In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 06-371V
Filed: August 26, 2014
(To be published[1])

FRANCIA HIRMIZ and PETER HIRMIZ, as best friends of their daughter, J.H.,	*	Vaccine Act Entitlement; Causation-in-fact; Influenza vaccine; Developmental Delay; Degeneration of Motor Skills and Body Control.
Petitioners,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	

John F. McHugh, New York, NY, for Petitioners.

Linda Renzi, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, Special Master.

This is an action in which the Petitioners, Francia Hirmiz and Peter Hirmiz, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[2]), on account of neurological degeneration in their daughter J.H., which they believe was caused by

[1] Because I have designated this document to be published, this document will be made available to the public unless petitioners file, 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).

two half-dose influenza vaccines administered on October 14 and November 16, 2004. For the reasons set forth below, I conclude that Petitioners are not entitled to an award.

I

APPLICABLE STATUTORY SCHEME AND CASELAW

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 showings 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)(l)(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)(l)(A); *see also Althen*, 418 F.3d at 1279; *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 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 factfinder 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. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is not needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11 v. HHS*, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v.*

HHS, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

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.

II

PROCEDURAL HISTORY

On May 8, 2006, Francia and Peter Hirmiz filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, as amended. The original petition alleged that a series of vaccinations administered in 2004 caused J.H. to experience "a degeneration of her motor skills and body control noticeable after mid-October of 2004." (Pet. at p. 1.)

Respondent filed a "Rule 4 Report" on July 14, 2006, contesting the claim.

On March 5, 2007, Petitioners filed an amended petition ("Am. Pet.") that altered their original claim of onset of J.H.'s condition. Specifically, Petitioners changed their initial assertion that "J.H. progressed normally for about eight months," to allege that she "progressed normally for about over ten months, *i.e.* at least until October 14, 2004." (Pet. at 1; Am. Pet. at 2.) In addition, the amended petition alleged that J.H. 's failure to progress resulted from the half-dose influenza vaccines that she received on October 14 and November 16, 2004. (Am. Pet., p. 3.)

An "onset hearing" was held before Special Master Abell on August 28, 2008. Both Petitioners testified regarding the onset of J.H.'s condition. (ECF No. 37.) Special Master Abell issued a bench ruling on January 14, 2010, finding that the onset of J.H.'s symptoms occurred between July 16 and October 14, 2004, *prior* to the receipt of her half-dose flu vaccine administered on October 14. (*See* Transcript of Proceedings (ECF No. 56) ("Abell Tr."), January 14, 2010; *see also* Findings of Fact, March 26, 2010.) Significantly, Special Master Abell found that the onset of J.H.'s developmental delays occurred between six and nine months of age, and that concerns were noted prior to her receipt of the first half-dose of flu vaccine. (Abell Tr. 12-13.)

This case was then reassigned to me on March 29, 2010, following Special Master Abell's retirement. (ECF No. 58.)

Subsequently, on January 9, 2012, Petitioners filed an expert report by James Oleske, M.D., accompanied by Dr. Oleske's *curriculum vitae*. (Exs. 15, 16.)[3] On May 9, 2012, Respondent filed an expert report and *curriculum vitae* of Stephen J. McGeady, M.D. (Exs. A, B.) An additional report by Dr. Oleske responsive to Dr. McGeady's report was filed on September 10, 2012. (Ex. 17.) On December 5, 2012, I conducted an evidentiary hearing in New York, New York, to receive testimony from the experts in this case. (*See* Transcript of Proceedings (ECF No. 104) ("3-Tr.") (December 5, 2012.) Drs. Oleske and McGeady were the only two witnesses to testify at that time. (*Id*.)

The parties then submitted post-hearing briefs. Petitioners' post-hearing memorandum was filed on May 15, 2013 (ECF No. 109), and Respondent's memorandum on August 22, 2013 (ECF No. 112). Petitioners filed a reply brief on October 9, 2013. (ECF No. 115.)

III

FACTUAL HISTORY

J.H. was born on January 12, 2004, along with her twin brother. (Ex. 4, p. 15.) During her initial months of life, J.H. appeared to be developing normally. She had well-child exams by Dr. Peera at age sixteen days and age six months. (Ex. 4, pp. 25-26.) No concerns regarding her development were noted. (*Id*.) She received various vaccinations on March 15, May 17, and July 16, 2004. (*Id*., pp. 10-12.) No adverse reactions to any immunizations were recorded. (*Id*.)

During her pediatric visit of July 16, 2004, the pediatrician checklist indicated that she was rolling over in both directions and "sits with support/alone." (Ex. 4, p. 25; Ex. 10, p. 7.[4]) However, when she returned on October 14, 2004, concerns about developmental delays were noted. (Ex. 4, p. 24; Ex. 10, p. 5.) Specifically, J.H. was not rolling over, and not sitting alone. (*Id*.) That new inability to roll over and to sit indicated some loss of skills between July and October 2004. It was also stated in the medical note of October 14, 2004, that J.H. had decreased muscle tone at that visit, and she received a half-dose of the influenza virus vaccine at that time. (*Id*.)

Approximately one month later, on November 16, 2004, J.H. received a second half-dose of the influenza vaccine (Ex. 4, p. 10(a); Ex. 10, p. 10), and was referred to a neurologist.

