

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-394V

Filed: August 29, 2008

Not To Be Published

FORREST and EKATERINA "KATIA"
BOWMAN, as the legal representatives of their
minor son, FORREST GEORGE BOWMAN,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Stroke; Pre-natal Stroke
Expert Credibility

Curtis R. Webb, Twin Falls, ID, for petitioner.

Lisa Ann Watts, United States Department of Justice, Washington, DC, for respondent.

DECISION¹

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL BACKGROUND

¹ Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. Id.

On May 15, 2006, petitioners, Forrest Bowman (hereinafter Mr. Bowman) and Ekaterina Katia Bowman (hereinafter Mrs. Bowman), filed a petition and medical records, on behalf of their minor son Forrest George Bowman (hereinafter Forrest) pursuant to the National Vaccine Injury Compensation Program² (“the Act” or “the Program”) alleging that Forrest suffered a stroke following the receipt of DTaP, Hib, Hepatitis B, and IPV vaccinations on October 23, 2003. Petition (hereinafter “Pet.”) at 1-2.³ On May 15, 2006 petitioners also filed an expert report from Thomas A. Schweller, M.D., in support of their petition for vaccine compensation. Petitioners’ Exhibit (hereinafter “Pet. Ex.”) 14. On August 11, 2006, respondent filed a Report pursuant to Vaccine Rule 4, which included an expert report from John T. MacDonald, M.D., contending that compensation was inappropriate and the petition should be dismissed. Respondent’s Report, filed August 11, 2006.

A fact hearing was held on December 12, 2006 (hereinafter Fact Hearing) to elicit testimony from Mrs. Bowman and three additional lay witnesses concerning their observations and interactions with Forrest preceding and subsequent to his October 23, 2003 vaccinations. The undersigned issued a fact ruling on December 19, 2006. Order filed December 19, 2006. Thereafter, additional expert reports were filed by each party and, subsequently, an expert hearing was held on September 28, 2007 (hereinafter Expert Hearing). Petitioner presented Thomas A. Schweller, M.D., as an expert witness. Respondent presented John T. MacDonald, M.D., as an expert witness. The case is ripe for resolution.

II. FACTUAL BACKGROUND

Forrest was born on August 3, 2003 after a difficult labor. Pet. Ex. 4 at 14-15. At birth Forrest was observed to be jaundiced, slow to nurse, and had a rash on his upper lip and trunk. Pet. Ex. 5 at 4, 22a. At his two-week check-up Forrest was noted by Coravalist Family Medicine

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 *et seq.* (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

³ Petitioners also alleged Forrest suffered an injury or condition set forth in the Vaccine Injury Table, encephalopathy, on October 23, 2003, and thus were entitled to the statutory presumption of causation. Pet. at 1-2. However, the undersigned ruled subsequent to the Fact Hearing held on December 12, 2006, “that petitioners allegations of a severe, encephalopathic-type reaction to the vaccine” were “not proven by a preponderance of the evidence.” Order filed December 19, 2006 at 1. This ruling effectively denied petitioners’ Table claim. Petitioners thereafter pursued a causation in-fact claim. That claim is the subject of this Decision.

to be “[t]hriving and gaining weight.” Pet. Ex. 6 at 1. On October 23, 2003 Forrest was seen by Dr. Norman Castillo for a two-month well child check. Id. at 2. Dr. Castillo discussed with Mr. and Mrs. Bowman various feeding and crying issues and noted Forrest was “a little fussy.” Id. However, Forrest was observed by Dr. Castillo as “thriving, growing well,” and “smiling” Id., and was given his initial DTaP, Hib, Hep B, and IPV vaccinations. Id. at 13.

The undersigned notes that what occurred at this point in Forrest’s medical history is subject to question. That is because the medical records diverge from Mrs. Bowman’s affidavit submitted in this case on May 15, 2006, Pet. Ex. 1, as well as her testimony at the Fact Hearing. Mrs. Bowman recounts Forrest cried inconsolably the night of his vaccinations, and that she found him lying motionless in his bed with his eyes wide open, and that Forrest had a fever of approximately 101 degrees. December 12, 2006 Fact Hearing Transcript (hereinafter “FH Tr.”) at 50-53; see also Pet. Ex. 1. Mrs. Bowman also recounts that she called Dr. Castillo’s office on October 24, 2003 to report these symptoms and that she brought Forrest in to be seen on either the 24th or 27th of October. Id. at 56. However, there is no record of either the phone call or an office visit within Forrest’s records with Corvallis Family Medicine. The medical records document that Forrest was next seen by Dr. Mark Rampton on October 30, 2003 for congestion and a cough. Pet. Ex. 6 at 3. Dr. Rampton’s records indicate Mrs. Bowman was “quite concerned about his URI” (upper respiratory infection) and thought Forrest needed antibiotics. Id. The record further notes that “reassurance” was given Mrs. Bowman and that there was “no need for antibiotics in this case.” Id. There is no mention made in Dr. Rampton’s record of any reaction, fever, or inconsolable crying by Forrest following his October 23, 2003 vaccinations. In an Order issued subsequent to the Fact Hearing, the undersigned rejected Mrs. Bowman’s contentions and found “consistent with the medical records Forrest did not suffer [an] acute reaction to his October 23 immunizations.” Order filed December 19, 2006 at 2.

