OFFICE OF SPECIAL MASTERS
Not for Publication
No. 04-242V
May 13, 2005

* *
BRYANT ARMSTRONG, by his Mother, JENNIFER ARMSTRONG, and Father, TROY ARMSTRONG,
Petitioners,
v.
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent.
* *

Michael G. McLaren, Memphis, TN, for petitioners.
Alexis B. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

[1] Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

On February 23, 2001, petitioners filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that DPaT vaccination that Bryant Armstrong (hereinafter, "Bryant") received on July 11, 2001 caused him a Table encephalopathy[2] and seizure disorder. On August 27, 2004, petitioners filed an amended petition that Bryant's DPaT vaccinations on July 11, 2001 and January 2, 2002 caused in fact his injuries.

The undersigned did not hold a hearing in this case, which is within her discretion. Section 300aa-12(d)(3)(B)(i).

FACTS

Bryant was born on December 28, 2000. Bryant's mother was on antibiotics and was febrile at the time of delivery at Bolivar Medical Center. Med. recs. at Ex. 2, p. 3. Bryant was lethargic with a decreased heart rate and decreased respiratory effort at delivery. *Id.* His clinical status was highly suggestive of septicemia, but his laboratory results argued against it on December 29, 2000. Med. recs. at Ex. 2, p. 4.

On July 11, 2001, when he was six months old, he received his third acellular DPT vaccine. Med. recs. at Ex. 4, p. 1. Two days later, on July 13, 2001, Bryant was admitted to Bolivar Medical Center, where he remained for three days, until July 16, 2001. He had a febrile seizure, bilateral otitis media, and vomiting. He had a several day history of left otitis media as well as his six-month immunizations. He had been treated with Zithromax for five days. He came to the ER by EMS with generalized tonic-clonic seizure activity and a 101° temperature. Until the day of admission, he had been in his usual state of health. His mother picked him up at

[2] During a telephonic status conference on September 1, 2004, petitioners' counsel stated that Bryant did not have a Table encephalopathy.

daycare on July 13th and he seemed a bit more somnolent than usual. He was vomiting almost daily. Med. recs. at Ex. 5, p. 4.

On July 13, 2001, Dr. William F. McArthur, at Bolivar Medical Center, wrote that Bryant's seizure was most likely secondary to his fever, and his fever was likely secondary to bilateral otitis media. Med. recs. at Ex. 6, p. 2.

When the EMS personnel had picked up Bryant on July 13th, he had had a seizure and was hot to the touch. Med. recs. at Ex. 6, p. 19.

On July 18, 2001, Dr. McArthur noted that, every 30 to 60 minutes, Bryant had altered consciousness and upper extremity twitching. He was given Ativan. Bryant was a bit somnolent, but alert and would interact. Med. recs. at Ex. 7, p. 2.

Bryant was at the University of Mississippi Medical Center from July 19-20, 2001 under the care of Dr. Albert W. Richert, Jr. Med. recs. at Ex. 8, p. 1. Dr. Richert notes that in Bryant's initial hospitalization, on July 14, 2001, i.e., the second day, he had episodes of a blank look and staring for 30 seconds. Subsequently, after discharge, he looked lifeless and had an afebrile seizure of 52 minutes. Med. recs. at Ex. 8, p. 1.

On August 20, 2001, Bryant saw Dr. Owen B. Evans, who found him very alert, attentive, and developmentally ahead for his age. Med. recs. at Ex. 8, p. 11.

Bryant received his fourth acellular DPT on January 2, 2002, when he was one year old. Med. recs. at Ex. 4, p. 1. The next day, January 3, 2002, at 2:10 p.m., Bryant was brought to the ER at Bolivar, crying. Med. recs. at Ex. 11, p. 6. He was alert and oriented. The seizure lasted 30 seconds. *Id.* His temperature was 97.8°. Med. recs. at Ex. 11, p. 2. Bryant's father brought him in, complaining that Bryant had a seizure without aura. It was questionable whether Bryant

was post-ictal. *Id*. The Emergency Medical Services note of January 3, 2002 states that Bryant was having a seizure. Med. recs. at Ex. 11, p. 8.