J.H.'s initial *neurological* evaluation occurred on December 20, 2004, and was performed by Dr. Stumpf. (Ex. 4, p. 371.) Dr. Stumpf observed that J.H. was socially and cognitively age-

[3] Exhibits filed by Petitioners were mostly designated by number. Exhibits filed by Respondent were designated by letter.

[4] Ex. 4, pp. 24 and 25 are copies of the *original* records of J.H.'s pediatric visits on July 16, and October 14, 2004. Ex. 10, pp. 5 and 7, are copies of Dr. Peera's "transcriptions" of the sometimes illegible portions of the originals.

appropriate, but diagnosed her with spastic diplegia and cerebral palsy. (*Id*.) Dr. Stumpf opined that J.H.'s cerebral palsy stemmed from "twinning." (*Id*.)

On January 18, 2005, J.H. had her 12-month well-child pediatric visit. (Ex. 10, p. 9.) The medical records note that, at that time, J.H. was unable to pull to stand, walk independently, or grasp objects. (*Id*.) The records also noted that J.H. could use single words, drink from a cup with help, and feed herself some solids. (*Id*.) The doctor's assessment was "well developed but with muscle weakness, motor delay." (*Id*.) The doctor's plan for J.H. was to follow up with neurology. (*Id*.)

In early 2005, J.H. was also attending physical therapy. Notes from her medical records indicate that although she was "not using her bilateral extremities as functionally as she used to," her parents reported "improvement in prone activity, sitting and lower limb kicking." (Ex. 6, p. 469.) This record indicates that "J.H. has been making progress since physical therapy has been initiated." (*Id*.)

J.H. thereafter deteriorated neurologically over the ensuing year, and she was evaluated and treated extensively by numerous physicians, including neurologists, geneticists, pediatricians, orthopedic surgeons, and physical and rehabilitation specialists at Children's Memorial Hospital. (*See generally* Ex. 6.)

In late March 2005, J.H.'s parents and her physical therapist noted a loss of milestones, difficulty feeding, and the onset of clenched fists. (Ex. 4, p. 356.) She returned to Dr. Stumpf on April 18, 2005, and he observed a significant increase in spasticity, which he attributed to her underlying cerebral palsy and the maturation of her nervous system. (*Id*.) However, he noted that because of the rapid progression, additional tests were needed to determine whether J.H. had a degenerative disorder. (*Id*.)

In May 2005, swallowing function studies and MRIs with contrast of the brain and cervical cord were administered and deemed normal. (Ex. 4, pp. 318, 347-48.) In June 2005, J.H. also had a normal EEG. (Ex. 4, p. 318.) By June 2005, J.H. had deteriorated to the extent that, as noted in a June 2005 Rehabilitation Institute of Chicago assessment, she "had very poor head control, trunk control." (Ex. 4, p. 334.) J.H. was at that time diagnosed with "spastic quadriplegia, etiology unclear." (*Id*.) Additionally, despite physical therapy, J.H.'s motor function worsened. (*Id*., pp. 324-25.)

In November 2005, however, J.H. was seen for an evaluation at the Mayo Clinic, since her doctors could not agree upon a specific genetic or metabolic defect had been found to explain her deteriorating neurological status. Despite extensive testing at the Mayo Clinic, J.H. still had no confirmed diagnosis. (*See generally* Ex. 5.)

In 2008, J.H. was seen and evaluated by Mark Geier, M.D. Dr. Geier performed further testing to procure an etiology or diagnosis for J.H.'s condition, including a whole genome microarray, but he also offered no diagnosis. (Ex. 8, p. 737.)

The parties agree that, to date, there has been no definitive diagnosis for J.H.'s condition. (*See, e.g.*, Ex. 15, p. 2; Ex. A, p. 11.)

IV

ISSUE TO BE DECIDED

In this case, Petitioners seek a Program award, contending that their daughter's neurological degeneration, including loss of motor skills and body control, was "caused-in-fact" by the two half-dose influenza vaccines that J.H. received on October 14 and November 16, 2004. After careful consideration, I conclude that Petitioners have *failed* to demonstrate causation.

Petitioners' theory of the case, while never very coherently organized by their expert, Dr. Oleske, may be briefly summarized as follows. Petitioners contend that the onset of J.H.'s condition occurred in two distinct phases that temporally corresponded with the administration of her two half-doses of flu vaccine on October 14, 2004, and November 16, 2004, creating what is known as a "challenge-rechallenge event," a circumstance in which a vaccine provokes the same response on two independent occasions. Petitioners allege, particularly in the absence of any other known etiology explaining J.H.'s condition, that "challenge-rechallenge" is proof of causation. Petitioners also seem to contend that a defect in J.H.'s immune system contributed to her neurologic deterioration.

Respondent disagrees. Respondent disputes Petitioners' claim that J.H.'s condition developed *following* J.H.'s first half-dose of flu vaccine, arguing that her medical records show that the onset of her developmental delay occurred *prior* to her flu vaccination of October 14, 2004. Respondent's expert also disputed the Petitioners' "challenge-rechallenge" theory, as well as various aspects of Dr. Oleske's causation presentation. Respondent argues that Petitioners have not demonstrated a causal link between J.H.'s condition and her flu vaccinations.

After carefully considering all of the evidence in the record, I must reject Petitioners' claim that her degenerative neurological disorder was caused or exacerbated by the two half-doses of influenza vaccination that J.H. received on October 14 and November 16, 2004. Petitioners have failed to demonstrate that it is "more probable than not" that this pair of vaccinations contributed to causing their daughter's condition. Instead, it appears more likely than not that J.H.'s condition predated these vaccinations.

