



On February 16, 2012, petitioners did file as Exhibit 13 an expert report from Dr. Robert Shuman, a pediatric neurologist, child neuropathologist, and neuroimager, who stated that vaccination had nothing to do with Anna Joelle's brain condition. In short, Dr. Shuman opined that Anna Joelle was born with periventricular leukomalacia (PVL) and arterio-venous malformation (AVM) which caused her seizures.

On February 17, 2012, the undersigned issued an Order to Show Cause why this case should not be dismissed in light of Dr. Shuman's detailed expert report whose conclusion was that a known factor unrelated to Anna Joelle's vaccinations caused her brain condition. The undersigned gave petitioners a deadline of April 17, 2012 to show cause why the undersigned should not dismiss their case.

On April 20, 2012, petitioners filed Exhibits 14-17. None of these exhibits supports petitioners' allegation of vaccine-caused ADEM. Exhibit 14 is a letter from Dr. Sarah Hopkins, a pediatric neurologist, dated February 13, 2011, stating she disagrees with Dr. Shuman that Anna Joelle has PVL and AVM. She does not offer an opinion as to the cause of Anna Joelle's brain condition. Exhibit 15 is another letter from Dr. Hopkins, dated August 10, 2011, stating that Anna Joelle had encephalopathy, regression of speech and of some social skills at age two which were temporally related to vaccinations. She does not say that the vaccinations caused Anna Joelle's encephalopathy, regression of speech and of some social skills.<sup>2</sup> Exhibit 16 is a letter from Dr. Anna W. Byars, a pediatric neuropsychologist, dated August 9, 2011, discussing Anna Joelle's significant language difficulties. She does not offer an opinion about causation. Exhibit 17 is a report, dated December 12, 2007, of a two-day video EEG of Anna Joelle's brain, showing no seizures but occasional irregular generalized spike and wave discharges in brief bursts lasting one to two seconds with one burst lasting four seconds. There is no opinion about causation.

On April 27, 2012, the undersigned held a telephonic status conference with counsel. Petitioners' counsel stated that petitioners were not going to file any more evidence and asked for a ruling on the record.

## **FACTS**

Anna Joelle was born on January 22, 2005.

On February 7, 2007, when she was two years old, Anna Joelle saw Dr. Jon. M. Strauss, who noted she had a six-word vocabulary. Med. recs. Ex. 4, at 29. She was administered her fourth DTaP and Comvax (haemophilus B influenza and hepatitis B) vaccinations. Med. recs. Ex. 4, at 30.

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<sup>2</sup> Petitioners do not allege a Table encephalopathy which would require a decreased level of consciousness for more than 24 hours. 42 CFR § 100.3(b)(2)(1)(B).

On April 24, 2007, Anna Joelle saw Dr. Robertson D. Ward. Her mother complained of behavior changes. Anna Joelle was not speaking as much and not stringing words together. Her mother was concerned that Anna Joelle might be autistic. A few weeks after her last appointment, she stopped talking much, spaced out, and seemed not to hear. Med. recs. Ex. 4, at 27.

On May 14, 2007, Dr. Ward noted Anna Joelle had an autistic disorder and unspecified otitis media. Her hearing was all right. Med. recs. Ex. 4, at 26, 27.

On June 22, 2007, Anna Joelle saw Dr. William C. Robertson, a neurologist, who diagnosed her with possible epileptic aphasia. There is a strong family history of febrile seizures in the mother and two other siblings. A third sibling had one seizure. One of the children had stereotypical behavior which raised a past concern of Asperger syndrome. Anna Joelle had some improvement in her speech lately and her vocabulary had increased to 20-30 words. Her mother's pregnancy with Anna Joelle was normal until six months gestation when there was a decrease in the growth of the fetus and calcification of the placenta. A caesarean section was done because of Anna Joelle's bradycardia. Med. recs. Ex. 7, at 1-2.

On September 4, 2007, Anna Joelle saw another neurologist, Dr. Robert J. Baumann, who diagnosed speech regression but noted that, since the last visit, Anna Joelle's mother said her daughter's speech had improved remarkably. Her vocabulary increased to over 50 words. She had no seizure-like events or worrisome change in behavior. Her behavior had improved and she was able to interact better with people. On physical examination, she was awake, alert, and fully and appropriately interactive with the examiner. She had fluent speech although her speech was still delayed. She could count from one to 15 and point at colors. Med. recs. Ex. 7, at 10, 11.

