 12, there was flareup in September 12, the seizures came back a week later and then they continued to progress and that's not an uncommon scenario of my patients with these type of disorders." Tr. at 188-89. Dr. MacDonald did not see any evidence that the September 12 vaccinations caused the September 13 flare-up. Id. at 189. Dr. MacDonald testified that in looking at the August and September events, there is nothing that would cause him to choose the second event as being causally related to Jake's long-term epilepsy. Id. at 190. He continued:

If anything, if you told me the sequence it seems logical to pick the first event. I mean, there is a point in time where epilepsy starts. Why would I ignore the August event which in some ways is more dramatic than the other events. So yeah, I don't see it as standing out in any way that would want me to implicate the immunization or anything else that occurred in the 24 hours prior to that.

Id. Dr. MacDonald explained that he believed the August 12 seizures were more severe than the seizures of September 13, because the August event involved three seizures over a period of time and Jake was in the hospital for a longer period. Id. at 191. However, Dr. MacDonald indicated that he did not think there was a big difference between the two events. Id. He did not believe that Jake was in status in either episode. Id. Moreover, the fact that Jake was sent home from the hospital after four hours lead Dr. MacDonald to believe that the September 13 event was not an overwhelming episode that caused irreversible brain damage. Id.

### 3. March 17, 2005 Order

To focus the case and to address the several key issues raised at hearing, the undersigned issued an order on March 17, 2005. In this order, the undersigned explained that petitioners' expert, Dr. Carney, has an extensive background in the study of seizure disorders. However, the undersigned found Dr. Carney's testimony to be somewhat speculative, and not in the mainstream of medical thinking, based on a comparison of his testimony to the medical literature he submitted, including his own paper. Dr. Carney's essential testimony was that the vaccines administered on September 12, 1998 caused a fever in Jake, which in turn initiated a "prolonged seizure" that damaged Jake's brain. However, as pointed out by the undersigned during the

hearing, there were several problems with Dr. Carney's testimony when measured against the medical literature he submitted. The following is a discussion of these problems as delineated in the March 17 order:

First is the question of whether James suffered a febrile seizure, that is a seizure caused by a fever. While there was a slight temperature rise in James, the records record a temperature of less than 100° F prior to his first seizure. Dr. MacDonald, respondent's expert, testified that the accepted definition of a febrile seizure is 102° F rectally prior to the seizure event. Dr. Carney provided no literature to support his contention that any elevation in temperature is sufficient to cause a seizure and thus to constitute a febrile seizure.

There is another obvious problem with Dr. Carney's testimony if accepted. That is, if in fact any elevation in temperature can cause a seizure, then the seizure in August, which was also accompanied by an elevation in temperature, would constitute a febrile seizure. If both seizures were febrile seizures, this raises the obvious question of the connection between the August seizure and the September seizure. As discussed below, this connection is implicated by another aspect of Dr. Carney's testimony regarding status epilepticus.

If on the other hand, the August seizures are not febrile seizures, according to petitioner's Exhibit 10, the September seizures would be excluded by definition as febrile seizures because "[s]eizures with fever in children who have experienced a previous nonfebrile seizure are excluded." P. Ex. 10 at 458. Dr. Carney must clarify his opinion regarding the relationship of the August seizure to the September seizure -- why or why not are they related?

Dr. Carney in his testimony distinguished the August seizures as less severe in duration and also consequence. James appeared normal following the seizures. In contrast, he contends that the September seizures were "prolonged" and, as supported in the literature, status epilepticus can result in severe brain damage. Unfortunately, once again, the literature does not support Dr. Carney.

It is uncontested that James' seizures lasted 20-25 minutes. In his affidavit, Dr. Carney wrote that febrile status epilepticus is "a seizure lasting longer than 10-15 minutes." Affidavit of Paul Richard Carney M.D., filed Nov. 19, 2003. He further testified that status epilepticus is a seizure greater than 5 minutes. However, the literature, including his own article at Exhibit 1, states uniformly that status epilepticus is a seizure or a group of seizures lasting a "minimum" of 30 minutes. Dr. MacDonald agreed with the 30 minute definition. Dr. Carney's efforts to shorten the time period or to explain away the literature definition, including his own article, were not only unpersuasive but was also seriously damaging to his credibility. If Dr. Carney was willing to ignore his own published literature, it raises the concern that other parts of his testimony are geared towards "winning"

the case as opposed to educating the court. That of course is why confirmatory literature is required, to protect the decision-maker from theoretical, speculative or unsupported expert testimony.

