Appeal No. 2015-5043

United States Court of Appeals

for the

Federal Circuit

FRANCIA HIRMIZ and PETER HIRMIZ, as best friends of their daughter, J.H.,

Petitioners-Appellants,

– v. –

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

APPEAL FROM THE UNITED STATES COURT OF FEDERAL CLAIMS
IN CASE NO. 1:06-VV-00371-CFL, JUDGE CHARLES F. LETTOW

BRIEF FOR PETITIONERS-APPELLANTS

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Form 9

FORM 9. Certificate of Interest

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Francia Hirmiz and Peter Hirmiz as best friends of their daughter, J.H. v. Secretary of Health and Human Services

No. 15-5043

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)
Francia Hirmiz and Peter Hirmiz as best friends of their daughter, J.H. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:
Francia Hirmiz and Peter Hirmiz as best friends of their daughter, J.H.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:
none

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:
none

4. ☐ The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:
John F. McHugh

February 17, 2015
Date

Signature of counsel
John F. McHugh
Printed name of counsel

Please Note: All questions must be answered
cc: Linda Sara Renzi, Esq.

CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes

STATEMENT OF RELATED CASES

No appeal in this case has been before this Court or any other court. To the knowledge of petitioner-appellant, no other related cases are pending in this Court or in any other court.

JURISDICTIONAL STATEMENT

The Court has jurisdiction over petitioner's appeal pursuant to 42 U.S.C. § 300aa-12(f), which contemplates a "petition" seeking review by this Court within 60 days of the entry of judgment. The final judgment was entered in the Court of Federal Claims on December 5, 2014. The Notice of Appeal (Petition for Review) was timely filed on January 17, 2015. The underlying Decision from the Office of the Special Masters of the United States Court of Federal Claims is a final order under § 300aa-12(f).

STATEMENT OF ISSUES

1. Where (1) the only record evidence of a cause of this child's catastrophic injury is consistent with a well understood, thus plausible, mechanism of injury, an anamnestic autoimmune reaction to two half-flu vaccinations, and (2) a close temporal relationship is confirmed by the child's weight chart and medical records, as well as her pediatrician's opinion as to the timing of onset, (3) all other possible causes of her disabling injury have been excluded by extensive investigations by two leading medical institutions, and (4) no pre-flu-vaccine condition is similar to

her post-vaccine condition, nor has any evidence been introduced to connect the two, was it arbitrary and capricious for the special master to find that the injury predated the flu vaccine and was idiopathic?

2. Where the petition attributes the child's undiagnosed crippling injury to one or more vaccinations she received in her first year of life, the most likely of which were two flu vaccinations which were followed by an immediate catastrophic onset of her current condition, was it error for the court to rule that because there were slight symptoms of some level of regression prior to the flu vaccination, but following a DTaP vaccination, the injury was idiopathic, on a record where all possible other causes have been excluded by the extensive investigations of two leading medical institutions?

3. Where after-the-fact histories disagree as to the date of onset of an unknown condition, but the treating physician's records state that the condition arose after the child's nine-month well-baby examination or in late 2004, was it error to find the unsupported opinion of respondent's expert more convincing than the statements of the treating physician whose opinion is supported by all objective evidence in the record?

SUMMARY OF ARGUMENT

The Amended Petition alleged that JH, born January 12, 2004, was a normal, happy, developing baby who was devastated by one or more adverse reactions to vaccinations administered between March 15, 2004 and November 16, 2004. A67, 70. The injury manifested itself as rapid degeneration of her motor skills and body control, after the second of two half-flu vaccinations administered in October and November of 2004. JH has limited control of her body due to spasticity which keeps her muscles ridged. Her condition is undiagnosed, despite the best efforts of two of the nation's leading medical institutions.

The decision of the court below was arbitrary and capricious and not in accord with law, because it found JH suffered from an idiopathic injury, a finding contrary to the great weight of the evidence, unsupported by substantial evidence and contrary to law.

Where the respondent has asserted that JH's injury predated the flu vaccinations, the respondent had the burden of proving that injury was not caused by a vaccine, since the prior condition, if any, arose immediately after the DTaP vaccination, which can cause similar serious neurological injury. The Amended Petition alleged JH was injured by one or more of the vaccines JH received before the onset of her symptoms and thus, fully anticipates the action of more than one

vaccine in causing JH's condition. All other causes but vaccines were eliminated by extensive investigations by two of the world's leading medical institutions.

The experts agreed that severe spasticity, the child's permanent injury, was the extreme opposite of a slight loss of muscle tone found before the first flu vaccination. Petitioner's expert's opined that the flu vaccination was the more likely than not cause of her chronic condition, because it clinically manifested itself as an anamnestic response to the two half-flu vaccinations, a classic autoimmune reaction, confirmed by slight immune abnormalities found in JH's central nervous system. He testified that despite the medically well-recognized possibility of a neurological injury from the DTaP vaccination she received on July 16, 2004, her condition in the summer and early fall of 2004 (1) consistent with variations seen in normal development (2) the only objective symptom was completely different from that of her post-flu injury and (3) her weight chart confirmed an injury commencing with or after the flu vaccinations. JH's pediatrician, stated that JH's development was normal as of her 9 month well-baby examination, and her degeneration started in late 2004.

Respondent's expert admitted that: (1) the progress of FH's deterioration after the flu vaccinations was extremely rapid; (2) her post flu symptoms were the opposite of anything reported previously; (3) her condition was undiagnosed; (4) her weight chart indicated that she suffered an injury which caused her to cease

gaining weight, (5) that her condition had to have a cause. All these factual admissions by respondent's expert point to an injury at the time of the flu vaccinations. No evidence was submitted connecting her pre-injury symptom, loss of muscle tone, to her post-injury condition, chronic severe spasticity, nor to show that the pre-flu vaccine condition predominated and the reaction to the flu vaccination had no significant effect.

In the face of these admissions, and the great weight of the evidence to the contrary, it was error for the Court to hold that all of JH's injury occurred before the flu vaccinations and was idiopathic when the slight symptoms relied upon closely followed the July 16, 2004 vaccinations which included DtaP, a known cause of neurological injury, without any evidence in the record excluding injury from that vaccine, or establishing another known cause as required by law.

STATEMENT OF THE CASE-FACTS

Petitioners seek compensation pursuant tot 42 U.S.C. 300aa et seq for an injury to their daughter JH from one or more vaccines administered to her in her first year of live.

JH was born on January 24, 2004. On October 16, 2004, Dr. Peera found that she had developed normally through that, her nine-month well-baby checkup.

A591. At that visit and on November 16, 2004 she received two half-flu vaccinations. A584

By December 9, 2004, JH was unable to control most of her body due to extreme spasticity. A566-568. She remains totally disabled and is in need of constant care and surveillance. Despite extensive examinations by Children's Memorial Hospital, Chicago and the Mayo Clinic, two of the world's leading medical institutions, there is no diagnosis. A698. All possibilities were fully examined and excluded. *Id*.

There is no dispute that JH developed normally from birth as a twin with her brother, on January 12, 2004, through her 6 month well-baby examination of July 14, 2004, at which time she received four vaccinations: DTaP, Hib, Hep B and Prevnar. A601-602. As of that date, no concerns about development were noted. *Id*. Mrs. Hirmiz reported, however, that both her twins cried for about two days after every vaccination A88 L. 3-9.

As the medical records of the well-baby visits are vague and illegible, Dr. Peera provided a translation. A592 et seq. She noted that JH rolled over on July 16, 2004, A5602, but did not on October 16, 2004. A600. She pointed out that the 6 month report about skills was from the parents, not due to observation by Dr. Peera. A602. Thus, any loss of skills followed the July 16, 2004 vaccinations.

Dr. Peera, and Dr. James Oleske, petitioners' expert, found her developmental progress through the October 2004 well-baby visit to be within normal expectations. A231 L. 20-23, A575. Dr. Oleske deemed it difficult to find any reason to believe developmental delay occurred before the October 2004 well-baby examination as the records were consistent with variations in normal development. A219 L 15–A220 L 13.

Dr. Peera's records contain a history she gave to the petitioners' insurance company in an effort to get JH treated at the Mayo Clinic. A693. It was written on September 12, 2005. She stated JH's condition had deteriorated for the prior nine months. Any possible doubt about the date of onset is resolved by her notes of July 29, 2005, which clearly state that JH developed normally through 9 months. A591. Thus, according to the treating physician, JH's condition arose after she received the two halves of the flu vaccination.

Histories by doctors at Children's Hospital and the Mayo Clinic, based upon parental interviews, place onset variously between six months and nine months. Special Master Abell had found that the parents' recollection of events was reliable but their recollection of timing was not reliable. A46 L15-20. In contrast, Dr. Peera was the treating physician and was attempting seek help for JH by giving the insurance company an accurate history.

Dr. Peera's history is further supported by the objective evidence. In photographs taken in August and September of 2004, JH is seen sitting up straight in a walker, holding her head up straight (A366), holding a toy up in her hand (A369), and using a pincer grasp (A367). However, by December 9, 2004, she had lost all of these abilities. A566-568, A385-386, A94 L. 10-A95 L. 1.

At JH's nine-month examination on October 14, 2004, Dr. Peera observed low muscle tone in her lower extremities, noting to observe to determine if a physical therapy referral would be made on the next visit. A575. At that visit, October 14, 2004, JH received the first half of the influenza vaccination. *Id*.

There were no medical records generated in the short period between the first and second halves of the flu vaccination.

The parents testified that after the first flu vaccination, JH ceased sleeping through the night and cried continually, which unlike her prior-post vaccine experience, did not stop. A89 Line 2-A90 L 16.