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, each side presented the expert reports and hearing testimony of one medical expert. At this point, I will briefly summarize both the credentials and the opinions of these expert witnesses.

A. Petitioners' expert

1. Dr. James M. Oleske, M.D., MPH

Dr. Oleske attended the University of Detroit from 1963-1967 and received a Bachelor of Science degree. (Ex. 16, p. 1.) From 1967-1971, Dr. Oleske attended the College of Medicine and Dentistry of New Jersey in Newark, New Jersey, where he graduated with a degree in medicine. (Ex. 16, p. l; 3-Tr. 4.) Dr. Oleske then went on to receive a Master's of Public Health degree from Columbia University in 1974. (Ex. 16, p. 1.) Dr. Oleske served as a student research fellow from 1968 to 1970 at the College of Medicine and Dentistry of New Jersey, Department of Pediatrics. (*Id*.) He interned and served as a resident at the College of Medicine and Dentistry of New Jersey, Department of Pediatrics, from 1971-1973. (*Id*.) His research fellowship took place at Emory University from 1974-1976. (Ex. 16, p. 1; 3-Tr. 4.) He thereafter served at Emory as a clinical instructor and fellow from 1974-1976. (Ex. 16, pp. 1-2.)

Dr. Oleske was licensed to practice medicine by the state of New Jersey and by the New Jersey Laboratory Director. (Ex. 16, p. 2.) He is certified by the Specialty Board of the American Board of Pediatrics, Sub-Specialty Board of the American Board of Allergy/ Immunology, the Sub-Specialty Board of the American Board of Pediatrics and Pediatric Infectious Diseases, and the American Board of Medical Laboratory Immunology. (*Id*.) He also is certified by the American Board of Hospice and Palliative Care, the American Academy of Pain Management, the Council of Certification of IRB Professionals, and the American Academy of HIV Medicine. (Ex. 16, p. 2; 3-Tr. 4.)

Dr. Oleske is currently serving as a Professor at the School of Public Health at the University of Medicine and Dentistry of New Jersey, as a Clinical Professor at the New Jersey School of Nursing, and as a Professor of Preventive Medicine and Pathology in the Department of Pediatrics at the University of Medicine and Dentistry of New Jersey. (Ex. 16, p, 3.) He also currently works as a consultant at the Allergy and Immunology & Infectious Diseases Matheny School and Hospital in Peapack, New Jersey. (*Id*.) Dr. Oleske's resume lists 212 peer-reviewed publications. (*Id.*, pp. 19-33.)

2. Summary of opinion of Petitioners' expert

Dr. Oleske stated in his first expert report that J.H.'s neurologic condition is likely due to "the multiple immunizations she received, in particular the two, half dosages of influenza vaccine she received at 9 and 10 mos. of age," in October and November of 2004. (Ex. 15, p. 2, *sic*.) In his second expert report (Ex. 17) and his hearing testimony, Dr. Oleske continued to focus primarily on the two influenza vaccinations, arguing that those vaccinations were temporally related to the onset of J.H.'s sudden and progressive neurological condition. (Ex. 17, pp. 1-2; 3-Tr. 5.)

Dr. Oleske's testified that the basis for his conclusion was "a clear onset of real neurological findings after the first [influenza] dose with very marked worsening after the second dose." (3-Tr. 5.) Dr. Oleske also testified that "[a]t 12 months, [J.H.'s growth] was in the

normal range, but at 15 months she was down between 15% and 20% * * *, the consequences of a severe event that occurred around 12 months." (3-Tr. 20.)

Additionally, Dr. Oleske opined that the immune studies that were done in 2008 showed immune abnormalities in J.H. (Ex. 15, p. 2.) Dr. Oleske opined that these immune abnormalities "could have been due" to an unusual immunological response to the flu vaccine that has also caused her neurological deterioration. (Ex. 15, p. 3.)

Dr. Oleske also speculated in his initial report that J.H.'s condition "may well" have been the consequence of a "missed SIDS" episode ("Sudden Infant Death Syndrome"). (Ex. 15, p. 3.) This theory appears to have been abandoned, however, as Dr. Oleske ultimately testified that he found no evidence of a missed SIDS episode in this case. (3-Tr. 96-97.)

B. Respondent's expert

1. Dr. Stephen J. McGeady, M.D.

Dr. Stephen McGeady attended Fordham University where he received a Bachelor of Science Degree in Biology in 1963. (Ex. B, p. 1; 3-Tr. 73-74.) He attended Creighton University where he graduated in 1967 with a degree in medicine. (Ex. B, p. 1; 3-Tr. 74.)

Dr. McGeady served as a rotating intern at the St. Vincent's Hospital in New York from 1967-1968. (Ex. B, p. 1; 3-Tr. 74.) He served as a resident in Pediatrics at the St. Christopher's Hospital in Philadelphia from 1970-1972. (*Id*.) He served as a fellow at Duke University in the Psychiatry and Allergy unit from 1972-1974. (Ex. B, p. 1.) He has been appointed Director of Pediatric Services at the Children's Heart Hospital in Philadelphia, Medical Director at the Children's Heart Hospital, Medical Director of the Children's Rehabilitation Hospital in Philadelphia, and Medical Director of the Jefferson Park Hospital. (Ex. B, p. 1.) He serves as the Director of the Allergy and Clinical Immunology Training Program at the Jefferson College of Medicine. (Ex. B, p. 1; 3-Tr. 74.) Currently, Dr. McGeady also serves as the Chief of the Allergy, Asthma, and Immunology Division, at the DuPont Hospital for Children in Wilmington, Delaware. (Ex. B, p. 1; 3-Tr. 73.)

