IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS
No. 08-185V
Filed: April 26, 2011
For Publication

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JAMES HOLMES,	*	Tetanus Vaccine; Seizure
	*	Disorder; Causation;
Petitioner,	*	Febrile vs. Afebrile Seizures;
v.	*	Expert Witnesses;
	*	Applicability of Scientific
SECRETARY OF HEALTH	*	Studies to Facts; Age of
AND HUMAN SERVICES,	*	Vaccinee as Factor in
	*	Applicability of Studies;
Respondent.	*	Opinions of Treating
	*	Physicians

* *

Richard Gage, Esq., Cheyenne, Wyoming, for petitioner.
Ryan Pyles, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION[1]

Vowell, Special Master:

On March 18, 2008, Ms. Christina Loudermilk ["Ms. Loudermilk"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], on behalf of her then-minor son, James Holmes ["James" or "petitioner"]. The petition was recaptioned upon oral motion at the July 30, 2010 causation hearing, as James had reached the age of majority. The case thereafter proceeded with James as the petitioner.

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[1] Because this decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

The petition alleged that the tetanus and diphtheria ["Td"] vaccination James received on August 17, 2005, caused him to suffer two seizures on August 18, 2005, causing a subsequent seizure disorder (epilepsy)[3] and unspecified neurological injuries.[4] Petition, ¶¶ 2-4. James was 14 years old when he received the vaccine and suffered his first two seizures.

In order to prevail under the Program, a petitioner must prove either a "Table" injury[5] or that a vaccine listed on the Table was the cause in fact of an injury [an "off-Table" injury]. Neither seizure disorders nor neurological injuries are listed as a Table injury for tetanus or diphtheria vaccines. Although the evidence establishes that petitioner received the Td vaccination as alleged, he failed to demonstrate that the Td vaccine can cause seizure disorders such as the epilepsy from which he suffers and that it did so in his case. Petitioner has therefore failed to link his vaccination to any illness, disability, injury, or condition. *See* § 300aa-11(c)(1)(C)(ii)(I). After considering the record as a whole,[6] I hold that petitioner has failed to establish entitlement to compensation.

I. Procedural History.

The petition was accompanied by medical records establishing James' Td vaccination on August 17, 2005, his treatment for seizures on August 18, 2005, and subsequent diagnoses of epilepsy, slowed mental processing, and memory difficulties.

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[3] Seizures are defined as "[a] clinical manifestation presumed to result from an abnormal and excessive discharge of a set of neurons in the brain. The clinical manifestation consists of sudden and transitory abnormal phenomena which may include alterations of consciousness, motor, sensory, autonomic, or psychic events, perceived by the patient or an observer." Commission on Epidemiology and Prognosis, International League Against Epilepsy, *Guidelines for Epidemiological Studies on Epilepsy*, EPILEPSIA 34(4):592-96, 593 (1993) ["ILAE Guidelines"], filed as Respondent's Exhibit ["Res. Ex."] A23. Epilepsy is defined as two or more seizures, unprovoked by any immediately identifiable cause. *Id*.

[4] Although the petition does not specify the neurological injuries suffered, subsequent filings indicate that some cognitive problems may have resulted either from James' seizure disorder or the medications used to treat the disorder. *See, e.g.*, Petitioner's Post-Hearing Brief, filed Oct. 5, 2010 ["Pet. Post-Hearing Br."] at 1-2.

[5] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2009), corresponding to the vaccine received within the time frame specified.

[6] *See* § 300aa–13(a): "Compensation shall be awarded...if the special master or court finds on the record as a whole–(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)." *See also* § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

An expert medical report by Dr. Marcel Kinsbourne was filed on June 8, 2009. Respondent filed her Vaccine Rule 4(c) report and the expert report of Dr. Shlomo Shinnar on September 4, 2009. Supplemental reports by both experts and medical literature were filed at various times over the next four months. On March 16, 2010, the special master then assigned indicated that the case was ready for an entitlement hearing.

The case was reassigned to me on March 31, 2010. I conducted an entitlement hearing on June 30, 2010. Prior to the hearing, the parties stipulated that the issues in dispute were: (1) whether the Td vaccination administered on August 17, 2005, caused the seizures James suffered on August 18, 2005; (2) whether James' subsequent epilepsy was the result of the August 18, 2005 seizures; and (3) whether James' mental and academic difficulties are the result of epilepsy caused by his vaccines.[7] Joint Pre-Hearing Submission, filed June 9, 2010, at 1. Post-hearing briefs were filed thereafter and the case is now ripe for resolution.[8]

I conclude that petitioner has failed to establish vaccine causation, and is thus not entitled to compensation. This conclusion is based on problems with the factual and medical underpinnings of the opinions advanced by Dr. Marcel Kinsbourne, petitioner's expert. Respondent's expert, Dr. Shlomo Shinnar, who was far better qualified to opine on seizure disorders than Dr. Kinsbourne,[9] proffered opinions that were supported by

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[7] Because there is insufficient evidence to conclude that the Td vaccination was the cause of James' epilepsy, it is unnecessary to reach any conclusion about what part, if any, of James' academic difficulties can be attributed to his epilepsy or the drugs used to treat it.

[8] The original transcript in this case was replete with errors, including many careless errors that changed the meaning of the testimony provided. After a status conference on November 4, 2010, I ordered the parties to submit the transcript to their experts for corrections. Based on the parties' agreement to numerous changes (*see* Joint Status Report, filed Jan. 20, 2011), I ordered a corrected transcript to be produced. That transcript was filed on January 31, 2011. This decision cites to that corrected transcript.

[9] Both expert witnesses are medical doctors who specialized in pediatric neurology after completing medical school. Transcript ["Tr."] at 6, 120-21. Most of the similarity in their qualifications ends there.

Doctor Kinsbourne. Doctor Kinsbourne is a member of the British Royal College of Physicians, which he described as "an umbrella specialist credential . . . covering neurology pediatrics." Tr. at 7. Beginning in 1980, Dr. Kinsbourne's clinical practice focused almost exclusively on patients with behavioral disorders. He has not had a hospital-based pediatric neurology practice since 1981. Tr. at 55. His current employment is as a professor at the New School, teaching graduate students in psychology how the brain works and supervising their research. Tr. at 9. He currently derives approximately 50% of his income from "legal matters," with the majority of those matters involving Vaccine Act cases. Tr. at 57. He has no publications on epilepsy. Tr. at 55-56.

the medical literature and the medical records, and which I found to be more reliable and persuasive than those of Dr. Kinsbourne.

II. Legal Standards Applying to Off-Table Causation Cases.

When a petitioner alleges an off-Table injury, eligibility for compensation is established when, by a preponderance of the evidence, petitioner demonstrates that he received, in the United States, a vaccine set forth on the Vaccine Injury Table and sustained an illness, disability, injury, or condition caused by the vaccine or experienced a significant aggravation of a preexisting condition. He must also demonstrate that the condition has persisted for more than six months.[10] Vaccine litigation rarely concerns whether the vaccine appears on the Table, the situs for administration, or whether the symptoms have persisted for the requisite time. In most Vaccine Act litigation, the issue to be resolved by the special master is whether the injury alleged was caused by the vaccine.

To establish legal cause in an off-Table case, Vaccine Act petitioners must establish each of the three *Althen* factors: (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 proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). The applicable level of proof is the "traditional tort standard of 'preponderant evidence.'" *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing *de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Pafford v. Sec'y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen,* 418 F.3d at 1278). The preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

Doctor Shinnar. He has a Ph.D. in neuroscience, in addition to his medical degree, and is board certified in neurophysiology, pediatrics, and neurology, with special competence in pediatric neurology. Tr. 120-21. He is an active teacher and clinician, and currently serves as a professor of neurology, pediatrics, and epidemiology at Albert Einstein College of Medicine. He is also the director of the epilepsy management center at Montefiore Medical Center in the Bronx, New York, where two-thirds of his clinical practice is in the care and treatment of children with epilepsy. He has conducted substantial research into seizure disorders in children, and currently holds an NIH grant for research on the consequences of prolonged febrile seizures. Tr. at 121-23. He has published more than 200 peer reviewed papers and book chapters, most of which are concerned with seizure disorders, including febrile seizures. He has testified once before in a Vaccine Act case, on behalf of petitioners. *See* Tr. at 122-24.

[10] Section 300aa–13(a)(1)(A). This section provides that petitioner must demonstrate "by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1)...." Section 300aa–11(c)(1) contains the factors listed above, along with others not relevant to this case.

An alternate formulation of the causation requirement in off-Table cases is the "Can it cause?" and "Did it cause?" inquiry used in toxic tort litigation. Prong 1 of *Althen* has been characterized as an alternative formulation of the "Can it cause?" query. Prong 2 of *Althen*, the requirement for a logical sequence of cause and effect between the vaccine and the injury, has been characterized as addressing the "Did it cause?" query. *See Pafford v. Sec'y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). Even if a vaccine has been causally associated with an injury, petitioner must still establish facts and circumstances that make it more likely than not that the vaccine caused his particular injury. The third *Althen* factor is subsumed into the "Did it cause?" inquiry.