On November 16, 2004, JH received the second half of the influenza vaccine. A580. 584. While there were no comments about JH's condition as of November 16, 2004, on November 17, 2004, Dr. Peera, noting the child's decreased muscle tone, referred her for a physical therapy evaluation. A622.[1] This

1 This referral was to St. Joseph's Hospital, It was changed to Children's Hospital when approved by the Insurer. A583, 621.

occurred at Children's Memorial Hospital on December 9, 2004. A388-390. On that examination -- just 23 days after the second half-flu vaccination -- JH was found to be

> "… developmentally delayed with her attainment of gross motor milestones… Significantly decreased strength due to increased tone/spasticity at bilateral lower extremities…displays decreased proximal trunk strength and neck extensor muscles… has increased tone/spasticity throughout bilateral lower extremities … Bilateral upper extremities also display some cogwheel rigidity with movement…the patent is unable to bring hands to midline or to grab for toys." A388-389.

These findings were deemed so severe that the therapist wanted JH to be seen by a neurologist the following morning. A390. Instead, on December 10, Dr. Peera, made several referrals to physicians at Children's Memorial Hospital, including to Dr. David Stumpf, a neurologist, A618, Dr. George Sisson, Developmental, A620 as well as referrals for laboratory tests. A619. These post-December 9 referrals contrast with the referrals of November 17, 2004 to St. Joseph's for "decreased muscle tone" A622 and even that of December 8 redirecting JH to Children's, still for decreased muscle tone. A621.

JH's weight charts establish that after the flu vaccinations, she failed to gain weight as expected for over nine months. She was in the 75% range at both six and nine months; she fell to about 60% by twelve months and to 10% by 15 months and 5% by eighteen months. A694.

On December 20, 2004, 34 days after the second flu vaccination, the neurologist Dr. Stumpf found

> "…increased tone in her lower extremities, particularly at her ankles where she requires great resistance to reach 90 degree in flexion. She had normal tone in her upper extremities. Her strength appeared to be normal…. When standing with support she is up on her toes and has a very slight tendency to scissor." A383-384.

Dr. Stumpf diagnosed her as CP, a diagnosis which was incorrect. See Mayo Clinic conclusion. A698.

These records establish that by December 9, 2004, JH suffered from crippling spasticity. In comparing JH's condition on October 14 with her condition as of December 20, 2004, respondent's expert testified that she evidenced a severe deterioration of her condition in that time period and that her spasticity, as of December 20, 2004 was the opposite of the slight loss of muscle tone seen on October 14, 2004. A294 L 1-6. The medical record contains no comment connecting the slight loss of muscle tone noted on October 14 with the spasticity reported for the first time on December 9, 2004, 22 days after the second half-flu vaccination.

On January 18, 2005, at her 12-month checkup, Dr. Peera noted that JH was not lifting her head, had motor weakness and motor delay, and noted referrals to Dr. Stumpf and for OT/PT. A604. Again, this contrasted markedly from the conditions seen in the August-September photographs, *supra*.

On July 29, 2005, Dr. Peera noted on her records, *inter alia:*

"After 9 months, started regressing." A616.

On September 12, 2005, Dr. Peera wrote a letter to the insurance company requesting that Jessica be seen by Dr. Suresh Kotogal, a neurodegenerative disorder specialist at the Mayo Clinic, because of her rapidly deteriorating condition. In support of her request, Dr. Peera stated that:

> "She was evaluated by Dr. Stumpf, a well-known neurologist at Children's Memorial Hospital and followed by him with multiple testing. Over the last nine months she continued to regress in the area of motor skills, and also language/swallowing skills. She is now presenting with a very concerning neurologic picture with constant irritability, dysphagia, weight loss, and deceleration in her head growth. The multiple testing which included two MRI's of the brain, EEG, extensive laboratory work up in genetic and metabolic disorders, all were inconclusive. Consultations with genetic service at Children's Memorial Hospital and with Dr. Gaebler at the Chicago Rehabilitation Institute were not able to provide us with an etiology for this degenerative condition."

A693. Nine months before this letter is the end of 2004, not in the summer of 2004. Dr. Peera was the treating physician during this entire period.

In summary, there is nothing in this record, other than vaccines, which could explain JH's condition. She had no injury birth or otherwise, no sickness and no genetic condition. A 696-98. The only possible causative factors found in this record are vaccinations. While the petition asserts that the injury was due to one or more of the vaccinations she received from birth to onset, there is a close temporal

relationship between her condition and the flu vaccinations, and between any condition arising in the summer of 2004 and the DTaP vaccination.

Her abnormal immunological results are found at A 430, 431, 432, A559. Some laboratory reports caution that the significance of results must be considered within the context of the patient's clinical picture. A 428, 561

EXPERT OPINIONS

Dr. James Oleske, is a pediatric immunologist, a professor and practitioner at the New Jersey College of Medicine and Dentistry. As such, he is fully familiar with, and deals with, developmental issues as well as inherited and acquired birth defects. A360, 623-674. His plausible theory of causation is:

> Autoimmunity is a well-recognized phenomenon. Indeed the flu vaccine is well known to be associated with Guillain-Barrie Syndrome (GBS), an autoimmune disease of the nervous system. Another reaction to the Flu vaccine is Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). CIDP is closely related to GBS in the fact that it is basically a chronic form of Flu vaccine GBS. CIDP features progressive weakness and loss of muscle use. The major difference between Influenza immunization reactions from GBS and CIDP is that the latter is a chronic condition. Both are autoimmune adverse effects of the flu vaccination and are demyelination diseases, i.e. the autoimmune attack is against the myelin, which insulates nerve cells, the absence of which can cause all the symptoms Jessica displays. Jessica's neurological evaluations and tests that have been unable to make a specific diagnosis, are nevertheless similar to an extreme case of CIDP which cannot be dismissed simply because a diagnosis cannot be confirmed without invasive procedures. The symptoms are the same, the vaccine is the same and there is no other reasonable explanation.

A362-364.

> It is well understood that causation in medicine is more probable than not where the same reaction follows the re-administration of anything, including a vaccine, (See, Ex. testimony of Susan S. Ellenberg, Ph.D., Director, Biostatistics & Epidemiology Division, Center for Biologics Evaluation and Research, Food and Drug Aministration Department of Health and Human Services. Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, House Committee on Government Reform, May 18, 1999. "An adverse event can be causally attributed to a vaccine more readily if… The event recurs on re-administration of vaccine ("positive re-challenge.")."

See A691. Further,

> … there was a well described onset after the first flu shot and after the second flu shot that progression accelerated, evidencing tragic, rare, but very real and not "perceived", vaccine related neurodegenerative damage that occurred in the brain of Jessica, starting with the initial Flu vaccine in October of 2004 and accelerating with the second dose of influenza vaccine. The vaccine related neurological injury is further supported and confirmed by the conclusion of extensive medical evaluations, at the most prestigious US Pediatric Neurological centers that Jessica has no known neurological diagnosis, after extensive testing, that can explain her brain injury. When there is no other diagnosed illness or probable cause, the temporal consistent and most likely etiology in Jessica's devastating neurodegenerative process is vaccine related injury. It is well established that an encephalopathy can exist in a brain and not be detectable by any safe non-invasive means (brain biopsy)

A362.

> .
> Now, could this undiagnosed severe deterioration have been the consequence of an early preliminary reaction to DPT followed by a more disastrous from influenza? That's speculation. Certainly, we know that the two doses of influenza, the second dose, caused marked deterioration so that there was an enhancement of the original insult. Whether there was a much more minor from the DPT, I don't know, but the workup and the evaluation of Jessica by really good people did not document any other

> underlying Diagnosed neurological or disease that could explain what happened to her."

A219 L 12 - A220-13, L 13. Dr. Oleske stated that according to an updated developmental chart, JH was within normal variations of development at nine months. A330 L 11-A332 L1.

Dr. Oleske supported his opinion that JH's current condition arose after the flu vaccinations, by reference to objective evidence. He pointed to JH's weight chart, A694, which showed that until her 9-month well-baby visit, Jessica's weight was in 75% range, but by the 15-month exam it was down to just above 10%. A694. Dr. Oleske stated that such a loss of trajectory is indisputable evidence of a severe event that had to have occurred around 11-12 months, as weight loss does not occur instantly -- it takes time. This drop in her growth pattern establishes

> "the kind of random neurological damage that occurs with an adverse event with immunizations." A227 L 20 A230 L 7.

Clearly, however, as the child's weight was in the 75% range at both 6 and 9 months, this is objective evidence that her devastating injury followed and did not precede the flu vaccinations.

Dr. Oleske described the significance of the pre- and post-vaccination photographs of JH, noting spasticity in her dorsiflexion, tight muscles A368, suggestive not of muscle disease but of primary neurological disease, whereby her muscles are in constant spasm. The pre-vaccination photographs show her ability

to cross her legs and hold them straight out; the post-vaccination photographs reflect the spasticity, including her hands, resulting from her syndrome. A636, 637, 639 A230 L 21-16; A269 L 17-24.

Dr. Oleske noted the tests performed at both hospitals discovered hyperactive immune-type responses in Jessica's central nervous system (A430-432) that tended to confirm the existence of an autoimmune reaction. A221 L 2-8. Notably, many laboratory reports indicate that all readings must be read in light of the clinical picture. See A435.

