

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 99-0855V
(Filed: May 16, 2013)
TO BE PUBLISHED¹

BRIAN FRANKLIN and ANDREA *
FRANKLIN, as legal representatives of *
Scott P. Franklin, a minor, *

Petitioners, *
v. *

Vaccine Act Entitlement;
Causation-in-fact;
Vaccination/Encephalopathy
Causation Issue;
Vaccination/Autism
Causation Issue.

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
Respondent. *

Gregory Kincaid and Allen Coon, Olathe, Kansas, for Petitioners.
Vincent Matanoski, Lynn Ricciardella, and Heather Pearlman, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master.*

This is an action in which the Petitioners, Brian and Andrea Franklin, seek an award under the National Vaccine Injury Compensation Program (hereinafter “the Program”²), on

¹ Because I have designated this document to be published, this document will be made available to the public unless petitioner files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute “medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” See 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b).

² The applicable statutory provisions defining the Program are found at 42 U.S.C. §300aa-10 *et seq.* (2006). Hereinafter, for ease of citation, all “§” references will be to 42 U.S.C. (2006). I will also sometimes refer to the Act of Congress that created the Program as the “Vaccine Act.”

account of an ongoing severe neurodevelopmental disorder in their son, Scott, that has been characterized as an Autism Spectrum Disorder (“ASD”). For the reasons set forth below, I conclude that the Petitioners are not entitled to an award on Scott’s behalf.

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. (§300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).)

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient’s injury was “caused-in-fact” by the vaccination in question. (§ 300aa-13(a)(1)(A); § 300aa- 11(c)(1)(C)(ii).) In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. (*Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).) The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. (§ 300aa 13(a)(1)(A); *see also Althen*, 418 F.3d at 1278; *Hines*, 940 F.2d at 1525.) Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. (*Althen*, 418 F.3d at 1279.) The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. (*Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).) Thus, the petitioner must supply “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;” the logical sequence must be supported by “reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony.” (*Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).)

The *Althen* court also provided additional discussion of the “causation-in-fact” standard, as follows:

Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

(*Althen*, 418 F.3d at 1278 (citations omitted).) The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting the petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id.* at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id.* at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the *reliability* of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert's* factors as a framework for evaluating the reliability of causation in-fact theories presented in Program cases. One of the factors listed in *Daubert* is whether the scientific theory "has been subjected to peer review and publication." (509 U.S. at 593.) The Court noted that while publication does not "necessarily" correlate with reliability, since in some instances new theories will not yet have been published, nevertheless "submission to the scrutiny of the scientific community is a component of 'good science,'" so that the "fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity" of a theory. (*Id.* at 593-94.)

II

FACTS AND PROCEDURAL HISTORY

A. Facts

Petitioners' son, Scott Franklin, was born on July 2, 1995, and released from the hospital on July 3, 1995. (Ex. 1, pp. 2-3.) On July 8, 1995, Scott was returned to the hospital due to a high bilirubin level in order to undergo incubator light treatment, but was subsequently released as a well-baby. (*Id.*³) The records of Scott's visits to his pediatrician during his first 15 months of life appear to indicate generally normal health and development. (Ex. 3, pp. 9-17.)

On October 7, 1996, at age 15 months, Scott received two immunizations--a measles, mumps, and rubella ("MMR") inoculation, and a "Tetramune"⁴ inoculation, at Dr. Seibel's office. (Ex. 3.2, p. 1.) Scott returned to Dr. Seibel ten days later, on October 17, 1996. (Ex. 3.4, p. 1.) The pediatrician's notes concerning that visit indicate that Scott was "pulling at his ears," was "fussy," had "loose stools," and had "low grade," apparently meaning a slight fever. (*Id.*) The notes made by Scott's mother concerning the same visit indicate that Scott was exhibiting symptoms including, "appetite/diarrhea/tired/fever/grouchy/gassy/yellow/red spots." (Ex. 46, p. 7.) Dr. Seibel concluded from the symptoms that Scott was "teething." (Ex. 3.4, p. 1.)

On July 16, 1997, during a two-year well-child visit to Dr. Seibel, the notation indicates that Scott had previously spoken, but was now not speaking. (Ex. 3.5, p. 1.) According to the record of that visit, Scott was not taking any medications, had no illness, and had *not* had any reactions to his immunizations. (*Id.*) It was recommended that Scott's parents contact Dr. Seibel if improvement in speech did not occur in the following two to three months. (*Id.*)

Scott visited Dr. Seibel on May 2, 1998, when it was noted that he was only saying two words, "does not establish eye contact," and "appears to 'tune [Dr.Seibel] out.'" At that visit, Scott was diagnosed with speech delay. (Ex. 3.5, p. 6.)

Potential developmental delay was addressed at Scott's three-year well-child examination on August 11, 1998. (Ex. 3.5, p. 7.) Scott's mother expressed concerns about Scott's continued minimal speech, as well as difficulties in interacting with others and self-stimulating behavior. (*Id.* at 8.) Dr. Seibel made a referral for an assessment of Scott's possible developmental delay and autism. (*Id.*)

³ Petitioners filed Exhibits 1 through 6.1 with the petition, and additional exhibits on several occasions thereafter. Respondent filed exhibits labeled from A to CC at various times. "Ex." references will be to those exhibits. "Tr." references will be to the pages of the transcript of the evidentiary hearing held on November 30, 2011.

⁴ Tetramune is a combined immunization against diphtheria, tetanus, pertussis, and haemophilus influenza type B ("Hib"). *Dorland's Illustrated Medical Dictionary* (31st ed. 2007), p. 1931.

Scott was examined by Dr. Aftab Qadir, at the Arnold Palmer Hospital on September 9, 1998. (Ex. 5.1, p. 6.) There, his parents reported that Scott “just quit talking” before his sister was born, about one year previously. (*Id.*) The remainder of the history was similar to that given to Dr. Seibel during the visit of August 10, 1998, although Mrs. Franklin added that her father and brother had “some of the same qualities as her son.” (*Id.*) The physician’s impression was “Pervasive developmental disorder NOS” and “Speech and Language Disorder.” (*Id.* at 7.)

Dr. John McReynolds evaluated Scott’s symptoms on October 20, 1998, and concluded that he suffered from “pervasive developmental disorder and severe language disorder,” but declined to identify a cause. (Ex. 31, p. 3.)

On November 12, 1998, Scott was seen by Dr. Michael Pollack for an initial visit at the Neurology Clinic of the Nemours Children’s Clinic. (Ex. 3.5, pp. 55-56.) The diagnostic impression was “autistic disorder.” (*Id.* at 56.) Follow-up visits to Nemours Children’s Clinic were made on January 6, January 22, and March 1, 1999, in which Scott was evaluated in the divisions of Genetics and Metabolism, as well as Gastroenterology. (Ex. 3.5, pp. 49-54.) No specific genetic or metabolic cause for Scott’s disorder was identified. (*Id.*)

On January 13, 1999, Scott was evaluated by Dr. Jeff Bradstreet. (Ex. 6, p. 1.) Dr. Bradstreet’s diagnosis was “autism.” (*Id.* at 3.) Dr. Cornelia Franz assessed Scott’s condition on February 6, 2001, and identified it as “autism.” (Ex. 28, p. 3.)

The medical records, in general, further indicate that Scott has continued to suffer, since that time, from a severe developmental disorder, which has consistently been labeled as “autism” or as a disorder falling within the autism spectrum.⁵

B. Procedural History

The Petitioners, Andrea and Brian Franklin, filed their Program petition on October 1, 1999, alleging that Scott’s severe developmental disorder was caused by his MMR vaccination of October 7, 1996. Proceedings were delayed for several years at Petitioners’ request, to give them time to assemble and file medical records and expert reports. During 1999 to 2002, Petitioners filed several expert reports of Dr. Jeff Bradstreet and Dr. John Menkes. (Exs. 6.1, 22, 23, 26.) Respondent filed “Rule 4 reports” indicating the view that compensation of the case was not appropriate. (ECF No. 47; ECF No. 50.) Respondent also filed several expert reports, opposing Petitioners’ claim. (Exs. A, C, E, G, K.)