Regardless of whether a case is analyzed under *Althen* or the "Can it cause?" formulation, petitioners are not required to establish identification and proof of specific biological mechanisms, as "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." *Althen*, 418 F.3d at 1280. The petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a "substantial factor"[11] in causing the condition and was a "but for" cause are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford,* 451 F.3d at 1355 (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners cannot be required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect...." *Capizzano*, 440 F.3d at 1325. Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y*, *HHS,* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

The medical theory must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 548-49. The

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[11] The recently approved Restatement (Third) of Torts has eliminated "substantial factor" in the factual cause analysis. § 26 cmt. j (2010). Because the Federal Circuit has held that the causation analysis in Restatement (Second) of Torts applies to off-Table Vaccine Act cases (*see Walther v. Sec'y, HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007); *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)), this change does not affect the determination of legal cause in Vaccine Act cases: whether the vaccination is a "substantial factor" is still a consideration in determining whether it is the legal cause of an injury.

Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, likewise requires that courts determine expert opinions to be reliable before they may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." 509 U.S. 579, 590 (1993) (footnote omitted). The Federal Circuit has stated that a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324.

Circumstantial evidence and medical opinions may be sufficient to satisfy *Althen's* second prong. *Capizzano*, 440 F.3d at 1325-26. Opinions of treating physicians may also provide the logical connection. *See Andreu v. Sec'y, HHS*, 569 F.3d 1367, 1376 (Fed. Cir. 2009); *see also Moberly,* 592 F.3d at 1323; *Capizzano*, 440 F.3d at 1326.

The requirement of temporal connection necessitates a showing that the injury occurred in a medically or scientifically reasonable period after the vaccination, not too soon (*see de Bazan*, 539 F.3d at 1352) and not too late (*see Pafford*, 451 F.3d at 1358). Merely showing a proximate temporal connection between a vaccination and an injury is insufficient, standing alone, to establish causation. *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A proximate temporal relationship, even when coupled with the absence of any other identified cause for the injury, is not enough to demonstrate probable cause under the Vaccine Act's preponderance standard. *Moberly*, 592 F.3d at 1323 (citing *Althen*, 418 F.3d at 1278).

In Vaccine Act cases, special masters are frequently confronted by expert witnesses with diametrically opposed positions on causation. When experts disagree, many factors influence a fact-finder to accept some testimony and reject other contrary testimony. As the Federal Circuit noted, "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases ... where there is little supporting evidence for the expert's opinion." *Moberly*, 592 F.3d at 1325-26. Objective factors, including the qualifications, training, and experience of the expert witnesses; the extent to which their proffered opinions are supported by reliable medical research and other testimony; and the factual basis for their opinions are all significant factors in determining what testimony to credit and what to reject.

The Vaccine Act itself contemplates that the special masters will weigh the merits of the evidence presented in making entitlement decisions. Special masters are not bound by any particular "diagnosis, conclusion, judgment, test result, report, or summary," and in determining the weight to be afforded to these matters, "shall consider the entire record...." § 300aa–13(b)(1). As the Supreme Court has noted, a trial court is not required to accept the *ipse dixit* of any expert's medical or scientific opinion, because the "court may conclude that there is simply too great an analytical gap

between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

The special master determines the reliability and plausibility of the expert medical opinions offered and the credibility of the experts offering them. Not all evidence carries equal weight with a trier of fact. A medical opinion on causation may be based on factually incorrect medical histories or it may be offered by someone without the necessary training, education, or experience to offer a reliable opinion. An expert's opinion may be unpersuasive for a variety of reasons. Courts, whether they deal with vaccine injuries, medical malpractice claims, toxic torts, or accident reconstruction, must base their decisions on reliable evidence. *See Daubert*, 509 U.S. at 594-96.

Although *Daubert* interpreted Federal Rule of Evidence 702, an evidentiary rule not applicable to Vaccine Act cases, it, nevertheless, provides a useful framework for evaluating scientific evidence in such cases. *Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (concluding it was reasonable for the special master to use *Daubert* to evaluate the reliability of an expert's testimony); *see also Ryman v. Sec'y, HHS*, 65 Fed. Cl. 35, 40-41 (2005) (special master performs gatekeeping function when determining "whether a particular petitioner's expert medical testimony supporting biological probability may be admitted or credited or otherwise relied upon" and as a "trier-of-fact [a special master] may properly consider the credibility and applicability of medical theories"). The special master's use of *Daubert*'s factors to evaluate the reliability of expert opinions in Vaccine Act cases has been cited with approval by the Federal Circuit more recently in *Andreu*, 569 F.3d at 1379, and *Moberly,* 592 F.3d at 1324.

Special masters weigh the evidence found in the medical records (*see, e.g., Ryman*, 65 Fed. Cl. at 41-42); consider evidence of bias or prejudice on the part of a witness, affiant, or expert (*see, e.g.*, *Baker v. Sec'y, HHS*, No. 99-653V, 2003 WL 22416622, at *36 (Fed. Cl. Spec. Mstr. Sept. 26, 2003)); weigh opposing medical opinions and the relative qualifications of experts (*see, e.g.*, *Snyder v. Sec'y, HHS*, 88 Fed. Cl. 706, 742-43 (2009); *Lankford v. Sec'y, HHS*, 37 Fed. Cl. 723, 726-27 (1997); *Epstein v. Sec'y, HHS*, 35 Fed. Cl. 467, 477 (1996)); examine medical literature, studies, reports, and tests submitted by either party (*see, e.g.*, *Sharpnack v. Sec'y, HHS*, 27 Fed. Cl. 457, 461 (1993), *aff'd*, 17 F.3d 1442 (Fed. Cir. 1994)); and may consider a myriad of other factors in determining the facts of the case and the mixed questions of law and fact that arise in causation determinations. Special masters decide questions of credibility, plausibility, reliability, and ultimately determine to which side the balance of the evidence is tipped. *See Pafford*, 451 F.3d at 1359.

By specifying petitioners' burden of proof in off-Table cases as the preponderance of the evidence, directing special masters to consider the evidence as a

whole, and stating that special masters are not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record (§ 300aa-13(b)(1)), Congress contemplated that special masters would weigh and evaluate opposing expert opinions in determining whether petitioners have met their burden of proof.[12] In weighing and evaluating expert opinions in Vaccine Act cases, the same factors the Supreme Court considered important in determining their admissibility provide the weights and counterweights. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (1999); *Terran*, 195 F.3d at 1316.

In an off-Table case, petitioners do not automatically shift the burden to respondent to prove an alternate cause merely by offering an opinion of a medical expert. Respondent may challenge the factual underpinnings of a causation opinion, the opinion itself, or both. *See de Bazan*, 539 F.3d at 1353-54. If the special master concludes that petitioner's evidence of causation is lacking, then the burden never shifts to respondent to demonstrate the "factors unrelated" as an alternative cause for petitioner's injury. *See Bradley v. Sec'y, HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed); *Johnson v. Sec'y, HHS*, 33 Fed. Cl. 712, 721-22 (1995), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996) (even in idiopathic disease claims, the special master may conclude petitioner has failed to establish a *prima facie* case). In *de Bazan*, the Federal Circuit explicitly stated that the special master may consider all of the evidence presented, including that of respondent, in determining whether petitioners have met their burden of proof. 539 F.3d at 1353-54.

As the Court of Federal Claims noted:

> As fact-finders, Special Masters, like juries, are often faced with the "battle of the experts" when it comes to interpreting facts. And as fact-finders, they may find that truth lies somewhere in between the opposing, uncompromising views of the partisan experts. Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions.... A fact-finder, especially one with specialized experience such as a Special Master, can accept or reject opinion testimony, in whole or in part. When the evidence is in, and it is time to apply the facts to the law, the expert's role is over. Partisan testimony then gives way as the Special Master evaluates the testimony in

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[12] *See* § 300aa–13(a)(1)(A) (preponderance standard); § 300aa–13(a)(1) ("Compensation shall be awarded...if the special master or court finds on the record as a whole..."); § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation and special master is not bound by any particular piece of evidence).

light of the entire record, based on reasonable inferences born of common experience or the product of special expertise.

Sword v. United States, 44 Fed. Cl. 183, 188-89 (1999) (citations omitted); *see also Moberly*, 592 F.3d at 1325 ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.") (citations omitted).

Bearing all these legal standards in mind, I turn to the evidence presented in this case. Certain facts are not in controversy, and I address those facts first, followed by the controverted facts and the medical opinions pertaining to causation that stem therefrom.

III. Applying the Law to the Facts.

A. The Facts Not in Controversy.

James' medical history prior to August, 2005, is not at issue in this case. On August 17, 2005, James, who was 14 years of age and appeared to be in good health, had a school physical. James received a Td vaccination[13] at this appointment. Petitioner's Exhibit ["Pet. Ex."] 6, pp. 2-4.