Petitioners also presented additional lay witness testimony at the Fact Hearing. Fact witnesses, Crystal Parrish, Elizabeth Wyatt, and Bridget Davis in their affidavits, Pet. Exs. 30, 31, 32, as well as during their testimony at the Fact Hearing, taken together, recount observing a change in Forrest’s use of his hands sometime after the October 23, 2003 vaccinations. The undersigned accepted the testimony of the fact witnesses that Forrest began to favor his left arm⁴ over his right arm “at some point” subsequent to his October 23, 2003 immunizations. Order filed December 19, 2006 at 2. The medical records for this period do not reflect Forrest’s hand problems. See Pet. Ex. 6 at 2-3. Thus, the undersigned qualified the fact ruling by stating “[t]he medical significance of these lay observations will be left to the experts.” Order filed December 19, 2006 at 2.

⁴ At various points in the medical records, and in the expert and fact testimony, references are made to Forrest’s hand or arm problems. The words hand and arm are used interchangeably to refer to the same problem, a symptom of Forrest’s stroke.

The first notation in the medical records of possible problems with Forrest's hand appear in February 2004, more than three months following his immunizations. Pet. Ex. 6 at 3. Forrest was seen by Dr. Castillo on February 10, 2004 for his six-month check-up. Id. Dr. Castillo noted all was "normal" with the exception that Forrest did not seem as active as a typical six month old and that he "[d]oes everything with his left hand." Id. Forrest was seen again by Dr. Castillo on March 30, 2004. Id. Dr. Castillo noted at that time that Mr. and Mrs. Bowman were concerned that Forrest was not using his right arm, and postponed Forrest's further immunizations until a neurological opinion was received. Id.

Forrest was evaluated by neurologist, Dr. James R. Schimschock, on April 27, 2004. Id. at 22-24. Dr. Schimschock recorded in his records that Forrest's parents noted that Forrest "tended to maintain his right hand in a fistful posture," and at three months he "showed a preference for his left hand when reaching for objects." Id. at 22. Dr. Schimschock noted that from Forrest's history "it is apparent that this child has had a long-standing right hemiparesis⁵ which is only becoming evident as his motor development progresses, emphasizing the asymmetry in upper extremity function." Id. Dr. Schimschock believed Forrest's hemiparesis was of "congenital or prenatal origin" and noted he reassured Mrs. Bowman that Forrest's "neurological symptoms were not in any way related to his immunizations." Id. at 23.

An MRI performed on May 7, 2004 of the brain revealed the following impression: "Areas of cystic encephalomalacia of the left frontoparietal temporal region with compensatory porencephalic dilatation of the posterior horn of the left lateral ventricle. These findings are consistent with a remote presumed in utero brain insult." Id. at 31.

III. DISCUSSION

A. Summary of Experts' Positions

The following is a brief overview of the experts' testimony.

Thomas a Schweller, MD.

Dr. Schweller is board-certified in pediatrics, neurology, and electroencephalography and completed a fellowship in neurology the final year of which was devoted entirely to electrophysiology. Transcript of September 28, 2007 Expert Hearing (hereinafter "Tr. at _") at 7; Pet. Ex. 15 at 1. Dr. Schweller has been in private practice since 1988 and estimates only two to

⁵ "Weakness affecting one side of the body." Stedman's Medical Dictionary 800 (27th ed 2000).

three percent of the patients he evaluates are children under one year. Tr. at 44. His practice encompasses several types of neurology, including: seizure disorder evaluations in homes for the disabled, evaluations involving electrical studies in “treating children with learning disabilities,” performing evaluations for Social Security Disability, and treating patients within the Workman’s Compensation system. Dr. Schweller also evaluates individuals suffering the “residual effects from motor vehicle accidents and slip-and-fall injuries.” Tr. at 6-7, 44-5, Pet. Ex. 15 at 1-2. Dr. Schweller does not diagnose or treat acute strokes and has not published on the subject. Tr. at 45-6.

Dr. Schweller opined at the Expert Hearing, as well as in his expert reports, that Forrest’s October 23, 2003 vaccinations caused his stroke. Pet. Ex. 14 at 3, Pet. Ex. 33 at 2, Tr. at 49. Dr. Schweller’s causation-in-fact theory as set forth in his reports and testified to at hearing can be summarized as follows:

I believe the October 23, 2003 immunization caused the stroke. An inflammatory reaction is known to occur after an injection or infection that will disturb the lining of blood vessels, resulting in the localization of platelet debris at this area of inflammation or it can break off and temporarily occlude an artery and cause a stroke. This is one of the primary causes of stroke in otherwise healthy children.

Pet. Ex. 33 at 2.

John T. MacDonald, M.D.

Dr. MacDonald is an associate professor of pediatrics and neurology at the University of Minnesota Medical School, University of Minnesota Hospital and Clinics. Respondent’s Exhibit (Resp. Ex.) B at 2, Tr. at 85. Dr. MacDonald is board-certified in psychiatry and neurology with a special competence in child neurology. Resp. Ex. B at 1. Dr. MacDonald has had approximately twenty years experience in clinical practice and hospital practice in pediatric neurology and estimates he has treated “thousands” of children over the years. Tr. at 86. Dr. MacDonald estimates approximately ten percent of his patients have been under one year of age. Further, specific to the issues presented in this case, Dr. MacDonald stated that he diagnoses and treats infants suffering acute strokes out of the hospital “every few months,” and treats “lots of strokes” at the hospital. Id. In addition, Dr. MacDonald lectures on the subject of strokes. Id. at 87.