There are two other problems with Dr. Carney's "prolonged seizure" definition. First, if in fact Dr. Carney is correct that status epilepticus is as short as 5 minutes, then once again the seizure of August 12 would be implicated as it would constitute status epilepticus. As such, the August 12 seizure could be fingered as the onset event, as Dr. MacDonald testified. Second, as respondent argued very persuasively, if Dr. Carney was correct that James suffered a brain injury after the September 13 seizure, why is there no manifestation of that injury in the following month? Dr. Carney rejoins that manifestations can be seen literally years following the acute event. If that is true, however, how does one dismiss the August seizure, that meets Dr. Carney's definition of febrile status epilepticus, as the initial damaging event? The argument that James appears normal after the seizure is of no moment since, as Dr. Carney argued in addressing respondent's argument, James was not exhibiting developmental defects for some time following the September seizure and that the defects may occur years after the acute event. The August 12 seizure meets all of Dr. Carney's definition of the acute event. Dr. MacDonald contended that other than the length of time of the seizures, 7 minutes versus 20-25 minutes, there appears to be nothing to distinguish the August 12 seizures from the September 13 seizures. Dr. Carney was unable to persuasively distinguish the two events, other than pointing out the fact of vaccination on September 12.

#### 4. The Post-Hearing Submissions

##### *Dr. Carney*

In response to the order of March 17, 2005, petitioners filed Dr. Carney's post-hearing submission on April 21, 2005. See P. Response, filed Apr. 21, 2005. Regarding the definition of febrile seizure, Dr. Carney submits definitions from two textbooks, which define a febrile seizure as a temperature of greater than 38.4° C (or 101.12° F). Id. at 1.<sup>13</sup> Accordingly, Dr. Carney states that since Jake's temperature was 101.9° F at the time of the August 12 seizure, his temperature was sufficiently elevated to provoke a febrile seizure. Id. Dr. Carney notes that Dr. MacDonald testified at the hearing that he accepted the 101° F threshold for febrile seizures. Id. n.3. Moreover, Dr. Carney posits that, based on the above definition of febrile seizure, the seizures that affected Jake on September 13 were not febrile seizures since Jake's temperature did not rise above 100.6° F. Id. However, contrary to Dr. Carney's note, a review of the transcript reveals that Dr. MacDonald testified that the definition of febrile seizure he accepted was a rectal

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<sup>13</sup>It should be noted that this information conflicts with Dr. Carney's testimony, in which he stated that the textbook definition of a febrile seizure "will be above 99", Tr. at 124, and conforms with Dr. MacDonald's testimony.

temperature of 101° F *at the time of admission to the emergency room.* See Tr. at 185. At the time of admission to the emergency room on August 12, Jake's temperature was 100.5° F and only later rose to 101.9° F. P. Ex. 12 at 633. Similarly, his temperature was 100.6° F upon admission to the emergency room on September 13. Id. at 631. Thus, accordingly to Dr. MacDonald's testimony, neither event was a febrile seizure as the temperature at the time of admission to the emergency room was less than 101° F and therefore did not provoke the seizure. See discussion, supra, at 13-14.

Regarding the definition of status epilepticus, Dr. Carney explains that due to debate in recent years, a new more accurate definition has resulted. P. Response at 2. Dr. Carney cites four articles which explain that "the traditional definition of status epilepticus, as a seizure lasting greater than 30 minutes, has been redefined as '...a continuous, generalized, convulsive seizure lasting > 5 minutes, or two or more seizures during which the patient does not return to baseline consciousness.'" Id. He explains that this definition is more consistent with current clinical practice, since it is unreasonable to wait for 30 minutes before initiating anticonvulsant therapy. Id. Specifically, Dr. Carney cites an article stating that "the operational definition of status epilepticus, *in young children*, should be continuous seizures for greater than 10-15 minutes, rather than 5 minutes, as is the case for adults." Id. (citing D. Lowenstein et al., It's Time to Revise the Definition of Status Epilepticus," 30 EPILEPSIA 120, 121 (1999)). He concludes:

Thus, under the current definition of status epilepticus as applied to young children, the seven minute seizure which occurred on August 12, did not constitute status epilepticus. This conclusion is bolstered by the medical records, based upon the fact that anticonvulsant intervention was not attempted. In contrast, the 20-25 minute seizure of September 13, *clearly did* constitute status epilepticus. Finally, unlike the simple August seizure, the September 13 seizure was focal.

Id. at 2-3. However, in reviewing the Lowenstein article, the undersigned discovered that Dr. Carney, in reaching his above conclusion, failed to include the crucial, clarifying sentence directly following the sentence he cited regarding the operational definition of status epilepticus in young children. It states:

However, in contrast to the availability of data on seizure durations in adults (see the following), there is a paucity of similar information from young children. *We are therefore unable to find a logical basis for providing an operational definition for status epilepticus in this younger group at this time.*

D. Lowenstein et al., It's Time to Revise the Definition of Status Epilepticus," 30 EPILEPSIA 120, 121 (1999) (emphasis added). Thus, it appears that, contrary to Dr. Carney's assertion, an "operational definition for status epilepticus, in young children" **in fact has not been found** to be "10-15 minutes" at this time. The undersigned was quite frankly shocked by Dr. Carney's inappropriate selective use of information from the Lowenstein article. This incident further buttressed the undersigned's lack of confidence in Dr. Carney's work in this case.

Dr. Carney reiterates his position that “[t]he seizure of August 12 was brief and resolved with no neurological impairment, in contrast to the seizure of September 13.” P. Response at 3. Dr. Carney explains that, contrary to the seizure of August 12, “the seizures and encephalopathy which occurred on September 13 “following the vaccinations received on September 12, did not resolve spontaneously and were “followed by additional seizures.” Id. Further, Dr. Carney finds “no relationship between the simple, febrile seizure of August 12, and the subsequent seizure of September 13, and the seizure disorder that developed thereafter. Id. Dr. Carney states that the literature shows, “the risk of developing epilepsy after a simple, *febrile seizure* is not substantially different from that for the general population.” Id. (emphasis added). Moreover, he avers that there is “substantial likelihood” that Jake suffered brain injury after the September 13 seizure. Id. Dr. Carney premises this contention on literature which indicates “that there is a very high likelihood of brain injury resulting from *status epilepticus*.” Id. (emphasis added). Thus, Dr. Carney bases his medical theory in this case on his continued belief that the August 12 seizure was febrile and the September seizure was status epilepticus.

Dr. Carney concludes “more likely than not, that the September 13 status epilepticus, and ensuing epilepsy, were caused by the September 12 vaccinations” because the vaccinations and the “prolonged seizure which did not resolve spontaneously, ie. status epilepticus, are correlated in time.” P. Response at 3-4. Dr. Carney quotes from literature which concludes that status epilepticus can cause central nervous system damage, and believes it is more likely than not that the vaccinations Jake received on September 12 “constituted the acute central nervous system damage insult that brought on the status epilepticus and epilepsy.” Id. at 4. Dr. Carney then goes on to discuss the literature linking the DT vaccine to seizures. Id. He notes that “the temporal relationship between immunizations and the onset of seizures has been examined by association, temporal shift, and no-effect models. Children classified as previously normal (like James) are suggested to fit the temporal shift model.” Id. Once again, Dr. Carney’s argument is based on his opinion that Jake was “normal” at the time of the September 13 event, thus discounting the August 12 event and the fact that Jake also appeared normal following the September event.