1. The Initial Seizure.

The following morning, James had a brief seizure, part of which was witnessed by his older sister. Pet. Ex. 9, p. 43. Emergency medical services ["EMS"] personnel arrived six minutes after a 911 call and transported James to the Swedish American Hospital ["SAH"]. Pet. Ex. 7, pp. 1, 3. In the ambulance, James was "alert," but unable to speak. Pet. Ex. 7, p. 3. The EMS personnel recorded James' vital signs as normal. *See* Pet. Ex. 7, pp. 1, 3. Although they did not record a temperature at the scene or in transport, handwritten notes taken from a pre-hospital radio report indicated that James was "[p]ost ictal,[14] warm, dry." *Id*., p. 1.

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[13] The Td (tetanus and diphtheria) vaccine is administered beginning in adolescence as a booster vaccine for the DTaP vaccines received in infancy and early childhood. *See* CDC, Recommended Childhood and Adolescent Immunization Schedule—United States, 2005, *Morbidity and Mortality Weekly* (Jan. 7, 2005), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5351-Immunizationa1.htm#tab.

[14] "Post-ictal" refers to the recovery period after the conclusion of the epileptic seizure. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (31st ed. 2007) ["DORLAND'S"] at 1524.

James' mother, who was not at home when the seizure occurred (*see* Tr. at 27-28), and his father, who witnessed part of the seizure (Pet. Ex. 9, p. 31), arrived at the emergency department and provided a history that indicated James had no fevers or chills, and had been eating normally. James' only complaint was that his arm hurt from his tetanus vaccination received the previous day. Pet. Ex. 9, p. 31.

At the SAH emergency department, James' temperature was 97.6°. Pet. Ex. 9, p. 31. Consistent with the observations of the EMS personnel (*see* Pet. Ex. 7, pp. 1, 3), Dr. Ximena Llobet, the emergency department physician who treated James, noted that his skin was warm and dry with no rash. Pet. Ex. 9, p. 32. She assessed the seizure as a generalized tonic-clonic seizure. *Id.*, p. 31.

After several hours of observation and a negative CT scan,[15] James was scheduled for an outpatient EEG[16] and released. Pet. Ex. 9, p. 32. No treatment for fever was administered, and there were no records indicating that James was either ill or feverish.

2. The Second Seizure.

As he was going to sleep at home that same afternoon, James had another seizure, with the onset of it witnessed by his mother, Ms. Loudermilk. Pet. Ex. 9, p.19. Once again, EMS personnel were called, and they transported James to SAH, arriving there within 15 minutes of the 911 call. Pet. Ex. 7, pp. 4-6. There were no references to fever during this transport. *Id*.

At the SAH emergency department, James had a rectal temperature of 99.9°[17] taken about 15 minutes after his arrival. Pet. Ex. 9, p. 10. The emergency department

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[15] "A CT scan refers to a computed tomography scan of the brain, a test used to diagnose central nervous system disease, including tumors, aneurysms, and hemorrhages. It consists of a computerized analysis of x-rays of the brain. MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS (4th ed. 2010) ["MOSBY'S"] at 1080-82.

[16] An EEG (electroencephalogram) measures the electrical activity of the brain. MOSBY'S at 573. The EEG was performed the next day, after a second seizure. Pet. Ex. 11, p. 29. No focal abnormalities or epileptiform discharges were seen.

[17] A rectal temperature is about one-half to one degree higher than an oral temperature. J. Nissl, *Health Key: Rectal, ear, oral, and axillary temperature comparison* (Apr. 21, 2009), *available at* http://www.healthkey.com/health/symptoms/fever/hw-tw9223,0,3865515.story, filed as Pet. Ex. 19, at 1. Using this conversion, James' temperature was not elevated. *See also* Tr. at 62 (testimony of Dr. Kinsbourne that a temperature of 97.6° is not elevated and agreeing that a 99.9° rectal temperature would be between 98.9-99.4° when converted to an oral measurement.)

records also indicated that James' oral temperature was 100°. Pet. Ex. 9, pp. 6, 20. James reported no headache, nausea, fever, chills, or chest pain prior to the seizure. Pet. Ex. 9, p. 19. He was administered Tylenol and Dilantin in the emergency department. Pet. Ex. 9, p. 10. The seizure was assessed as a generalized tonic-clonic seizure. Pet. Ex. 9, p. 12.

The emergency room physician, Dr. Anthony Schultz, observed that there was a small inflammatory reaction at the site of the Td vaccination, but also noted that the site was not red or warm, and there was no sign of lymph node swelling. Pet. Ex. 9, p. 13. Doctor Schultz administered Dilantin and admitted James for observation.

A nursing note described James' shoulder as "swollen" from his vaccination (*id*., p. 9), but an examining physician, Dr. Wen-Ho Yang, described James' left deltoid as warm, slightly indurated,[18] and tender to touch. He recorded that there was no abscess and no area of redness.[19] *Id*., p. 20. James described the pain in his arm "as the usual sensation after vaccination." *Id*., p. 19.

James' hospital course was unremarkable, with no additional seizures noted. Pet. Ex. 9, pp. 17-18, 20-21, 26. He "did not develop any fevers, neck stiffness, nausea, or vomiting" during his hospital stay. *Id.*, p. 17. All screening tests were negative, including a toxicology screen, CT, EEG, EKG, and echocardiogram.[20] He was diagnosed with "new onset seizures." Pet. Ex. 9, p. 17 (discharge summary). There is no evidence that James was suffering from either an afebrile or a febrile illness at the time of his seizures or shortly thereafter. James was referred to Dr. Philip Miner, a neurologist, for follow up. *See* Pet. Ex. 8, p. 1.

3. Subsequent Treatment.

James remained seizure free and on Dilantin through his initial visit on September 6, 2005 with Dr. Miner. Doctor Miner recorded that James had experienced two generalized, afebrile seizures on August 18, 2005, and his assessment was

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[18] "Indurated" means hardened. DORLAND'S at 947.

[19] It appears that Dr. Yang's examination was based on observations after James left the emergency department and was admitted to the hospital. *See* Pet. Ex. 9, p. 21 (referring to earlier treatment in the emergency department).

[20] An EKG, or electrocardiogram, records electrical impulses that stimulate the heart to contract, and it is used to evaluate cardiac problems. MOSBY'S at 567. An echocardiogram is an ultrasound used to evaluate the structure and function of the heart. *Id.* at 919. *See also* Pet. Ex. 8, p. 1 (neurologist's comment that the CT and EEG were read as normal).

"[s]econdarily generalized seizures of unclear etiology." Pet. Ex. 8, p. 1. Ms. Loudermilk expressed concern at this visit that James did not "look quite right" on Dilantin, and Dr. Miner switched the medication to Depakote. *Id*.

At the next visit to Dr. Miner on September 28, 2005, James was still seizure free, but he had a rash and Ms. Loudermilk thought he was very forgetful. Pet. Ex. 8, p. 5. Doctor Miner switched James to Trileptal. *Id.* On October 7, 2005, during the transition period between Depakote and Trileptal, James experienced another seizure. *Id*., p. 11 (mistakenly recording the date as October 11, 2005); Pet. Ex. 9, p. 56. This seizure resulted in a diagnosis of epilepsy. Pet. Ex. 8, p. 15.

B. The Contested Facts.

The primary factual dispute concerns whether the two initial seizures on August 18, 2005 were complex febrile seizures. A febrile seizure is defined as a seizure "occurring in childhood after age 1 month, associated with a febrile illness not caused by an infection of the [central nervous system], without previous neonatal seizures or a previous unprovoked seizure." ILAE Guidelines, Res. Ex. A23 at 593. A complex febrile seizure is defined as "focal, prolonged (lasting for more than either 10 minutes or 15 minutes), or multiple (occurrence of more than one seizure during the febrile illness)." S. Shinnar, *Febrile Seizures*, *in* Pediatric NEUROLOGY: PRINCIPLES & PRACTICE 1079 (Swaiman, et al. eds, 4th ed. 2006), filed as Res. Ex. A8 (internal citations omitted); *see also* Tr. at 48-49.

Based on his interpretation of the medical records, Dr. Kinsbourne opined that James had a fever at the time of both initial seizures, and that these seizures met the criteria to be classified as complex febrile seizures. Pet. Ex. 14 at 2; Tr. at 54, 64; *see also* Tr. at 48-49, 57.

Doctor Shinnar opined that James did not have a fever at the time of his initial seizures. Res. Ex. A at 4; Tr. at 126, 133. Alternatively, even if James had a slight fever after the second seizure, he did not experience febrile seizures, because the fever was not high enough and James was too old for a diagnosis of febrile seizures. Tr. at 127-29, 133-34. Additionally, as the first seizure was clearly afebrile, he did not have two provoked seizures in one day, which are necessary to establish the seizures as complex. *See* Tr. at 126.[21]

[21] Dr. Shinnar acknowledged, however, that if James' seizures were febrile, he would have also categorized them as complex. Tr. at 126.