Dr. McGeady is certified by the American Board of Pediatrics, the American Board of Allergy and Immunology, and the Board of Diagnostic and Laboratory Immunology. (Ex. B, p. 11; 3-Tr. 74.) He is licensed in Pennsylvania, Delaware, and New Jersey. (Ex. B, p. 1.) Dr. McGeady's resume lists 54 peer reviewed articles. (Ex. B, pp. 2-6.)

2. Summary of opinion of Respondent's expert

Dr. McGeady opined that there "is no clear association of any specific vaccine with the onset of [J.H.'s] neurological deterioration, nor can a precise time of onset of her deterioration be established." (Ex. A, p. 4; *see also* 3-Tr. 76-77.) Dr. McGeady could find no evidence in the medical records that J.H. had any sort of immune dysfunction in her first six months of life, and

testified that she received routine immunizations during that time without any reported adverse reaction. (3-Tr. 77.)

Dr. McGeady further opined that J.H. showed signs of loss of skills between *July and October* of 2004, *prior* to the flu vaccinations in question. (Ex. A, p. 4.) While J.H.'s ability to roll over and to sit up had been described in the pediatric note of July 16, 2004 (Ex. 10, p. 7), in the note of her visit of October 14, 2004, those skills were noted to be *missing* (Ex. 10, p. 5), indicating a loss of skills (Ex. A, p. 4). Dr. McGeady also pointed to the notation of decreased muscle tone in the lower extremities in the October 14, 2004 note, and the fact that a referral for occupational/physical therapy was to be considered at the next visit. (Ex. A, p. 4.) Dr. McGeady noted that for an infant not to have made significant physical skill acquisition between the ages of six and nine months (July to October of 2004) would be highly abnormal, and to have *lost s*kills in that time period would be alarming. (Ex. A, p. 4; 3-Tr. 83-84.) And since the first influenza immunization was given during the visit of October 14, 2004, he concluded that it is not possible that the influenza vaccines could have been responsible for J.H.'s deteriorating neurological status, which began *before* that visit. (Ex. A, pp. 4-5.) Dr. McGeady opined that it seems likely that the perceived rapid deterioration beginning in late 2004 was merely an extension of a neurodegenerative process *already* in motion prior to October 14. (Ex. A, p. 5.)

Dr. McGeady also persuasively disagreed with the "immune dysfunction" and "challenge/rechallenge" arguments put forth by Dr. Oleske.

VI

SUMMARY OF MY OPINION

After reviewing the record of this case, I have found that Dr. Oleske's view of the case was quite unpersuasive, while Dr. McGeady's opinion was far more persuasive. There are several reasons for this conclusion.

First and foremost, Dr. Oleske based his opinion on a plainly flawed assumption as to the time of onset of J.H.'s neurological symptoms. Dr. Oleske concluded that J.H.'s symptoms *began* shortly *after* her flu vaccination of October 14, 2004. However, J.H.'s medical records show quite clearly that, as Dr. McGeady concluded, J.H.'s symptoms began between July and October of 2004, prior to her first flu vaccination.

Second, there were a number of additional deficiencies in Dr. Oleske's testimony. Dr. Oleske simply failed to offer any persuasive testimony as to why one should conclude that J.H.'s flu vaccinations might have caused her neurologic deterioration. Dr. Oleske offered testimony that J.H. might have an immune dysfunction, but that theory was persuasively refuted by Dr. McGeady. Dr. Oleske offered testimony concerning the concept of "challenge-rechallenge," but that testimony was also strongly refuted. Dr. Oleske's testimony was, in general, vague and wholly unpersuasive, while that of Dr. McGeady was clear and persuasive.

VII

DR. OLESKE'S OPINION IS BASED ON A CLEARLY FLAWED ASSUMPTION AS TO THE ONSET OF J.H.'S NEUROLOGICAL DETERIORATION

As summarized above, the most glaring deficiency in Dr. Oleske's causation opinion in this case is that Dr. Oleske based his opinion on a *plainly flawed* assumption as to when the onset of J.H.'s neurological symptoms began. Dr. Oleske concluded that J.H.'s symptoms *began* shortly after her flu vaccination of October 14, 2004, and *sharply increased* after her vaccination of November 16, 2004. However, J.H.'s medical records show quite clearly that, as Dr. McGeady concluded, J.H.'s symptoms instead began between July and October of 2004, *prior* to her first flu vaccination.

In regard to this issue of the onset of J.H.'s symptoms, in the unusual procedural posture of this case, another special master of this court has *already* studied the onset issue, and has indicated an understanding of the onset history that is plainly at *odds* with the onset assumption upon which Dr. Oleske based his opinion. That is, prior to transferring this case to me upon his retirement, Special Master Abell held an evidentiary hearing for the sole purpose of determining the "onset" of J.H.'s condition. In reaching his determination, Special Master Abell considered the weight to be afforded to the contemporaneous medical records, as well as the extent to which the contradictory testimony of J.H.'s parents should be credited. (Abell Tr. 4-6[5].) Special Master Abell noted the Petitioners' burden to establish the facts by a preponderance of the evidence (*i.e.*, more likely than not). (Abell Tr. 3.) Although he determined that J.H.'s parents were "in general, credible people, very concerned, very moral" (Abell Tr. 10), he ultimately determined that the *medical records* were entitled to greater weight in those areas in which the parents' memories differed from the contemporaneous medical records (Abell Tr. 17).