On January 8, 2002, Dr. Evans noted that Bryant had a seizure the prior week associated with his immunizations. Dr. Evans thought the immunizations were coincidental. Bryant's growth and development were normal. He was awake, alert, and active. Med. recs. at Ex. 12, p. 1.

Submissions

Jennifer Armstrong submitted her affidavit, dated January 16, 2004. P. Ex. 36. She states that for the two days following his July 11, 2001 immunizations, Bryant ran a low-grade fever. She administered Motrin. On July 13, 2001, in the afternoon, when Bryant's father went to pick him up and sit him on the floor, Bryant leaned over and began having tonic-clonic movements of his upper and lower extremities. These were more on the right than on the left and lasted for about 30 minutes. They called an ambulance, which took him to Bolivar Medical Center where Bryant stayed until July 16, 2001. While at Bolivar, Bryant started having episodes where he would turn red, get a blank look, and stare for about 30 seconds. He had 20 to 25 of these episodes on July 14th and about 10 episodes on July 15th. On the day of discharge from the hospital, Bryant had 10 episodes.

On July 18, 2001, because Bryant, who continued to have these episodes, became very lethargic, he was brought back to Bolivar. He began having a seizure lasting approximately 52 minutes, consisting of left-sided arm and leg tonic-clonic movements with eyes deviated to the left. He was treated with Phenobarbital and Ativan. On July 19, 2001, Bryant was transferred to

the University of Mississippi Medical Center. An EEG on July 19th showed right hemispheric slowing.

On November 17, 2001, Bryant was admitted to Bolivar because of simple seizures starting the day before. At about 6:00 p.m. on July 17th, he had generalized tonic-clonic seizures. During the month of December 2001, Bryant had a cold. On January 2, 2002, Bryant received his fourth acellular DPT vaccination. The next day, January 3, 2002, Bryant began screaming, jerking all over, more on the left than on the right, had eye deviation to the left, and turned blue.

Troy Armstrong's affidavit, dated January 16, 2004, is similar to Jennifer Armstrong's affidavit. P. Ex. 37.

Jennifer Armstrong submitted a second affidavit, dated June 18, 2004, stating that when she began keeping a seizure journal in January 2002, she wrote that Bryant did not have a fever before his first seizure, but that was erroneous. P. Ex. 41.

Troy Armstrong's second affidavit, dated June 18, 2004, is similar. P. Ex. 42.

Petitioners filed the report of Dr. Marcel Kinsbourne, a pediatric neurologist, dated June 15, 2004. P. Ex. 43. He states that Bryant's 30-minute seizure two days after his third acellular DPT would have qualified him for inclusion in the National Childhood Encephalopathy Study or NCES (Alderslade, et al., 1981), which found a significant association between whole cell DPT and severe acute neurologic illness, including acute encephalopathy and seizures lasting more than 30 minutes. Bryant's fever also includes him in the Institute of Medicine (IOM) conclusion that DPT can cause chronic nervous system dysfunction (Stratton, et al., 1994, at 15). Dr. Kinsbourne concludes that pertussis vaccine caused Bryant's continuing refractory seizure disorder.

Respondent filed the report of Dr. Yuval Shafrir, a pediatric neurologist, dated October 7, 2004. R. Ex. A. Dr. Shafrir could not find a record of Bryant's third DPaT [it is in the medical records at Ex. 4, p. 1]. R. Ex. A, p. 3. He states that Bryant's fourth DPaT when he was 12 months old could not have been DPT and wonders if it were MMR. R. Ex. A, p. 7. [The medical records at Ex. 4, p. 1, show it to be DPaT.] Dr. Shafrir states that Bryant's fever was due to an acute infection. He said Bryant continued to suffer from severe ear infections after his initial hospitalization and ultimately required tympanostomy tubes, which did not control his ear infections. R. Ex. 1, p. 10. Dr. Shafrir states that it is much more likely that Bryant had a febrile convulsive status epilepticus on July 13, 2001 as a result of his acute infection than as a result of his vaccination. *Id.*