Dr. Oleske thus opined that where specialists at two highly-regarded medical institutions could find no explanation for JH's condition, he must consider that an "…immune evaluation which indicates that she has subtle as well as more significant abnormalities in her immune function with very high levels of eosinophils. These immune abnormalities could have been due to an unusual immunological response to the flu vaccine that has also caused her neurological deterioration, exacerbated after the second half-dose flu immunization. I have seen cases of immunization injury and post-infections complications that manifest with neurological and immunological abnormalities." A344-345. The record is therefore consistent only with the clinical picture of an autoimmune reaction.

Respondent's expert, Dr. Stephen J. McGeady, is also a pediatric immunologist. While asserting that JH's condition arose after her July 16, 2004

six-month examination, Dr. McGeady agreed that Dr. Peera had indicated that JH's disability started at about one year. A296 L 4-11. He further agreed that JH's growth charts established an insult of some kind to have occurred which caused that loss of growth. A306. In commenting upon JH's record from October to December 2004, he stated:

> "From hypertonia to spasticity is quite the progression, yeah. One's the opposite of the other." A294 L 1-6.

Dr. McGeady agreed that a neurological degenerative disease requires an insult to develop. A322 L 23- A323 L 8. To support his assertion that the flu vaccinations had no effect on JH, Dr. McGeady asserts that her parents were only concerned with JH's failure to keep up with her brother, A295, ignoring the detailed list of findings by the physical therapist in that same report, A566-568, and those of Dr. Stumpf in December 2004. A383. He dismissed Dr. Peera's time line as someone recalling something. A296 L 10-11. Finally, he agreed with Dr. Oleske that JH's weight chart establish that "there was an insult to the child at that time". A306 L 17-21. He agreed that there were findings of an immunological abnormality in JH (A301 L 7-22) and that after extensive testing the Mayo Clinic found no cause of JH's condition and no diagnosis. A300 L 2-7. Dr. McGeady admitted that some neurological conditions cannot be diagnosed. A 300 L 8-13. Yet he dismissed all of this as he did not believe there was any connection to the flu vaccinations.

ARGUMENT

STANDARD OF REVIEW

The Omnibus Budget Reconciliation Act of 1989, Pb. L. 101-239 sec. 6601(h), 103 Stat, 2106, 2289, amended the Vaccine Act in 2006, limiting review of a Special Master's finding of fact to an arbitrary and capricious standard.

42 U.S.C. 300aa-13 states;

> Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—
>
> > (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title,

The arbitrary and capricious standard of review requires that a decision by an Article 1 special master be supported by substantial evidence. See 5 U.S.C. 706 (E).

Speculation has been held to be insufficient to support a determination under the arbitrary and capricious standard. *See Shah v. INS,* 220 F.3d 1062, 1071 (9th Cir. 2000) (speculation and conjecture may not form the basis of an adverse credibility determination). Expert testimony which is refuted by hard evidence in the record cannot support a decision even under the arbitrary and capricious standard. *Akinmade v. INS,* 196 F.3d 951, 957 (9th Cir.1999) (Judge Nies concurring). "Substantial evidence means 'more than a mere scintilla' and 'such

relevant evidence as a reasonable mind might accept as adequate to support a conclusion.' " *Huvis Corp. v. United States*, 570 F.3d 1347, 1351 (Fed.Cir. 2009) (quoting *Consol.Edison Co. v. NLRB,* 305 U.S. 197, 229 (1938)). Indeed, the decision must be "in accordance with the weight of the evidence, not simply supported by enough evidence " *Steadman v. S. E. C.,* 450 U.S. 91, 99 (1981).

Remedial legislation like the National Childhood Vaccine Injury Act should be construed in a manner that effectuates its underlying spirit and purpose, which is to award compensation to vaccine-injured persons quickly, easily, and with certainty and generosity. Public Health Service Act § 2101, 42 U.S.C.A. § 300aa-1. A claim of injury due to a product is a common law tort. Congress has denied vaccine injured persons access to Article 3 Courts. A standard of review which allows an Article I special master to deny compensation against the weight of the evidence is a denial of due process of law. A standard with does not require close questions to be resolved in favor of the petitioner is contrary to law. *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 550 (Fed.Cir. 1994). Indeed:

> The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. …the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

H.R. REP. 99-908, P.L. 99–660, HEALTH PROGRAMS, 1986 U.S.C.C.A.N. 6344, 1986 WL 31971,*18.

THE SPECIAL MASTER'S DECISION THAT ONSET WAS IDIOPATHIC IS NOT IN ACCORD WITH LAW AND IS NOT SUPPORTED BY THE RECORD

Here, the court found that JH's condition arose before the flu vaccination, concluding it was idiopathic. A court's decision is arbitrary and capricious where its is contrary to law. 42 U.S.C. § 300aa-13 reads, in relevant part:

> "…factors unrelated to the administration of the vaccine"--
>
> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
>
> (B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Here JH was normal in July when she received several vaccines including DTaP. The petition in this case attributed JH's injury to the action of one or more of the vaccines she received from birth through the end of 2004. The petition was not limited to the flu vaccinations of October and November of 2004. In any case;

> …all vaccine injuries have a genetic base. Susceptibility always plays a role. Indeed, the Federal Circuit has held, non-vaccine environmental factors contribute to the injury. In such circumstances, when concurrent forces cause a single harm, the Federal Circuit has held, the burden is on [Respondent] to show that the alternative cause is so predominant that the vaccine is insignificant. *See Shyface v. Sec'y of HHS,* 165 F.3d 1344, 1352–53 (Fed.Cir.1999). Therefore, the Court has stated, if evidence establishes equally plausible etiologies for an injury then the petitioner should prevail. *See Knudsen v. Sec'y of HHS*, 35 F.3d 543, 550 (Fed.Cir.1994). In such

> cases, [Respondent] must eliminate the vaccine as a substantial contributing factor. See *Shyface,* 165 F.3d at 1353.

Sucher v. Secretary of Health and Human Services, Not Reported in Fed.Cl., 2010 WL 1370627 *34 (Fed. Cl. 2010).

Here, the respondent has offered no such evidence. Petitioner's expert testified that the DTaP vaccination she received in July may have played some role in her deterioration, but he stated that the evidence available as to deterioration after that vaccination was consistent with in variations seen in normal development. Thus, he deemed that evidence, under all the circumstances, to be insufficient for him to make that association. But he did testify that the fact that DTaP vaccine could cause neurological injury was well recognized. A219 L. 15 – A220 L. 13. See the extensive discussion in *SucheR, supra.*

Indeed the connection between DTaP and encephalopathy has been well recognized by the Office of Special Masters. *See Perez v. Sec'y of HHS,* 2008 WL 763301, at *40 (Fed.Cl.. March 4, 2009) (finding as a matter of fact, that encephalopathy can be caused by the component of the DTaP vaccine, *Johnson v. Secretary*, 2010 WL 3291932*15 (Cl. Ct. 2010) containing an extensive discussion of evidence showing that a cellular DTP causes adverse reactions, but to a lesser extent than whole-cell DTP, in *Romero v. Sec'y of HHS,* No. 07–671V, 2010 WL 2766761 (Fed.Cir.Spec.Mstr.2010), In addition, the Table recognizes that a

vaccine containing pertussis can cause encephalopathy. *See* 42 C.F.R. § 100.3 (linking "[v]accines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e .g.,* DTP, DTaP, P, DTP–Hib)" with "[e]ncephalopathy"). *Sucher v. Secretary*, supra at *37. Indeed in *Sucher* the Special Master noted that "… the medical literature seems to reiterate, the threat of serious adverse reactions previously associated with whole-cell pertussis did not disappear with the introduction of toxoiding pertussis toxin, but continues to be a concern, one that is reflected in the medical literature filed in this matter."

Therefore, while the petitioners here believe that JH's injury was caused by the flu vaccinations she received in October and November of 2004 a plausible theory or causation exists as to the DTaP vaccination JH received in July. The symptoms the respondent relied upon which arose in the summer of that year are consistent with a DTaP injury particularly where, as here, JH cried for two days following its administration. Further respondent made no effort to establish that the pre-flu vaccine symptoms were either related to those found on December 9, 2004, nor that they were not related to the DTaP vaccine. This was respondent's legal obligation, not petitioners'. See *Shyface, supra* at 1353. Nor was there any effort to show that that pre-flu vaccination condition so predominated as to render the catastrophic events following the flu vaccination superfluous. *Shyface, supra*.

Under 42 U.S.C.A. § 300aa-13, factors unrelated to the vaccine cannot be idiopathic.

Here, the records of the treating physician, Dr. Peera, and her communications with JH's insurer all state that JH's deterioration started in late 2004. A decision ignoring this opinion is arbitrary and capricious. *See Capizzano v. Secretary of Health and Human Services*, 440 F.3d 1317, 1326 (Fed. Cir, 2006) (ignoring the opinion of the treating physician is reversible error). Further, the symptoms found on October 16, 2004 were minor. "The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history." H.R. REP. 99-908, P.L. 99–660, HEALTH PROGRAMS, 1986 U.S.C.C.A.N. 6344, 1986 WL 31971*15.

Histories from Children's Memorial Hospital in Chicago and from the Mayo Clinic state dates of onset variously based on the reports from the parents. Their recollection as to the timing of events was found unreliable by Special Master Abell as they deem events to have happened earlier than established in the records. A46.

Where, as here, the petitioner has established that the vaccine can cause such injuries, that such an injury occurred immediately after the flu vaccinations, it was the respondent's burden to establish not only that the injury arose before the flu

vaccination but that the flu vaccine's effects were immaterial, and that the July vaccinations did not cause the injury. A decision finding an earlier idiopathic onset following the July vaccines, without evidence satisfying any of these criteria, is arbitrary and capricious.

