In the United States Court of Federal Claims

No. 15-789V
Filed: August 20, 2020
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LINDSEY MARTIN and RAYNARD MARTIN, parents of I.R.M., a minor,	*	
Petitioners,	*	
v.	*	**Vaccine; Motion for Review; Expert Opinions; Althen v. Secretary of Health & Human Services.**
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

* *

Richard Gage, Richard Cage, PC, Cheyenne, WY, for petitioners.

Mark K. Hellie, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for respondent. With him were **Gabrielle M. Fielding**, Assistant Director, Torts Branch, Civil Division, **Catharine E. Reeves**, Deputy Director, Torts Branch, Civil Division, **C. Salvatore D'Alessio**, Acting Director, Torts Branch, Civil Division, and **Ethan P. Davis**, Acting Assistant Attorney General, Civil Division.

O P I N I O N

HORN, J.

On July 27, 2015, petitioners Lindsay and Raynard Martin, on behalf of their deceased son, I.R.M, filed a petition for compensation with the National Vaccine Injury Compensation Program (Vaccine Program), under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1–300aa-34 (2018) (Vaccine Act). Petitioners allege that I.R.M.'s flu vaccination, administered on September 24, 2014, was the cause of his death two days later on September 26, 2014. On May 8, 2020, Chief Special Master Brian Corcoran of the United States Court of Federal Claims determined petitioners were not entitled to compensation. See generally Martin v. Sec'y of Health & Human Servs., No. 15-789V, 2020 WL 4197748 (Spec. Mstr. Fed. Cl. May 8, 2020). On June 6, 2020,

[1] This Opinion was issued under seal on August 20, 2020. The parties did not propose any redactions to the August 20, 2020 Opinion, and the court, therefore, issues the Opinion without redactions for public distribution.

petitioners filed a motion for review pursuant to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (Vaccine Rules) (2019) in this court to review the Chief Special Master's decision denying entitlement. The parties briefed the motion after which oral argument was held.

FINDINGS OF FACT

Petitioners' son, I.R.M., was born on September 1, 2011. On September 24, 2014, at approximately 4:00 p.m., I.R.M. received an intranasal dose of Flumist, a flu vaccination, during a well-child visit with his pediatrician. As indicated in the Chief Special Master's decision, "[t]he records reveal no evidence of any immediate or transient reaction of the kind often associated with vaccination, such as fever or lethargy." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *1. On September 25, 2014, the first day following his vaccination, I.R.M. was noted to be active and playing and provided no indication of a concerning reaction. On the morning of September 26, 2014, approximately 40 hours post-vaccination, I.R.M. was observed to be feeling tired and had unusual difficulty in waking that morning. Later that morning I.R.M. was taken to his babysitter, who put him down for a nap at approximately 1:30 p.m., and subsequently checked on I.R.M. during his nap and did not notice anything amiss. Around 4:00 p.m., however, I.R.M.'s mother found I.R.M. unresponsive, face down in vomit, with discoloration in his nose and ears. I.R.M.'s jaw was stiff, which made cardiopulmonary resuscitation or CPR difficult. Paramedics transported I.R.M. to the Riverside Hospital emergency room in Columbus, Ohio. Following unsuccessful resuscitation attempts in the emergency room, I.R.M. was pronounced dead at 5:05 p.m. on September 26, 2014. At the time of his death, I.R.M. had no discernable health concerns of note apart from an ear deformity that was identified before I.R.M. turned two, which caused ear infections and resulted in tubes being placed in his ears. I.R.M. received his usual vaccines on schedule without notable complications.

I.R.M.'s babysitter presented differing statements concerning the circumstances on the day of I.R.M.'s death. She noted in a contemporaneous statement to the police on September 26, 2014 that the morning passed "unremarkably." Subsequently, however, I.R.M.'s babysitter stated that I.R.M. seemed tired and was reluctant to eat and that I.R.M. told her that he did not feel well. This prompted I.R.M.'s babysitter to put him down for a nap on the day that he died under the assumption that he was tired.

On September 28, 2014, an autopsy was performed and the autopsy report officially stated that the cause of death was undetermined and noted no congenital abnormalities or signs of trauma. The pathological findings of the autopsy included mild to moderate pulmonary edema and congestion, mild to moderate cerebral edema and congestion, equivocal focal acute hypoxia-ischemia changes in the hippocampus, and hippocampal malformation. Genetic testing could not rule out a cardiac channelopathy. Efforts to determine I.R.M.'s cause of death were complicated by the fact that key organs, including the heart, had been harvested for donation, which inhibited direct dissection or visualization of the heart grossly or microscopically, and as such the autopsy report could not rule out cardiac infections or cardiomyopathies.