*Dr. MacDonald*

As requested by the order of May 4, 2005, respondent filed Dr. MacDonald’s response to Dr. Carney’s definition of status epilepticus on June 6, 2005. See Respondent’s Notice of Filing Exhibits I Through P, filed June 6, 2005. In his report, Dr. MacDonald agreed with Dr. Carney that there has been discussion in the neurology community that the definition of status epilepticus utilizing the 30-minute time frame of continued seizure activity should be modified. R. Ex. I at 1. Dr. MacDonald stated however that the debate centers around the treatment issues. Id. Specifically, current practice is to begin treatment after a seizure persists for 5 to 10 minutes. Id. However, with respect to the definition of status epilepticus, Dr. MacDonald opined that most still agree that it is defined as 30 minutes of continuous or repetitive seizure activity. Id. He concluded:

Since irreversible damage to the child’s nervous system is unlikely from continuous seizures of 30 minutes duration, most Neurologists and the current medical

literature still support the 30-minute time frame for defining the actual occurrence of status epilepticus, whether or not any earlier drug treatment was begun.

Id. at 2.

## **B. Weighing the Experts' Opinions**

Dr. Carney's medical theory of this case is that the vaccine Jake received on September 12, 1998 caused a seizure of sufficient length and severity to constitute status epilepticus, which led to brain damage and ultimately death. Dr. Carney avers that the seizure Jake suffered on August 12, 1998 was not the beginning of Jake's seizure disorder but merely a simple, one-time event. In contrast, Dr. MacDonald sees no evidence of the vaccine causing harm and contends that the August seizure was the onset of Jake's epilepsy. After considering the entire record, which includes the experts' testimony, the undersigned reasserts his initial observations expressed in the March 17, 2005 order and finds fault with Dr. Carney's theory. First, however, a few words about the experts.

Dr. Carney has an impressive CV. However, his testimony was anything but impressive. In the undersigned's seventeen years of evaluating experts in this Program, Dr. Carney ranks at the top for verbal jousting. A review of his testimony reveals virtually no point on which Dr. Carney was challenged that he did not initially counter and then – when faced with documentation – he backpedaled, conceded, and yet continued to maintain his opinion. He consistently gave non-answers to straightforward questions only to concede the point after several transcript pages of follow-up questions. The undersigned was left with little confidence in Dr. Carney's testimony and the distinct impression that Dr. Carney had a conclusion in mind that no amount of evidence was going to upset. Dr. Carney's post-hearing submission did nothing to change the undersigned's opinion of his testimony.

Dr. MacDonald testified consistent with the records and his experience. However, while providing reliable testimony regarding the underlying medical issues, the undersigned found Dr. MacDonald's standard for proving causality to be too high. For example, when questioned about whether the DT or hepatitis B vaccinations can cause a fever, Dr. MacDonald replied "Yes." Tr. at 200. Given that it is generally accepted that a fever can cause a seizure, when asked whether it follows that if the vaccines could cause a fever, then they could also cause a seizure, Dr. MacDonald responded:

I'm not saying that's impossible. I'm just saying the evidence that I rely on that is well-documented has not shown fever seizures, per se in my knowledge to be *unequivocally related*. Whether that can occur on a rare event, I have no way of disproving that.

Id. (emphasis added). "Unequivocally related" is not the legal standard for causation. However, this defect in Dr. MacDonald's testimony is not critical since the undersigned is relying only on his credible testimony regarding the foundational medical issues presented in this case.

The essence of Dr. Carney's opinion is that a vaccination can cause a fever, a fever can cause a seizure, and a seizure of sufficient duration and severity – status epilepticus – can cause brain damage, as we see in this case. This medical theory has been accepted by special masters on a number of occasions in past cases. The complicating factor in this case is that Jake experienced a seizure on August 12, prior to receiving the vaccinations on September 13. Dr. Carney says that the August 12 seizure was an isolated event with no subsequent medical significance. Dr. MacDonald says the August 12 event is part of Jake's seizure disorder, indicating that something prior to receiving the vaccinations is the cause of Jake's disorder. Thus, the focus of Dr. MacDonald's testimony was to show the similarities between the seizures of August 12 and September 13, while the focus of Dr. Carney's testimony was to show the dissimilarities between the two events. In the end, the undersigned agrees with respondent that, in respondent's counsel's words, "[t]here's not a dime's worth of difference" between the two seizure events. Tr. at 150. Thus, Dr. Carney's medical theory must fail.