### **Dr. Shuman's Expert Report**

On February 16, 2012, petitioners filed the expert report of Dr. Robert M. Shuman who states that the cause of Anna Joelle's neurological problems was a prenatal insult manifested by slow heart beat (bradycardia) during labor, meconium staining, and metabolic acidosis. Ex. 13, at 12. He states that Anna Joelle has a brain condition called periventricular leukomalacia<sup>3</sup> due to repeated intrauterine distress between 28 and 36 weeks gestation.

On page four of his report, Dr. Shuman states that the first brain MRI done on Anna Joelle in 2007 when she was two and one-half years old showed PVL in her polar cerebral white matter in the parietal-occipital-temporal region, manifested by numerous teardrop-shaped

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<sup>3</sup> Periventricular leukomalacia is "bilateral necrosis of the white matter of the brain adjacent to the lateral ventricles, seen in the neonatal period, especially in premature newborns, and manifested by chalky, yellowish-white plaques in the white matter, with proliferation of astrocytes and microglia; cyst formation may lead to multicystic encephalopathy." Dorland's Illustrated Medical Dictionary 1030 (32d ed. 2012).

cavities in her brain aligned along the fiber planes of the white matter of the trigone of the lateral ventricles. These cavitations in this place, with their orientation, size and shape, are quintessential signs of PVL, presaging the findings of arterio-venous malformation<sup>4</sup> discovered in Anna Joelle's brain in 2011.

Dr. Shuman describes his further examination of Anna Joelle's brain MRIs showing a tangle of veins draining into an area called the superior sagittal sinus (SSS)<sup>5</sup> with evidence of old blood product (hemosiderin) and scarring on the undersurface of the temporal lobes. Anna's sinuses of her cerebral venous system are abnormally enlarged in order to accommodate the increased flow in her parietal-occipital brain due to the AVM. Ex. 13, at 6. In a description of a 2011 brain MRI, Dr. Shuman notes the hugely dilated triangular-shaped SSS and the increased numbers of dilated cerebral veins draining into the SSS. Ex. 13, at 8. The largest vein on Anna Joelle's left brain was pushed down and away from the inner surface of her skull by a vascularized thickening of the dura which had a great many vessels transversing it. The right side of Anna Joelle's brain was also thickened but not as much as the left side. *Id.* Dr. Shuman also notes the prominent straight sinus in the center of Anna Joelle's brain; the straight sinus is too large in order to help carry away all the cerebral blood flowing through the dural sinus varix around the posterior SSS. Ex. 13, at 8-9.

Continuing his analysis of Anna Joelle's 2011 MRI, Dr. Shuman states that the posterior half of the cerebral dura in the near-midline section shown is thickened. Excess tissue representing an old clot occludes the venous channel in the middle third. The venous channel in the posterior third is dilated in a triangular shape which he terms "fusiform." There is excess tissue below the dilated SSS at the parietal-occipital fissure, consistent with an old clot. The superior margin of the sphenoid bone is replaced by a relatively large bubble of black representing increased blood flow through the cavernous sinus. The olfactory tissue is coated with intense white signal consistent with old blood (hematoidin, a product of blood break down). The abnormal black signal continues on the undersurface of the olfactory gyrus in front of the cavernous sinus, indicative of hemosiderin on its surface. Ex. 13, at 10.

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<sup>4</sup> Arterio-venous malformation is "a congenital anomaly of the brain vasculature composed of arterial and venous channels with many interconnecting shunts without a capillary bed; clinical characteristics include hemorrhage, headache, and focal epileptic seizures." *Id.* at 1098.

<sup>5</sup> The superior sagittal sinus is "one of the sinuses of the dura mater; it begins in front of the crista galli and extends backward in the convex border of the falx cerebri. Near the internal occipital protuberance it ends in a variable way in the confluence of the sinuses, usually ending in the right transverse sinus. It receives the superior cerebral veins, communicates with the lateral lacunae, and is partially invaginated by arachnoidal granulations." *Id.* at 1721. The dura mater of the brain is "composed of two mostly fused layers: an endosteal outer layer (endocranium) adherent to the inner aspect of the cranial bones, . . . and an inner meningeal layer. Venous sinuses and the trigeminal ganglion are located between the layers." *Id.* at 573.