IN REJECTING RECHALLENGETHE COURT BELOW RENDERED THE PETITIONERS' BURDEN IMPOSSIBLE

The court below found that re-challenge was rejected because Dr. Oleske had not submitted literature or other evidence to establish that flu vaccine can damage the brain. The Special Master failed to comprehend that re-challenge alone is conclusive proof of causation, without more. Here the record establishes that there was a slight reaction to the first flu vaccination and a massive reaction to the second.

> "Once you are sensitized with two previous vaccines, the third vaccine initiates what's called the recall, or the anamnestic response ... [which is the immune system's] ability to remember. And it not only remembers, but it remembers with a vengeance.

Murry V. Secretary H.H.S., Not Reported in Fed.Cl., 2009 WL 3288300*15 (Fed.Cl., 2009). *Capizzano v. Secretary of Health and Human Services*,. 2004 WL 1399178, at *16, (CL Ct 2004) held that re-challenge was "such strong proof of causality that it is unnecessary to determine the mechanism of cause—it is understood to be occurring." While reversed on other grounds, this conclusion stands. See: .*Freeman v. Sec'y of Health & Human Servs.,* No. 04–1528V, 2009

WL 5103594, at *12 (Fed.Cl. Spec. Mstr. Dec. 9, 2012); *Hall v. Sec'y of Health & Human Servs.,* No. 02–1052B, 2007 WL 312084, at *7 (Fed.Cl. Spec. Mstr. Oct. 4, 2007).

> Rechallenge is compelling evidence because it happens to a particular person. The specificity fulfills respondent's demand, based upon *Hodges, Grant, Bunting, and Hasler*, that a petitioner bring forth evidence to show that he or she suffered an injury due to the vaccination.[2]

Hall, supra. Proof of an anamnestic reaction alone fulfills all three *Althen* prongs.

Here the Special Master increases the petitioner' burden, particularly here where JH's condition has never been seen before, has not been diagnosed and were causation is established by a strong temporal relationship and re-challenge.

> Under pertinent law, however, the scientific shortcomings of Petitioner's case—lack of scientific literature or confirmatory studies—do not preclude a finding of causation-in-fact. See *Cedillo v. Secretary of Health and Human Services* 617 F.3d 1328, 1339 (Fed. Cir 2010). (noting a petitioner's injury is not required to be recognized by the medical community or in the literature). The pertinent standards are not those of the scientist. The Vaccine Program requires neither epidemiological evidence nor identification of a specific biological mechanism to explain vaccine injury. All that is required is a plausible, reliable explanation.

Daily v. Secretary of Health and Human Services, Not Reported in Fed.Cl., 2011 WL 2174535*8, (Fed.Cl., 2011).

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2. *Hodges v. Sec'y HHS* 9 F.3d 958, 960 (Fed, Cir, 1993), *Grant v. Sec'y HHS.*, 956 F.2d 1144, 1148 (Fed.Cir.1992), *Bunting v. Sec'y HHS,* 931 F.2d 867, 873 (Fed.Cir.1991), *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir.1983)

Daily is one of numerous cases recognizing that the flu vaccine can cause a neurological injury. Indeed it was found to have caused Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) the injury that Dr. Oleske stated proved that flu vaccine could cause injury and having symptomology similar to JH's. A362-363. Dr. Oleske testified that he had dealt with such cases in his practice, and his resume establishes that he is well qualified to testify to these facts based upon his own expertise and medical experience. A623-674.

Overwhelming evidence of re-challenge is in the record. The day after the second vaccination, on November 17, 2004, Dr. Peera referred JH for PT noting loss of muscle tone, Ex. 4 p 280 precisely the condition noted in October and which the mother said worsened after the first vaccination. A89 Line 2-A90 L 16. But on December 9, just three weeks later, the Physical Therapist described the severe spasticity JH still suffers from. It is significantly different from the condition noted in October. "A professional license carries with it a degree of presumed competence." *In re Hanft*, 274 B.R. 917, (Bkrtcy.S.D.Fla.,2002) citing; *In re Baiata,* 12 B.R. 813, 820 (Bankr.E.D.N.Y.1981). Dr. Peera would not have missed these extreme symptoms had they existed on November 16.

Dr. Oleske opined that the only plausible and likely explanation for JH's condition is an autoimmune reaction, evidenced by the similarity of JH's symptoms to those of CIDP, a disease the flu vaccination is known to cause but which cannot

be proved without a brain biopsy, an invasive and dangerous procedure. Ex. 17 pg. 4. Thus, better proof is not available and is not necessary, because

> to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.

Althen v. Sec'y HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005), *quoting Knudsen v. Sec'y HHS*, 35 F.3d 543,549 (Fed.Cir. 1994).

Any review of this record establishes that re-challenge has been established, because the first flu vaccination caused JH to cry continuously and not sleep through the night, and to begin to lose weight. The rapid deterioration of JH immediately followed the second exposure to the flu vaccine. The concerted efforts of physicians at two highly-regarded medical institutions have ruled out all other causes of her condition.

A decision based upon a medical opinion which is demonstrably incorrect, such as that of Dr. McGeady, that her condition in October was the same as the crippling condition she suffered in December, is arbitrary and capricious because it is contrary to the evidence, including Dr. McGeady's admission that the conditions were opposites, Dr. Peera's statements, and the weight charts, all establishing the late 2004 onset of the predominant injury..

> "[C]ontrary scientific explanations can serve as evidence of arbitrary and capricious agency decision-making, *see Tucson Herpetological Soc'y v. Salazar*, 566 F.3d 870, 879 (9th Cir. 2009)."

League of Wilderness Defenders/Blue Mts. Biodiversity Project v. Connaughton, 752 F.3d 755, 764 (9th Cir. 2014). See M*otor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983) (noting that an agency's failure to offer an explanation for its decision that runs counter to the evidence before it is arbitrary and capricious*); Islander E. Pipeline Co. v. State of Connecticut*, 467 F.3d 295, 313 (2d Cir. 2006) (observing that an agency's failure to mention contrary scientific studies renders its conclusions arbitrary and capricious). Indeed, a decision which is inconsistent with the clear evidence in the record is incomprehensible and entitled to no deference by a reviewing court, even under the arbitrary and capricious standard. *Haselwander v. McHugh,* 774 F. 3d 990, 994 (D.C. Cir. 2014).

The only evidence about the two conditions -- muscle weakness and spasticity -- was the uncontroverted testimony of petitioners' expert. Dr. Oleske, who explained that lack of tone is a muscle disease, while spasticity is neurological. TR 61 L 9-20 *supra*. Therefore, the medical records establish that onset of symptoms of chronic spasticity occurred between the second flu vaccination and December 9, 2004. This fact, and the fact that chronic spasticity is her injury, were confirmed by the treating physician, Dr. Peera, who detected the mild loss of muscle tone on October 14, 2004 but in all her reports after that date, stated that the onset of JH's crippling condition was after that nine-month

examination, i.e.,after the flu vaccinations, a statement objectively confirmed by JH's weight chart.

A decision which is not "in accordance with the weight of the evidence, not simply supported by enough evidence" is arbitrary and capricious. *Steadman v. S. E. C. supra*.

AN AUTOIMMUNE ATTACK ON THE NERVOUS SYSTEM IS PLAUSIBLE, PROBABLE AND ENTIRELY CONSISTENT WITH THE FACTS

Contrary to the Special Master's conclusions, the petitioners have fulfilled the requirements of *Althen, supra*. They have presented a plausible medical theory, an autoimmune attack, established to be more likely than not by the anamnestic reaction she had to the second flu vaccination and as the only abnormality found in all the tests done on JH, is a slight stimulation of the immune system within her central nervous system. A430, 431. Within her clinical picture this is evidence that it is more likely than not that "…JH had an autoimmune reaction to the flu vaccination." A220 L. 2-A221 L 22; A224 L. 20 –A225 L. 10.

The evidence in the record is fully consistent with an anamnestic response -- renewed rapid production of an antibody on the second (or subsequent) encounter with the same antigen, i.e., the flu antigen. This is a classic autoimmune response, and it is the mechanism by which all vaccines work. A225 L. 15- 25. *Hargrove ex rel. Wise v. Secretary of Health and Human Services* Not Reported in Fed.Cl.,

2009 WL 1220986*37, (Fed.Cl., 2009). The fact that her condition, a condition medicine has not encountered before, is autoimmune, is supported by "…the negative auto-immune work up for recognized conditions. The temporal relationship between the flu vaccinations and the marked deterioration Jessica demonstrated with the initial and then second Flu vaccination… In addition to a temporal relationship, there is the absence of other underlying conditions or causes." Thus, all that is left is the evidence of an autoimmune response in the central nervous system and "the well understood and thus more plausible mechanism of biological action/interaction with the vaccine, including any of its components." A362. No other explanation for JH's condition has been offered or proved. Indeed, doctors at two leading medical institutions have eliminated all other possible causes of JH's condition. A695-698. The vaccines stand alone as the only thing JH encountered which could cause her condition.

"The elimination of alternative causes may be key to establishing causation when no definitive mechanism for the harm is understood." *Walther v. Sec'y of HHS,* 458 F.3d 1146, 1149–50 (Fed.Cir.2007). Petitioner "may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient." *Id.* Here, Children's Memorial Hospital, the Mayo Clinic and Dr. Peera could find no other cause. A695-698.

Where, as here, the only evidence of a cause in the record is consistent with a well understood, thus plausible, mechanism of injury, an autoimmune reaction, and where, as here, the temporal relationship is established by her weight chart and her pediatrician and is fully consistent with such an injury, and where, as here, no alternate known cause of her injury has been established, it is an abuse of discretion and a clear violation of the intent of Congress as well as contrary to the national interest in instilling confidence in the Vaccine Program, to deny this child's claim.