⁵ “Autism spectrum disorder” is a *general* classification which includes five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger’s Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term “autism” is often utilized to encompass *all* of the five types of disorders falling within the autism spectrum. (*Id.*) Scott’s own disorder has been characterized as “autistic disorder” (Ex. 3.5 at pp. 55-56); as PDD-NOS (Ex. 5.1, p. 3); or simply as “autism” (Ex. 6, p. 3), all of which labels indicate that Scott’s disorder falls within the general category known as “autism” or “autism spectrum disorder.”

From 2003 until January 15, 2008, there was no activity in the case, again at the Petitioners' request, as the Petitioners chose to await the outcome of the Omnibus Autism Proceeding ("OAP") test cases. The Omnibus Autism Proceeding was a *general* proceeding under the Program in which attorneys representing about 5,000 different Program petitioners worked together in an attempt to demonstrate that certain types of vaccines, including the MMR vaccine, can cause the neurodevelopmental disorder known as "autism."⁶

On January 15, 2008, Petitioners were ordered to file all medical records relating to Scott's illness, as well as a statement addressing whether they wanted to continue, or await the outcome of the OAP. (ECF No. 69.) On February 19, 2008, Petitioners filed a "Statement of Compliance," indicating that they had filed all relevant medical records. (ECF No. 70.)

On June 4, 2008, Petitioners filed an Amendment to their petition, raising an "alternative" allegation that if Scott's developmental disorder was not *initially* caused by his MMR vaccination, it was significantly aggravated by that vaccination. (ECF No. 75.)

On February 12, 2009, three special masters separately issued decisions in the first three "test cases" in the OAP: *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009); and *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). All three decisions determined that the evidence *failed* to demonstrate any general causal connection between the MMR vaccine and the development of autism spectrum disorders. These decisions were each subsequently affirmed, on appeal, by three different judges of the U.S. Court of Federal Claims. *Hazlehurst v. HHS*, 88 Fed. Cl. 473 (2009); *Snyder v. HHS*, 88 Fed. Cl. 706 (2009); *Cedillo v. HHS*, 89 Fed. Cl. 158 (2009). Subsequently, the two cases that were appealed to the U.S. Court of Appeals for the Federal Circuit, *Cedillo* and *Hazlehurst*, were again affirmed. *Cedillo v. HHS*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, 604 F.3d 1343 (Fed. Cir. 2010). (The *Snyder* case was not appealed to the Federal Circuit.)

In March 2010, the same three special masters issued three more opinions in three more OAP "test cases," this time rejecting the *second* causation theory presented in the OAP, that *thimerosal-containing vaccines* can cause autism. *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). None of those decisions were appealed.

The Petitioners in this case, after the first three OAP test case decisions were issued, informed the court that they now wished to proceed with their claim, and would be filing a new expert opinion in support. On April 26, 2010, Petitioners filed an expert medical report from Dr. J. Ivan Lopez. (Pet. Ex. 38.) Shortly thereafter, Petitioners filed a supplemental expert report from Dr. Lopez, as well as an affidavit from Cornelia Franz, M.D. (Pet. Exs. 39, 42.) Respondent filed responsive expert reports from Dr. Neal Halsey and Dr. Max Wiznitzer. (Resp.

⁶ For further discussion of the OAP, see *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), at *8-11.

Exs. P, Q.) Petitioners filed another supplemental expert report from Dr. Lopez on February 17, 2011. (Pet. Ex. 43.)

After Petitioners and Respondent filed their expert reports in 2010 and 2011, I conducted an evidentiary hearing on November 30, 2011. At that hearing, Petitioners relied solely on the testimony of Dr. Lopez, while Respondent presented oral testimony from Drs. Wiznitzer and Halsey. At the hearing, I requested that the parties file post-hearing briefs. Petitioners' post-hearing brief was filed on April 30, 2012, and Respondent's post-hearing brief was filed on July 3, 2012. On August 16, 2012, Petitioners' counsel informed the court that he did not intend to file a post-hearing reply brief. Thus, the case is now ripe for a ruling concerning the issue of "entitlement," *i.e.*, whether Petitioners have demonstrated that they are entitled to a Program award on Scott's behalf.

III

ISSUE TO BE DECIDED

In this case, Petitioners seek a Program award, contending that the developmental disorder from which Scott suffers was "caused-in-fact" by an "encephalopathy" resulting from one of the vaccinations that he received on October 7, 1996. After careful consideration, I conclude that Petitioners have failed to demonstrate causation.⁷

Petitioners' theory of the case, as presented at the evidentiary hearing and in their post-hearing brief, may be briefly summarized as follows. Petitioners contend that Scott's condition of severe developmental delay, described above at pp. 4-5, should *not* be considered an autism spectrum disorder ("ASD"). Petitioners contend that Scott's condition, instead, was caused by an "encephalopathy" (brain injury) resulting from one of the vaccinations that he received on October 7, 1996. (*See* "Petitioners' Post Trial Memorandum" filed on April 30, 2012, at pp. 17-21.)

Respondent disagrees, contending that Petitioners have failed to meet the burden of proving causation. Respondent argues that Scott's clinical history, in the days after the vaccinations in question, is *inconsistent* with the "encephalopathy" that Petitioners allege. Respondent's experts believe that Scott has a typical case of ASD, which has nothing to do with any vaccinations.

⁷ Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

After carefully considering all of the evidence in the record, I must *reject* Petitioners' claim⁸ that Scott's severe neurodevelopmental condition, which has been characterized as an ASD, was caused by one of his vaccinations.

IV

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, each side relies upon the expert reports and hearing testimony of medical experts. At this point, I will briefly summarize both the qualifications and the opinions of those expert witnesses.

A. *Petitioners' experts*

1. *Dr. J. Ivan Lopez*

Dr. J. Ivan Lopez attended La Salle University School of Medicine from 1977 to 1982. (Ex. 44. at 9.) He completed his residency in orthopedic surgery in Mexico City between 1984 and 1988. (*Id.* at 3.) He completed his pediatric residency at the University of South Alabama Department of Pediatrics from 1992 to 1993, followed by his neurology residency, at the University of South Alabama, from 1993 to 1997. (*Id.* at 2.) From 1997 to 2003, Dr. Lopez worked in private practice in both Florida and Georgia. (*Id.*) He became an Assistant Clinical Professor of Pediatrics at Mercer University School of Medicine in 2002, and then an Associate Professor of Neurology at the University of South Alabama in 2003, where he continued to work in various capacities until 2009. During the time of his testimony in this case, Dr. Lopez was an Associate Professor of Neurology and Pediatrics at the University of Alabama in Birmingham. (*Id.*; Tr. 69.) He is board-certified by the American Board of Psychiatry and Neurology, with a special qualification in Child Neurology. (Ex. 44, p. 13.)

Dr. Lopez filed an expert report in this case on April 26, 2010, Exhibit 38; a supplemental report, on October 12, 2010, Exhibit 42; and an additional supplemental report on February 17, 2011, Exhibit 43. Dr. Lopez also testified at the evidentiary hearing in Orlando, Florida, on November 30, 2011.