As Special Master Abell explained, at J.H.'s six month visit with Dr. Peera in July of 2004, it was noted that she "rolls over in both directions, according to the parents, reaches for objects, transfers objects from one hand to the other, vocalizes, babbles, is more verbal than her brother, according to the parents, and she eats various things, soups, veggies, fruits, etc. In other words, to all intrinsic purposes, she appears normal for her age in time." (Abell Tr. 7.) At J.H.'s nine-month visit on October 14, 2004, however, it was noted that she was "not rolling over, not sitting alone," so that "she has lost * * * an ability that she had." (*Id*. at 8.) It was also noted at the October visit that J.H. had slightly *decreased muscle tone* in her lower extremities. (*Id*. at 7-8.) Thus, Special Master Abell concluded, the medical records of July and October of 2004 indicate that J.H. had *already begun* experiencing a loss of skills prior to receiving her first flu vaccination on October 14, 2004. (Id. at 8.)

[5] As noted above, Special Master Abell held his evidentiary hearing, at which he heard, in person, the testimony of Jessica's parents, on August 28, 2008, and the transcript of that hearing was filed into the record of this case on September 23, 2008 (ECF No. 37). Special Master Abell later gave an oral ruling concerning the onset issue on January 14, 2010, which was transcribed. (Abell Tr., ECF No. 56, filed on February 18, 2010.)

In addition, Special Master Abell compared the parental testimony to the records containing *additional histories* that J.H.'s parents related when she visited specialist physicians during the following months. He noted that those histories given by the parents, like the medical records of July and October 2004, also indicate that J.H.'s neurological deterioration began *well prior* to the October 2004 flu vaccination. For example, Special Master Abell noted specifically that the records of J.H.'s visit to the Mayo Clinic clearly point back to the period when she was six to eight months old--*i.e.*, *July to September* of 2004--as the time when the first symptoms of her neurological demise began. (Abell Tr. 11-12.) He further noted that in "several" different medical histories, J.H.'s parents noted that her developmental progress began to fall noticeably behind the progress of her twin brother at about age six months--again, in *July* of 2004. (*Id*. at 11-12.) Special Master Abell noted that the medical records as a whole indicate that J.H.'s developmental and neurological progress stopped--that is, she leveled off or "plateaued"--about July of 2004. (*Id*. at 12-13.) He added that the records in general indicated a clear *loss* of skills between July and October of 2004. (*Id*. at 13.) He found it "clear" that there was a "retrogression" in J.H.'s neurological development *prior* to the vaccination of October 2004. (*Id*. at 15.)

In making these findings, Special Master Abell, as noted above, stressed that he found J.H.'s parents "in general" to be "credible" and "moral" people. (Abell Tr. at 10.) He did *not* find that they were intentionally failing to tell the truth. But when he compared their testimony to the clear statements in J.H.'s medical records, he found that the medical records gave a more accurate history of J.H.'s neurological development and deterioration than did some of the parental testimony. (Id. at 12.) That special master found "clear discrepancies or inconsistencies" between some of the parental memories and the medical records, and to the extent of those inconsistencies he found the *medical records* to be more believable. (*Id*. at 17.)

I, too, have read the testimony of J.H.'s parents and compared them to the notations in the medical records. I concur with Special Master Abell's analysis in this regard.[6] I concur entirely with Special Master Abell's comparison of the records made in July and October of 2004, and his firm conclusion from those two records.

Further, Dr. McGeady interpreted the medical records exactly as both Special Master Abell and I have. Comparing the records of July and October of 2004, Dr. McGeady, too, firmly concluded that J.H. was already exhibiting symptoms of her neurological demise *prior* to the first flu vaccination in October. (Ex. A, p. 4; 3-Tr. 83-84.) Dr. McGeady also explained that in the medical records he saw no evidence of a sharp decline in J.H.'s neurological condition after *either* the October or November vaccinations. (3-Tr. 85-87.)[7]

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[6] I note that after the case was transferred to me, the Petitioners did *not* request that I hear their testimony myself.

[7] It is also noteworthy that when J.H. first saw a neurological specialist on December 20, 2004, and the neurologist recorded a history of her neurological problems, that neurologist did *not* mention either of the influenza vaccinations, or indicate either that J.H. had the onset of her neurological symptoms in October of 2004, or that her neurological symptoms worsened soon after her second flu shot in November of 2004. (Ex. 4, p. 371.) In fact, that history seems to indicate that the family first noticed the symptoms of J.H.'s neurological deterioration at age *six months*, or in July of 2004, rather than in October of 2004 as Dr. Oleske assumed.

In sum, because Dr. Oleske based his causation opinion on the clearly incorrect assumption that J.H.'s neurological demise began *after* the influenza vaccination of October 2004, Dr. Oleske's causation opinion may be *rejected for that reason alone*.