Dr. Shafrir continues that Bryant did not have an encephalopathy because, after recovering from his seizures, he was alert and playful, although he had episodes of staring. He calls Bryant's ear infection bilateral purulent otitis. Together with fever and vomiting, Dr. Shafrir views them as part of an acute illness that caused his febrile status epilepticus. He states that DPaT vaccine is much less likely to cause high fever. *Id*. He then goes on to say that medical literature shows how rare fever is after receiving DPaT compared to having bilateral purulent otitis. As support that an infection must have caused Bryant's July 13, 2001 fever, he refers to Bryant's subsequent course over the years of having viral illnesses and fever. He comments erroneously that Bryant did not receive pertussis at his 12-month vaccination. He further denies that even whole-cell DPT which causes febrile seizures can cause chronic seizure disorder.

His report is accompanied by seven medical articles in support of his assertions:

Tab 1: "Current Topic. Do seizures damage the brain? The epidemiological evidence," by C.M. Verity, 78 *Arch Dis Child* 78-84 (1978) (suggests that brain damage from prolonged seizure activity happens less frequently than was previously reported).

Tab 2: "A New Method for Active Surveillance of Adverse Events from Diphtheria/Tetanus/Pertussis and Measles/Mumps/Rubella Vaccines," by P. Farrington, et al., 345 *Lancet* 567-69 (1995) (found an increased incidence of convulsions up to three days post-DPT vaccination; this effect was limited to the third dose of vaccine [the July 11, 2001 DPaT was Bryant's third dose]).

Tab 3: "A Controlled Trial of Two Acellular Vaccines and One Whole-Cell Vaccine Against Pertussis," by D. Greco, et al., 334 *New Eng J Med* 6:341-48 (1996) (fever although infrequent after DPaT occurred significantly more often in DPaT-vaccine recipients than in DT-vaccine recipients [for one DPaT manufacturer, there were 988 cases of fever; for another DPaT manufacturer, there were 588 cases of fever; for whole-cell DPT, there were 5,425 cases of fever; for DT, there were 151 cases of fever]; there was even one case of seizures after DPaT compared to three cases of seizures after whole-cell DPT).

Tab 4: "The Risk of Seizures After Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine," by W.E. Barlow, et al., 345 *New Eng J Med* 656-61 (2001) (found significantly elevated risk of febrile seizures after DPT, but children with febrile seizures post-vaccination did not have a higher risk for subsequent seizures or neurodevelopmental disabilities than children with febrile seizures who had not been vaccinated; mentions one study finding the risk of febrile seizures after DPT was elevated during the first three days post-vaccination but only in association with the third dose [as in Bryant's case]).

Tab 5: "Risk of Seizures After Measles-Mumps-Rubella Immunization," by M.R. Griffin, et al., 88 *Ped* 5:881-85 (1991) (this is irrelevant since this case does not involve MMR).

Tab 6: "Convulsive Status Epilepticus in Children," by V. Gross-Tsur and S. Shinnar, 34 *Epilepsia* (Suppl. 1) S12-20 (1993) (fever causes epilepsy in 20-28% of children with status epilepticus; the authors call fever the sole acute provocation of status epilepticus in children and the child may be neurologically normal or abnormal; status epilepticus is very common in children with seizure onset before one year of age; 11-25% of children with status epilepticus will experience at least two episodes).

Tab 7: "Clinical Research. Short-Term Outcomes of Children with Febrile Status Epilepticus," by S. Shinnar, et al., 42 *Epilepsia* 1:47-53 (2001) (children with febrile status epilepticus were more likely to be neurologically abnormal; possible that there is a vulnerable subgroup of children in whom febrile status epilepticus is either a marker for preexisting damage and/or a cause of additional damage to an already vulnerable brain).