2. *Dr. Cornelia Franz*

Dr. Franz is a board-certified pediatrician, in practice for 25 years in Orlando, Florida. (Ex. 39 at 1.) She attended Wake Forest University as an undergraduate, and subsequently received her medical degree from Bowman Gray School of Medicine in Winston-Salem, North Carolina. (*Id.*) She completed her pediatric internship in Lexington, Kentucky. (*Id.*) Following her internship, she did a fellowship in Adolescent Medicine at Cincinnati Children's Hospital. (*Id.*) Dr. Franz was the founder of The Franz Center in Orlando, Florida, wherein she conducts a

⁸ Petitioners' claim in this case is solely a "causation-in-fact" claim. They do *not* argue that Scott suffered a "Table Injury" encephalopathy, as that injury is defined in the applicable regulations. (See, *e.g.*, "Petitioners' Post Trial Memorandum," filed on April 30, 2012.)

practice which specializes in general pediatrics. (*Id.*) She routinely provides vaccines to patients as part of pediatric care, and has privileges at the Arnold Palmer Hospital for Children and Women in Orlando. (*Id.*)

3. *Summary of opinions of Petitioners' experts*

Petitioners ultimately relied most heavily on the opinion of Dr. Lopez, who was the only expert that they presented at the evidentiary hearing. In his three written expert reports (Exs. 38, 42, 43), and in his hearing testimony (Tr. 68-133, 273-281), Dr. Lopez opined that one of the vaccinations that Scott received on October 7, 1996, caused him to suffer an “encephalopathy”--*i.e.*, a brain injury--which encephalopathy caused Scott’s subsequent developmental disorder.

In his third written report, Dr. Lopez proposed a *mechanism* by which the vaccination caused the brain injury, a process known as “molecular mimicry.” (Ex. 43, p. 1.) In this process, he explained, some portion of the vaccine “closely resembles the molecular structure of the myelin sheath of the neurons, thereby confusing the immune system of the individual.” (*Id.*) In other words, because of this resemblance, the body’s immune system mistakenly attacks the neurons, which are a component of the brain, in what is known as an “autoimmune” process. Dr. Lopez also described this process as a “post-vaccination encephalomyelitis,” meaning a swelling of the myelin sheath of the brain, due to the misguided attack by the immune system. (Ex. 38, p. 2.)

In further explanation, Dr. Lopez opined that Scott’s developmental disorder, while it does include *symptoms* similar to those of autism, should *not* be characterized as “autism.” Dr. Lopez opined that if a *cause is known* for a disorder such as Scott’s, that disorder is thereby disqualified from the category of autism. (Ex. 42, p. 1; Ex. 43, p. 1.)

Petitioners also rely, secondarily, on the opinion of Dr. Franz, who has been Scott’s treating pediatrician.⁹ Dr. Franz did not testify at the evidentiary hearing, but supplied an affidavit, which stated that “[b]ased on my 25 years of experience as a pediatrician, and after reviewing the photographs and DVD footage supplied to me, it is my opinion that Scott Patrick Franklin* * * was developing normally and meeting appropriate milestones for his age at 11 months. He thereafter suffered some form of neurologic injury, which resulted in loss of language and regression in behavior and most likely permanent injury to his brain.” (Ex. 39,

⁹ As noted above, soon after they filed their petition, Petitioners filed written reports of two other experts, Dr. James Jeffrey Bradstreet and Dr. John Menkes. (Exs. 6.1, 21, 22, 23, 26.) However, as also noted, they then chose *not* to pursue their case to a ruling at that time, but chose instead to wait for the outcome of the Omnibus Autism Proceeding. After the publication of the autism “test case” opinions described above (see p. 6), petitioners elected *not* to rely upon the opinions of Dr. Bradstreet and Dr. Menkes, but to instead rely solely upon the opinions of Drs. Lopez and Franz. (See, *e.g.*, Tr. 153.) Accordingly, I have not analyzed the opinions of Dr. Bradstreet and Dr. Menkes in this Decision. However, I note that I have read the reports of Drs. Bradstreet and Menkes, and have found them to be unpersuasive. Moreover, I found those opinions to be persuasively refuted by the experts reports of Drs. Wiznitzer and Halsey filed by Respondent, particularly Exs. C and E.

p. 2.) Dr. Franz added that Scott's neurodevelopmental disorder "would be consistent with an encephalopathic reaction to vaccination," and that "more likely than not his neurological damage was caused by encephalopathy after vaccination." (*Id.*)

B. Respondent's experts

Respondent has relied primarily on the expert reports and testimony of two experts, Drs. Wiznitzer and Halsey.¹⁰

1. Dr. Max Wiznitzer

Dr. Max Wiznitzer is a pediatric neurologist with an active clinical and research practice, who has diagnosed and treated thousands of children with ASDs. (Tr. 208-10, 213; *see also* Ex BB.) Dr. Wiznitzer received a B.S. in Medical Education in 1975 from Northwestern University. (Ex. D at 1.) He received his M.D. from Northwestern University in 1977. (*Id.*) Dr. Wiznitzer completed his residency in pediatrics at the Children's Hospital Medical Center of Cincinnati from 1977 through 1980, and thereafter completed his fellowship in developmental disorders at the Cincinnati Center for Developmental Disorders in 1981. (*Id.*)

Dr. Wiznitzer is board-certified in pediatrics, pediatric neurology, and neurodevelopmental disabilities. (Tr. 204.) He is an Associate Professor of Pediatrics, Neurology and International Health at Case Western Reserve University School of Medicine, and a staff child neurologist at the Rainbow Babies and Children's Hospital in Cleveland, Ohio. (Tr. 202-03.) Dr. Wiznitzer is a member of the American Academy of Neurology, the American Academy of Pediatrics ("AAP"), and the Child Neurology Society. (Tr. 204, 206.) He sits on the AAP's Executive Committee for the Council on Children with Disabilities, and is the neurology representative to the Autism Subcommittee of the AAP. (Tr. 210-11.) He has also extensively researched and published articles and papers on autism. (Tr. 212-13; *see also* Ex. BB.)

2. Dr. Neal Halsey

Dr. Halsey received a B.S. in Zoology from the University of Wisconsin in 1967. He then received his M.D. from the University of Wisconsin in 1971. (Ex. F at 1.) In 1972, Dr. Halsey completed an internship at the Children's Hospital, Denver, Colorado. (*Id.*) He was then a General Medical Officer of the Indian Health Service at the U.S. Public Health Service Hospital in Fort Yates, North Dakota, from 1973 to 1974. (*Id.*; Tr. 158.) Dr. Halsey completed his residency at the University of Colorado Medical Center from 1974 to 1975. (Ex. F at 2.)

¹⁰ Respondent also filed expert reports of Drs. John MacDonald and John Sever. However, those reports primarily were devoted to refuting the petitioners' early expert reports of Drs. Bradstreet and Menkes. Accordingly, while I have read the reports of Drs. MacDonald and Sever, they have not played any role in my resolution of this case.

Additionally, Dr. Halsey has served as a professor at Tulane University from 1980 through 1985, in both the Department of Pediatrics and the Department of Tropical Medicine. (*Id.* at 2.) Dr. Halsey also has served at The Johns Hopkins University, School of Hygiene and Public Health, from 1985 to present, and works primarily in the International Health Department, with a primary office in the Institute for Vaccine Safety. (Ex. F at 2; Tr. 159-60.) Dr. Halsey has also served in many medical organizations and written many publications regarding immunization. (*See generally* Ex. F; Tr. 162.)

Dr. Halsey is board-certified in pediatrics and in pediatric infectious diseases. (Tr. 158.) During Dr. Halsey's time at the Indian Health Service, he dealt with a measles epidemic and conducted an investigation about the measles vaccine and its ability to protect against disease. (Tr. 159.)

Additionally, Dr. Halsey has written over 200 peer-reviewed publications on vaccine-preventable diseases and immunizations, has authored or co-authored over 40 book chapters pertaining to immunizations, and has been a reviewer or editor for dozens of journals. (Tr. 162-63.) Dr. Halsey has served on advisory committees for the American Academy of Pediatrics, particularly the Committee for Infectious Diseases, which he chaired for four years. (Tr. at 162.) He has also served ten years in the Centers for Disease Control and Prevention's Advisory Committee for Immunization Practices. (Tr. 162.) Furthermore, Dr. Halsey served seven years on the World Health Organization's Research and Development Committee for the expanded program on immunization. (Tr. 161-62.)