CONCLUSION

By reason of the above errors, this Court should set aside the decision of the Court of Federal Claims and render a decision based upon the record awarding compensation to the petitioners and remanding for a determination of the amount of compensation.

Dated, New York, N.Y.
April 8, 2015

/s/John F. McHugh
233 Broadway, Suite 2320
New York, N.Y. 10279
212-483-0875

ADDENDUM

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., Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES Respondent.	Vaccine Act Entitlement; Causation-in-fact; Influenza vaccine; Developmental Delay; Degeneration of Motor Skills and Body Control.

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* skills 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 VIII(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.

In the United States Court of Federal Claims

No. 06-371V

(Filed: December 4, 2014)

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FRANCIA HIRMIZ and PETER HIRMIZ, as best friends of their daughter, J.H.,	Vaccine case; administration of half-doses of influenza vaccine to a child; causation related to neurological degeneration; pre-existing condition
Petitioners,	
v.	
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Defendant.	
**********	

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

Linda S. Renzi, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for defendant. With her on the briefs were Joyce R. Branda, Acting Assistant Attorney General, Civil Division, Rupa Bhattacharyya, Director, Torts Branch, Civil Division, Vincent J. Matanoski, Deputy Director, Torts Branch, Civil Division, and Gabrielle M. Fielding, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER

LETTOW, Judge.

Petitioners, Francia and Peter Hirmiz, on behalf of their daughter, J.H., seek review of a decision by a special master dated August 26, 2014, denying them an award under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755 (1986) (codified, as amended, at 42 U.S.C. §§ 300aa-1 to -34) ("Vaccine Act"). Petitioners allege that the injection of their daughter with two half-doses of influenza vaccine, administered on October 14, 2004 and November 16, 2004, caused her subsequent severe neurological degeneration. The Secretary of Health and Human Services ("the government") acknowledges J.H.'s compromised condition but argues that its cause is unrelated to inoculation of the vaccine.

J.H. to date has no confirmed diagnosis. Petitioners claim an off-Table vaccine injury for which they must establish causation in fact by a preponderance of the evidence. *See* 42 U.S.C. §§ 300aa-11(c)(1)(B), (C)(ii)(I); 300aa-13(a)(1); *Althen v. Secretary of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The special master, applying the test set forth in *Althen*, denied relief on the ground that petitioners "failed to demonstrate that it is 'more probable than not' that this pair of vaccinations contributed to causing their daughter's condition." *Hirmiz v. Secretary of Health & Human Servs.*, No. 06-371V, slip op. at 7 (Fed. Cl. Spec. Mstr. Aug. 26, 2014) ("Entitlement Decision").[1] The special master additionally noted that "it appears more likely than not that J.H.'s condition predated these vaccinations." *Id.* Petitioners challenge the special master's decision, maintaining that their theory of an autoimmune attack on the nervous system triggered by the vaccinations is "plausible, probable[,] and entirely consistent with the facts," claiming that the special master "arbitrarily ignored the great weight of the evidence," and averring that his conclusion was "contrary to law." Pet'rs' Pet. for Review of the Decision of the Office of Special Mstrs. dated Aug. 26, 2014 ("Pet'rs' Mot.") at 1, 16, 18, ECF No. 121.[2] The petitioners' motion for review has been fully briefed and a hearing was held on November 13, 2014.

STATEMENT OF FACTS

J.H. and her twin brother were born on January 12, 2004. Entitlement Decision at 5. During the first few months of her life, J.H.'s development appeared normal. *Id.* She had well-child exams at the ages of sixteen days and six months and received vaccinations for DTaP, HIB, Hep B, and Prevnar on March 15, May 17, and July 16, 2004. *Id.* No concerns or adverse reactions to any immunizations were recorded. *Id.* The pediatrician's checklist for the pediatric visit held on July 16, 2004 indicated that J.H. was capable of rolling over in both directions and "sits with support/alone." *Id.* (quoting Ex. 4 at 25, Ex. 10 at 7).[3]

The first mention in the record of J.H.'s developmental delays was generated on October 14, 2004. On that date, a medical note chronicling J.H.'s pediatric visit stated that J.H. was not rolling over and not sitting alone, indicating a loss of some skills between July and October

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[1]The Entitlement Decision was rendered by a special master who had been assigned to the case after the originally assigned special master had retired.

[2]In their motion, petitioners state that J.H. suffered "an obvious aggravation of any prior condition." Pet'rs' Mot. at 1. Nonetheless, until the hearing held on the motion for review, petitioners had not raised a significant-aggravation claim before the special masters. Such a claim would require analysis under the six-part test outlined in *Loving ex rel. Loving v. Secretary of Dep't of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009). *See W.C. v. Secretary of Dep't of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Petitioners did move at the hearing to amend their petition for compensation to state such a claim. Hr'g Tr. 52:11-18 (Nov. 13, 2014). The court will address a putative significant-aggravation claim in the analysis that follows.

[3]The exhibits petitioners presented to the special masters are designated numerically, while the government's exhibits are marked with letters.

2004. Entitlement Decision at 5. J.H. was also observed to have decreased muscle tone on her left extremity. *Id.*; Pet'rs' Mot. at 3. J.H. received a first half-dose of the influenza virus vaccine on that date. Entitlement Decision at 5. Petitioners testified that after the first influenza vaccination they noticed that J.H. cried continuously, no longer slept through the night, and lost her ability to support her own weight. Pet'rs' Mot. at 3. J.H. received a second half-dose on November 16, 2004, approximately one month after receiving the first half-dose. Entitlement Decision at 5. This dose was received at a pediatric visit during which she was also referred to a neurologist. *Id.*[4]

J.H. had a PT evaluation at Children's Memorial Hospital on December 9, 2004, at which she was found to be "developmentally delayed with her attainment of gross motor milestones" and suffered "[s]ignificantly decreased strength due to increased tone/spasticity at bilateral lower extremities . . . [,] display[ed] decreased proximal trunk strength and neck extensor muscles," and "ha[d] increased tone/spasticity throughout bilateral lower extremities." Pet'rs' Mot. at 4 (quoting Ex. 4 at 368-69). At that time, J.H. was "unable to bring hands to midline or to grab for toys." *Id.* J.H.'s first neurological evaluation was performed by Dr. David Stumpf on December 20, 2004. Entitlement Decision at 5. Dr. Stumpf observed "increased tone in her lower extremities" due to "great resistance to reach 90 degree[s] in flexion" and diagnosed J.H. with spastic diplegia and cerebral palsy, which he suggested resulted from "twinning." Pet'rs' Mot. at 5 (quoting Ex. 4 at 371); Entitlement Decision at 6. Early in 2005, J.H. suffered a marked neurological deterioration. For several months, J.H.'s mother reported that she gained no weight, a fact reflected in her weight chart, which lists J.H. in the 75th percentile at 9 months of age, in the 60th percentile at 12 months, in the 10th percentile by 15 months and only in the 5th percentile at 18 months. Pet'rs' Mot. at 4; *see also* Pet'rs' Reply to Resp't's Post Hearing Mem. at Exs. D, E, ECF No. 115. At her 12-month well-child pediatric visit on January 18, 2005, the medical records indicate that although J.H. could use single words, drink from a cup with help, and feed herself some solids, she was unable to pull to stand, walk independently, or grasp objects and was no longer lifting her head. Pet'rs' Mot. at 5; Entitlement Decision at 6. The doctor assessed J.H. to be "well developed but with muscle weakness, motor delay." Entitlement Decision at 6 (quoting Ex. 10 at 9). J.H. also began physical therapy in early 2005, which her parents reported improved her "prone activity, sitting and lower limb kicking;" her medical records, however, noted that she was not "using her bilateral extremities as functionally as she used to." *Id.* (quoting Ex. 6 at 469).

Subsequently, J.H. was evaluated extensively at Children's Memorial Hospital by a number of physicians, including neurologists, geneticists, pediatricians, orthopedic surgeons, and physical and rehabilitation specialists. Entitlement Decision at 6. In late March 2005, her parents and physical therapist noted difficulty feeding, inability to maintain a sitting position, and the onset of clenched fists. *Id.* When Dr. Stumpf reevaluated her on April 18, 2005, he observed a significant increase in spasticity and noted that additional tests were needed to determine whether J.H. had a degenerative disorder. *Id.* At her 15-month check-up on April 19, 2005, Dr. Peera assessed her with global developmental delays and "CP," *i.e.*, presumably, cerebral palsy. Pet'rs' Mot. at 6. J.H.'s swallowing function studies and MRIs with contrast of

[4]There are no medical records for the period between the administration of the first and second halves of the influenza vaccination. Pet'rs' Mot. at 3.

the brain and cervical cord, administered in May 2005, were deemed normal. Entitlement Decision at 6. In June 2005, J.H.'s diagnosis of cerebral palsy was reassessed after Dr. Stumpf found her to have atypical features. *Id.* at 7. During that time, she was diagnosed with "spastic quadriplegia, etiology unclear" and was assessed at the Rehabilitation Institute of Chicago as being characterized by "very poor head control [and] trunk control." Entitlement Decision at 6 (quoting Ex. 4 at 334). Despite physical therapy, J.H.'s motor function worsened. *Id.* In November 2005, J.H. was evaluated at the Mayo Clinic where, despite extensive testing, her doctors could not agree on a diagnosis. *Id.*

In 2008, J.H. was evaluated by Mark Geier, M.D. who performed additional testing, including an entire genome microarray, but was similarly unable to offer a diagnosis. Entitlement Decision at 6. To date, J.H. has no definitive diagnosis for her neurological condition. *Id.*

PROCEDURAL HISTORY

Mr. and Mrs. Hirmiz filed their petition for compensation on behalf of J.H. under the Vaccine Act on May 8, 2006. Their original petition alleged that "a series of vaccinations administered on March 15, 2004, May 17, 2004, [and] September 17 and 18, 2004" caused J.H. to experience "a degeneration of her motor skills and body control noticeable after mid-October of 2004." Resp't's Mem. in Resp. to Pet'rs' Mot. for Review ("Resp't's Mem.") at 4, ECF No. 123 (quoting Pet'rs' Pet. for Compensation, ECF No. 1). After the government contested that claim, petitioners altered their position regarding the onset of J.H.'s condition in an amended petition filed on March 5, 2007. Entitlement Decision at 4. Unlike the original petition, which asserted that "J.H. progressed normally for about eight months," the amended petition alleged that J.H. progressed normally "for about over ten months, *i.e.*, at least until October 14, 2004" and asserted that J.H.'s failure to progress resulted from the half-dose influenza vaccines administered on October 14, 2004 and November 16, 2004. Pet'rs' Am. Pet. (filed with the court in paper form) at 1.