1. The Initial Seizure Was Not Febrile.

Relying on an EMS description that James was warm and dry during transport as well as a mistaken impression that James' mother witnessed the initial seizure (*see* Pet. Ex. 7, pp. 1, 3; Pet Ex. 14 at 1), and apparently discounting the normal temperature recorded in the emergency room (Pet. Ex. 14 at 1; Pet. Ex. 9, p. 28), Dr. Kinsbourne contended that James' initial seizure was a febrile seizure. Pet. Ex. 14 at 2; Pet. Ex. 18 at 1; Tr. at 57-59.

He was simply wrong. Doctor Kinsbourne relied on the record created for James' emergency room visit for his second seizure, not his first, in opining that the first seizure was febrile. *See* Pet. Ex. 18 at 1 (citing Pet. Ex. 9, pp. 6 and 12, and calculating James' oral temperature upon his first admission to be 101° based on records of a temperature taken at his second admission).[22] In preparing his expert report and initial testimony, Dr. Kinsbourne either missed or ignored the fact that James' temperature was 97.6° at the SAH emergency room after the first seizure. *See* Pet. Ex. 9, p. 28. He conceded during his testimony that a 97.6° temperature was normal. Tr. at 62.

Doctor Kinsbourne also referred to what he termed "contemporaneous[]" statements by James' mother that he felt "hot" as evidence that James was febrile during his first seizure. Pet. Ex. 14 at 2. The evidence indicates that Ms. Loudermilk was not at home at the time of the first seizure. *See* Pet. Ex. 9, p. 31; Tr. at 27-28.

I find no reliable evidence that James was febrile at the time of his initial seizure. The recorded temperature is more accurate than tactile measurements of skin temperature. *See* Pet. Ex. 19 at 1 (recommending against use of even plastic strip thermometers because they measure skin temperature, not internal body temperature); *see also* Tr. at 137-38. The term "warm" is relative, and, in the context of the EMS and emergency department records in which it appears, "warm" as applied to James does not appear to refer to fever. *See* Pet. Ex. 7, pp. 1, 3. This conclusion is buttressed by the physician's narrative that James had a temperature of 97.6°, but which also described his skin as "warm and dry." Pet. Ex. 9, pp. 31-32. Additionally, James denied having fever or chills (*id*., p. 31), and the skin temperature assessment was made on an August day in Chicago (Tr. at 82-83).

[22] Dr. Kinsbourne also misread the temperature taken at the second admission as an axillary temperature when it was recorded as an oral temperature. *See* Pet. Ex. 18 at 1; Pet. Ex. 9, p. 6; Tr. at 63.

2. The Second Seizure Was Not Febrile.

Doctor Kinsbourne relied on two measured temperature readings[23] taken in the emergency department at SAH and the emergency room record's notation of "fever"[24] to contend that James was febrile at the time of his second seizure and therefore he experienced a febrile seizure. *See* Pet. Ex. 14, p. 1; Tr. at 29-30. However, the emergency room physician who evaluated James considered the two temperature readings taken in the emergency room, and Ms. Loudermilk's report that James felt warm, but he did not diagnose a febrile seizure. *See* Pet. Ex. 9, p. 12. The treating physician's opinion upon admission included a history that James did not have a fever prior to his second seizure (*see* Pet. Ex. 9, p. 19), and the discharge record did not reflect an assessment of a febrile seizure (*see* Pet. Ex. 9, pp. 17-18).

Dr. Kinsbourne's opinion that James' temperature was elevated was shaped, at least in part, by his misreading of the medical records. Dr. Kinsbourne read Pet. Ex. 9, p. 6, as reporting an axillary temperature of 100°, which he converted to an oral temperature of 101°. Pet. Ex. 18 at 1. During cross examination this error was brought to his attention. Although the upper left hand corner of Pet. Ex. 9, p. 6, indicated that the 100° temperature was measured orally, Dr. Kinsbourne testified that this portion of the medical record was cut off on the copy of the medical record he used to write his report. When shown the complete record, he acknowledged that the temperature was taken orally. Tr. at 63-64.

This mistake in how the temperature was measured is significant because Dr. Kinsbourne translated an axillary temperature of 100° to an oral temperature of 101°, which he opined would meet the threshold requirement of fever used by most studies to determine whether febrile seizures present an increased risk of subsequent unprovoked seizures.[25] Pet. Ex. 18 at 1. Indeed, some literature establishes a 100° axillary

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[23] He relied on the emergency department record of a 99.9° temperature taken rectally (the equivalent of a reading of 98.9- 99.4° if measured orally) and an oral temperature of 100°. Pet. Ex. 9, pp. 6, 11; Tr. at 62.

[24] In spite of his earlier reliance on EMS records of skin warmth, Dr. Kinsbourne apparently discounted the EMS record for the second seizure stating James' skin temperature was normal when they evaluated him at his home. *See* Pet. Ex. 7, p. 4. Doctor Schultz, who treated James after the second seizure recounted: "Mother states the patient did feel warm, however, she did not take his temperature." Pet. Ex. 9, p. 12. Thus, there is a dispute regarding James' tactile temperature between his mother and the EMS personnel.

[25] Dr. Kinsbourne testified that, "from the point of view of standardization," he would classify a patient as febrile with a temperature of 100.4° measured rectally. Tr. at 59. He added that in his own view, "there's a continuum of elevated temperature." Tr. at 60.

temperature as febrile. *See* A. Berg, et al., *A Prospective Study of Recurrent Febrile Seizures*, NEW ENGL. J. MED. 327: 1122-27 (1992), filed as Res. Ex. A1 (determining eligibility for a febrile seizure as "a seizure that occurred while the child had a rectal temperature of at least 101°F (38.3°C) or an axillary temperature of at least 100°F (37.8°C) documented either in the emergency department or in the history").

However, axillary measurements are simply not relevant in this case, as James' temperature was recorded orally and rectally on the second emergency room visit. James' rectal temperature was 99.9°. Petitioner's own exhibit asserts, "[r]ectal temperatures are generally thought to be the most accurate," at least with respect to a "young child." *See* Pet. Ex. 19. A rectal temperature of 99.9° is insufficient to qualify as febrile.

Doctor Shinnar opined that James was not febrile at the time of the seizures, but more importantly, he opined James did not have a febrile illness and was too old to experience "complex febrile seizures." Tr. at 126-27, 130, 133-136, 144. Doctor Shinnar testified that "febrile illness implies that you have a sustained temperature … that could take weeks or many days" (Tr. at 135), and even the peak recorded temperature of 100° did "not constitute a fever" (Tr. at 133, 196-97; *see also* Res. Exs. A at 4; C at 2). James' 100° temperature was taken at 4:00 PM, "which is when you would expect the peak temperature" based on normal daily fluctuation alone.[26] Tr. at 133. Doctor Shinnar acknowledged that the emergency room triage note indicated "fever" (*see* Pet. Ex. 9, p. 6), but opined that this temperature would be too low to provoke a seizure. Tr. at 134; Res. Ex. C at 2.

I find, based on the temperature readings, plus the triage note reflecting "fever" (Pet. Ex. 9, p. 6), that James had a slightly elevated temperature after his second seizure. James' temperature was slightly above normal at the time he arrived at the hospital.

The uncontroverted evidence demonstrates that body temperature typically rises in the afternoon and that seizures themselves may produce a transient rise in temperature. *See* Tr. at 61, 66 (testimony of Dr. Kinsbourne); *id.* at 134, 136 (testimony of Dr. Shinnar). The fact that James remained afebrile and displayed no signs of illness

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[26] An example of fluctuation in periodically recorded temperatures appears at Pet. Ex. 9, p. 14. James' temperature was taken as a part of his other vital signs at 15-minute intervals during his emergency room stay after his second seizure. The chart shows that James' temperature fluctuated between 97° and 100° in the more than two hours he spent in the emergency room. His temperature rose and fell throughout this period, but never rose above the 100° temperature recorded initially.

throughout his hospitalization also demonstrated that the slight elevation in his temperature was not indicative of a febrile illness. Pet. Ex. 9, pp. 17-18.

Assuming, *arguendo*, that James did have a slight fever at the time of the second seizure, the significance, if any, of this fever is dependent on the medical expert opinions below. Doctor Kinsbourne relied on James having a fever at the time of both seizures for his opinion on causation. Tr. at 57-59.

C. Causation Issues and Opinions.

1. The Matters in Controversy.

Prior to the causation hearing, the parties stipulated that the issues in dispute included two questions: (1) whether the Td vaccine caused James' initial seizures and (2) whether the subsequent epilepsy was the result of these initial seizures. Joint Pre-Hearing Submission filed June 9, 2010.

Petitioner argues forcefully that respondent conceded *Althen's* first prong in this case. Pet. Post-Hearing Br. at 2. Respondent's submissions do not include any concession. *See, e.g.*, Respondent's Post-Hearing Brief, filed Oct. 5, 2010 ["Res. Post-Hearing Br."] at 12. The initial question in dispute listed in the stipulation includes both the "Can it cause?" and "Did it cause?" formulation of *Althen*'s first two prongs, because the "Did it cause?" formulation necessarily includes the answer to the "Can it cause?" question. If it did, it can.