3. *Summary of opinions of Respondent's experts*

Respondent's experts strongly disagree with Dr. Lopez' assertion that any of Scott's vaccinations caused, or have had any effect on, his ongoing developmental disorder. In response to Dr. Lopez' argument that Scott does not have autism, Dr. Wiznitzer testified that Dr. Lopez "is totally wrong" in his definition and understanding of autism. (Tr. 226-27.) Dr. Wiznitzer testified that, contrary to Dr. Lopez' testimony, autism is not a "murky" or a "vague" term. (Tr. 226.) Rather, "[a]utism is a well-defined entity. We know what it is." (Tr. 226.) Dr. Wiznitzer agrees with Scott's treating physicians, who opined that Scott has an ASD, and explained that Dr. Lopez is simply wrong in his contention that for an individual to be considered autistic, the cause of the disorder must be unknown. (Tr. 227, 243.)

Further, both Dr. Wiznitzer and Dr. Halsey strongly disagreed with Dr. Lopez' opinion that Scott suffered an *encephalopathy* in the ten days after his vaccinations of October 7, 1996. Both discussed Scott's symptoms that were reported during Scott's return visit on October 17, 1996, and opined that such symptoms did *not* indicate that Scott was suffering from an encephalopathic process at that time. (Ex. P, p. 1; Ex. Q, p. 3; Tr. 167-71, 240-42, 283-85.)

RESPONDENT'S EXPERTS WERE FAR MORE PERSUASIVE IN GENERAL

For all of the reasons set forth in this section and the sections of this Decision below, I conclude that Petitioners have *failed* to demonstrate that it is “more probable than not” that Scott’s vaccinations of October 7, 1996, played *any* role in causing or aggravating his severe neurodevelopmental disorder. And the first of the reasons for this conclusion is simply that I found Respondent’s primary experts, Drs. Wiznitzer and Halsey, to be far more persuasive than the experts upon whom Petitioners relied, Drs. Lopez and Franz.

A. *Qualifications*

In this regard, I start with the qualifications of the opposing experts relative to the issues raised by Petitioners’ claim. In short, the credentials of Respondent’s experts are vastly superior. Scott is a child who has been given a diagnosis within the *autism* spectrum by several of his treating physicians, and as a part of his opinion in this case Dr. Lopez argues that such autism diagnosis is *not* a proper diagnosis for Scott. However, Dr. Wiznitzer disputes that part of Dr. Lopez’s opinion, and, with regards to the topic of autism, Dr. Wiznitzer is *far* more qualified than Dr. Lopez.

Dr. Wiznitzer regularly diagnoses and treats autism as a major part of his everyday clinical practice. (Tr. 209, 218.) He has participated with national committees in designing protocols for the screening and diagnosis of autism. (Tr. 211.) He has participated in developing protocols for treating autism as well. (Tr. 212.) He has participated in major research projects concerning autism. (Tr. 212-13.) And he has published articles about autism. (Tr. 213.)

In contrast to Dr. Wiznitzer, Dr. Lopez acknowledged that in his clinical practice, he does *not* treat autism, nor diagnose autism. (Tr. 134, 145.) He has never been involved in studies of autism. (Tr. 143.) He has published no articles about autism. (Tr. 144.)

In a similar fashion, Dr. Halsey is far more qualified than Dr. Lopez in terms of knowledge of the causation of disease by the measles vaccine and other vaccines. Dr. Halsey is board-certified in the area of pediatric infectious disease. (Tr. 158.) In a long and distinguished career, he has served in many medical organizations concerning vaccinations. (See generally Ex. F; Tr. 162.) He has served as the director of the Institute of Vaccine Safety at the Johns Hopkins Hospital. (Tr. 160.) He served for ten years on the Committee on Infectious Disease of the American Academy of Pediatrics, including four years as its chair. (Tr. 162.) He served for seven years on the immunization committee of the World Health Organization. (Tr. 161-62.) He has written more than 200 peer-reviewed publications concerning immunizations and vaccine-preventable diseases, has authored or co-authored over 40 book chapters pertaining to immunizations, and has been a reviewer or editor for dozens of medical journals. (Tr. 162-63.)

In contrast to Dr. Halsey, Dr. Lopez claimed no special experience concerning vaccines, vaccine-preventable diseases, or vaccine-safety issues. He acknowledged that he has never

studied the measles vaccine, and has published no written material concerning vaccines. (Tr. 143-144.)

B. General deficiencies in Dr. Lopez' testimony

But even more importantly than the vast gap in *qualifications*, between Dr. Lopez and Respondent's primary experts, was the even greater gap in the experts' *ability to explain* their opinions. The written reports and hearing testimony of both Drs. Wiznitzer and Halsey seemed to me to be coherent and logical. In contrast, the written reports of Dr. Lopez were short and not well explained, while his hearing testimony was often poorly explained, self-contradictory, and less than logical.

In fact, throughout his participation in the case, I often had difficulty understanding exactly what the opinion of Dr. Lopez was, much less his *reasoning* for that opinion. For example, Dr. Lopez began his first expert report by quoting a one-paragraph description of a well-known condition that was often seen after infection with the wild measles *virus*, commonly known as "measles encephalitis" or "measles encephalopathy." (See Ex. 38, p. 1, first paragraph.¹¹) That caused me, Respondent's experts, and apparently even Petitioners' own attorney (see, *e.g.*, Tr. 81-82, 93) to believe that Dr. Lopez was identifying Scott's *MMR* vaccination, particularly the measles vaccine, as the culprit in Scott's disorder, and was opining that Scott had suffered from a form of "measles encephalopathy" or "measles encephalitis."¹² Then, during his hearing testimony on direct exam, Dr. Lopez again referred to the *same* description of "measles encephalopathy" with which he had begun his first expert report (Tr. 81, line 19, to Tr. 82, line 2), and testified explicitly that such description *did* fit the description of Scott's case set forth in Scott's medical records. (Tr. 82, lines 7-11.) Again, this testimony of Dr. Lopez made it appear that he was opining that Scott suffered from the well-recognized condition of "measles encephalopathy" or "measles encephalitis."

However, Dr. Halsey, the renowned measles expert, then testified that while "measles encephalitis" was well-recognized as occurring after infection by the measles *virus*, and occasionally after exposure to the measles *vaccine*, in contrast, *Scott's symptoms*, as described in his visit 10 days after his vaccinations in question, were *nothing like* the well-recognized "measles encephalitis" condition. (Tr. 167-71.)

In response, Dr. Lopez changed or clarified his testimony in a fairly drastic way. Suddenly, he now "agreed with Dr. Halsey that Scott didn't have measles encephalitis." (Tr. 274.) Dr. Lopez added that he "didn't recall" saying that Scott had "measles encephalitis" (*id.* at

¹¹ That paragraph turns out to have been mostly a *direct quote* from an article by Dr. Menkes, which appears at Ex. 22a, p. 681, in this case. However, in his Ex. 38 Dr. Lopez neither used quotation marks nor indicated where the material was from.

¹² In both his Ex. 38 (p. 1) and during his hearing testimony, Dr. Lopez quoted from the Menkes textbook excerpt, in which this well recognized post-measles condition is described as "encephalopathy" (see Tr. 81, line 19). However, as Dr. Halsey testified, this condition is more often called "measles encephalitis." (Tr. 169-72, 177.)

line 19), and seemed to suggest that if he had so stated, his statement had been a “mistake” (*id.* at line 20). Dr. Lopez then appeared to opine that Scott had suffered a *different* type of encephalopathic reaction to a vaccination, with much less drastic symptoms than those of classic “measles encephalitis.” (Tr. 274-79.)

Dr. Lopez also “clarified” at the hearing, under cross-examination, another crucial point that was far from clear in his written reports. He explained that it was not necessarily the *measles* vaccine that caused Scott’s condition, but could have been *any* of the seven separate vaccines that Scott received on October 7, 1996. (Tr. 104.) (As noted above, Scott received the measles, mumps, and rubella vaccinations, as part of the MMR inoculation, and also the diphtheria, tetanus, pertussis, and haemophilus influenza type B vaccinations, as the four components of the Tetramune immunization.) This testimony again undermined Dr. Lopez’ reliability as an expert, because he had begun his first expert report with a quotation that seemed to attribute Scott’s condition to a *measles* vaccination, and then *specifically indicated* in his direct examination that Scott suffered from “measles encephalopathy.” (Tr. 93, lines 18-21.) In other words, Dr. Lopez’ apparent ambivalence as to whether he was pointing specifically to the *measles* vaccine, or generally to *any* of the seven vaccines, cast doubt on his reliability.