On August 28, 2008, an "onset hearing" was held before the originally assigned special master, at which petitioners testified about the onset of J.H.'s condition. Entitlement Decision at 4; Transcript of Proceedings, Aug. 28, 2008 ("2008 Tr."), ECF No. 37 (submitted to the court in paper form). On January 14, 2010, the special master issued a bench ruling, finding that the onset of J.H.'s symptoms occurred between July 16, 2004 and October 14, 2004, before the administration of J.H.'s influenza vaccinations:

> [T]here is some form of regression which has been initiated prior to the 14th of October. It seems to deteriorate, or accelerate, rapidly between October 14 and November, whatever the date was, perhaps the 16th, yes, and thereafter. In fact, the records are replete with that acceleration of degeneration of whatever the problem is.

Transcript of Proceedings, Jan. 14, 2010 ("2010 Tr."), at 15, ECF No. 56; *see also* Hr'g Tr. 14:18 to 16:24 (Nov. 13, 2014).

Following the initially assigned special master's retirement, the case was reassigned to another special master. Entitlement Decision at 4.[5] After the filing of expert reports by the petitioners and the government, a second evidentiary hearing was held on December 5, 2012, to hear testimony from the parties' experts. *Id.* at 5; Transcript of Proceedings, Dec. 5, 2012 ("2012 Tr."), ECF No. 104. During that hearing, petitioner's expert, Dr. James M. Oleske, testified that J.H.'s neurological condition was likely due to the two half dosages of influenza vaccine she received at 9 and 10 months of age, which were temporally related to the onset of her worsening neurological symptoms. Entitlement Decision at 8.[6] Dr. Oleske asserted that a severe decline started to occur at 12 months of age, causing her growth to decrease drastically over the next three months. *Id.* at 8-9; 2012 Tr. at 20-22, 70. He suggested that J.H.'s neurological deterioration may have been due to an unusual immunological response to the flu vaccine. Entitlement Decision at 9. The government's expert, Dr. Stephen J. McGeady, disagreed and testified that there was no evidence in J.H.'s medical records that she suffered immune dysfunction in her first six months of life and emphasized that J.H. received routine immunizations early in her life without any reported adverse reactions. *Id.* at 9-10; 2012 Tr. at 77-78, 85.[7] Dr. McGeady opined instead that J.H. demonstrated signs of a loss of skills between July and October of 2004, before the administration of the influenza vaccinations. Entitlement Decision at 10; 2012 Tr. at 87. According to Dr. McGeady's testimony, "for an infant not to have made significant physical skill acquisition between the ages of six and nine months (July to October 2004) would have been highly abnormal, and to have *lost* skills in that time period would be alarming." Entitlement Decision at 10 (emphasis in original); 2012 Tr. at 82-83. Dr. McGeady concluded that it was more likely than not that J.H.'s rapid deterioration in late 2004 was an extension of a neurodegenerative process that began before October 14, 2004. Entitlement Decision at 10.

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[5]Petitioners did not thereafter request that the new special master personally hear testimony regarding the onset of J.H.'s condition. Resp't's Mem. at 5 n.5.

[6]Dr. Oleske is a pediatric immunologist, serving as a Professor at the School of Public Health, University of Medicine and Dentistry of New Jersey, a Clinical Professor at the New Jersey School of Nursing, and a Professor of Preventive Medicine and Pathology in the Department of Pediatrics at the University of Medicine and Dentistry of New Jersey. Ex. 16 at 3. His resume lists 212 peer-reviewed publications. *Id.* at 19-33. 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 Pediatric and Pediatric Infectious Diseases, the American Board of Medical Laboratory Immunology, 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. *Id.* at 2.

[7]Dr. McGeady serves as Director of the Allergy and Clinical Immunology Training Program at the Jefferson College of Medicine and as Chief, Allergy, Asthma, and Immunology Division, DuPont Hospital for Children. Ex. B at 1. His resume lists 54 peer-reviewed articles. *Id.* at 2-6. He is certified by the American Board of Pediatrics, the American Board of Allergy and Immunology, and the Board of Diagnostic Laboratory Immunology. *Id.* at 1.

On August 26, 2014, the successor special master issued a decision denying compensation to petitioners. Entitlement Decision at 2. The special master held that petitioners failed to prove by a preponderance of the evidence that the half doses of influenza vaccine administered to J.H. on October 14, 2004 and November 16, 2004 caused J.H.'s neurological degeneration. *Id.* at 7, 20. In so holding, the special master relied on the three-prong framework for establishing causation outlined in *Althen*, 418 F.3d 1274, requiring a petitioner to establish by preponderant evidence that the vaccination caused the 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.

Entitlement Decision at 16 (quoting *Althen*, 418 F.3d at 1278).[8]

Regarding the first element of the *Althen* analysis, the special master observed that the petitioners failed to show "that influenza vaccinations of any kind can cause the type of injury from which J.H. suffers." Entitlement Decision at 19 (original emphasis omitted). The special master concluded that petitioners could not establish the first prong because their reliance on "immune dysfunction" and "challenge/rechallenge" theories was insufficient to meet the burden of demonstrating a plausible medical theory. *Id.* With regard to *Althen*'s second prong, the special master noted that the petitioners did not meet their burden of establishing cause and effect because they were unable to show that J.H. suffered rapid neurological downturns after either of her influenza vaccinations. *Id.* In addition, the special master observed that petitioners were unable to demonstrate that J.H.'s case fit either an "immune dysfunction" or a "challenge/re-challenge" scenario. *Id.* Finally, in analyzing the third prong of *Althen*, the special master concluded that petitioners failed to establish a proximate temporal relationship between the influenza vaccinations and J.H.'s injury. *Id.* The special master found that petitioners' expert, Dr. Oleske, relied upon a flawed assumption of fact regarding the onset of J.H.'s neurological disorder and failed to offer any persuasive evidence as to when the first symptoms of an influenza-vaccine-caused disorder may appear. *Id.* at 19-20.

Petitioners filed a Motion for Review in this court on September 23, 2014.

STANDARDS FOR REVIEW

Under the Vaccine Act, in reviewing a decision of a special master on a motion for review, the court may take any of the following actions:

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[8]The special master noted that the *Althen* analysis could be applied despite J.H.'s lack of an official diagnosis because both parties' experts agreed that J.H. suffered neurological degeneration and there is no affirmative burden on the petitioner to establish a specific diagnosis. Entitlement Decision at 17-18 (citing *Kelley v. Secretary of Health & Human Servs.*, 68 Fed. Cl. 84, 100 (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.")).

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2).

The special master's determinations of law are reviewed *de novo*, *Andreu v. Secretary of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009), and findings of fact are reviewed for clear error, *id.*; *see also Broekelschen v. Secretary of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious." (citing *Capizzano v. Secretary of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006))). In making his determination, the special master must "consider all relevant and reliable evidence." Rule 8(b)(1) of the Vaccine Rules of the United States Court of Federal Claims; *see also* 42 U.S.C. § 300aa-13(b)(1) ("[T]he special master or court shall consider the entire record and the cause of the injury, disability, illness, or condition until the date of the judgment of the special master or court."). A special master's findings regarding the probative value of presented evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial evidence." *Doe v. Secretary of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton v. Secretary of Health & Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996)); *see also Porter v. Secretary of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). Nonetheless, a deferential standard of review "is not a rubber stamp." *Porter*, 663 F.3d at 1256 (O'Malley, J., concurring in part and dissenting in part). The special master must draw plausible inferences and articulate a rational basis for his decision. *Hines ex rel. Sevier v. Secretary of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *see* 42 U.S.C. § 300aa-13(b)(1). Although the special master need not address every individual piece of evidence presented in the case, *see Doe*, 601 F.3d at 1355; he cannot dismiss contrary evidence to the extent that it appears that he "simply failed to consider genuinely the evidentiary record before him," *Campbell v. Secretary of Health & Human Servs.*, 97 Fed. Cl. 650, 668 (2011); *see also Paluck ex rel. Paluck v. Secretary of Health & Human Servs.*, 104 Fed. Cl. 457, 467 (2012).

The Vaccine Act was originally adopted by Congress to "establish a [f]ederal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (2d Sess. 1986), *reprinted in* 1986 U.S.C.C.A.N. 6334, 6334. Congress established a Vaccine Injury Table to allow for a generous remedial program.[9] For cases falling within the timing and other specifications of a Table injury, causation is conclusively presumed. *Hodges v. Secretary of Health & Human*

[9]The original Vaccine Injury Table was published at 42 U.S.C. § 300aa-14(a). The Secretary of Health and Human Services has periodically revised the Table pursuant to notice-and-comment rulemaking under the authority of 42 U.S.C. § 300aa-14(c), and the current version of the Vaccine Injury Table, as amended, is set out at 42 C.F.R. § 100.3.

Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). For claims falling outside the scope of the Table, however, the claimant is required to prove causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), -13(a)(1)(A); *Althen*, 418 F.3d at 1278.

Causation in fact is proved by a petitioner who satisfies each of three *Althen* factors by preponderant evidence. *Althen*, 418 F.3d at 1278 (quoted *supra*, at 6). Expanding on these criteria for establishing causation, the Federal Circuit stated that "[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Id.* (citation omitted) (internal quotations omitted). Once the petitioner has made a prima facie case of causation, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the administration of the vaccine . . . ." *de Bazan v. Secretary of Health & Human Servs.*, 539 F.3d 1347, 1352 (citation omitted) (internal quotation omitted).

The Federal Circuit has interpreted the "preponderance of the evidence" standard for Vaccine Act cases as the same as the standard used in traditional tort cases, *see Moberly ex rel. Moberly v. Secretary of Health & Human Servs.*, 592 F.3d 1315 (Fed. Cir. 2010), requiring the claimant to establish "more probable than not" causation, *Althen*, 418 F.3d at 1279 (citation omitted). "'[C]lose calls regarding causation are resolved in favor of injured claimants.'" *Andreu*, 569 F.3d at 1378 (quoting *Capizzano*, 440 F.3d at 1325-26). The preponderance standard employed by the Vaccine Act "allow[s] the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," *Althen*, 418 F.3d at 1280. Thus, proof by a preponderance of the evidence does not require "scientific certainty." *Bunting v. Secretary of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Rather, determination of causation under the Act involves "ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen ex rel. Knudsen v. Secretary of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (citations omitted). Therefore, a finding of causation in fact in vaccine cases can be "based on epidemiological evidence and the clinical picture . . . without detailed medical and scientific exposition on the biological mechanisms." *Id.* at 549 (citing *Jay v. Secretary of the Dep't of Health & Human Servs.*, 998 F.2d 979, 984 (Fed. Cir. 1993)).

While a special master may base his or her decision on medical opinion alone, *Althen*, 418 F.3d at 1279-80, he or she is "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324 (citing *Terran v. Secretary of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). In addition, the special master may also consider medical literature or epidemiological evidence in reaching an informed judgment as to whether a particular vaccination caused a particular injury. *See LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1339-40 (Fed. Cir. 2014).

ANALYSIS

Based on the lack of a formal diagnosis for J.H.'s severe neurological impairment, it is undisputed that petitioners' claim involves an "off-Table" condition, *i.e.* an injury not listed in the Vaccine Injury Table delineated in 42 U.S.C. § 300aa-14(a). *See* 42 U.S.C. § 300aa-

11(c)(1)(C)(ii). Accordingly, petitioners bear the burden of proving causation in fact by a preponderance of the evidence. Based upon the record, four separate possible theories of J.H.'s condition have been or may be posited:

1. **Challenge/Rechallenge Scenario:** J.H. was healthy until she received the October 2004 injection; she had adverse reaction then; in November 2004 she received a second dose, and her condition soon became drastically worse.

2. **All Other Possible Causes Have Been Eliminated:** J.H.'s condition (according to medical experts) must have been prompted by a trigger; extensive testing has eliminated all other potential causes of her condition, leaving only the influenza vaccinations, implicating a theory akin to *res ipsa loquitur*.

3. **Exacerbation of Underlying Condition:** J.H. suffered from an underlying immunological condition prior to October 2004, but the half-doses of the influenza vaccination caused her condition to develop into a severe neurological impairment.

4. **Other Vaccination Received in July 2004 was Cause:** Plaintiff's expert Dr. Oleske, admitted that J.H.'s receipt of other vaccines in July 2004 was a possible cause of J.H.'s impaired condition, but claimed this possibility was mere "speculation" because it could not be proven.

Conceptually, possibilities 1, 2, and 4 fit within the *Althen* causation principles, while possibility 3 would require consideration of the *Loving* significant-exacerbation factors.

A. Causation Under *Althen* Factors

The special master's denial of the petitioners' petition rested largely on evidence suggesting that J.H.'s neurological degeneration predated her receipt of the two half-doses of the influenza vaccine on October 14, 2004 and November 16, 2004, respectively. The second special master found Dr. McGready's testimony to this effect more persuasive than the contrary view of Dr. Oleske, which the second special master concluded suffered from several deficiencies. Entitlement Decision at 10. Most importantly, the special master noted that Dr. Oleske based his opinion on a "plainly flawed" assumption regarding the onset of J.H.'s neurological symptoms. *Id.* at 10-11. While Dr. Oleske concluded that J.H.'s symptoms did not begin until after her first influenza vaccination on October 14, 2004, the special master observed that this testimony was refuted by both the findings of the original special master after the 2008 onset hearing and J.H.'s medical records.

The special master's conclusion regarding the onset of J.H.'s symptoms is supported by both the facts and the record. J.H.'s medical records document a change in J.H.'s circumstances between her six-month visit with Dr. Peera in July of 2004 and her nine-month visit on October 14, 2004. Entitlement Decision at 11. At six months of age J.H. was able to roll over in both directions, reach for objects, babble, and appeared normal for her age. At nine months, however, J.H. was no longer rolling over or sitting alone and had decreased muscle tone in her lower

extremities. *Id.* The testimony of J.H.'s parents similarly supports that the onset of J.H.'s condition occurred prior to October of 2004. In several different medical histories, J.H.'s parents noted that her development began to fall behind that of her twin brother at about six months of age, in July 2004. *Id.* at 12. Finally, the records of J.H.'s visit to the Mayo Clinic identify July to September of 2004 as the period of the first symptoms of her neurological deterioration. *Id.* The original special master at the onset hearing weighed the testimony of J.H's parents with that of her medical records. *Id.* He noted that while he found J.H.'s parents to be "credible" and "moral" people, he believed that the medical records as a whole indicated that J.H.'s neurological development was deficient in July of 2004. 2010 Tr. at 10.

Petitioners argue that the second special master ignored a significant portion of the record in rendering his decision. Specifically, they emphasize that the original special master stated that J.H.'s condition was a "form of retrogression" which initiated before October 14th, 2004. In this first special master's view, J.H.'s condition "seem[ed] to deteriorate, or accelerate, rapidly between October 14 and November [16th] and thereafter," demonstrating an "acceleration or degeneration of whatever the problem is." 2010 Tr. at 15. They contend that the second special master's lack of acknowledgment of the first special master's statements about acceleration, coupled with other probative evidence, including dated photographs of J.H.'s worsening condition over time, amounted to impermissibly "don[ning] blinders to . . . [evidence] lthat contradicted his findings." Pet'rs' Mot. at 15 (quoting *Shapiro v. Secretary of Health and Human Services*, 105 Fed. Cl. 353, 357 (2012), *aff'd*, 503 Fed. Appx. 952 (Fed. Cir. 2013)). Contrary to petitioners' contention, however, there is no indication in the second special master's thorough opinion that he failed to consider the evidence petitioners cite. In the opinion, the second special master explained that he reviewed the findings of the first special master and also conducted a detailed review of both the testimony of J.H.'s parents and notations in J.H.'s medical records. Entitlement Decision at 12. Furthermore, the first special master's bench ruling does not conflict with the second special master's decision. The first special master deliberately refrained from drawing any medical conclusions in his ruling. He neither identified a cause for J.H.'s neurological nose-dive nor suggested that the influenza vaccination itself aggravated her condition; he merely identified a time – a period undisputed by the parties – during which J.H.'s symptoms worsened significantly. The second special master accepted that J.H. experienced a dramatic neurological decline in the period after October 14th, but concluded through his analysis of the *Althen* factors that the evidence did not demonstrate that the decline was caused by J.H.'s vaccinations. *Id.* at 19-20.

In addition, the second special master undertook an overall review of petitioners' various theories of causation. First, he addressed petitioners' theory that an unusual immunological response to the influenza vaccine contributed to J.H.'s neurological disorder. Entitlement Decision at 13-15. His rejection of this theory was based on the absence of any medical literature or any plausible explanation by Dr. Oleske indicating that the influenza vaccine was capable of causing an unusual immunological response that could lead to a severe neurological decline. *Id.* In that respect, Dr. McGeady explained that nothing in J.H.'s records indicated that J.H. was immunologically abnormal or unusually susceptible to infections. *Id.* Petitioners dispute Dr. McGeady's conclusion that J.H. was immunologically normal after the flu vaccinations, relying primarily on results from tests at the Mayo Clinic in 2005. *See* Hr'g Tr. 22:16 to 23:1 (Nov. 13, 2014) ("We have the flu vaccination coming in, we have the theory that

it could be an autoimmune reaction, and we have the evidence from the Mayo Clinic and from Children's Hospital of evidence of an immune response in her central nervous system. So, we know there's an auto — there's a possibility of an autoimmune reaction. We have symptoms of it. We have fingerprints of it in the tests. They are slight fingerprints, but they are fingerprints. And then we have the work of Children's Hospital excluding everything else."). To further support the theory of an autoimmune reaction, petitioners point to two autoimmune conditions, Guillain-Barré syndrome and Chronic Inflammatory Demyelinating Polyneuropathy, both of which are known to be caused by flu vaccines. Pet'rs' Mot. at 8 (citing Dr. Oleske's testimony, Ex. 17 at 3-4).[10] The special master discounted those conditions as providing any analogy to J.H.'s condition, commenting that "Dr. Oleske failed to point to any medical articles or other actual evidence demonstrating that influenza inoculations can injure the brain." Entitlement Decision at 13.