In Dr. Shuman's next analysis of Anna Joelle's 2011 brain MRI, he notes her demonstrably abnormal deep cerebral venous drainage system. The Vein of Galen and the Straight Sinus are thick walled and unduly prominent because of their thick walls. These deep cerebral veins drain the deep tissues fed by the varix of the posterior SSS. There is hematoidin over the inferior surface of the olfactory cortex. She has an enlarged cavernous sinus because of the increased blood flow through it. Ex. 13, at 11. A 48-hour video EEG done when Anna Joelle was nearly three years of age showed generalized epilepsy in her sleep. Ex. 13, at 12. She was diagnosed with primary or idiopathic generalized epilepsy. Id.

Dr. Shuman disagrees with petitioners' allegation that Anna Joelle had ADEM post-vaccination. The brain MRIs do not show signs of post-vaccinal demyelination. Her white matter disease is confined to the cerebral hemispheres and does not involve the cerebellum or brainstem. Anna Joelle's white matter disease is in the distribution typical of PVL and is not typical of ADEM. Ex. 13, at 12. Anna Joelle has epilepsy at night, meaning her seizure threshold is better when she is awake and worse in sleep. Nocturnal generalized epilepsy is likely secondary to Anna Joelle's PVL. Fifty percent of children with PVL who survive intrauterine distress have epilepsy. Id.

Dr. Shuman states that AVMs grow throughout life, and they cause bleeding and clotting. The blood from an AVM remains in the brain cortex and subarachnoid space. Extravascular blood breaks down to hemosiderin (iron freed from the hemoglobin protein). Id. Hemosiderin in nerve tissue is very epileptogenic, i.e., likely to cause seizures. Ex. 13, at 13. The cause of Anna Joelle's seizures is not only the PVL and intrauterine distress but also bleeding from the AVM. Id. Dr. Shuman states that it is very likely that Anna Joelle's AVM interfered with good cerebral perfusion during her mother's labor, producing the meconium staining and her metabolic acidosis at birth. The AVM has continued to grow and, as it grows larger, the cerebral tissue becomes more dystrophic. A dystrophic cortex is also epileptogenic. Blood in the leaks from the AVM is epileptogenic as well. Dr. Shuman finds Anna's neurologic disorder, including her AVM, PVL, neonatal distress, and epilepsy, causally interrelated. He states, "Vaccines have minimal or no discernible relationship to these developmental disruptions." Id. Dr. Shuman recommends that surgeons remove Anna Joelle's AVM as soon as possible since the natural history of an AVM is to grow larger, produce more dystrophy of the cortex where it is located, and clot and bleed repetitively. The growing and bleeding of the AVM causes Anna Joelle more irreparable harm. Id.

## DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by “reputable medical or scientific explanation[,]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioners must show not only that but for the vaccines, Anna Joelle would not have had developmental regression and seizures, but also that the vaccines were a substantial factor in bringing about her alleged injury. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Since petitioners filed their petition two years ago, they have not provided evidence to make a prima facie case. Their expert Dr. Shuman opposes their allegation that Anna Joelle's vaccinations caused her condition and that she had ADEM. See generally Ex. 13. Dr. Shuman states that a neonatal injury caused Anna Joelle's PVL and AVM which led to bleeding in her brain and consequent regression and seizures. Petitioners' Exhibits 14-17 do not provide any support for their allegation. Dr. Hopkins' disagreement with Dr. Shuman's diagnosis of PVL and AVM does not indicate support of petitioners' allegation of vaccine causation (Ex. 14). Dr. Hopkins' statement that there was a temporal relationship between Anna Joelle's non-Table encephalopathy, and regression of speech and of some social skills fails to provide a medical theory causally connecting the vaccinations to these deficiencies (prong one of Althen) or a logical sequence of cause and effect (prong two of Althen) (Ex. 15). The remaining two Exhibits 16 and 17 are totally irrelevant as to causation.

Petitioners have failed to make a prima facie case of causation in fact. The undersigned GRANTS their motion for a ruling on the record and DISMISSES this case.

### CONCLUSION

This petition is DISMISSED. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.<sup>6</sup>

**IT IS SO ORDERED.**

April 30, 2012  
DATE

s/Laura D. Millman  
Laura D. Millman  
Special Master

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<sup>6</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.