Turning back to the experts' theories of causation, contrary to Dr. Carney's argument, the evidence does not support a difference between the August and September seizures. Dr. Carney argued that the two events are different in that, unlike the September episode, the August event involved: 1) evidence of intercurrent illness; 2) a simple, febrile seizure; 3) no status epilepticus; and 4) no evidence of subsequent neurological damage. However, a close examination of the two seizures reveals no substantive difference. In fact, Dr. MacDonald testified credibly that the August seizure was medically more severe than the September seizure. See Tr. at 190.

Dr. Carney opined that the August seizures were caused by an intercurrent illness, while the September seizures were caused by vaccinations. On cross-examination, Dr. Carney testified that the evidence of intercurrent evidence in August was the "[f]ever, temperature." Tr. at 149. However, when it was brought to his attention that in September Jake also had an elevated temperature, Dr. Carney, conceded "yes, there was potential evidence for intercurrent on the 13<sup>th</sup> [of September]." Id. Dr. MacDonald testified that he believed Jake was suffering from an intercurrent illness with a brief fever associated with it on September 12. Tr. at 178.

Dr. Carney argued that the August event involved a simple, febrile seizure, and the September event involved an afebrile seizure, with status epilepticus. Respondent's counsel questioned Dr. Carney about what difference in temperature he observed between the August and September events, as they both involved initial temperatures around 100 that increased to over 101. Tr. 149-50. Dr. Carney replied "He's over 99, he's warm, he's febrile. Uh-huh." Id. at 150. Moreover, Dr. Carney argued that while the medical records do not actually state that Jake had a simple, febrile seizure, because Jake was not treated with anticonvulsant medicine Dr. Carney believes it was. However, upon further questioning, Dr. Carney conceded that anticonvulsants were also not given following the September event. Id. at 151. Dr. MacDonald stated that both events were associated with fever. Id. at 175. However, as with the September event, he did not find the August event to involve a febrile seizure, because, as he explained, his definition of febrile

seizure requires a fever of 101° F rectally upon admission to the emergency room. Id. at 185.<sup>14</sup>

Dr. Carney further contended that the September episode – lasting 20 to 25 minutes – was a prolonged seizure, or status epilepticus, but the August event – lasting 6 to 7 minutes – was not. During his cross-examination of Dr. Carney, respondent’s counsel asked, “So really the only difference between the first event and the second event is that in your opinion he had an episode of status epilepticus during the second event that he didn’t have in the first event ... if you assume the definition of 20 minutes?” Tr. at 151. Dr. Carney replied, “Right.” Id. In earlier testimony, Dr. Carney indicated that the literature, including his own article, defines status epilepticus as at least 30 minutes of continuous seizure activity; however, Dr. Carney further stated that he teaches using the five minute standard and most practitioners agree that any seizure lasting five minutes or longer meets the definition of a status epilepticus. See Tr. at 121, 162.<sup>15</sup> Thus, under Dr. Carney’s 30 minutes criteria for defining status epilepticus, neither the August or September seizures would be classified as status. Similarly, accepting his criteria of defining status epilepticus as continuous seizures lasting longer than 5 minutes, both events would be classified as status. Thus, following either of Dr. Carney’s proposed definitions, both the August and September episodes would be classified together as either status or non-status seizures. Again, under either line of testimony, there was no discernable difference between the two seizures. Dr. MacDonald testified that he defines status epilepticus using the 30 minute criteria. Id. at 175. In his post-hearing submission, Dr. MacDonald expanded on this, explaining that current practice is to begin treatment after a seizure persists for 5 to 10 minutes. Dr. MacDonald did not believe Jake was in status epilepticus in either episode. Tr. at 191.