Dr. MacDonald at the Expert Hearing, as well as in his expert reports, took issue with Dr. Schweller’s opinion that the October 23, 2003 vaccinations caused Forrest’s stroke, opining that Forrest suffered a pre-natal stroke. Dr. MacDonald explained that Forrest’s

subtle development of early hand preference during infancy is typical of a remote brain stroke that occurs before birth and is in stark contrast to those infants with postnatal acquired brain stroke, due to trauma, infection, etc., that presents with an acute degree of unilateral weakness that is immediately noted by the parents and brings the child to medical attention.

Resp. Ex. G at 1. Dr. MacDonald testified consistently at hearing with his written analysis of this case.

B. Legal Standard

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.⁶

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). The undersigned ruled subsequent to the Fact Hearing that Forrest did not suffer an encephalopathy, a “Table Injury,” after his October 23, 2003 vaccinations. Order filed December 16, 2006. Thus, petitioners must prove that the vaccine in-fact caused Forrest’s injury, a so-called “off-Table” case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused or significantly aggravated the injury alleged. See, e.g., Bunting v. Sec’y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec’y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec’y of Dept. of Health & Human Servs., 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, “[petitioners

⁶ A preponderance of the evidence standard requires a trier of fact to “believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.” In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

must] show a medical theory causally connecting the vaccination and the injury.” Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec’y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Sec’y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec’y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec’y of Dept. of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by “[a] reputable medical or scientific explanation” which is “evidence in the form of scientific studies or expert medical testimony.” Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960; ⁷

⁷ The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

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

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

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

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a

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

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Sec’y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners’ burden is to produce “preponderant evidence” demonstrating: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.” The Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the

peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 (“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.”); see also, Gall v. Sec’y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec’y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter “Capizzano III”]. Moreover, the Federal Circuit stated, “The purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” Id.

The Federal Circuit affirmed Althen’s three-part test in Capizzano III and in Pafford v. Sec’y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel in Pafford, however, explained that the three prongs in Althen “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner’s burden to rule out other competing possible causes of the injury in establishing that the vaccine was the “but-for cause of the harm.” Id. at 1355, 1357; see also Althen at 1281. (“[T]he elimination of other causes [] is merely a recitation of this court’s well-established precedent.”). But see Walther v. Sec’y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (“[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.”).

However, the legal requirement that a petitioner support her proposed causation theory with a “sound and reliable medical or scientific explanation” is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 (“A reputable or scientific explanation must support this logical sequence of cause and effect.”). Thus, when considering the evidence in a case, the special master is to “consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties.” Vaccine Rule 8©; see also DeBazan v. Sec’y of Dept. of Health & Human Servs., 70 Fed. Cl. 687, 699 n.12 (2000) (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation;” Campbell v. Sec’y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781 (2006). (Althen’s requirement of a “reputable medical or scientific explanation” “[l]ogically [] requires a special master to rely on reliable medical or scientific evidence”); Manville v. Sec’y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (2004) (“Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact’s process, simply, is to determine the probativeness of that evidence.”). Petitioners’ case is measured against these standards.

C. Analysis

Subsequent to the Fact Hearing, the undersigned rejected petitioners’ allegations of Forrest suffering an encephalopathy following his October 23 immunizations. Order filed December 19,

2006. However, petitioners continued to pursue their claim of vaccine injury by alleging that Forrest's immunizations caused in-fact his stroke. Thus, the issue to be resolved is whether petitioners have demonstrated by a preponderance of the evidence that the vaccination Forrest received on October 23, 2003 more likely than not caused his injury, a stroke. For the following reasons the undersigned finds petitioners failed to establish a "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec'y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999).

As an initial matter, the credibility of the experts is critical to the determination in this case. While credibility is nearly always an issue in vaccine cases, in disputes like this one - where the medical and factual information is subject to interpretation - experience and understanding of the medical issues is essential in correctly correlating the factual information with the medicine. In this case, there was a stark contrast between the experts, and thus their credibility. Dr. Schweller has minimal experience with strokes in children. While he "distinctly remember[s] cases of stroke who have had a change in the walking pattern," he does not have "acute hospital-based practice" and thus does not treat acute strokes. Tr. at 45. Dr. Schweller has not written on the subject of strokes. Id. at 46. In contrast, Dr. MacDonald has treated "thousands" of children over the years. Tr. at 86. He has diagnosed infants who have suffered strokes, and sees an acute stroke "every few months." Id. In addition, he lectures on strokes. Id. at 87. Their respective testimony was consonant with their experience; Dr. Schweller's being extremely general, highly speculative, and notable for frequent use of qualifying language (the use of "may" and "if" discounted greatly the value of his opinions, see Tr. at 25), while Dr. MacDonald's testimony was very specific and well-grounded in his experience. Thus, the undersigned relied upon Dr. MacDonald's testimony over Dr. Schweller's in resolving interpretive questions of the medical issues involved in this case.

Before discussing the evidence presented, it is important to note that the parties agree that Forrest suffered a stroke. Agreed Upon Facts and Issues for Decision filed November 30, 2006. Thus, the issue presented is what caused the stroke? Dr. Schweller opined that the vaccines were the cause, while Dr. MacDonald contended that the stroke pre-dated the immunizations. Petitioners simplify the case to determining whether petitioners have proven by a preponderance of the evidence that Forrest suffered a post-vaccination stroke. Petitioner's Post-Hearing Brief (hereinafter Pet. PH Brief) filed January 22, 2008 at 1, 6. While other issues present in this case, for example is there reliable evidence of vaccines causing strokes, the initial issue of when the stroke occurred is critical since Dr. Schweller agreed on cross examination that the factual predicate for his opinion that Forrest's vaccinations caused his injury was that the stroke occurred post his immunizations.