Second, the special master's rejection of petitioners' "challenge/rechallenge" theory of causation was supported by the fact that J.H. suffered the first symptoms of her neurological disorder *before* her first influenza vaccination, which is inconsistent with a "challenge/re-challenge" scenario. *Id.* at 15.[11] Although the special master's decision did not appear to address in this context the significant worsening of J.H.'s condition in late 2004 and early 2005, those changes did not follow immediately after the half-dose influenza vaccinations.

B. Signification Aggravation Theory

During the hearing held on November 13, 2014, petitioners moved to amend their petition for compensation to incorporate a significant-aggravation claim, arguing that an autoimmune reaction to the flu vaccine may have exacerbated an underlying condition, resulting in J.H.'s neurological decline. Hr'g Tr. 52:11-14, 50:14-19 (Nov. 13, 2014) ("[I]f the pleadings don't cover the aggravation, I move to amend the pleadings to conform that proof, as we do all the time in court when things turn out differently."). In support of their theory, petitioners cite results from the Mayo Clinic and Children's Hospital suggestive of an autoimmune reaction and the general timing of J.H.'s accelerated neurological decline, which followed her receipt of the vaccines. Hr'g Tr. 22:16 to 23:19 (Nov. 13, 2014). The government counters that a significant-aggravation claim was never fully developed in the pleadings or by petitioners' expert. Hr'g Tr. 39:11-21 (Nov. 13, 2014).

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[10]Guillain-Barré syndrome is a disorder in which the body's immune system attacks part of the peripheral nervous system. Chronic Inflammatory Demyelinating Polyneuropathy is a neurological disorder characterized by progressive weakness and impaired sensory function in the arms and legs. This condition is often considered the chronic counterpart to the acute Guillain-Barré syndrome.

[11]A "challenge/rechallenge" circumstance exists when a person has a reaction to one administration of a vaccine or drug and then suffers worsened symptoms after an additional administration of the same vaccine or drug. Entitlement Decision at 15. A challenge/rechallenge theory can be used to establish causation. *Id.* (citing *Capizzano v. Secretary of Health & Human Servs.*, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Sp. Mstr. June 8, 2004), *aff'd*, 63 Fed. Cl. 227 (2004), *rev'd on other grounds*, 440 F.3d 1317 (Fed. Cir. 2006).

Under Rule 15(b)(2) of the Rules of the Court of Federal Claims ("RCFC"), a party may move at any time to amend the pleadings to incorporate an issue that is tried by the parties' express or implied consent.[12] The decision to grant such a motion rests in the sound discretion of the trial court. *See Grand Light & Supply Co. v. Honeywell, Inc.*, 771 F.2d 672, 680 (2d Cir. 1985) (citing *Browning Debenture Holders' Comm. v. DASA Corp.*, 560 F.2d 1078, 1086 (2d Cir. 1977)).[13] The purpose of RCFC 15(b) is to enable the pleadings to conform to issues "actually tried, not to extend the pleadings to introduce issues inferentially suggested by incidental evidence in the record." *Id.* (quoting *Browning Debenture*, 560 F.2d at 1086). The rule should also be applied in a manner that avoids unfair prejudice, which may occur where a party seeks to apply evidence presented on a separate issue to a new claim added after conclusion of the trial, *see id.* at 680 (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330–31 (1971); *Cook v. City of Price*, 566 F.2d 699, 702 (10th Cir. 1977)), or if the opposing party did not have the opportunity to defend against the new claim and might have offered additional evidence had it been aware of the claim, *see id.* (citing *International Harvester Credit Corp. v. East Coast Truck*, 547 F.2d 888, 890 (5th Cir. 1977)).

In this instance, petitioners waited to raise a significant-aggravation claim until after a decision was rendered by the special master following the conclusion of percipient witness and expert testimony. While the evidence cited by petitioners that would support a significant-aggravation theory was submitted at the hearings before both special masters, it was submitted in support of separate and distinct theories of causation, *i.e.*, a challenge/rechallenge scenario and an immunological response causing neurological dysfunction beginning *after* the administration of the influenza vaccine. Therefore, the issue of significant aggravation is "inferentially suggested by incidental evidence" rather than "actually tried," *Grand Light*, 771 F.2d at 680 (citation omitted), and there was no implied consent by the government to try the issue in the underlying proceedings, *see, e.g.*, *Paul Revere Life Ins. Co.*, 354 F.3d 1005, 1013 (9th Cir. 2004) (noting that Fed. R. Civ. P. 15(b) "does not permit amendments to include issues which may be [merely] inferentially suggested by incidental evidence in record" (citations omitted)); *DRR, LLC v. Sears, Roebuck and Co.*, 171 F.R.D. 162, 165 (D. Del. 1997) (finding that an issue was not tried by implied consent of parties when relevant evidence was introduced at trial only in support of the original claim and the opposing party was not put on notice that the additional issue was being tried); *Metcalf Const. Co. v. United States*, 102 Fed. Cl. 334, 343 (2011) (noting "where evidence is introduced at trial to establish a properly pled issue, implied consent may not be assumed as to issues not pled").

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[12]This Rule states in pertinent part:

> When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move--at any time, even after judgment--to amend the pleadings to conform them to the evidence and to raise an unpleaded issue. But failure to amend does not affect the result of the trial of that issue.

RCFC 15(b)(2).

[13]RCFC 15(b) mirrors Fed. R. Civ. P. 15(b). The court accordingly will look to precedents applying Fed. R. Civ. P. 15(b) in addition to those addressing RCFC 15(b).

Moreover, allowing the claim at this stage of the litigation, over eight years after the filing of the original petition for compensation in May 2006, would unfairly prejudice the government. *See Baker v. Goldman, Sachs & Co.*, __ F.3d __, __, 2014 WL 5840501, at *12 (1st Cir. Nov. 12, 2014) (noting that plaintiffs' general argument that the defendant's failure to disclose relevant facts about a transaction in violation of a specific statute was insufficient to put defendant on notice of a claim falling under a different statute); *Rodriguez v. Doral Mortg. Corp.*, 57 F.3d 1168, 1172 (1st Cir. 1995) (plaintiff may not "leave defendants to forage in forests of facts, searching at their peril for every legal theory that a court may some day find lurking in the penumbra of the record"). Notably, the legal test for significant-aggravation claims differs from that applicable to petitioners' other claims.[14] Importantly also, no testimony whatsoever has been presented on a significant-aggravation theory by an expert witness. Indeed, petitioners concede that a significant-aggravation theory would contradict the testimony of their own expert, Dr. Oleske, who testified that J.H. developed normally until October 14, 2014. Hr'g Tr. 51:15-17 (Nov. 13, 2014) ("Dr. Oleske still doesn't believe this child had a problem in the summertime. He and I disagree."). In these circumstances, the court declines to permit petitioners to amend their petition to incorporate a significant-aggravation claim at this stage of the proceedings.

C. Synopsis

In sum, due to evidence that the onset of J.H.'s condition occurred prior to the administration of the two half-dose influenza vaccinations and the lack of evidence supporting the persuasiveness of petitioners' proffered medical theories, the court finds that the special master weighed the evidence of record and made determinations in accord with law. Applying the pertinent evidentiary standard, the court concludes that the special master's finding of a lack of causation was supported by substantial evidence and was neither arbitrary nor an abuse of discretion.

CONCLUSION

For the reasons stated, petitioners' motion for review is DENIED, and the decision of the special master rendered on August 26, 2014 is AFFIRMED.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Judge

[14]The six-part *Loving* test that pertains to a significant-aggravation claim, *see Loving*, 86 Fed. Cl. 135, adds three factors to the causation criteria specified in *Althen*, *see supra*, at 2 n.2.

In the United States Court of Federal Claims

No. 06-371 V

FRANCIA HIRMIZ and PETER HIRMIZ, as best friends of their daughter, J.H.

JUDGMENT

v.

SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES

Pursuant to the court's Opinion and Order, filed December 4, 2014, , affirming the special master's Decision, filed August 26, 2014,

IT IS ORDERED AND ADJUDGED this date, pursuant to Appendix B, Vaccine Rule 30, that the petition is dismissed. No costs.

Hazel C. Keahey
Clerk of Court

December 5, 2014 By: s/ Debra L. Samler

Deputy Clerk

NOTE: As to election, 90 days from this or the issuance of the appellate court's mandate, see Appendix B, Rule 33.

Represented petitioners' motions for attorneys' fees and costs shall be filed within 180 days of judgment, see Vaccine Rule 13. Pro se petitioners may seek litigation costs within 180 days of judgment.

As to petition for review, 60 days from this date, see Appendix B, Rule 32. Petition for review and filing fee of $505.00 should be mailed to the following address: Clerk, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW, Washington, DC 20439.

United States Court of Appeals for the Federal Circuit

CERTIFICATE OF SERVICE

FRANCIA HIRMIZ, ET AL. V. SECRETARY OF HEALTH AND HUMAN SERVICES
APPEAL NO. 2015-5043

I, Natasha S. Johnson, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Counsel for Petitioners-Appellants to print this document. I am an employee of Counsel Press.

On April 10th, 2015, Counsel for Appellants has authorized me to electronically file the foregoing **Brief for Petitioners-Appellants** with the Clerk of Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

/s/ Natasha S. Johnson
Natasha S. Johnson

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

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/s/ John F. McHugh
John F. McHugh