There were other glaring flaws and self-contradictions in Dr. Lopez’ reports and hearing testimony that diminished his persuasiveness as an expert. For example, in his first expert report, Dr. Lopez stated that there was evidence that Scott was suffering from a condition known as subacute sclerosing panencephalitis (“SSPE”). (Ex. 38, p. 2.) But then, in his second report, Dr. Lopez discarded that allegation, admitting that Scott did not suffer from SSPE. (Ex. 42, p. 1.)

Similarly, Dr. Lopez opined in his second written report that Scott was suffering from an “ongoing and persistent autoimmune process.” (Ex. 42, p. 1, part (c).) Yet, in his hearing testimony, he changed his opinion on that point as well, stating that Scott was *not* suffering from an *ongoing* autoimmune process. (Tr. 101.)

There were other major discrepancies in Dr. Lopez’ logic that made him seem, in the final analysis, to be very unpersuasive. Two of those flaws will be described at length in the next two sections of this Decision. First, Dr. Lopez insisted that Scott’s condition should not be labeled “autism,” for a very strange reason, despite the fact that Scott’s treating physicians have consistently diagnosed him with autism. (See part VI of this Decision below.) Second, Dr. Lopez’ entire opinion is dependent on a description of symptoms that Scott displayed about 10 days after his vaccinations in question, when in fact such symptoms, as actually described in the medical records, seem to be very *minor* ones. (See part VII of this Decision below.) Again, Dr. Lopez’ analysis of these symptoms seemed illogical on its face, even before being thoroughly refuted by respondent’s more qualified experts.

In contrast to the vagueness, ambivalence, self-contradiction, and illogic of Dr. Lopez’ testimony, the testimony of Drs. Wiznitzer and Halsey was coherent, consistent, and logical throughout.

To be sure, I do *not* conclude that Dr. Lopez was *intentionally* being less than candid and honest. Nor do I have any reason to doubt that Dr. Lopez is a competent clinical practitioner in his field. My conclusion is simply that, in general, the presentations of Drs. Wiznitzer and Halsey in this case were far more persuasive than that of Dr. Lopez.¹³

VI

DR. LOPEZ WAS UNPERSUASIVE IN ARGUING THAT AUTISM IS NOT AN ACCURATE DIAGNOSIS FOR SCOTT

As noted above, a key part of Dr. Lopez' opinion in this case is that he believes that Scott's neurodevelopmental disorder should *not* be considered to be within the autism spectrum. Dr. Lopez has opined that if one can identify a *cause* for a neurodevelopmental disorder, which he believes that he has for Scott's disorder (*i.e.*, a vaccination cause), then such disorder should *not* be considered to be *autism*. (*E.g.*, Ex. 42, p. 1; Ex. 43, p. 1.)

However, based upon the record of this case, I conclude that Dr. Lopez is simply wrong on this point.

First, as explained above (pp. 10-12), Dr. Wiznitzer is far better qualified than Dr. Lopez to opine concerning the topic of autism. And Dr. Wiznitzer testified persuasively that Dr. Lopez is "totally wrong" in his understanding of autism. (Tr. 226.) Dr. Wiznitzer testified that Dr. Lopez was incorrect to state that if a specific cause can be identified, then the disorder is thereby not autism. (Tr. 227.) Dr. Wiznitzer listed several types of autism for which specific causes *are* known. (*Id.*) Dr. Wiznitzer testified that autism is clearly the correct diagnosis for Scott. (Ex. P, p. 1; Tr. 243.)

Further, Scott's medical records show that his own treating physicians have consistently identified Scott as having a disorder within the autism spectrum. For example, on November 12, 1998, Scott was given the diagnosis of "autistic disorder" by Dr. Michael Pollack. (Ex. 3.5, p. 56.) On September 9, 1998, Dr. Aftab Qadir noted that Scott has "pervasive developmental

¹³ I have found two instances in which other special masters of this court have commented on the opinions offered by Dr. Lopez in Vaccine Act cases. In *Banks v. HHS*, 2007 WL 2296047, at *13 (Fed. Cl. Spec. Mstr. July 20, 2007), Special Master Abell relied upon the opinion of Dr. Lopez, finding him to be "personally and professionally credible."

On the other hand, a vaccine-causation opinion by Dr. Lopez was recently rejected emphatically by Special Master Vowell in *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Sept. 28, 2012). In that case, as in this one, Dr. Lopez opined that a neurodevelopmental disorder, which had been described as "autism," should *not* be considered to be autism because Dr. Lopez considered it to have been vaccine-caused. Special Master Vowell rejected that opinion as incorrect, just as I do in this case. (2012 WL 594060 at *13, and fn. 49.) Referring to Dr. Lopez' causation opinion in the *Henderson* case in general, Special Master Vowell stated that a "better example of both circular and *post hoc, ergo propter hoc* reasoning would be difficult to find." (*Id.* at *3.)

disorder NOS,” another diagnosis within the autism spectrum.¹⁴ (Ex. 5.1, p. 3--*see also* fn. 5 above.) On January 13, 1999, Dr. Jeff Bradstreet stated that Scott’s disorder was “autism.” (Ex. 6, p. 3.) Dr. Cornelia Franz also diagnosed Scott’s condition as “autism.” (Ex. 28, pp. 1-3.)

In short, the record of this case indicates that Dr. Lopez is quite wrong in this part of his opinion. Contrary to the opinion of Dr. Lopez, Scott clearly does suffer, tragically, from a disorder within the autism spectrum.

VII

THE EVIDENCE DOES NOT SUPPORT A CONCLUSION THAT SCOTT’S SYMPTOMS OF OCTOBER 17, 1996, WERE INDICATIVE OF AN ENCEPHALOPATHY

As explained above, the second major component of Dr. Lopez’ opinion in this case is his interpretation of the symptoms that Scott experienced about 10 days after his vaccinations on October 7, 1996. As noted, Scott returned to Dr. Seibel ten days later, on October 17, 1996, and the physician’s notes concerning the visit indicate that Scott was “pulling at his ears,” was “fussy,” had “loose stools,” and had “low grade,” apparently meaning a slight fever. (Ex. 3.4, p. 1.) The notes made by Scott’s mother concerning the same visit indicate that Scott was exhibiting symptoms including, “appetite/diarrhea/tired/fever/grouchy/gassy/yellow-red spots.” (Ex. 46, p. 7.) Dr. Lopez has interpreted those symptoms to indicate that Scott was suffering at that time from an “encephalopathy”--*i.e.*, a brain injury--caused by a misguided reaction of his immune system to one of the seven vaccines that Scott received on October 7. (Exs. 38, 42, 43; Tr. 72-73.) However, consideration of the entire record makes me conclude that Dr. Lopez is quite mistaken in his interpretation of those symptoms. There are two major reasons for this conclusion.

First, Scott’s treating pediatrician at the time, Dr. Siebel, noted those symptoms, but was apparently *not* alarmed at all by them. The pediatrician clearly did *not* conclude from those symptoms that Scott was undergoing an encephalopathy, since he did not send Scott to a hospital or to a specialist. Based on those symptoms, the treating pediatrician concluded instead that Scott was “teething.” (Ex. 3.4, p. 1.) It is quite dubious that Dr. Lopez’ re-interpretation, years later, of the written notations concerning Scott’s symptoms, would be more reliable than the assessment of the pediatrician who actually examined Scott at the time.

Further, Dr. Seibel specifically noted on July 16, 1997, 10 months after the shots in question, that Scott had *not* suffered any “immunization reaction.” (Ex. 3.5 at 1.)