Ms. Watts: Well in this case, your opinion seems to squarely rely on your finding that the onset of the stroke occurred post-vaccine; is that correct?

Dr. Schweller: That's correct.

Tr. at 54-55. Accordingly, resolution of whether Forrest suffered a post-vaccination stroke is central to the determination of the viability of Dr. Schweller's opinion. If the evidence does not support a post-vaccination stroke, Dr. Schweller's opinion necessarily fails. As petitioners readily concede, whether the stroke occurred post-immunization "is not an easily answered question." Pet. PH Brief at 6.

After considering the entire record in this case, the undersigned finds that the evidence preponderates in favor of respondent that Forrest's stroke predated his October 23, 2003 immunizations.⁸ In contrast to Dr. Schweller's speculative testimony, Dr. MacDonald testified convincingly that based upon the Forrest's medical history, the clinical course of a pre-natal stroke and the clinical course of a post-natal stroke, Forrest's MRI results, and the opinions of Forrest's treating physicians, Forrest did not suffer a post-vaccination stroke.

As an initial matter, Dr. MacDonald explained the causes of an in utero stroke.

Well, there's a long list, but basically, there are structural abnormalities of the brain. They can be genetic, or acquired. There are infectious causes. There's a whole host of rare metabolic diseases. There's trauma to the mother and the baby. And the more commonly described thing recently are a whole long list of coagulation abnormalities that occur in the last trimester that cause damage to the fetal brain.

Tr. at 88. Dr. MacDonald noted that based on testing done on Forrest, "one of the coagulation factors is grossly abnormal." *Id.*, referencing Pet. Ex. 37. Dr. MacDonald explained in great detail the recent understanding regarding the risk from coagulation defects and how the medical understanding has evolved over the past ten years of the relationship of coagulation defects and strokes in infants. Tr. at 89-92. Forrest had this risk factor. Tr. at 90; Pet. Ex. 37. Dr. Schweller was unaware of these test results until shown the exhibit at hearing. Tr. at 51.

Dr. MacDonald testified that the changes in Forrest's arm usage, were not consistent with an acute change, but rather indicative of a pre-natal stroke. Tr. at 98. Dr. MacDonald opined Forrest more likely than not suffered an intrauterine stroke based upon his clinical picture. Dr.

⁸ By resolving this case on the narrow issue of when the stroke occurred, it is not necessary to resolve the question of whether vaccines can plausibly cause strokes. When asked, Dr. MacDonald said it was "possible" but that the "level of evidence is poor" and it is "not generally accepted." Tr. at 112.

MacDonald cogently explained infants who suffer pre-natal strokes are often identified immediately based upon experiencing seizures. However, other infants, such as Forrest, appear healthy initially “and then slowly over the first year, people start to notice the baby is moving one side more than the other.” Tr. at 91-92. Dr. MacDonald notes that due to a baby’s developing nervous system reaching out is “unusual under four months of age.” Id. at 93. But that around “four to five months most babies can start to reach out. By six months we expect them to reach out.” Id. Therefore, due to the developing nervous system Dr. MacDonald opined “the first time you identify what you think is the asymmetry is not in itself a sign that the stroke occurred right before then.” Id. In the instant case Dr. MacDonald opined

[t]his child’s clinical picture is quite typical for an infant presenting in the first year of life with early hand preference, which is eventually recognized as a hemiparesis, and most are due to an in utero stroke of the central nervous system, mostly occurring during the third trimester of pregnancy. Hemiparesis is most prominent in the upper extremities and the spasticity develops over many months, so that at birth and in the first few months this is rarely noticed; and only over time as the child begins to reach out after four months of age is the asymmetry and hand use and movement noted.

Resp. Ex. A at 3. Dr. MacDonald addressed the undersigned’s Order after the Fact Hearing finding, that there was a change in Forrest’s arm usage sometime after the October 23, 2003 vaccinations, by explaining

I would expect that to be true. There is a point in time where they’re not going to see this asymmetry, just like you wouldn’t - you have to have reached a developmental level where the connections from the right brain to the left arm, and the left brain to the right arm have given you enough function to see there is an asymmetry. And that typically, to have the motor reaching coordination, is usually around four to five months. . . .The myelin has to form. And until it forms, you’re not going to be able to see an asymmetry. . . . [N]o one sees a difference until time has gone by, and then, as here, there is this somewhat confusing, when did it occur, but I think it’s there, and then finally, at six plus months, even the doctor sees it then. But these are **subtle changes**.

Tr. at 100-101 (emphasis added).

Dr. MacDonald contrasts these subtle, albeit identifiable, changes in Forrest’s arm usage with the more dramatic acute changes he has identified in infants who suffered a post-natal strokes after infection.

[T]hey're suddenly flaccid, the arm, and usually the leg is not working. . . . So I would expect, if this had occurred somewhere close this immunization, for whatever reason, it's not just the arm we should be worrying about. The leg should be out. . . . Plus typically these kids are irritable. . . . They usually throw up because they're so upset. And these parents are usually in the emergency room immediately. . . . Again, I would say they are there within hours. . . . [A]nd it's usually something that can be timed very closely, unlike in this case, where the timing here I have no idea who saw what when. The doctor did not see anything until much later. And even there it was subtle. So I see nothing here that I could even use the word "acute" logically. Everything points to a chronic process.

Tr. at 97-98.

[I]n this case, when you see this much damaged brain, for that to have occurred post-birth, this is not going to be a subtle change. This degree of weakness, which should also involve the leg, too is going to be so obvious, acutely, that this is not a subtle process. So this is not going to be something . . . the doctor a week later doesn't see. That's just not in the cards.