Perhaps some of petitioner's confusion regarding the first *Althen* prong—the requirement for a reliable medical theory—stems from how questions regarding the medical theory in this case are formulated. The answer to the "Can it cause?" question depends on the object of the question. If the question is, "Can a Td vaccination cause fever?", the answer is clearly that it can. *See* AMERICAN ACADEMY OF PEDIATRICS, RED BOOK: 2006 REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES 518-20 (27th ed. 2006) ["Red Book 2006"] at 519, filed as Res. Ex. D. If the question is "Can fever provoke seizures?" the answer in the abstract is again "Yes, it can." *See* ILAE Guidelines, Res. Ex. A23 at 593. If the question is formulated as "Can seizures cause more seizures, in the form of a seizure disorder?" the answer is also "Yes, they can." *See, e.g.*, J. Annegers, et al., *Factors Prognostic of Unprovoked Seizures after Febrile Convulsions*, NEW ENGL. J. MED. 316(9): 493-98 (1987) ["Annegers"] at 496, filed as Res. Ex. A21 and as Pet. Ex. 15.

However, these are simplistic formulations of increasingly complicated and nuanced medical matters. For example, in the "Can fever cause seizures?" question, the more nuanced and correct answer is, "Yes, provided the fever is high enough." *See*

S. Shinnar & T. Glauser, *Febrile Seizures, in* PEDIATRIC EPILEPSY: DIAGNOSIS AND THERAPY 293 (J. Pellock, et al. eds., 3d ed. 2008) ["Shinnar & Glauser"], filed as Res. Ex. A10. The complete answer to the "Can seizures themselves cause a seizure disorder?" is "Very prolonged or complex seizures appear to predispose someone to subsequent seizure disorders, but brief febrile seizures do not." *See, e.g.*, S. Shinnar, *Do Febrile Seizures Lead to Temporal Lobe Epilepsy? Prospective and Epidemiological Studies*, *in* FEBRILE SEIZURES (T. Baram & S. Shinnar eds., 2002) ["Shinnar 2002"] at 89-94, filed as Res. Ex. A7.

An additional issue is how "conditional causation" fits into the *Althen* causation analysis. If the answer to the "Can it cause?" question is "Yes, but only when factors X, Y, and Z are present," are factors X, Y, and Z part of the reliable medical theory, or do they fit somehow into *Althen*'s prong 2, the logical connection between the vaccine and the injury, or both? Practically speaking, whether all the necessary conditions are met is what matters, whether they are part of the theory or part of the logical connection. If petitioner cannot show that the necessary conditions X, Y, and Z exist in his case, his causation in fact claim fails. Logically, however, as prong 1 of *Althen* is the medical theory, the necessary conditions for biological plausibility are encompassed in the medical theory.

I interpret the pre-hearing stipulation, the arguments in the post-hearing briefs, and all of the evidence submitted in light of this analysis. Respondent, through the testimony of her expert, Dr. Shinnar, conceded that a Td vaccine can cause fever; a febrile illness can provoke febrile seizures in young children; and young children who experience complex febrile seizures have an increased risk of developing subsequent seizure disorders. However, he qualified the increased risk by explaining that the length of the febrile seizure is the primary factor that predisposes a child to develop a subsequent seizure disorder.

Doctor Kinsbourne formulated the causation equation somewhat differently, in asserting that complex febrile seizures alone predispose someone to a subsequent seizure disorder. I find Dr. Shinnar's opinions about the causal connection between febrile seizures and subsequent seizure disorders more persuasive and reliable that those of Dr. Kinsbourne, in view of Dr. Shinnar's considerable expertise in the diagnosis and treatment of such disorders, his research credentials in the field, and the medical literature filed by both parties.

Ultimately, however, even under Dr. Kinsbourne's formulation of the causation chain in this case, petitioner's case fails, because the factual predicate for Dr. Kinsbourne's opinions is lacking. In the following sections, I break down Dr. Kinsbourne's causation opinion into its component parts and compare its elements against the evidence.

As concisely stated in his pre-hearing brief, "petitioner contends that the tetanus vaccine administered to James caused an adverse immunological response that resulted in an injection site reaction and a fever, which then caused a seizure. James [sic] seizure then led to numerous other seizures. James [sic] initial seizure, and subsequent seizures, had adverse neurological consequences, namely an encephalopathy." Petitioner's Pretrial Memorandum, filed June 9, 2010, at 2.[27] Petitioner also contended that James' first seizure was a febrile event. *Id*. The evidence in support of these contentions consisted primarily of the opinions of three treating doctors and Dr. Kinsbourne.

2. Petitioner's Evidence.

a. Treating Doctors.

In support of causation in fact, petitioner points to the opinions of three physicians who saw James at SAH on the day of his initial seizures, Drs. Llobet and Schultz in the emergency room and Dr. Yang on admission to the pediatric ward. Each attributed the seizures to the tetanus vaccination, with Dr. Llobet indicating that seizures were a listed side effect of the vaccine[28] (Pet. Ex. 9, p. 32); Dr. Schultz providing no rationale for his opinion (*id.,* p. 13), and Dr. Yang erroneously attributing the seizures to a reaction to horse serum in the vaccine (*id*., p. 21). Doctor Kinsbourne indicated that Dr. Yang was misinformed on this point, as no horse serum is used in the Td vaccine. Tr. at 75-76; *see also* Res. Post-Hearing Br. at 22.

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[27] Although Dr. Kinsbourne referred to a comment in one of Dr. Miner's records reflecting that James had "encephalopathy" (Pet. Ex. 14 at 2 (citing Pet. Ex. 11, p. 15)), he did not appear to rely directly on the tetanus vaccine producing a causation-in-fact encephalopathy. *See* Pet. Ex. 14 at 3. Instead, he seemed to be using the term to refer to the alteration in James' mental status as reported by James' mother. Doctor Kinsbourne opined that this was due to brain damage caused by the seizure disorder. However, he agreed that an encephalopathy could be temporary. Tr. at 85. Doctor Shinnar disagreed that this entry reflected brain damage; he testified that Dr. Miner's records described a drug side effect, and noted that Dr. Miner changed James' medication in response. Tr. at 159. As Dr. Miner never again used the term encephalopathy to refer to James' condition, I conclude that Dr. Shinnar's interpretation was correct.

[28] Doctor Llobet did not indicate what references she consulted. This is significant because tetanus vaccinations are often given in conjunction with pertussis vaccinations, in a formulation known as DTaP, DTP, or Tdap. The Td vaccine James received does not contain pertussis. Unlike the pertussis containing vaccines, such as Tdap, there are no contraindications or precautions against administration of a Td vaccine to a child or adolescent with a history of seizures. *See* Red Book 2006, Res. Ex. D at 519; *see also* Tr. at 67-70 (testimony of Dr. Kinsbourne, acknowledging that the Red Book 2006 indicates that those with encephalopathy, coma, or prolonged seizures can receive Td vaccines). I note that the only reference that mentioned that seizures were associated with tetanus vaccines was Pet. Ex. 16 at 4 and 12, which is discussed in more detail below.

These treating physicians' opinions were countered by that of Dr. Miner, the neurologist who treated James after the two initial seizures, and who diagnosed James' epilepsy.[29] He also noted the temporal proximity of the Td vaccination to the onset of James' initial seizures, but he recorded that James' seizures were of "unclear etiology." Pet. Ex. 8, p. 1. Like the other treating physicians, he did not provide any reasons for his conclusion, but even Dr. Kinsbourne conceded that a neurologist would be better qualified to diagnose the cause of seizures than physicians with less specialized training. Tr. at 72.

Although entitled to weight (*see Andreu*, 569 F.3d at 1375), the three treating physicians' opinions added little to Dr. Kinsbourne's opinion.

b. Doctor Kinsbourne's Hypothesis.

Petitioner's "Can it cause?" case is based primarily on Dr. Kinsbourne's testimony and report. His opinion can be broken down into two parts, the first dealing with the cause of the initial seizures, and the second dealing with the cause of the subsequent seizure disorder. His hypothesis on the cause of the initial seizures is that they were the result of a febrile reaction to the tetanus component of the Td booster that James received the prior day. *See* Pet. Ex. 14 at 2-3; Tr. at 12, 20-23, 31-32. For the second part of the causation chain, establishing that James' epilepsy was caused by his initial seizures, Dr. Kinsbourne opined that the initial seizures were "complex febrile seizures." Pet. Ex. 14 at 2; Tr. at 57, 92. He also opined that those who experience complex febrile seizures are at a substantially increased risk of subsequently developing seizure disorders. Tr. at 48-53, 101-02.