VIII

ADDITIONAL REASONS TO CREDIT DR. MCGEADY'S TESTIMONY OVER THAT OF DR. OLESKE

As noted above, because Dr. Oleske based his testimony on a clearly flawed assumption as to the time of *onset* of J.H.'s neurological dysfunction, his causation opinion can be readily dismissed for that reason alone. But I will also briefly discuss several additional reasons to discount Dr. Oleske's causation opinion.

A. Dr. McGeady's testimony was more persuasive in general.

In general, Dr. McGeady's presentation was substantially more persuasive than that of Dr. Oleske. Dr. McGeady was better able to answer questions and defend his opinion. Dr. Oleske's opinion was plagued by gaps in logic.

Most glaringly, Dr. Oleske simply failed to put forth any coherent presentation of *evidence or reasoning* to support his causation conclusion. As explained above, Dr. Oleske opined that J.H.'s neurological degeneration was initially caused by her first influenza vaccination in October of 2004, and then exacerbated by her second influenza vaccination one month later. But Dr. Oleske simply failed to offer any coherent evidence for the proposition that an influenza vaccination is even *capable* of damaging a child's brain so as to result in causing or exacerbating a neurological deterioration. Dr. Oleske failed to point to any medical articles or other actual evidence demonstrating that influenza inoculations can injure the brain. He failed to persuasively explain by what mechanism influenza vaccinations might injure the brain.

And Dr. McGeady, on the other hand, was persuasive in pointing out the lack of any scientific support for Dr. Oleske's speculations. He found that Dr. Oleske's theory of the case was not persuasive, but instead was "most unlikely." (Ex. A, p. 11.) Dr. McGeady found no causal association at all between J.H.'s influenza vaccinations and her neurological disorder. (Ex. A, p. 12; 3-Tr. 76-77, 93.) He explained that, unfortunately, for some neurological disorders, like that of J.H., no cause is ever identified. (3-Tr. 102.) He opined that J.H.'s neurological condition would have been the same had she never had the influenza vaccinations. (3-Tr. 87.)

B. Dr. McGeady was persuasive in refuting Dr. Oleske's speculation that a dysfunction of J.H.'s immune system might have had a role in causing neurological degeneration.

In theorizing as to *how* J.H.'s influenza vaccinations might have caused her neurological dysfunction, Dr. Oleske repeatedly pointed to possible *immunological problems* in J.H. In his

first expert report, he pointed to the "presence of abnormal immune studies" in J.H.'s records. (Ex. 15, p. 2.) He asserted that J.H. had "immune abnormalities" which "could have been due to an unusual immunological response to the flu vaccine that has also caused her neurological deterioration." (*Id*. at 3.) In his second report, he stated that the "injury" that J.H. "suffered due to the vaccine" could be due to "an immune-mediated toxic response." (Ex. 17, p. 3.) During his hearing testimony, he again pointed to "abnormalities" in J.H.'s immune system. (3-Tr. at 13.)

It is notable, however, that while in his second expert report Dr. Oleske theorized that J.H. "is the victim of a toxic-autoimmune reaction" to her two flu vaccinations (Ex. 17, p. 5), at the hearing, he backed off from that position, conceding that there is insufficient evidence of a "toxic" response and characterizing it instead as simply "an immune-mediated response." (3-Tr. 17.)

Further, Dr. Oleske never explained *why* he thought that influenza vaccine might be capable of causing an unusual immunological response that could lead to the type of severe neurological demise such as the one that J.H. suffered. He never pointed to any medical literature supporting his reasoning on this point. His opinion seemed to amount to mere speculation, or guesswork. When pressed on cross-examination, the best he could do was to suggest, without documentation, that "some" unspecified vaccines can lead to "neuroimmune reactions" (3-Tr. at 58), apparently reasoning that because "some" vaccines can cause "neuroimmune reactions," the *influenza* vaccination is capable of causing the type of neurological degeneration from which J.H. suffered.

To the contrary, Dr. McGeady testified that he saw no merit in Dr. Oleske's speculation that an immune system response caused or contributed to J.H.'s neurological disorder.

First, Dr. McGeady explained that J.H.'s medical records do not support a conclusion that J.H. even *has* immune dysfunction, from whatever source. (Ex. A, pp. 6-7; 3-Tr. 77.) Dr. McGeady noted that the existence of an abnormal number of lymphocytes in one 2008 test of J.H. *does* not indicate that J.H. had any immune system abnormality in 2004-2005, when she suffered her fairly abrupt neurological demise. (Ex. A, pp. 6-7.) To the contrary, Dr. McGeady explained that the high lymphocyte count in 2008 could just mean that J.H. was experiencing an infection on that day in 2008. (Ex. A at 7.) He explained that the Mayo Clinic records *do not* show that the *Mayo Clinic* concluded that J.H. had an immune dysfunction. (3-Tr. 91, 94-95.)

Further, Dr. McGeady added that after review of J.H.'s overall records, it does *not* appear that J.H. is unusually susceptible to infections, indicating that J.H. is not immunologically abnormal. (Ex. A at 7; 3-Tr. 77, 96.)

In short, there is no significant evidence that J.H. even has an immune dysfunction. And even if she did, Dr. Oleske has provided no evidence for his speculations either (1) that the *influenza vaccinations* caused such immune dysfunction, or (2) that such immune dysfunction contributed to her *neurological* disorder. In sum, Dr. Oleske's speculation about a possible

immune dysfunction in J.H. contributing to her neurological disorder is just that--nothing but mere speculation without any significant evidence behind it.