Petitioners filed the expert report of Dr. Thomas E. Long, a board-certified otolaryngologist, dated January 17, 2005. P. Ex. 46. Dr. Long states that Bryant's vaccination prior to his first seizure caused or was at least a substantial factor in contributing to the fever which preceded his first seizure. Bryant did not have an acute inflammatory process at the time of his seizure. In the absence of his vaccination, the fever and subsequent seizure would probably not have occurred. On July 3, 2001 (8 days before vaccination), Bryant's pediatrician, Dr. McArthur, diagnosed Bryant with an upper respiratory infection and otitis media. He prescribed Zithromax, which is normally taken for five days. It maintains therapeutic blood levels for 10 to 12 days after its initiation and is widely used for bacterial upper respiratory

infections and otitis media. Since Bryant had therapeutic blood levels of Zithromax when he received DPaT vaccine, he was adequately covered for his infection on July 13, 2001, the date of the initial seizure. Therefore, fever on July 13, 2001 seems less likely secondary to otitis media.

Dr. Long also comments that there is no indication that Bryant's tympanic membranes were red or swollen, which would indicate acute inflammation. He sees many children in his practice with pus contained in each middle ear space, and, in the absence of specific findings of acute inflammation, they do not vomit and have fever (signs of systemic illness). Dr. Long states that, although vomiting is a frequent accompaniment of otitis media, in the absence of acute inflammation, Bryant's vomiting was not likely to be caused by his middle ear effusion. P. Ex. 46, p. 2. He concludes that Bryant's DPaT most likely played a substantial role in causing the fever associated with Bryant's first seizure.

Petitioners filed Dr. Long's supplemental report, dated March 31, 2005. P. Ex. 48. He does not dispute that Bryant had purulent middle ear effusion, as noted by Dr. McArthur in his July 16, 2001 discharge summary. But purulent effusion is not by itself a sign of acute otitis media. Purulent effusion without acute inflammation does not cause fever. Dr. Long denies that there is compelling evidence that Bryant had acute otitis media on July 13, 2001.

In addition, Dr. Long does not dispute Dr. McArthur's finding that both of Bryant's tympanic membranes were injected. He just disputes that injected tympanic membranes confirm the presence of acute otitis media. "Injected" usually means blood vessels are dilated. That, to Dr. Long, is not a sufficient indication of acute otitis. Dr. McArthur's description does not fall within the classic findings of an acute otitis media, which is manifested by red and swollen

tympanic membranes. "Injected" most commonly describes dilated blood vessels commonly seen in tympanic membranes with or without middle ear effusion.

Dr. Long notes that Dr. McArthur is a pediatrician, not an otolaryngologist. Dr. Long has 26 years of practical experience in otolaryngology. He opines that Dr. McArthur's observations "simply do not describe the classical findings of acute otitis media which would be expected to be accompanied by a febrile response." P. Ex. 48, pp. 1-2. Dr. Long sees many patients who are not acutely ill, but have chronic purulent middle ear effusions.

Dr. Long concludes that Bryant's otitis media was not in an acute stage when the vaccination was given. Therefore, it would be highly unlikely for acute otitis to flare up while he was adequately covered by the antibiotic Zithromax. It is not unusual for purulent effusion to persist in the middle ear even when antibiotics are used. Bryant's vomiting could have been caused by many things, including the vaccination. Dr. Long again states that the DPaT played at least a substantial role in causing the fever associated with Bryant's first seizure. P. Ex. 48, at 2.

DISCUSSION

The Vaccine Act affords petitioners two theories of recovery, thereby allowing them to prove causation by showing that either: (1) a Table-injury occurred or (2) the vaccine was the cause-in-fact of the injury. The former theory is governed by Section 14(a) of the Act which contains a Vaccine Injury Table. If the injuries described in this Table occur within the statutorily defined time period, petitioners have proven the existence of a "Table-injury," creating a rebuttable presumption of causation.