Thus, petitioner's causal chain is that: (1) the tetanus vaccination provoked a febrile response;[30] (2) the fever caused seizures; (3) these seizures met the definition of complex febrile seizures; (4) complex febrile seizures are likely to lead to a seizure

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[29] On October 7, 2005, James had two unprovoked seizures on the same day. Pet. Ex. 9, p. 59. This resulted in James' diagnosis with epilepsy (*see* Pet. Ex. 8, p. 11). This diagnosis is itself evidence that Dr. Miner did not consider the earlier two seizures, occurring on the same day, to be febrile (provoked) seizures. The diagnostic criterion for epilepsy is two or more unprovoked seizures occurring at least 24 hours apart; in this case, the August 18th seizures were counted as one unprovoked seizure and the October 7th seizures counted as the second unprovoked seizure. *See* A. Berg, et al., *Newly Diagnosed Epilepsy in Children: Presentation at Diagnosis*. EPILEPSIA 40: 445-52, 446 (1999), filed as Res. Ex. A18. I note that Dr. Shinnar was one of the co-authors of this article. *See also* ILAE Guidelines, Res. Ex. A23, at 593 (setting forth the same definition).

[30] Febrile seizures are often referred to in expert reports and medical literature as "provoked" seizures, meaning that the fever provoked the seizure. Tr. at 49-50; *see also* ILAE Guidelines, Res. Ex. A23 at 594.

disorder; and (5) they did so in James' case. Additionally, in his second report, Dr. Kinsbourne stated that seizures and convulsions are a listed side effect of tetanus toxoid, citing to Pet. Ex. 16.[31] *See* Pet. Ex. 18 at 1. Each component of Dr. Kinsbourne's hypothesis is set forth in greater detail below.

Doctor Kinsbourne's opinion rested on the premise that James had a fever and, thus, febrile seizures. Without a fever, there could be no diagnosis of complex febrile seizures. Complex febrile seizures are a necessary foundation for Dr. Kinsbourne's causation opinion. Tr. at 57-59.

(1) The Tetanus Vaccine Provoked a Febrile Response.

The mechanism by which Doctor Kinsbourne opined that the tetanus vaccine produced fever was based on an inflammatory reaction at the injection site,[32] which indicated "an intense immune reaction, involving proinflammatory cytokines." Pet. Ex. 14 at 2-3; Tr. at 20. One such cytokine, known as interleukin 1β ["IL-1β" or simply "IL-1"] is a pyrogen (a fever-producing substance). S. Gatti, et al., *Mechanisms of Fever and Febrile Seizures: Putative Role of the Interleukin-1 System*, *in* FEBRILE SEIZURES (T. Baram & S. Shinnar eds., 2002) ["Gatti"] at 169-70, filed as Res. Ex. A24. According to Dr. Kinsbourne, IL-1 can provoke seizures in those with a lowered seizure threshold, even in the absence of a fever. Tr. at 21-23; *see* Gatti, Res. Ex. A24, at 180-81. He asserted in his report that proinflammatory cytokines were capable of "directly provoking epileptogenesis" (*see* Pet. Ex. 14 at 2-3), and he testified similarly that IL-1 can produce

[31] Petitioner's Exhibit 16 is a fact sheet, covering dose information, contraindications, drug interactions, and possible side effects for tetanus toxoid when administered as a single vaccination. It is not specific to the vaccine that James received, which was Td, a tetanus toxoid and diphtheria combination. The fact sheet's source is "Micromedex Healthcare Series, Drugdex Evaluations (2006)," according to Pet. Ex. 14 at 4. Doctor Kinsbourne testified that this is a document presenting drug evaluations. Tr. at 13. The neurological effects listed do include convulsions, but the exhibit specifies that these are complications "reported following the administration of tetanus toxoid" (Ex. 16 at 4), and it cites a product information sheet (*id.* at 4, 15), which is typically included in the packaging of a vaccine. Reports of events following vaccination, without additional evidence of a causal association, are unpersuasive as evidence that the vaccine can cause the injury. *See Stapleford v. Sec'y, HHS*, No. 03-234V, 2009 WL 1456441, at *11 (Fed. Cl. Spec. Mstr. May 1, 2009), *aff'd*, 89 Fed. Cl. 456 (2009); *Werderitsh v. Sec'y, HHS*, No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005). Petitioner's Exhibit 16 also advises patients to call their doctor if they experience anaphylaxis, fever, chills, muscle or joint pain, seizures, or other symptoms. *Id*. at 12.

[32] To some extent, Dr. Kinsbourne's view of the nature of the injection site reaction was factually incorrect. He relied upon redness at the injection site (*see* Pet. Ex. 14 at 3), but, once again, he misread the medical records. They reflected that the injection site was not red. *See* Pet. Ex. 9, pp. 13, 20.

seizures, even in the absence of fever[33] (Tr. at 23). However, his testimony made it clear that he was relying on the presence of fever for his opinion in this case. Tr. at 57-59. Doctor Kinsbourne testified that without fever or without complex seizures, he would not present an opinion favorable to causation. Tr. at 59.[34] In his second report, Dr. Kinsbourne opined that the time frame for seizures after vaccination in James' case was medically appropriate, but he did not explain why. Pet. Ex. 18 at 3; *see also* Tr. at 18.

(2) James' Fever Caused the Initial Seizures.

Doctor Kinsbourne testified that James' fever caused the initial seizures. Tr. at 32, 57-59, 94. This is an exceedingly weak link in Dr. Kinsbourne's causal chain as he proffered nothing more than his opinion that James' fever was sufficient to cause seizures in someone with a lowered or reduced "seizure threshold." Tr. at 89-90, 93-94. I found no evidence that James had a fever at the time of his initial seizure, and, at best, only a slight fever after his second seizure.

Likewise, there is no evidence that James had a lowered seizure threshold. No childhood medical record reported seizures with earlier fevers. *See generally* Pet. Exs. 8, pp. 30, 33-34; 9, p. 2 (reporting febrile illnesses, but no reports of seizures). Although he was on anti-seizure medication, he nevertheless continued to experience breakthrough seizures. *See*, *e.g.*, Pet. Ex. 13, pp. 14-15 (visit on June 1, 2007, reporting additional seizures); Pet. Ex 8, p. 21 (reporting seizure in mid-May, 2006). In spite of the history of breakthrough seizures, James did not experience seizures with a febrile illness he developed on February 6, 2007. *See* Pet. Ex. 6, pp. 35-36 (103° fever recorded and a history of two days of febrile illness). To rely on the initial seizures themselves as evidence of a lowered seizure threshold would be circular reasoning.

(3) James' Initial Seizures were Complex Febrile Seizures.

In his expert report as well as his testimony, Dr. Kinsbourne opined that the two initial seizures "collectively meet the definition of complex febrile seizures." He defined complex febrile seizures as seizures that are provoked by fever and: (1) that are partial

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[33] I note that this testimony was based on a rat study. Tr. at 23. *See* Gatti, Res. Ex. A 24 at 180-81. Doctor Shinnar agreed that IL-1 injected directly into the brain of rats could cause seizures, as the article stated, but commented that this article was misleading on this point because simply "heating" the rats to raise their body temperature also produced seizures. Tr. at 145-46.

[34] Doctor Kinsbourne also said that without fever, the vaccine "might have caused" the seizures, "but I'm not presenting that case to the court at this time." Tr. at 58. "Might have caused" is not "more probable than not."

in onset; (2) that last longer than 10-15 minutes; or (3) those in which there are multiple seizures within a 24-hour period.[35] Pet. Ex . 14 at 2; Tr. at 48-52.

Because James had a second seizure with focal features[36] within a few hours of his first seizure, followed by secondary generalization, and because he believed that James had a fever at the time of his first seizure, and had a "low-grade fever" in the emergency department after his second seizure, Dr. Kinsbourne opined James had complex febrile seizures. Pet. Ex. 14 at 2; Tr. at 51-52.

(4) Complex Febrile Seizures Can Cause Epilepsy.

Relying on the Annegers study,[37] filed by both parties, Dr. Kinsbourne opined that individuals who experience complex febrile seizures are at a significantly increased risk of developing seizure disorders. Tr. at 49-54. He asserted that "[c]omplex febrile seizures are well known to be associated with the risk of subsequent recurrent seizures, meeting the definition of epilepsy," and noted that subsequent unprovoked (afebrile) seizures "represent[] the interaction of the provocative event with an underlying seizure predisposition." Pet. Ex. 14 at 3.

Even viewing the medical records as Dr. Kinsbourne does, James had only two of the three criteria for complex febrile seizures (focal in nature and two seizures within 24 hours) necessary to raise the risk of a subsequent afebrile (unprovoked) seizure. With two complex features, the Annegers study found the risk of a subsequent unprovoked seizure to be between 17-22%. Res. Ex. A21 at 495.

(5) Therefore, James' Epilepsy was Caused by the Td Vaccine.

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[35] Doctor Kinsbourne relied on a publication co-authored by Dr. Shinnar for these diagnostic factors. *See* A. Berg & S. Shinnar, *Complex Febrile Seizures*, EPILEPSIA 37(2): 126-33 (1996) ["Berg & Shinnar"], filed as Res. Ex. A4.