C. Petitioners' "challenge-rechallenge" theory is not persuasive.

Petitioners' post-hearing briefs assert that J.H.'s case is an example of the "challenge/rechallenge" theory of causation, and that such challenge/rechallenge theory supports a conclusion that J.H.'s neurological disorder was vaccine-caused. I find no merit in this argument.

It is noteworthy that Dr. Oleske's first expert report did not even mention "challenge/rechallenge." (Ex. 15.) His second expert report only briefly mentions that concept. (Ex. 17, pp. 2, 5.) During the evidentiary hearing, Dr. Oleske again only briefly mentioned the concept, in response to a question by petitioners' counsel. (3-Tr. 18.) Therefore, it is not even clear to what extent Dr. Oleske actually significantly relied upon the "challenge/rechallenge" concept in developing his causation theory in J.H.'s case.

In any event, after closely studying the record of this case, I firmly conclude that the "challenge/rechallenge" concept does *not* apply to this case.

To be sure, if a true instance of "challenge/rechallenge" occurs, that can indeed be powerful evidence of causation. As Dr. Oleske explained, "challenge/rechallenge" refers to a situation where a person has a reaction to one administration of a vaccine or drug, and then "suffers worsened symptoms after additional administration of that same vaccine or drug." (Ex. 17, p. 5.) For example, in one Vaccine Act case, it was noted that the challenge/rechallenge theory could be successfully used to establish causation. *Capizzano v. HHS*, 2004 WL 1399178 (Fed. Cl. Sp. Mstr. 2004), *rev'd* on other grounds 440 F.3d 1317 (Fed. Cir. 2006). In that case, the special master stated that the "challenge/rechallenge cases are such strong proof of causality that it is unnecessary to determine the mechanism of cause -- it [causation] is understood to be occurring." 2004 WL 1399178 at *15-16.

Unfortunately for Petitioners, however, the actual facts of J.H.'s case clearly do *not* fit the challenge/rechallenge scenario.

In this case, as explained above, and contrary to Dr. Oleske's assumption, J.H. clearly did not suffer the first symptoms of her neurological disorder after her first influenza vaccination in October of 2004 (see Section VII), *nor* did she suffer a second rapid onset of symptoms after her second influenza vaccination in November of 2004. To the contrary, as discussed above, the record of this case makes it clear that J.H., unfortunately, was already experiencing the initial symptoms of her neurological disorder during the months *prior* to her first influenza examination. Further, as Dr. McGeady explained (3-Tr. 85-87), the records do *not* indicate any sharp change in J.H.'s neurological symptoms after either her October or November influenza vaccinations. Of course, there is no doubt that J.H.'s disorder, which clearly was present prior to her October vaccination, *did* significantly worsen in late 2004 and early 2005. But the medical

records made during that time period do *not* point to any rapid turn for the worse in her symptoms after *either* of the vaccinations in question.

Accordingly, I do *not* find that J.H.'s case fits the "challenge/rechallenge" scenario, as petitioners assert. The challenge/rechallenge argument is not persuasive in this case.

D. Summary concerning causation issue

In short, Dr. Oleske's assertion concerning immune deficiency playing a role in J.H.'s disorder, as well as his assertion concerning "challenge/rechallenge," are both found to be without merit. I find his causation theories to be wholly unpersuasive, and I find the contrary testimony of Dr. McGeady to be persuasive.

IX

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 the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the 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 this part of my Decision, then, I will briefly explain how this case 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 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 interpretive 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; (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 face, 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)(l)(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 the influenza vaccines that J.H. received contributed to the causation of her tragic neurodevelopmental disorder.

B. Petitioners may reach the Althen analysis despite the lack of a specific diagnosis in this case.

Before addressing the individual *Althen* prongs in this case, I note that Respondent argued that as a threshold matter, without even reaching the *Althen* test, I must reject Petitioners' claim for a failure to identify "at least one defined and recognized injury." (ECF No. 112, p. 12.) For the reasons discussed below, I disagree.

To be sure, as Respondent points out, the Federal Circuit has held that "if the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which *injury* was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." *Lombardi v. HHS*, 656 F.3d 1343, 1352 (Fed. Cir. 2011), (citing *Broekelschen v. HHS*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)) (emphasis added). The Federal Circuit has also held, however, that "the special masters are not 'diagnosing' vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the child's injury or that the child's injury is a table injury, and whether it

has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury." *Knudsen v. HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994); *see also Lombardi*, 656 F.3d at 1351.

In *Lombardi*, the petitioner alleged that she suffered three different conditions. Respondent disputed all three potential diagnoses and advanced five additional possible conditions. *Lombardi*, 565 F.3d at 1353-54. In *Broekelschen*, the petitioner received a differential diagnosis from his treating physicians, and the petitioner claimed to be suffering from one of the identified conditions while respondent claimed that the other identified condition was present. *Broekelschen*, 618 F.3d at 1342-43. In both cases, the decision ultimately turned on *which* injury among competing suggestions was actually suffered. Thus, the Federal Circuit indicated that the special masters were correct to consider the reliability of the petitioner's *diagnosis* before exploring causation under *Althen*. *Broekelschen*, 618 F.3d at 1346; *Lombardi*, 565 F.3d at 1352. Put another way, these decisions indicate that where the respondent presents evidence of an alternate diagnosis, the special master may consider the respondent's evidence of that alternative diagnosis as part of the master's evaluation of the petitioner's *prima facie* showing of an injury, potentially mooting the *Althen* causation test. (*See, e.g., Broekelschen*, 618 F.3d at 1350 (holding that "the special master properly considered the government's alternative evidence on injury prior to determining causation"). However, this is *not* the same as putting an affirmative burden on the petitioner to come forward with a specific diagnosis, as Respondent argues. *See, e.g., Kelley v. HHS*, 68 Fed. Cl. 84, 100 (Fed. Cl. 2005)("The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury--regardless of the ultimate diagnosis.").