Here, petitioners alleges a causation in fact seizure disorder as a result of Bryant's receiving acellular DPT vaccine. Petitioners are proceeding on a theory of causation in fact. To

satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioners must not only show that but for the acellular DPT vaccine Bryant would not have had seizures, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

Although the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), listed various criteria for the federal district court judges to follow in their role as gatekeeper for the admission of scientific and medical evidence, such criteria are merely aides in evaluation, rather than prescriptions, for the Office of Special Masters. Even in federal district courts, "Daubert's list of specific factors neither necessarily nor exclusively applies . . . in every case . . . [and its] list of factors was meant to be helpful, not definitive." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141, 151 (1999).

In the Office of Special Masters, even the Federal Rules of Evidence are not required.[3] Invariably, consistent with the legislative intent in creating the Vaccine Program, the special masters admit most evidence. But see, Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." Thus, the task before the undersigned is not to delineate how petitioners' evidence of seizure disorder does or does not satisfy the Daubert litany of support in peer-reviewed medical literature, concurrence among a majority of physicians in the fields of

[3] CFC Rules, Vaccine Rule 8(b) Evidence. "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties."

neurology and otolaryngology, and confirmative testing of methodology. Rather, the task is to determine medical probability based on the evidence before the undersigned in this particular case.

As for epidemiological support for causation, the Federal Circuit in Knudsen ruled for petitioners even when epidemiological evidence directly opposed causation from a vaccine. In Knudsen, even though epidemiological evidence supported the opposite conclusion, i.e., that viruses were more likely to cause encephalopathy than vaccinations, the Federal Circuit held that that fact alone was not an impediment to recovery of damages. In Knudsen, the Federal Circuit stated:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.

35 F.3d at 550.

So, too, in this case, although the medical literature establishes only that acellular DPT vaccine may cause adverse reactions in a small number of vaccinees, the theory underlying that causation is the same as all three doctors (Dr. Kinsbourne, Dr. Shafrir, and Dr. Long) expressed in this case: fever prompted Bryant's seizures. That Dr. Shafrir thinks it more likely that an acute otitis media would cause the fever than the DPaT is legally not persuasive because (1) the Federal Circuit in Knudsen rejected the very same reasoning; and (2) Dr. Long's opinion, standing unchallenged, is that Bryant's middle ear perfusion would not have caused fever.

From the beginning of this case, the undersigned queried whether this case were similar to Shyface, supra, i.e., were DPaT and otitis media both substantial factors in causing the fever that provoked Bryant's seizures? In Shyface, the Federal Circuit held that DPT and e.coli bacterial infection were both substantial factors in causing Cheyenne's fever which led to his death, and that, but for the DPT, he would not have had his high fever which led to his death.

Although the medical records per Dr. McArthur, a pediatrician, state that Bryant's fever was due to acute otitis media, petitioners filed a report from Dr. Long, an otolaryngologist with 26 years of experience, who stated that Bryant did not have acute otitis media, but rather a middle ear perfusion which would not have caused fever. Therefore, the only substantial factor causing his fever was DPaT vaccine. Here, then, there are not two substantial factors as in Shyface causing Bryant's fever which caused his seizure, just one: the DPaT.

Respondent declined the opportunity, in a status conference dated February 17, 2005, to provide a report from a specialist in ear infections, such as an ENT doctor or an otolaryngologist, who is even more specialized in ear infections, to counter Dr. Long's reports. Respondent chose to rely solely upon the records of the pediatrician Dr. McArthur and the expert medical report of Dr. Shafrir, a pediatric neurologist.

The permissible inference from respondent's failure to provide a contrary otolaryngologic report to Dr. Long's refutation that Bryant's middle ear perfusion caused his fever leading to his seizure is that, had respondent provided a report from an expert in ear infection, it would not have helped respondent's defense. McCormick on Evidence, 5th ed. (1999), § 264, discusses the permissible negative inference for failing to put on a witness: "When it would be natural under the circumstances for a party to call a particular witness... and the party fails to do so, tradition

has allowed the adversary to use this failure as the basis for invoking an adverse inference." [footnotes omitted].