[36] A focal seizure is one that originates in a specific area of the brain, and results in seizures that involve only one body part or one side of the body. A focal seizure may progress to a generalized seizure, one involving both sides of the body. Tr. at 37-38. James' inability to speak after his first seizure suggested that the seizure originated in the left hemisphere of his brain. Tr. at 33-35. Based on Ms. Loudermilk's description of James as initially looking upward and to the right, Dr. Kinsbourne opined that the second seizure also began in the left hemisphere of James' brain. Tr. at 40-41.

[37] *See* Annegers, Res. Ex. A21 at 495. The risk of subsequent afebrile (unprovoked) seizures after an initial febrile seizure ranges from 2.4% in children who had simple febrile seizures to 49% in children who had three complex features associated with their initial febrile seizure (focal in origin, prolonged seizures, and repeated seizures in conjunction with the initial febrile illness).

Doctor Kinsbourne attributed the subsequent epilepsy to the initial seizures, opining that "the tetanus vaccination of August 17, 2005 caused or triggered James Holmes' generalized epilepsy." Pet. Ex. 14 at 3; *see also* Tr. at 51-54. According to Dr. Kinsbourne, James suffered a brain injury caused by events "unleashed" by his Td vaccination and the complex febrile seizures that followed. This resulted in the subsequent seizures and the epilepsy diagnosis rendered some two months after the initial seizure. Tr. at 54, 93-94.

3. Respondent's Case.

Respondent relied on the expert reports and testimony of Dr. Shinnar. Although there were some aspects of Dr. Kinsbourne's testimony and reports with which Dr. Shinnar concurred,[38] he disagreed with most of Dr. Kinsbourne's assertions about seizure disorders in general and James' disorder in particular. He emphatically disagreed with Dr. Kinsbourne on the central issue of causation, testifying that there was no causal relationship between the Td vaccination and either James' initial seizures or his subsequent epilepsy. Tr. at 124-25.

In contrast to Dr. Kinsbourne's generalizations, Dr. Shinnar's opinions were careful, nuanced, and supported by the medical literature filed, much of which he authored. His opinions reflected his considerable experience in studying and treating seizure disorders. Doctor Shinnar differentiated febrile seizures from epilepsy. *See generally* Tr. at 130, 146-47, 151-54, 199. Febrile seizures result from febrile illnesses in childhood. Tr. at 130, 146. Epileptic seizures can be provoked by acute central nervous system insults, including infection, stroke, and trauma, but can also be unprovoked, resulting from static encephalopathy caused by earlier infection, stroke or trauma, genetic defects, or may be of unknown etiology. ILAE Guidelines, Res. Ex. A23 at 594; *see also* Tr. at 174 (trauma); 177 (neurological abnormalities and unknown etiology).

Because I found that James had no fever at the time of his initial seizure; that he had, at most, a temperature of 100° after his second seizure; and that he did not have a febrile illness either before or after either seizure, Dr. Kinsbourne's opinion on causation lacks a factual basis. It was clear that Dr. Kinsbourne misread the medical records in forming his conclusion that James was febrile at the time of the first seizure and had an "elevated" temperature at the time of the second seizure. This mistake alone justifies

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[38] Doctor Shinnar agreed that IL-1 causes fever in humans (Tr. at 143-44); that James' initial seizures were focal, with secondary generalization (Tr. at 126, 156); and that those children who have complex febrile seizures have a higher incidence of subsequent epilepsy, although he did not agree that there was a causal relationship between the two conditions (*see* Tr. at 196-98).

rejecting Dr. Kinsbourne's opinion. *See Perreira v. Sec'y, HHS*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it.").

However, because Dr. Kinsbourne, in effect, diagnosed James as having complex febrile seizures, I set forth Dr. Shinnar's contrary medical opinion to explain my conclusions on the issue of causation. I am mindful that special masters do not diagnose; they rely on medical professionals to do so. In accepting Dr. Shinnar's opinion that James did not have complex febrile seizures, I necessarily reject Dr. Kinsbourne's causation opinion, which was predicated on his contrary diagnosis. *See* Tr. at 57, 59. Doctor Shinnar concluded that James was not febrile during either seizure, but he also addressed other problems with Dr. Kinsbourne's diagnosis.

Doctor Shinnar's successful refutation of Dr. Kinsbourne's diagnosis of complex febrile seizures, and his other testimony undercutting Dr. Kinsbourne's causation opinion, are set forth in more detail below.

a. James Did Not Have Complex Febrile Seizures.

Doctor Shinnar defined febrile seizures as those "occurring in infancy and childhood associated with febrile illness." Tr. at 126-27. Unlike Dr. Kinsbourne's largely unsupported opinion that adolescents could have febrile seizures, the medical literature, including literature authored by others, supported Dr. Shinnar's definition. *See, e.g.*, ILAE Guidelines, Res. Ex. A23 at 593; National Institutes of Health Consensus Development Conference, *Febrile Seizures* 3(2) (1980) ["NIH Consensus Development Conference"] at 1, filed as Res. Ex. A22.[39]

For a seizure to be classified as febrile, the child must have a fever of 101° Fahrenheit (or 38.4° Centigrade), although the fever may not be evident until after the seizure, when the underlying febrile illness manifests. Shinnar & Glauser, Res. Ex. A10 at 293; A. Berg, et al., *Childhood-onset epilepsy with and without preceding febrile seizures*, NEUROLOGY 53: 1742-48, 1743 (1999), filed as Res. Ex. A6; *see also* Tr. at 130, 133. The mean temperature in the illnesses that provoke febrile seizures is 103-104°. Tr. at 130, 133-34. The lowest temperature used in any study of febrile seizures and their sequelae is 100.4°, a higher temperature than any that James experienced. Tr. at 133-34.

More significantly, true febrile seizures occur only in the context of a febrile illness, not simply a fever. Tr. at 146; ILAE Guidelines, Res. Ex. A23 at 593; *see also*

[39] I note that this exhibit does not contain internal pagination, and the exhibit was not paginated prior to filing. Accordingly I refer to its pages by the .pdf page number.

NIH Consensus Development Conference, Res. Ex. A22 at 3. There was no evidence whatsoever that James had any illness in the period before or after his initial seizures.

Doctor Shinnar also emphasized that febrile seizures are a disorder of childhood, not adolescence. Tr. at 127-29. The median age of onset for the condition is 18 months of age. Onset above seven years of age is rare. In the Annegers study, Res. Ex. A21, upon which Dr. Kinsbourne relied, only 12% of the children were older than three years of age. Tr. at 127-28; *see* Annegers, Res. Ex. A21 at 495. Doctor Shinnar testified that in the studies of febrile seizures, 99% of the children were below seven years of age. Tr. at 127-28. In Dr. Shinnar's own research on several thousand children, the oldest children to experience a febrile seizure were nine years old and 12 years old, and researchers debated whether those were truly febrile seizures or something else. *See* Tr. at 127-28, 132-33. A peer reviewer criticized the inclusion of children over five years of age in his studies (Tr. at 128-29), indicating the opinion of experts in the field that febrile seizures occur only in the very young. That febrile seizures are a disorder of early childhood was a proposition well supported by the medical literature filed by both parties. Although children aged 10 years and older may have seizures in the presence of fever, the vast majority of those already have a seizure disorder; the fever is a trigger, not a cause. Adolescents such as James may experience febrile illnesses, but they do not experience febrile seizures in the absence of an underlying seizure disorder. Tr. at 129-32.

In summary, Dr. Shinnar opined that James was neither febrile nor experiencing a febrile illness at the time of or shortly after his initial seizures. *See* Tr. at 133. If James had been considered for inclusion in any study of seizures, he would have been classified as having had a first unprovoked (afebrile) seizure. Tr. at 134-35; *see also* Res. Ex. A at 3.[40] James was too old to meet the parameters of the studies of complex febrile seizures, and thus the studies that predicted increased risk of subsequent seizures were inapplicable to his case. Res. Ex. A at 3-4; *see also* Tr. at 136. Based on James' age and the characteristics of his seizures, Dr. Shinnar opined that James' initial seizures were the first manifestation of his epilepsy. Res. Ex. A at 3; Tr. at 158, 189-90.

[40] The pages of Res. Ex. A, the report of Dr. Shinnar, were not numbered. Page references begin with the page containing Dr. Shinnar's letterhead as page 1, and conclude with page 8, which contains references 14-26.

b. Other Evidence Undercutting Dr. Kinsbourne's Opinion.

In addition to demonstrating that Dr. Kinsbourne's diagnosis of complex febrile seizures was incorrect, Dr. Shinnar provided other compelling testimony undercutting petitioner's cause-in-fact case.

(1) No Causal Relationship between Tetanus Vaccine and Epilepsy.