Finally, Dr. Carney argued that Jake was normal following the August event, but experienced brain damage following the September episode. When asked at what point he would expect evidence of a brain injury to manifest following a severe episode of status epilepticus, Dr. Carney indicated that it can take up to 20 years before recurrent seizures develop. Tr. at 151-52. Moreover, when questioned if he would expect a child whose brain was substantially damaged from an episode of status epilepticus to be discharged four hours after admission, as was the case here, Dr. Carney replied that it was, “rather quick, but he apparently bounced back and looked fine.” Id. at 153. During cross-examination, Dr. Carney conceded that a diagnostic work-up and examination performed six days after the September event, which included a normal lumbar puncture, head CT, brain MRI and electroencephalogram, revealed no abnormalities. See Tr. at 154. Respondent’s counsel continued his cross-examination, reading from a note dated October 29, 1998, approximately six weeks after the September event, which indicated that Jake’s developmental history and exam was normal, he was recently evaluated at the early intervention

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<sup>14</sup>Additionally, as indicated by P. Ex. 10, because the August seizure was afebrile, any subsequent seizure cannot be classified as the onset of the seizure disorder. See discussion, supra, at 10 & n.10.

<sup>15</sup>However, in his post-hearing submission, Dr. Carney changed the definition to 10-15 minutes. But as shown, this was based on an inappropriate reading of Lowenstien’s article. See discussion, supra, at 17.

program and, though some subtle deficits were noted, these did not warrant therapeutic intervention. *Id.* at 154-55. Accordingly, respondent's counsel asked Dr. Carney, "So this [note] would seem to indicate that six weeks later there's still not a lot going on with his development?" Dr. Carney replied, "Uh-huh." Respondent's counsel also went over a list of neurologic findings from the October 29 visit and asked Dr. Carney, "those are normal things that you would see at a normal neurologic exam?" *Id.* at 155. Dr. Carney responded, "Yes." *Id.* Dr. MacDonald did not find the September event to be an overwhelming event that caused brain damage, as evidenced by the fact that Jake was sent home from the hospital after only four hours. *Id.* at 191.

In the final analysis, based upon both Dr. MacDonald's credible testimony and, after persistent questioning, Dr. Carney's eventual recognition, there simply is little to no difference between the two seizures. The August seizure was: 1) afebrile; 2) not treated with anticonvulsants; 3) not status epilepticus; and 4) there was no discernible brain damage. Similarly, the September seizure was: 1) afebrile; 2) not treated with anticonvulsants; 3) not status epilepticus; and 4) there was no discernible brain damage. Each reason Dr. Carney gave for the September seizure as the onset of Jake's seizure disorder applied equally to the August seizure. Thus, it is logical to conclude with Dr. MacDoanld that they were part of the same process which began prior to Jake receiving the vaccinations, or to agree with Dr. Carney that, as the August seizure was an isolated non-damaging event, so was the September seizure. What is clear is that none of the evidence that Dr. Carney put forth to link the September 12 vaccinations to Jake's seizure disorder withstood scrutiny.

Dr. Carney failed in every respect to support his medical theory, which was based on the second seizure in September, rather than the first seizure in August, being the onset of Jake's seizure disorder. To make this argument successfully, Dr. Carney needed to distinguish the August and September events. This Dr. Carney failed to do. His verbal efforts greatly damaged his credibility and he did not succeed in demonstrating the foundational medical facts required for his medical theory – that the seizures following the vaccination differed from the seizures preceding vaccination. Dr. MacDonald stuck to the evidence and provided a clear and logical sequence of events. He was a far more persuasive witness. Dr. MacDonald's testimony comported with the records, literature and far more persuasively made the case that more likely than not the September seizure was part of an ongoing seizure disorder process which began or at least included the August seizure, which preceded the September 13, 1998 vaccinations.<sup>16</sup> Accordingly, as their expert did not provide credible testimony demonstrating by a preponderance of the evidence that the vaccines were the cause of Jake's seizure disorder, petitioners have failed to meet their burden of proof under the Act.

#### **IV. CONCLUSION**

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

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<sup>16</sup>Petitioners advanced no argument that the September 12 vaccinations significantly aggravated the August 12 seizure, and the facts do no support such an argument.

case fails because the medical records and the experts' testimony support that Jake's seizure disorder began in August 1998, and not in September 1998 as petitioners argue. Thus, petitioners failed to demonstrate that Jake's seizure disorder and subsequent death were caused-in-fact by the vaccinations he received on September 12, 1998. For the reasons discussed above, petitioners fail to qualify for an award under the Program. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the Clerk is directed to enter judgment accordingly.

**IT IS SO ORDERED.**

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Gary J. Golkiewicz  
Chief Special Master