Cases cited include Secondino v. New Haven Gas Co., 147 Conn. 672, 165 A.2d 598, 600 (1960) (personal injury plaintiff failed to call treating physician); Feldstein v. Harrington, 4 Wis.2d 380, 90 N.W.2d 566, 571 (1958) (defendant failed to call physician who examined plaintiff at defendant's request).

At the very least, the undersigned is left with a strong statement from an expert in ear infections who, with clear and persuasive reasoning, refutes the assumption in the medical records that Bryant had acute otitis media when he was taken to the hospital on July 13, 2001, and further that his ear infection was merely purulence (injection or dilation of blood vessels) which would not cause fever.

Respondent's expert Dr. Shafrir states that Bryant's ear infection is more likely to be the cause of his febrile seizure than the DPaT. He assumes Bryant had a severe ear infection on July 13, 2001 because, in Bryant's subsequent medical history, he had numerous ear infections. This is an untenable assumption. Just because Bryant had later ear infections does not mean that Bryant had an ear infection on July 13, 2001 sufficient to cause a fever.

Dr. Shafrir says that bilateral purulent otitis and vomiting are much more likely to cause febrile status epilepticus than DPaT and cites a medical article which shows the risk of fever after DPaT vaccination to be 43 to 72 in 1,000 administrations of two DPaT vaccines. However, the Federal Circuit in Knudsen stated that the fact that an infectious process may be more likely to cause, in that case, an encephalopathy, did not mean that DPT did not cause it in that case. Similarly, the fact that DPaT rarely causes fever does not mean that it did not do so in this case.

In Bryant's subsequent medical history, Dr. Shafrir states his seizures, especially his generalized tonic-clonic seizures, were typically associated with viral illness and fevers. This does not negate that the July 11, 2001 DPaT caused Bryant to have fever which provoked his seizures. It rather confirms that whatever causes Bryant to have a fever causes him to seize.

Dr. Shafrir then mistakenly concludes that Bryant's 12-month vaccination did not include pertussis, and ponders whether it might have been MMR, an erroneous assumption. *Id*. He proceeds to a discussion that even whole-cell DPT, which causes fever, does not cause chronic seizure disorders. The undersigned has ruled contrary to this point on numerous occasions. See, e.g., McMurry v. Secretary of HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. 1997) (whole-cell DPT caused fever causing seizure disorder). In fact, the undersigned has also ruled that acellular DPT, if it causes a fever, can lead to seizure disorders. Noel v. Secretary of HHS, No. 99-538V, 2004 WL 3049764 (Fed. Cl. Spec. Mstr. 2004) (acellular DPT caused fever causing seizure disorder). Dr. Shafrir's report was not helpful to the undersigned in any way, and the undersigned relies upon the opinions expressed in the reports of Dr. Kinsbourne and, most particularly, of Dr. Long.

The undersigned holds that Bryant's July 11, 2001 DPaT was a substantial factor in causing his fever and, but for the vaccination, he would not have had the fever, and further holds that the fever caused his seizures.

Since Bryant's January 2, 2002 DPaT was not followed by fever, the undersigned does not accept that it caused Bryant's January 3, 2002 seizure.[4] But, by then, Bryant already had a

[4] The undersigned has never accepted that either whole cell or acellular DPT causes afebrile seizures. See Nanez v. Secretary of HHS, No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003); Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, *11

seizure disorder which the July 11, 2001 DPaT played a substantial factor in causing, and, but for the July 11, 2001 DPaT, would not have then occurred because he would not have had a fever.

CONCLUSION

Petitioners are entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon to discuss the filing of life care plans, unless the parties agree on a joint life care plan. The parties should be aware that alternate dispute resolution is available to them as well, and if they choose ADR, they should contact the undersigned. Should the parties not be able to settle this case, the undersigned will hold a damages hearing.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master

(Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002); Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The Institute of Medicine (IOM) also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.