Id. at 108. In the instant case Forrest was seen by Dr. Mark Rampton one week subsequent to his vaccinations, and the doctor did not notice anything unusual during the course of the visit regarding Forrest's arm usage or any other neurological deficit. Pet. Ex. 6 at 3. In fact, Mrs. Bowman brought Forrest in for an URI, and it is noted that "she is quite concerned about his URI." Id. Dr. MacDonald commented that "there's no mention of any acute changes" and even with the witness testimony "I can't get a timeline." Tr. at 99-100. He stated that this is "understandable" because it is an "evolving process" and "is very typical for an interuterine stroke." Id. Dr. MacDonald stressed in his testimony that the change in Forrest's arm, specifically the observation from Ms. Parrish "of the hand being held in an unusual manner, with his fist clenched and the hand held toward the body," did not suggest an acute hemiparesis. Id. at 108. "That's a chronic change. That can take weeks if not months to develop. That would not be at all compatible with something in the week or so before. That's a chronic change." Id. Dr. MacDonald explained persuasively why these apparent inconsistencies between the lay witnesses and doctors appear. He stated that the symptoms of stroke in an infant are so subtle that "the doctor may not see it until much later, the family members may or may not spot something, but can't pinpoint it." Tr. at 95; see also Id. at 101, 104. He juxtaposed the symptoms of an interuterine stroke with those of a post-natal acquired stroke where

these parents usually are in the emergency room immediately. . . . it's a different picture, and it's usually something that can be timed very closely, unlike in this case, where the timing here I have no ideal who saw what when. The doctor didn't see anything until much later. And even there it was subtle.

Tr. at 98; see also Tr. at 104. Thus, relying heavily on Dr. MacDonald's expertise and testimony and applying the facts of the instant case to the clinical course of a typical pre-natal stroke versus a post-natal stroke clearly indicates that Forrest suffered a pre-natal stroke, and thus did not suffer a post-vaccination (post-natal) stroke.

The undersigned notes that Dr. MacDonald's opinion that Forrest suffered a pre-natal stroke is consistent with the opinion of Forrest's treating neurologist and the interpretation of his MRI. The Federal Circuit has instructed the special masters that "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano 440 F.3d at 126 citing Althen 418 F.3d at 1280. After evaluating Forrest on April 27, 2003, Dr. James R. Schimschock opined that Forrest's hemiparesis was of "congenital or prenatal origin" and noted he reassured Mrs. Bowman that Forrest's "neurological symptoms were not in any way related to his immunizations." Pet. Ex. 6 at 23. Likewise, Forrest's May 7, 2004 MRI findings were noted to be "consistent with a remote presumed in utero brain insult." Id. at 31. Dr. MacDonald's testimony was also consistent with other records at the time of Forrest's immunizations. Forrest's well baby visit on October 23, the date of his immunizations, does not note any hand abnormalities. Pet. Ex. 6 at 2. Based upon this record, petitioners contend that normal hand use is "implied." Pet. PH Brief at 2. However, at Forrest's October 30 visit, at the time when petitioners contend that Forrest was exhibiting left hand bias, there is no notation by the doctor of any hand abnormalities. Pet. Ex. 6 at 3. In fact, Forrest was seen for the mother's concern with Forrest's URI. Id. Petitioners had no adequate explanation for why it was reasonable to "imply" normal hand usage from the October 23 record, but ignore the same "implication" from the October 30 record. Finally, it was not until February, 10, 2004, more than three months following his immunizations, that Dr. Castillo noted left hand issues. Id. From the fact witnesses and the medical records, Dr. MacDonald stated that he could not "pin down a timeline", Tr. at 104, but that is "typical for an interuterine stroke." Id. at 95. While at various times relying upon these records for his opinion of a sudden change in Forrest, when questioned intently, Dr. Schweller conceded that the medical records and fact witnesses do not evidence a sudden change in Forrest. Tr. at 82-3.

As a starting point for his opinion, Dr. Schweller needed to prove that Forrest's stroke occurred after the immunization. If the evidence showed that the stroke occurred prior to immunization, it would obviously be impossible for the vaccine to have caused the stroke. Based upon Dr. MacDonald's persuasive testimony, the undersigned finds that the stroke did in fact pre-date Forrest's immunizations. Accordingly, Dr. Schweller's opinion necessarily fails, as does petitioners' case.

In making this finding, the undersigned viewed not only the strength of Dr. MacDonald's testimony, but also considered the extreme weakness of Dr. Schweller's testimony.⁹ Dr.

⁹The unpersuasiveness of Dr. Schweller's testimony will be reviewed further, infra at 17-19.

Schweller's evidence of a post-immunization stroke is premised on the alleged occurrence of an acute event. Dr. Schweller's highly speculative testimony is seen through examining this alleged acute change in Forrest relied upon so heavily by Dr. Schweller for his opinion. What is the evidence to support a post-vaccination stroke? Dr. Schweller's opinion rests upon his belief that Forrest suffered an **acute change** in the use of his right arm post-vaccination and that this type of change represents a recent rather than a remote stroke. Tr. at 68; see also Tr. at 61 ("if you are using two hands one day, and you use one the next day, that is an acute change, and that is inconsistent with a preexisting condition.") Dr. Schweller took this position although he agreed that strokes may occur in children that appear otherwise healthy and that an acute event does not necessarily precede a stroke. Tr. at 47. The evidence of when Forrest manifested his stroke is difficult to discern with any degree of certainty. Such difficulties were not surprising to Dr. MacDonald as he stated the signs of stroke in infants are very subtle and discrepancies as to when they occurred are "very typical for an interuterine stroke." Tr. at 95; see also Id. at 98, 100, 104. However, Dr. Schweller maintains his belief is bolstered by the testimony of the witnesses at the Fact Hearing. Tr. at 76. Ms. Wyatt testified at the Fact Hearing Forrest used his hand equally when she cared for him between September 19 and September 30, 2003. FH Tr. 6, 8-10, 14-15. Ms. Parrish testified Forrest she observed Forrest clutching his right arm in an odd angle on either the 28th or 30th of October 2003. Id. at 18, 20. Ms. Davis testified that she noted Forrest had a preference for his left hand and that his left hand was noticeably stronger than his right hand when she visited on October 31, 2003. Id. 36-41. The undersigned accepted the testimony of the fact witnesses that sometime after Forrest's immunizations there was a change in how he used his arms.