¹⁴ In their post-hearing brief, petitioners point out that one of Scott’s physicians, Dr. Qadir, diagnosed him not with “autism” but with “Pervasive Developmental Disorder--NOS”). (Brief at p. 7, para. 33; Ex. 5.1, p. 3.) However, “Pervasive Developmental Disorder Not Otherwise Specified,” also known as “PDD-NOS,” in fact, *is* one of the disorders included within the autism spectrum. *See, e.g.*, Tr. 262-63; *King v. HHS*, No. 03-584V, 2010 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010).

Second, Respondent's experts were quite persuasive in their opinions that Dr. Lopez' interpretation of Scott's symptoms was grossly mistaken. Dr. Halsey testified strongly in this regard. (Tr. 167-76.) Dr. Halsey noted that the pediatrician's notation that Scott "drinks well," in the notes of the October 17 visit (Ex. 3.4, p. 1), contradicts Dr. Lopez' conclusion that Scott was suffering from an encephalopathy at that time. (Tr. 168.) Dr. Halsey summarized that Dr. Lopez' interpretation of Scott's symptoms "just doesn't make sense; it doesn't meet anybody's case definition for encephalopathy." (Tr. 167.) Dr. Halsey explained that an infant's symptoms would have to be much more severe to justify a conclusion that the child was undergoing an encephalopathy. (Tr. 168, 170, 171, 200-201.)

Dr. Wiznitzer also testified that the symptoms in Scott's records do *not* justify Dr. Lopez' inference of an encephalopathy. (Tr. 240-42.) Dr. Wiznitzer, like Dr. Halsey, pointed to the notation that Scott was drinking well at the time, as indicative that Scott was not encephalopathic. (Tr. 241.) Dr. Wiznitzer explained that the pediatric records did not indicate any impairment of Scott's consciousness or significant change in his mental status. (Tr. 240-41.) He opined that if Scott were actually undergoing an encephalopathy, the pediatrician would have recognized it. (Tr. 241.) And he also noted that if Scott had suffered a post-vaccination encephalopathy, that would have appeared on Scott's MRI as damage to the gray matter of his brain, which it did not. (Tr. 231-32.)

In this regard, I also note that Dr. Lopez' testimony on this point changed significantly during the evidentiary hearing. As explained above (p. 13), after the measles expert, Dr. Halsey, testified that Scott's symptoms on October 17 could not possibly justify a diagnosis of the well-recognized condition of "measles encephalitis," Dr. Lopez then seemed to opine that Scott had a *different* type of reaction to a vaccination, with much less drastic symptoms than those of classic "measles encephalitis." (Tr. 274-79.) However, Dr. Halsey then testified in rebuttal that he also disagreed with Dr. Lopez' new theory that Scott experienced not classic "measles encephalitis," but some type of *lesser* encephalopathic reaction that could have been caused by any of the seven vaccines that Scott received on October 7, 1996. (Tr. 282-86.) Dr. Halsey, with his extensive background in the field of vaccines and vaccine safety issues, testified that he knew of no evidence whatsoever to support the Dr. Lopez' theory that one of the vaccines that Scott received could have caused an encephalopathy that began with Scott's very mild symptoms of October 17, 1996, but went on to result in Scott's severe permanent neurodevelopmental disorder. (Tr. 283-285.) Dr. Halsey testified that Dr. Lopez' proposed scenario is neither plausible nor reasonable. (Tr. 285, 289-90.)¹⁵

In short, based on the record as a whole I must reject the essence of Dr. Lopez' opinion, that based upon the symptoms that Scott experienced about October 17, 1996, he suffered a vaccine-caused encephalopathy that also caused his permanent, severe neurodevelopmental disorder. That theory of Dr. Lopez seems extremely unlikely on its face, because it is based

¹⁵ Petitioners asserted in their post-hearing brief that Dr. Halsey "conceded" that it would be "plausible" that a vaccine "might" cause an encephalopathy "that occurred within a few days of vaccination." (Post-Trial Memo, p. 11, para. 59; see Tr. 284-85.) But Dr. Halsey then went on specifically to explain that there was no reason to suppose that the type of *mild symptoms* displayed by Scott about October 17, 1996, were evidence of an encephalopathy. (Tr. 285, 289-90.)

upon such mild reported symptoms. That theory is also contradicted by the diagnosis of “teething” made by Scott’s own treating pediatrician on October 17. (Ex. 3.4, p. 1.) And, finally, Dr. Lopez’ theory was convincingly refuted by two well-credentialed experts, Drs. Halsey and Wiznitzer. I reject Dr. Lopez’ theory.

VIII

DR. FRANZ’ OPINION DOES NOT CHANGE MY CONCLUSION

As previously noted, Petitioners rely not only upon the expert opinion of Dr. Lopez, but also upon the opinion of Dr. Cornelia Franz, who was Scott’s treating pediatrician. Dr. Franz did not testify at the evidentiary hearing. Instead, she supplied an affidavit, which stated that “[b]ased on my 25 years of experience as a pediatrician, and after reviewing the photographs and DVD footage supplied to me, it is my opinion that Scott Patrick Franklin * * * was developing normally and meeting appropriate milestones for his age at 11 months. He thereafter suffered some form of neurologic injury, which resulted in loss of language and regression in behavior and most likely permanent injury to his brain.” (Pet. Ex. 39 at 2.) Dr. Franz added that Scott’s neurodevelopmental disorder “would be consistent with an encephalopathic reaction to vaccination,” and that “more likely than not his neurological damage was caused by encephalopathy after vaccination.” (*Id.*)

Dr. Franz is a board-certified pediatrician with over 25 years of practice, and has treated Scott herself. (Ex. 39, p. 1.) Accordingly, I greatly respect her opinion, and have given it careful consideration.¹⁶ However, in my final analysis, I find that Dr. Franz’ opinion is strongly outweighed by the rest of the evidence in the record concerning the causation issue, particularly the testimony of Drs. Halsey and Wiznitzer.

In this regard, I note that not only did Dr. Franz not testify, but she also did not set forth in her written opinion any detailed explanation concerning *why* she believes that Scott’s neurodevelopmental disorder was vaccine-caused. (See Ex. 39.)

In support of her opinion, Dr. Franz gave the following explanation in her affidavit. She noted that she compared photographs of Scott taken in July of 1996, to photos taken on December 25, 1996. (Ex. 39, p. 1, paras. 5-6.) She also compared *videos* of Scott taken in March and June of 1996 with videos taken in May of 1997. (*Id.* at pp. 2-3, para. 7.) Dr. Franz explained that while the July 1996 photos and May/June 1996 videos show a normal child, the December 1996 photos and May 1997 videos show a neurologically-damaged child. (*Id.* at pp.

¹⁶In *Capizzano v. HHS*, the U.S. Court of Appeals for the Federal Circuit stressed that “medical records and medical opinion testimony are favored in vaccine cases, *as treating physicians are likely to be in the best position to determine* whether “a logical sequence of cause and effect shows that the vaccination was the reasons for the injury.” 440 F. 3d 1317, 1326 (Fed. Cir. 2006) (emphasis added, citation omitted). Similarly, in several cases, judges of this court have, in resolving the Vaccine Act causation issues, relied heavily upon the statements of treating physicians contained in the vaccinee’s medical records. *See, e.g., Zatushni v. HHS*, 69 Fed. Cl. 612, 623 (2006); *Kelley v. HHS*, 68 Fed. Cl. 84, 100 (2005).

2-3, paras. 6, 8.) From that difference in the photos and videos, Dr. Franz concluded that Scott must have “suffered some form of neurologic injury” in the meantime. (*Id.* at p. 2, para. 9.) She added that such injury “would be consistent with an encephalopathic reaction to vaccination.” (*Id.*)

Dr. Franz, however, did not explain why she believes that the neurological change or injury to Scott was *caused by a vaccination*. She did not explain *which vaccine* she thought might have caused the injury, nor by *what mechanism* any vaccine might have caused the injury, nor why she thinks any of the vaccines in question are *capable* of causing the type of severe neurodevelopmental disorder from which Scott suffers. Given these deficiencies in her affidavit, I cannot conclude that she made a persuasive causation argument.