Doctor Kinsbourne relied on Pet. Ex. 16 to establish that the tetanus vaccine can cause seizures. Pet. Ex. 14 at 3. Doctor Shinnar testified that Pet. Ex. 16 was not reliable evidence of causation. The exhibit appeared to be based on nothing more than case reports, which, as Dr. Shinnar acknowledged, may be useful in describing causal relationships when they deal with rare occurrences. As neither tetanus vaccinations nor seizures are rare, with about 90% of adolescents receiving a tetanus booster vaccination, a case report of a seizure in close temporal proximity to a tetanus vaccination is useless as evidence of a causal relationship.[41] Tr. at 139-42. Furthermore, a causal relationship is unlikely in view of the fact that tetanus vaccines are recommended for administration to individuals with seizure disorders. *See* Red Book 2006, Res. Ex. D at 519; *see also* Tr. at 67-69 (testimony of Dr. Kinsbourne, acknowledging that the Red Book 2006 indicates that those with encephalopathy, coma, or prolonged seizures can receive Td vaccines).

In one of the more nuanced portions of his testimony, Dr. Shinnar acknowledged that in a young child, vaccines can cause a fever, and thus, in some very young children, a tetanus vaccine might provoke a febrile seizure. *See* Tr. at 198-201. Because Pet. Ex. 16 did not differentiate based on age, the comment on page 4 of the exhibit regarding convulsions had little applicability to James' case. If James had been an infant and had developed a fever within a day or two of his vaccination, Dr. Shinnar would agree that the vaccine provoked the febrile seizure by causing the fever. However, he would still disagree that the febrile seizure was responsible for any subsequent epilepsy, absent evidence of a very prolonged seizure. Tr. at 198-201.

[41] *See Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053, at *36 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed. Cl. 126 (2010) (citing the Federal Judicial Center's *Reference Manual on Scientific Evidence* for the proposition that case studies as proof of a causal association "must be regarded with caution").

(2) No Causal Relationship Between Short Febrile Seizures and Epilepsy.

Assuming, *arguendo,* that James did have a fever, Dr. Shinnar disagreed that short febrile seizures could cause epilepsy. Tr. at 190-91. He asserted that the primary factor that affects the likelihood of developing a subsequent seizure disorder after initially febrile seizures is the duration of the seizure. Very prolonged seizures, which he defined as those exceeding 30 minutes in length[42] (often referred to as "status epilepticus"),[43] may produce brain injury, and it is the brain injury that results in the later epilepsy. Res. Ex. A at 4; Tr. at 197-201. A review of the filed medical literature supports Dr. Shinnar's testimony. *See, e.g.*, Shinnar 2002, filed as Res. Ex. A7 at 89-94; Shinnar & Glauser, Res. Ex. A10, at 295.

Very prolonged febrile seizures are specifically linked to temporal lobe epilepsy. Tr. at 187-88; C. Dubé, et al., *Interleukin-1β Contributes to the Generation of Experimental Febrile Seizures*, ANN. NEUROL. 57: 152-55 (2005) ["Dubé"], filed as Res. Ex. A25. In about 10-15% of children with very prolonged febrile seizures, an MRI or CT scan performed within 72 hours will show acute changes in the brain. Tr. at 189. These brain lesions may eventually produce epilepsy. James did not have temporal lobe epilepsy, nor were his seizures prolonged. Tr. at 51-52, 201-02.

Doctor Shinnar also pointed to variability in the rates of febrile seizures in the United States and Japan as one piece of evidence that short febrile seizures do not cause epilepsy, in addition to epidemiological studies that he and others conducted. In Japan, about 9% of children experience febrile seizures; in the United States, about 3% of children do so. Nevertheless, the rates of epilepsy in children in both countries are the same. Tr. at 197; *see also* Shinnar 2002, Res Ex. A7 at 89.

(3) The IL-1 Hypothesis is not Supported by the Medical Evidence.

Doctor Kinsbourne identified IL-1 as the biological mechanism by which James' initial seizures were produced. He relied on the local inflammatory reaction on James'

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[42] Some studies categorized shorter periods of seizures as "prolonged," but all of the periods used were longer than the self-limited initial seizures that James experienced. *See, e.g.*, A. Berg, et al., *Classification of Complex Features of Febrile Seizures: Interrater Agreement*, EPILEPSIA 33(4): 661-66, 662 (1992), filed as Res. Ex. A2 (characterizing a prolonged seizure as lasting 10 minutes or more).

[43] The Berg & Shinnar study, Res. Ex. A4, used seizure length of greater than or equal to 30 minutes in length to define status epilepticus. *Id.* at 127. *See also* ILAE Guidelines, Res. Ex. A23, at 593 (defining status epilepticus as a single seizure of longer than 30 minutes in duration or a series of seizures between which function is not regained lasting collectively longer than 30 minutes).

arm to demonstrate that IL-1 was being produced, and was therefore available to cause James' seizures. Tr. at 20-26.

Doctor Shinnar candidly acknowledged that part of Dr. Kinsbourne's causal chain was correct, in that the release of sufficient quantities of IL-1 can cause fever and produce seizures, citing to a chapter in a book he edited.[44] However, he also asserted that there had to be enough IL-1 present to produce a systemic febrile reaction before seizures occur. *See* Tr. at 144-45; Res. Ex. A at 4. He explained that the inflammatory reaction at the vaccination site was not sufficient to demonstrate enough IL-1 present to cause a seizure, because there was no evidence of a systemic febrile reaction. Tr. at 143.

Furthermore, even when there is sufficient IL-1 to produce a fever in an infant or young child, much larger quantities are needed to produce fever in an adolescent or an adult. The immature brain responds to IL-1 differently from the older brain. Tr. at 147-48. In discussing the rat study that Dr. Kinsbourne relied upon for his IL-1 hypothesis, Dr. Shinnar explained that there is an order of magnitude difference between chemicals that can trigger seizures in infant rats and those needed to do so in adolescent or older rats. He also noting that heating an immature rat to 39° Celsius would produce the same seizure effect. Tr. at 145-48.

Both expert witnesses agreed that James' initial seizures were focal seizures, with secondary generalization. According to Dr. Shinnar, the focal nature of these seizures also made the IL-1 theory advanced by Dr. Kinsbourne unlikely because IL-1 is a systemic cytokine. A systemic cytokine released by inflammation in James' arm after the vaccine would affect the whole brain, not just one region alone, and would thus be unlikely to cause focal seizures. *See* Tr. at 151-52.

(4) Focal Seizures are Associated with Epilepsy.

One of the causes of epilepsy is damage to particular areas of the brain. For this reason, focal seizures—seizures that originate in a particular region of the brain—are themselves associated with an increased risk of epilepsy because they reflect an underlying focal brain abnormality. Tr. at 151-52, 198-99.

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[44] Gatti, filed as Res. Ex. A24. The book chapter discussed the cytokine IL-1β as the most potent endogenous pyrogen (fever producer). *Id*. at 170-71. A second reference by some of the same authors indicated that IL-1β could bind to certain brain receptors, producing a decreased seizure threshold. *See* Dubé, Res. Ex. A25 at 154-55.

(5) Timing.

According to Dr. Shinnar, the timing of James' October, 2005 seizures, which led to his diagnosis of epilepsy, would be too soon for the onset of epilepsy after febrile seizures. Res. Ex. A at 4. The usual latency period to develop epilepsy is 8-11 years. *Id.*; Shinnar 2002, Res. Ex. A7 at 95. He also opined that a number of epilepsy syndromes have onset in adolescence, a point with which Dr. Kinsbourne concurred. Res. Ex. A at 5; Tr. at 70-71,105.

IV. Conclusion.

This case was more a rout than a "battle of the experts." Most of the "facts" upon which Dr. Kinsbourne relied were not established; he either misread or misinterpreted the medical records. Furthermore, Dr. Kinsbourne lacked the research qualifications and clinical expertise in diagnosing and treating febrile seizures and epilepsy to prevail over an opposing expert with truly impressive qualifications in these areas.

Doctor Kinsbourne has been criticized in the past for extrapolating from studies of the DPT vaccine to the DTaP vaccine. *See, e.g.*, *Tembenis v. Sec'y, HHS*, No. 03-2820V, 2010 WL 5164324, at *8 n.9 (Fed. Cl. Spec. Mstr. Nov. 29, 2010) (citing *Simon v. Sec'y, HHS*, No. 05-941V, 2007 WL 1772062, at *7 (Fed. Cl. Spec. Mstr. June 1, 2007)). Here, he extrapolated from studies of infants and young children, whom he acknowledged have brains that are very different from older children and adolescents (Tr. at 106), to apply their findings and conclusions to a seizure disorder in an adolescent.

Doctor Kinsbourne's opinions rested on faulty premises, both with regard to the medical records and the scientific research. Because James' initial seizures were afebrile seizures, they did not meet the clinical requirements for a diagnosis of complex febrile seizures. Based on James' age and the lack of any febrile illness, I find that the studies showing an increased risk of seizure disorders after complex febrile seizures are simply not relevant to his case. The facts and circumstances pertaining to James' initial seizures do not logically connect his case to the limited circumstances under which complex febrile seizures can result in subsequent seizure disorders. Thus, petitioner has failed to establish causation under *Althen*.

As petitioner has not demonstrated by a preponderance of the evidence that his condition was caused in fact by the Td vaccination he received on August 17, 2005, the petition for compensation is therefore **DENIED**. 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.

s/Denise K. Vowell
Denise K. Vowell
Special Master