Regarding the change in the use of his right arm, the undersigned finds that petitioners' allegation is supported. Ms. Wyatt was particularly credible on this issue. She testified strongly that just prior to the October 23 immunization, Forrest's arm strength was equal in both arms. Ms. Wyatt is not medically trained, but she explained in ways familiar to the undersigned as a parent, how she played with Forrest. From this playing, from a lay person's perspective, one could reasonably conclude that Forrest utilized both his arms in equal fashion.

At *some point* following his immunization, Forrest began relying more heavily on his right arm. The first medical observation of this tendency is Dr. Castillo's February 10 note at Forrest's six-month visit. However, the parents consistently reported to the treating doctors that this change began shortly following the October 23 immunization. Accordingly the undersigned finds that the lay witnesses' non-medical observations show that Forrest used both arms equally and with equal strength prior to immunization, but that changed to favoring his left over his right following vaccination. The medical significance of these lay observations will be left to the experts.

Order filed December 19, 2006 at 2 (emphasis added). After considering the entire record of the case, including the experts opinions and testimony, it is clear that one cannot determine with any

accuracy when Forrest began manifesting his stroke. Dr. Schweller interpreted the lay witness testimony to support a “sudden change” in Forrest’s use of his hand. Tr. at 83; see also Id. at 61 (“using two hands one day, and you use one the next day, that is an acute change. . .”). But he had to concede that the testimony and records do not support such an abrupt change. See Tr. at 62, 83. And while the record could be interpreted to support, as the undersigned found in the fact ruling, that Forrest was using his arms equally prior to vaccination, but “at some point” following immunization he relied more on his right arm, the undersigned is now convinced based upon the entire record that one cannot determine with any level of certainty when Forrest’s stroke symptoms manifested - whether prior to immunization, post immunization and if prior or post, when. Several reasons are given for this conclusion. First, although the some fact witnesses saw Forrest before and after his immunizations, none testified as to the condition of his arm both before and after his immunizations. Thus, while the undersigned found based upon Ms. Wyatt’s testimony that Forrest’s “arm strength was equal in both arms,” there was no reliable evidence of when following the immunization Forrest began relying more heavily on his left arm. Id.; see also Tr. at 77-78. The medical records do not clarify the facts. As was discussed earlier, Forrest’s October 23 exam does not indicate any problems with his hands. Pet. Ex. 6 at 2. In addition, contrary to the fact testimony, Forrest’s October 30 doctor’s visit for a URI does not indicate any hand problems either. Id. at 3. While the October 23 exam is consistent with the fact witness testimony that Forrest was normal prior to the immunization, the October 30 exam is inconsistent in that the witnesses were saying that Forrest had changed at this point while the doctors are not noting any change. It was not until the February 10, 2004 visit that Dr. Castillo noted potential problems with Forrest’s hands. Id. While Dr. Schweller noted this inconsistency, he stubbornly maintained his position that there was a sudden change in Forrest. See Tr. at 82-83. Dr. MacDonald on the other hand saw this factual dilemma as “typical” of the chronic process following an interuterine stroke. See Tr. at 95, 98.

As stated in the undersigned’s factual ruling, the “medical significance of these lay observations will be left to the experts.” Order filed December 19, 2006 at 2. The reason the undersigned includes this language in fact rulings is because the factual hearings are conducted without the benefit of expert testimony. Thus, the lay observers, such as the undersigned, are at a disadvantage as to whether the testimony being given is logical in the context of the medical process. While, Ms. Wyatt’s testimony was perfectly believable, after considering Dr. MacDonald’s testimony that “the onset of the symptom, as defined by the observer does not correlate with the onset of the actual stroke” and that “the doctor may or may not see it until much later, the family members may or may not spot something, but can’t pinpoint it,” Tr. at 94-5, it is clear that the testimony cannot be used to time the events with the precision that Dr. Schweller relies upon. The undersigned found that “at some point following his immunization” Forrest exhibited hand problems, and based upon the testimony, the medical records and Dr. MacDonald’s persuasive testimony, the best guess as to when Forrest’s problems were seen is sometime after the October 30 exam but before the February 10, 2004 exam.