Moreover, I must give Dr. Franz’ opinion far less weight than the opinions of Drs. Wiznitzer and Halsey, who not only wrote detailed reports refuting Dr. Franz’ causation conclusion, but were willing to testify in order to *explain* their views at length, and were able to do so in a highly persuasive manner.

Dr. Wiznitzer also specifically addressed Dr. Franz’ affidavit in his hearing testimony, convincingly pointing out the flaws in Dr. Franz’ approach to the case. (Tr. 244-45, 261-62.) As an expert in diagnosing autism--in contrast, there is no evidence that Dr. Franz has any special experience concerning autism--Dr. Wiznitzer disagreed with the way in which Dr. Franz used photographs to come to a conclusion about Scott. (Tr. 244-45, 258-59.) Dr. Wiznitzer also addressed what seems to be the reasoning implied in Dr. Franz’ affidavit--*i.e.*, that because Scott seemed normal, then later seemed autistic, he must have suffered a neurological injury in the meantime. (Ex. 39, p. 2, para. 9.) Dr. Wiznitzer explained why that is faulty reasoning, and his explanation was persuasive. (Tr. 261-62.)

In short, while I respect the opinion of Dr. Franz’, I found that it was strongly outweighed by all of the contrary evidence in this case.

IX

“SIGNIFICANT AGGRAVATION” SUGGESTION

In their “Amendment to Petition” filed on June 4, 2008, Petitioners stated an “alternative” position in the case, namely that “in the alternative, if any disease process [already] existed [in Scott] at the time of vaccination, the vaccination itself was of substantial significant aggravation of such condition.” However, Petitioners since then have argued *only* that one of Scott’s October 1996 vaccinations *originally caused* his neurodevelopmental disorder, and have *not* argued “significant aggravation” as an alternative claim.

Moreover, I find no substantial evidence of “aggravation” in the record. Petitioners clearly have failed to demonstrate that Scott’s disorder, be it labeled autism or otherwise, was aggravated by any vaccination.

PETITIONERS' CASE FAILS THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the “causation-in-fact” issue in Vaccine Act cases. The court stated as follows:

Concisely stated, *Althen*'s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (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. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' “causation-in-fact” theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits *specifically* within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy *any* of the parts of the *Althen* test.

A. *Relationship between Althen Prongs 1 and 2*

One interpretative issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide “(1) a medical theory causally connecting the vaccination and the injury,” and “(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a “causal” connection between “the vaccination” and “the injury.” However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the “can cause” vs. “did cause” distinction. That is, in many Program opinions issued prior to *Althen* involving “causation-in-fact” issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n.42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the “can cause” requirement, and Prong 2 of *Althen* is the “did cause” requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the “can it?/did it?” test, used by the special master in that case, was equivalent to

the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the *type* of vaccination in question *can* cause the *type* of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the *particular* vaccination *did* cause the *particular* condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an *overall matter*, a petitioner must demonstrate that it is “more probable than not” that the *particular* vaccine was a substantial contributing factor in causing the *particular* injury in question. That is clear from the statute itself, which states that the elements of a petitioner’s case must be established by a “preponderance of the evidence.” (§ 300aa-13(a)(1)(A).) And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is “more probable than not” that any of the vaccines that Scott received contributed to the causation of Scott’s tragic neurodevelopmental disorder.

B. Petitioners have failed to establish Prong 1 of Althen in this case

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. In this case, however, the Petitioners have failed to show that any of the vaccines that Scott received on October 7, 1996, *can* cause the type of injury from which Scott actually suffers--*i.e.*, an autism spectrum disorder.

To be sure, the evidence in the case confirms that the *wild measles virus* can cause a well-recognized condition known as “measles encephalitis” or “measles encephalopathy.” And some experts have suggested that the attenuated (weakened) form of the measles virus contained in the measles vaccine might also be capable of causing “measles encephalitis,” though that suggestion is unproven. (*E.g.*, Tr. 170-71.) However, in this case Petitioners’ own expert Dr. Lopez eventually conceded that Scott did *not* have “measles encephalitis.” (Tr. 274.)

Thus, the Petitioners’ burden in this case under *Althen*’s Prong 1 would be to show that one of Scott’s vaccines *can* cause the type of neurodevelopmental disorder from which Scott *actually suffers--i.e.*, autism. This they have clearly failed to do. As explained above, neither Dr. Lopez nor Dr. Franz even *asserted*, much less demonstrated, that any of the vaccines Scott received can cause autism. Accordingly, in this case Petitioners have clearly failed to demonstrate Prong 1 of *Althen*.

C. Petitioners have failed to establish Prong 2 of Althen in this case

Under *Prong 2*, the Petitioner would need to show that it is “more probable than not” that one of Scott’s vaccinations *did* cause Scott’s own severe neurodevelopmental disorder. But this they have failed to do, for all the reasons detailed at pp. 11-19, above. Thus, Petitioners have also failed to establish Prong 2 of *Althen* in this case.

D. Prong 3 of the Althen test

Since I have explained why Petitioners have failed to satisfy either of the *first two* prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong.

E. This is not a close case

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” (418 F. 3d at 1280.) Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I found that Dr. Lopez' theory was not at all persuasive, while Respondent's experts were *far* more persuasive.

XI

ISSUE OF OAP “GENERAL EVIDENCE,” EXHIBITS Z AND AA

As explained above, Scott has been diagnosed as suffering from the neurodevelopmental disorder known as “autism.” For that reason, Petitioners chose, as described above, to delay the resolution of their case for several years, to await the outcome of the Omnibus Autism Proceeding (OAP). As further described, when the outcome of the OAP test cases was unfavorable to the vaccine-causation theories, the Petitioners in this case then chose to rely upon the opinions of Drs. Lopez and Franz. In response, Respondent filed the expert reports of Drs. Wiznitzer and Halsey, as described, but also sought permission to file certain additional evidence from the OAP test cases into the record of this case. Specifically, on August 30, 2011, Respondent filed excerpts of OAP hearing testimony given by two of respondent's experts, Dr. Diane Griffin and Dr. Brian Ward. (Exs. Z, AA.) The issue of whether such excerpts were appropriate to be considered in this case was discussed at length during several status conferences. (See, *e.g.*, my Orders dated March 28, July 5, August 17, and October 27, 2011.) I permitted the filing of those two exhibits, over Petitioners' written objection filed on October 3, 2011, because those two experts had testified concerning the potential effects of the *measles* virus and *measles* vaccine on the human brain, and Dr. Lopez' theory appeared, *at that time*, to be that the *measles* portion of Scott's MMR vaccination caused his neurodevelopmental disorder by damaging his brain.

In permitting the *filing* of those two exhibits, however, I stressed during the status conferences that I was *not* making a final ruling as to whether I would *actually utilize* those two exhibits in deciding the case. That would depend on the evidence that was to be presented at the evidentiary hearing on November 30, 2011, and whether the evidence in the two exhibits proved to be relevant to Dr. Lopez' theory as presented at the evidentiary hearing. I further stressed that we would *revisit* the issue of the relevance of the two exhibits at the conclusion of the evidentiary hearing, and, if necessary, in the parties' post-hearing briefs.¹⁷

Ultimately, however, I concluded that the two exhibits in question were *not* relevant to the Petitioners' theory, as finally clarified by Dr. Lopez during the November 30 hearing. Those

¹⁷ I note that the evidentiary hearing was originally scheduled for two days, November 30 and December 1, 2011, but actually was finished by the close of the first day.

exhibits, therefore, played *no role whatsoever* in my resolution of this case. Once I heard Dr. Lopez' clarification of this theory during the November 30 hearing, and the refutation of that theory by Respondent's experts during that hearing, I concluded that there was *no relevance* to the two exhibits, because, as explained above, Dr. Lopez clarified that his theory was *not* related specifically to the *measles* vaccine.