In any event, the present case does not present conflicting diagnoses, in contrast to both *Lombardi* and *Broekelschen*. Rather, in this case none of J.H.'s treating physicians has come forward with a specific diagnosis, and both Petitioners' and Respondent's experts agree that there is no available specific diagnosis for J.H.'s tragic neurological disorder. (See, Ex. 15, p. 2, noting the lack of a definitive diagnosis in J.H.'s medical records and characterizing the condition as a "unique syndrome".) Yet, despite the lack of a precise diagnosis, both experts agree as a basic proposition that the injury from which J.H. suffers is a *neurological degeneration*. (3-Tr. 5-6; 115-16.) The question in this case, then, is not the formal *name* of the neurological condition that J.H. suffered, but whether J.H.'s influenza vaccinations *caused* her neurological degeneration, as Petitioners allege, or whether the cause of J.H.'s condition remains a mystery, as Respondent contends. In this regard, Respondent does not offer any alternative diagnosis, but simply challenges Petitioners' theory as to whether J.H.'s influenza vaccinations can cause or did cause her condition.

Thus, while no diagnosis precisely naming J.H.'s neurological disorder exists, I do not find that there is any reason to preemptively decide this case, as Respondent suggests, without considering the *Althen* test. Rather than raising an alternate diagnosis, Respondent raises precisely the issues to be decided under *Althen*.

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

Turning, then, to the *Althen* analysis, under Prong 1 of *Althen* a petitioner must, as described above, 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 wholly *failed* to show that influenza vaccinations of any kind *can cause* the type of injury from which J.H. suffers.

Here, as described in Sections VIII(B) and (C) above, Petitioners seem to rely on "immune dysfunction" and "challenge-rechallenge" theories to establish that influenza vaccinations are capable of causing a neurological condition like that from which J.H. suffers. For the reasons described in Sections VIIl(B) and (C), however, Petitioners' reliance on those theories was clearly insufficient to meet petitioners' burden of demonstrating a plausible medical theory. Therefore, Petitioners plainly have failed to establish Prong 1 of *Althen* in this case.

D. Petitioners have failed to establish Prong 2 of Althen.

Under Prong 2, the Petitioners would need to show that it is "more probable than not" that J.H.'s vaccinations *did* cause her *own* severe neurodevelopmental disorder--*i.e.*, to show "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. However, Petitioners have completely failed to make such a showing.

That is, for the reasons described in detail above, I find that the Petitioners have failed to establish that the onset of J.H.'s condition took place after her first influenza vaccination; that she suffered rapid neurological downturns after *either* of her influenza vaccinations; that she suffers from "immune dysfunction;" or that her case fits a "challenge/rechallenge" scenario. Therefore, I find that Petitioners plainly have failed to meet their burden under the second *Althen* prong.[8]

E. Petitioners have failed to establish Prong 3 of Althen.

Finally, under *Althen* Prong 3, a petitioner must demonstrate "a proximate temporal relationship between the vaccination and injury." *Althen*, 418 F.3d at 1278. The Federal Circuit has further clarified that *Althen* Prong 3 requires "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in fact." *DeBazan v. HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

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[8] Citing to *Knudsen v. HHS*, 35 F.3d 543 (Fed. Cir. 1994), Petitioners stress that they are not required to prove "the mechanism of injury," and note that "the determination of causation under the Vaccine Act involves ascertaining whether the sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." (ECF 109, p. 18.) Petitioners are correct in these assertions, but I have *not* required them to demonstrate a "mechanism" of injury, or to prove causation to a scientific certainty. Rather, Petitioners have fallen far short of showing that it is "more probable than not" that vaccinations played any role in causing or exacerbating J.H.'s tragic disorder.

Since I have found that Petitioners have failed meet their burden on the first two *Althen* prongs, I need not reach the question of whether they have failed to meet their burden under the third prong. But in the interest of completeness, I also find that Petitioners have failed to establish Prong 3. For the reasons explained at Section VII above, I find that Petitioners' expert relied upon a *flawed* assumption of fact concerning the *onset* of J.H.'s neurological condition. Moreover, since Dr. Oleske was totally unpersuasive in arguing that there is any reason to think that influenza vaccinations even *can* cause the type of neurological degeneration that J.H. suffered, so also he failed to offer any persuasive evidence as to *when* the first symptoms of such an influenza vaccine-caused disorder might appear.

F. 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 find that Petitioners have failed to meet *any* of the *Althen* prongs. They have not only failed to come forward with a plausible medical theory, but have also failed to find adequate support in the record for the theories that they did advance. This is simply not a close case at all.

IX

CONCLUSION

The record of this case demonstrates plainly that J.H. and her 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 Petitioners in this case are *not* entitled to a Program award.[9]

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

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