In addition to this lack of factual support for a “sudden change” in Forrest, Dr. Schweller’s

own statements undermined his opinion. Critical to Dr. Schweller's opinion is an acute change in Forrest's use of his arm. Dr. Schweller opined that the change in the use of Forrest's arm was acute and therefore indicative of a post-vaccination stroke. Tr. at 7-11, 33-34, 55, 60-62. When asked what timeframe defines an "acute" event, Dr. Schweller testified that it would occur "certainly within 24 to 48 hours." Tr. at 69. However, on several occasions during his testimony, Dr. Schweller conceded that the record contains no evidence to support such an acute change. See Tr. at 62 (no evidence to "indicate a change from one day to the next"); Tr. at 83 (no evidence of a "sudden change" based upon the fact witnesses.) Throughout his testimony, Dr. Schweller stated that Forrest's arm problems occurred either five or eight days following immunization. See Tr. at 8, 68. Based upon that timeframe, he testified that there was an "acute change" in Forrest's arm. Id. at 68. Incredibly, Dr. Schweller proceeds to define acute as "24 to 48 hours" and concede that the shortest measurement of time he relies upon for his opinion - five days - is not an acute event. Tr. at 73-74. This testimony quite frankly is nonsensical. It becomes totally unreliable when Dr. Schweller is asked to clarify and he agrees that he assumes there was an acute change in the use of Forrest's left arm after the October 23, 2003 vaccinations "[b]ecause I don't have any evidence of any abnormality before that point in time, so it had to be an acute change." Tr. at 78. The undersigned questioned Dr. Schweller "[s]o your acute reaction or acute event is actually an **assumed** occurrence?", to which Dr. Schweller replied "[y]es." Tr. at 75 (emphasis added).

Dr. Schweller's testimony in this case failed any conceivable test for reliability. He conceded that he does not have the clinical experience to support his testimony, he conceded that the medical literature he provided does not support his case, he conceded that the most generous time frame for petitioner's case - five days - is not an acute event, which occurrence underpins his entire testimony, he conceded that the acute occurrence he relies upon is an assumed occurrence, and finally he conceded that the treating doctors and MRI scans do not support an acute event but rather support respondent's theory of the case. Needless to say, the undersigned was not impressed in the least with the quality of Dr. Schweller's testimony in this case and finds him to be not credible.

Petitioner raised one argument in her post-hearing brief that deserves addressing. Petitioner argues that based upon Dr. MacDonald's testimony pre-natal strokes are not observed in children until after four months of age. Pet. PH Brief at 7, citing Tr. at 119. The implication from this argument is that if you would not see a pre-natal stroke at this tender age, the stroke would have to have another cause - in this case the immunization. There are several problems with petitioner's argument. As petitioner notes, Forrest was born on August 3, 2003 and was not yet four months when Ms. Davis testified to Forrest's left hand preference. Id. First, the undersigned did not accept at face value Ms. Davis' testimony, but found that "[a]t some point following his immunization, Forrest began relying more heavily on his left arm over his right arm." Order filed December 19, 2006 at 2. As discussed above, after considering Dr. MacDonald's testimony, the undersigned agrees with Dr. MacDonald that the timing in this case is subject to many differing interpretations. Tr. at 98 ("I have no idea who saw what when.").

Again, it should be noted that the doctor at the October 30, 2003 visit did not note symptoms of stroke. It was not until February 10, 2004 that a doctor first noted Forrest's problems. Pet. Ex. 6 at 3. Secondly, reading Dr. MacDonald's entire testimony on when symptoms of stroke are seen in infants, one cannot draw the absolute line of time demarcation that petitioner advances. While Dr. MacDonald did say that it is "definitely after four" months before signs of asymmetry are seen, in responding to petitioner's counsel's question of whether signs would be seen at three months, Dr. MacDonald responded "[y]ou might see something if it were profound." Tr. at 119. Thus, similar to the reasons Dr. MacDonald gave for why it is so difficult to see the signs of stroke in an infant, see Tr. at 92-3, children develop at different times and develop differently which prevents applying absolutes to any one child. Dr. MacDonald gave ranges for development, and it would be improper to apply those ranges in the categorical sense petitioners advance.

Finally, the undersigned notes again he was completely unconvinced by Dr. Schweller's testimony, particularly his testimony regarding a post-immunization stroke. Dr. Schweller's theory, which he testified repeatedly to in response to intense questioning, is that the immunizations Forrest received caused an inflammatory process which in combination with unidentified risk factors in the host caused a stroke. See Tr. at 11-26, 53. However, when dissected, Dr. Schweller's theory and opinion fails completely from a lack of any reliable support. Dr. Schweller begins to build his case from a study showing that infections contribute to strokes by causing systemic inflammation. Tr. at 11, 14; Pet. Ex. 16¹⁰ (Smeeth article.) Two obvious problems arise from Dr. Schweller's reliance on the Smeeth article, the authors found no support for vaccinations creating a likewise increased risk and the study involved adults, not children. In fact, the article's conclusion was:

Our findings provide support for the concept that acute infections are associated with a transient increase in the risk of vascular events. By contrast, influenza, tetanus, and pneumococcal vaccinations do not produce a detectable increase in the risk of vascular events.

Id. at 2 Dr. Schweller understood these defects, but continued to rely on the article. He stated that "I believe **if** [vaccinations] create a similar inflammatory response to the infection, that they would contribute in the same way." Tr. at 15 (emphasis added). When asked the logical question why if in Dr. Schweller's opinion vaccines cause a similar inflammatory response to that of infections the article was reaching different findings for vaccines and infections, Dr. Schweller responded:

¹⁰ Liam Smeeth et al., Risk of Myocardial Infraction and Stroke after Acute Infection or Vaccination, 351;25 N Engl J Med 2611, 2611-8, (Dec. 16, 2004) (hereinafter Smeeth article).