Similarly, no expert for either side referred to Exs. Z and AA during the evidentiary hearing, and in the post-hearing briefs of *both* parties, no references were made to Exs. Z and AA.

Accordingly, I did not review Exs. Z and AA in the course of resolving this case. Those exhibits played no role in my analysis of this case, which was based solely on the presentations of the experts upon whom the parties *did* rely--*i.e.*, Drs. Lopez, Franz, Halsey, and Wiznitzer.¹⁸

XII

PETITIONERS' OTHER ARGUMENTS

I also briefly address several points raised by Petitioners in their post-hearing brief, filed on April 30, 2012.

A. "*Objective confirmation*" argument

For example, Petitioners note, correctly, that no "objective confirmation" is required to establish proof of vaccine-causation. (Brief at 22.) However, I have not required any such "objective confirmation." I have required Petitioners only to demonstrate that it is "more probable than not" that Scott has a vaccine-caused injury--but they have failed, by far, to do so.

B. "*Alternative cause*" argument

Petitioners also seem to argue that Respondent failed to pinpoint a cause, other than the vaccines, for Scott's tragic disorder. However, the identification of a cause was never *Respondent's* burden. Petitioners never came close to fulfilling *their burden* of establishing a *prima facie* case of causation under the *Althen* test, so the burden never shifted to Respondent to point to an alternative cause.

C. *Banks* opinion

Petitioners, in addition, discussed at length the case of *Banks v. HHS*, 2007 WL 2296047, 2007 U.S. Claims Lexis 254 (Fed. Cl. Spec. Mstr. July 20, 2007.) The *Banks* opinion is, indeed, an interesting one, but in the final analysis it is so different from this case that it offers no substantial assistance to Petitioners' case here.

¹⁸ In other words, I resolved this case *solely* upon the record of this case, without reference to any evidence from the OAP record.

To be sure, in *Banks*, the same Dr. Lopez was the primary expert witness for the petitioners, and the special master, based in part upon Dr. Lopez' testimony, did conclude that an infant's severe neurodevelopmental disorder, which appears to have been a form of autism, was caused by an MMR inoculation. But the facts of that case were *far different* from those here. For example, in *Banks*, the infant experienced a significant seizure, a clear sign of brain malfunction, 16 days after the MMR inoculation. (2007 WL 2296047 at *2.) In this case, in contrast, Scott exhibited only the very minor symptoms described above, about 10 days post-inoculation, which were diagnosed by his pediatrician merely as evidence of "teething."

As another example, the *Banks* infant had a brain scan done on the day after the above-mentioned seizure, only 17 days post-vaccination, and on that scan *positive evidence* of a demyelinating process was found. (*Id.* at 3.) In this case, in contrast, there exists no such clearcut evidence of brain malfunction in the period soon after inoculation. Further, in *Banks*, the special master found that the infant's autism was the result of a specific neurologic condition known as "ADEM" (*id.* at *15), and the Respondent's expert in that case acknowledged that it was "biologically plausible" that the measles vaccine *could* trigger ADEM (*id.* at 13). No similar circumstances exist in this case.

In short, the *Banks* case involved facts far different from this case. And Dr. Lopez' causation theory offered in *Banks* appears to have differed greatly from his theory offered in this case. Further, in *Banks*, the special master was not presented with the expert testimony of Drs. Wiznitzer and Halsey, which I found to be so persuasive in this case. Accordingly, while I find the *Banks* opinion to be interesting, and I respect the special master who issued it, I do *not* find that the *Banks* opinion offers any substantial support for the *very different* causation theory advanced by Dr. Lopez under the *far different* facts of this case.

D. Hannah Poling case

Petitioners also point to a Vaccine Act case involving a child named Hannah Poling, in which Hannah's family received a Program award on her behalf. (Brief at 25-28; see also fn. 1, p. 11 of that Brief.) Petitioners argue that Scott's case is similar to the *Poling* case. This argument, however, is also without merit.

First, Petitioners, rather strangely, do *not* cite to any opinion or decision, published or otherwise, in the *Poling* case. They did not attempt to file into the record of this case any documents from the *Poling* case, or about Hannah Poling. They do not cite to any part of the record of this case in which any of their experts discussed or commented on the *Poling* case. Petitioners' counsel, rather, simply asserts, without saying why, that "the facts of the Poling case are probably familiar to all with any association to the vaccine court." (Brief at 25.)

Petitioners go on to describe certain facts that they assert to be facts of the Poling case. (*Id.* at 25-26.) They even place *quotation marks* around a phrase that allegedly describes Hannah's diagnosis, without saying what they are "quoting" from. (*Id.* at 26.) Petitioners argue that the facts of this case and the *Poling* case are similar to each other, and therefore I should make an award on Scott's behalf.

Petitioners' argument in this regard must be rejected, for many reasons. First, it is highly inappropriate as a matter of law that, after the evidentiary record in this *Franklin* case was closed, Petitioners should simply *allege* facts about another case, without stating where they obtained those alleged facts. I must reject this argument for that reason alone.

Further, a public document relating to that *Poling* case does in fact exist, which is a published opinion relating to a procedural issue in that case--*Poling v. HHS*, No. 02-1466V, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. April 10, 2008).¹⁹ That published opinion does not set forth in any detail the facts of the *Poling* case, but it does briefly explain that compensation was awarded in *Poling* because the Respondent *conceded* that the facts of that case demonstrated that a vaccination "significantly aggravated an underlying mitochondrial disorder" in Hannah. (*Id.* at *1.)

Thus, from the only published opinion that sheds any light at all on the *Poling* case, the only facts that we know make it clear that the *Poling* case was, in fact, *far different* from this case--*i.e.*, Hannah Poling had an "underlying mitochondrial disorder." Such a disorder is *not* alleged in Scott's case. Further, we know that the *special master* in *Poling* did not make a *finding* that a vaccine aggravated Hannah's disorder, but rather the Respondent *conceded* the case, for reasons unexplained.

Therefore, in my view, the Petitioners' argument in this case concerning the *Poling* case is late, completely unsupported, and offers no support at all for the contention that Scott Franklin has suffered a vaccine-caused injury.

E. Arguments concerning Dr. Wiznitzer

Petitioners further complain that Dr. Wiznitzer, while clearly an expert on autism, is "biased" in that he has frequently testified for the Respondent in Vaccine Act cases, but has never testified for a petitioner in an actual Vaccine Act hearing. (Brief at 28.) Dr. Wiznitzer explained, however, that in a number of cases he was asked to support the Respondent's position in a Vaccine Act case, but could not do so. (Tr. 215-16.) He has also supported vaccine-causation cases of a number of his own patients. (Tr. 214-15.) To be sure, Dr. Wiznitzer clearly does not agree with those who believe that a substantial number of cases of autism in this country have been caused by vaccinations. However, I have found that, in each case in which he has testified before me, Dr. Wiznitzer closely examined the facts of the case, used his considerable medical expertise to analyze those facts, and presented his honest opinion concerning the case. I do not find that he has been a "biased" witness in this or any other case.

Finally, Petitioners' brief also argues, without any citation whatsoever to the record in this case, that Dr. Wiznitzer erred concerning the issue of "eye contact" by Scott. (Brief at 29.) Without citation to the record, I have not located this allegedly mistaken testimony. In any event, based on the overall record of this case, I find that Dr. Wiznitzer was a very knowledgeable and persuasive witness, far more persuasive than Petitioners' witnesses.

¹⁹ I also found another published opinion from that same *Poling* case, but that relates only to an attorneys' fees award. See *Poling v. HHS*, No. 02-1466V, 2011 WL 678559 (Fed. Cl. Spec. Mstr. Jan. 28, 2011).

XIII

CONCLUSION

The record of this case demonstrates plainly that Scott Franklin and his family have been through a tragic medical ordeal. They are certainly deserving of great sympathy. Congress, however, designed the Program to compensate only the individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or “causation-in-fact” evidence, to a listed vaccine. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award.²⁰

/s/ George L. Hastings, Jr.

George L. Hastings, Jr.
Special Master

²⁰ In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.