Well, I think part of it is - it has to do with the agents that are used, and it has to do with the age of the individual that is being studied. So one **cannot be certain that the child will have the same reaction.**

Tr. at 15-16 (emphasis added). Therein lies the second obvious deficiency of the Smeeth article, it dealt with adults. In fact, Dr. Schweller when questioned why the Smeeth article should not be interpreted as evidence against his theory since the article found no increased risk from vaccines, Dr. Schweller stated that:

The immune response **may be different** in children. And so I don't know that you can make a judgment that these - you cannot get similar inflammatory response in children to these adults that were studied, and that they were very unique vaccines that were looked at.

Id. at 21 (emphasis added). The undersigned interprets Dr. Schweller's response as a retreat from relying on Smeeth, since the study was of adults, and the "immune response may be different in children." Id. In fact, the authors undermined the Dr. Schweller's analogy of the vaccine mechanism of causing stroke to that of infection by finding that "we saw no effect of vaccination on risk, probably because both the magnitude and the duration of the inflammation induced by vaccination are small, as compared with naturally occurring infection." Pet. Ex. 16 at 8. So what was the evidence that a vaccine can cause an inflammatory response similar to infections by which it could precipitate a stroke? Dr. Schweller relied on a study involving the typhoid vaccine. Pet. Ex. 19¹¹. Dr. Schweller contended that this study showed that the typhoid injection caused an inflammatory response which would cause an increased risk of stroke in the individual. When asked to reconcile his statement regarding the Smeeth article that "very unique vaccines []were looked at" with his reliance on a study involving the typhoid vaccination, Dr. Schweller responded:

Well, I think you make the judgment with typhoid that at least in that particular agent there are changes that occur that are supportive of systemic inflammatory process.

Tr. at 21. In response to the court that those inflammatory changes related to typhoid only, Dr. Schweller responded "right." Id. While the authors did find that the typhoid vaccine generated a "mild inflammatory reaction," pet. Ex. 19 at 2, there is no indication in that article or any of the other articles submitted by Dr. Schweller that similar findings were made regarding the

¹¹ Aroon D. Hingorani, et al., Acute Inflammation Impairs Endothelium-Dependent Dilatation in Humans, 102 *Circulation* 994, 994-9 (Aug. 29, 2000).

vaccinations involved in this case. Dr. Schweller agreed that the articles he submitted do not support the connection between vaccines and strokes. Tr. at 56. Through this examination, it was very clear to the undersigned that Dr. Schweller was promoting a theory that was based upon supposition - that the vaccines involved created an inflammatory response which could cause a stroke - but that there was no reliable support for his believe. Counsel attempted to clarify Dr. Schweller's testimony with the following exchange:

Q If the inflammation from an infection contributes to strokes, is there any reason to believe that the inflammation from vaccinations cannot?

A That's my thinking is that they should be similar **if** the degree of inflammation is similar.

Tr. at 25 (emphasis added.) Dr. Schweller's response encapsulates the problem with his testimony - there is simply no reliable basis for his theory. Dr. Schweller conceded that the literature he submitted does not support his theory that the vaccines administered to Forrest caused his stroke. Tr. at 55-56. He stated that the literature supports a "potential mechanism" but that literature does not support the specific vaccines given to Forrest and do not support effects in children since the literature involved adults. *Id.* at 56. Dr. Schweller agreed that the authors did not reach the conclusions that he was drawing in this case. *Id.* He agreed that the authors concluded that vaccines were not associated with higher levels of vascular disease. *Id.* Finally, in the absence of support from the literature he submitted, Dr. Schweller agreed that he could not "identify for us any particular clinical experience, laboratory studies, anything that supports [his] conclusions" that the type of inflammation caused by vaccines is a viable mechanism for causing a stroke. *Id.* at 57. While petitioners are not required to produce medical literature supporting their case, *Althen* 418 F.3d at 1279, petitioners must produce some reliable support. *Daubert*, 509 U.S. at 590 (Scientific knowledge "connotes more than subjective belief or unsupported speculation."); *Terran* 41 Fed. Cl. at 336 ("*Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence."). Dr. Schweller by his own admission could provide no support whatsoever. His testimony amounted to, in a most generous characterization, speculation, and speculation is not acceptable in establishing a probability. *Snowbank*, 6 Cl. Ct. at 486 (Mere conjecture or speculation will not establish a probability.).

Since petitioners' medical theory relies upon a fact they are unable to establish, that Forrest suffered a post-vaccination stroke, petitioners' theory must fail. "The conclusions of experts are only as sound as their factual predicate." *Bowman v. Sec'y of Health and Human Services*, No. 04-1734, 2008 WL 1990844 at *11 (Fed. Cl. Spec. Mstr. Jan. 30, 2008) citing Respondent's Post Hearing Brief at 14 brief citing *Castillo v. HHS*, 1999 WL 605690 at *13 (Fed. Cl. Spec. Mstr. July 19, 1999) (citing *Davis v. HHS*, 20 Cl. Ct. 168, 173 (1990)); *Loesch v. United States*, 645 F.2d 905, 915 (Ct. Cl. 1981) (citing *State of Washington v. United States*, 214 F.2d 33, 43 (9th Cir. 1954), cert. denied, 348 U.S. 862 (1954)). Thus, petitioners have failed to

establish “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury,” nor has petitioner demonstrated by a preponderance of the evidence that Forrest’s October 23, 2003 vaccinations were the “but for” cause of his injury as required by the Federal Circuit. Althen at 1278, Capizzano III at 1352, Pafford, 451 F.3d at 1355.

Accordingly, the undersigned finds that petitioner has not established by a preponderance of the evidence that Forrest’s October 23, 2003 vaccinations were the legal cause of Forrest’s stroke. Petitioners’ claim is denied. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master