On July 27, 2015, petitioners filed a petition under the National Vaccine Injury Compensation Program, which was assigned to Chief Special Master Corcoran, who subsequently ordered petitioners to file expert reports and respondent to file a Rule 4(c) Report. In December 2015, petitioners filed initial reports by expert witnesses Dr. Marcel Kinsbourne and Dr. Alan Levin. In January 2016, Respondent filed its Vaccine Rule 4(c) Report and argued that an entitlement award was not appropriate. In December 2016, respondent filed expert reports by Dr. Christine McCusker and Dr. Brent Harris, after which petitioners filed supplemental reports by Dr. Alan Levin and Dr. Marcel Kinsbourne in May 2017. The Chief Special Master then ordered petitioners to consider filing a supplemental expert report, which prompted petitioners to file an expert report by Dr. Douglas Miller in April 2018. Thereafter, respondent filed a supplemental report by Dr. Harris in response to Dr. Miller's report. In September 2019, both sides filed post-hearing briefs.[2] Ultimately, the Chief Special Master received reports and heard testimony from five experts: Dr. Levin, Dr. Kinsbourne, and Dr. Miller for the petitioners, and Dr. McCusker and Dr. Harris for the respondent. Petitioners' expert Dr. Miller, a neuropathologist, filed a single expert report on April 4, 2018. In his decision, Chief Special Master Corcoran summed up petitioners' Dr. Miller's credentials, stating:

> Dr. Miller studied biology in college and graduated from Williams College in 1974 with highest honors. He then earned his M.D. at the University of Miami School of Medicine in 1978. Two years later he obtained his Ph.D. in physiology and biophysics from the University of Miami. After his formal education he began his residency training at the Massachusetts General Hospital, where he was a anatomic pathology resident from 1980 to 1982. Then he served as a neuropathology resident from 1982 to 1984. Dr. Miller also serves on the editorial boards of three neurology or neuropathology journals. Dr. Miller is not an immunologist.
>
> Dr. Miller is currently a clinical professor at the University of Missouri School of Medicine, and (since the fall of 2018) has been interim chair for the Department of Pathology and Anatomical Sciences, where he performs different teaching duties. He identified himself as the sole neuropathologist in Central Missouri, resulting in him being called on to assist medical examiners in autopsies (sometimes in criminal contexts) where neuropathologic issues are raised. In such circumstances, he will commonly examine brain or other central nervous system tissues to evaluate "unexpected findings."

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *2 (internal citations omitted).

[2] After the filing deadline of April 11, 2019, respondent filed a four page supplemental report from Dr. McCusker. Petitioners objected to the untimeliness of respondent's filing and asked that it be stricken. Alternatively, respondent argued that the supplemental report was intended to address six additional items of petitioners' post-trial filings, which would require that respondent be permitted to respond or that the items be stricken. Chief Special Master Corcoran granted petitioners' motion to strike in his May 8, 2020 decision. See Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *34-35.

In his testimony, on behalf of petitioners, Dr. Miller found it significant that I.R.M.'s autopsy report did not specify an anatomic cause of death and that I.R.M.'s death fell under the category of sudden unexpected death of child (SUDC). Dr. Miller did not contest the coroner's autopsy report and concurred with the observations of Dr. Harris, respondent's pathologist expert. Dr. Miller's opinion was that I.R.M. had a brain abnormality which was "[p]resent from the moment he was born" and which predated any vaccines, and that this abnormality sometimes seen in autopsies of people who have epilepsy. In stating his opinion Dr. Miller cited similarities between I.R.M.'s death due to SUDC and sudden infant death syndrome (SIDS) and referenced a study by Dr. Hannah Kinney, which suggests that various factors like brain abnormalities and sleep position are associated with SUDC and SIDS. See H. Kinney et al., Sudden Death, Febrile Seizures, and Hippocampal and Temporal Lobe Maldevelopment in Toddlers: A New Entity, 12 Pediatr. Dev. Pathol., 6:455–63 (2009) (Kinney I). The Chief Special Master summarized Dr. Miller's theory, stating:

> Such a sleep seizure might result in a "fatal event" characterized by a cessation of breathing and brain edema. Dr. Miller deemed it "well settled" that children with this particular brain abnormality possess a risk factor for unexplained death, noting that they are overrepresented amongst those with diagnosed epilepsy who die (an occurrence termed sudden unexplained death in epilepsy, or "SUDEP"), as well as in SIDS [Sudden Infant Death Syndrome] or SUDC [Sudden Unexpected Death of Child].[3] He later admitted, however, that Kinney I expressly did *not* state that this hippocampal anomaly was also associated with SIDS—and although he claimed familiarity with "subsequent studies" since Kinney I's publication in 2009 making this link, he did not file any in this matter. Kinney I at 8 ("[a]lthough prone sleep position is associated with SIDS, febrile seizures

[3] Dr. Miller evaluated slides of I.R.M.'s brain tissue and noted that one slide showed evidence of an abnormality with I.R.M.'s dentate gyrus, a section of the hippocampus. In his decision, Chief Special Master Corcoran noted:

> Medical studies, however, have associated abnormal development of the dentate gyrus with not only seizure propensity (since it was often seen in patients diagnosed with epilepsy), but also have proposed that this kind of abnormality might explain sudden infant death syndrome ("SIDS") as the product of single nocturnal seizure, although SIDS has been more closely associated with other risk factors (in particular sleeping in a prone position). *Id.* at 17–18, 41, 43; H. Kinney et al., *Sudden Death, Febrile Seizures, and Hippocampal and Temporal Lobe Maldevelopment in Toddlers: A New Entity,* 12 Pediatr. Dev. Pathol., 6:455–63 (2009), filed as Ex. 64 (ECF No. 46-1) ("Kinney I").

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *3 (emphasis in original; internal citations omitted).

> and hippocampal abnormalities are not"). He [Dr. Miller] also noted that because the presence of the abnormality could only be detected on autopsy, its exact causal role in seizure or sudden unexplained death was ultimately unknown. ("[y]ou can't say that the seizure was generated by the abnormality").

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *3 (capitalization in original; internal citations omitted) (brackets added; footnotes omitted). Dr. Miller also presented a "seizure threshold" as part of his causation opinion, which the Chief Special Master summarized as follows:

> The neurons making up the dentate gyrus are pyramidal, or triangular, in structure, and evidence of their cell death (whether due to hypoxic or ischemic insult) can easily be discerned under magnification given the idiosyncratic form of these neurons. A child possessing the abnormality alleged herein could be characterized as having a lower threshold to seizure, and might even have had subclinical seizures in the past. Thus, evidence of some prior subclinical seizures would support the contention that a later seizure explained sudden death. He saw some such evidence from I.R.M.'s brain tissue slides (although he admitted the evidence was at best "suggestive" of prior seizures).

Id. at *4 (internal citations omitted). Dr. Miller found evidence of both prior and existing seizures in slides containing I.R.M.'s brain tissue, in which Dr. Miller identified an abnormality in the hippocampus and the abnormal presence of astrocytes, which are referred to as "Chaslin gliosis."[4] Dr. Miller also considered the circumstances surrounding I.R.M.'s death to be illustrative of a seizure in association with an abnormality. Dr. Miller considered I.R.M's death as the result of receiving administration of the Flumist vaccine to be "the kind of event that Dr. Kinney and her colleagues have been describing in association with his hippocampal abnormality, that in sleep, he had a seizure event which caused him to stop breathing, and that led to the brain starting to swell, and he died." Dr. Miller's opinion was that vaccination would cause production of "a variety of inflammatory cytokines" that could cross the blood-brain barrier, enter the brain and "lower seizure thresholds." On cross-examination Dr. Miller stated that he was "not naming specific cytokines" and that:

> There are many, many kinds of cytokines. And some of them are proinflammatory and some of them are anti-inflammatory and there are all sorts of regulatory functions. It is largely a subset of proinflammatory

[4] In defining "Chaslin gliosis" Chief Special Master Corcoran stated, "Chaslin gliosis is '[a] condensation of usually delicate horizontal glial fibers that are normally found in the cortex, immediately beneath the pial surface, thought to be a consequence of convulsions.' William Pryse-Phillips, *Companion to Clinical Neurology* 180 (2003)." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *4 n.7.

> cytokines that are documented to reduce neuronal excitability. So therefore lower seizure threshold.
>
> And IL-1 beta [a type of cytokine] is certainly one of those. There has been some literature on IL-6 as well, and abnormalities of IL-6 signaling. And a lot of that is in the SIDS literature and probably not directly relevant here, but could be brought in as an analogy if somebody wanted to.

(capitalization in original) (brackets added). Moreover, Dr. Miller could not "say this as certainty" that I.R.M. suffered from a seizure and that there was no evidence to show that I.R.M. was affected by one prior to I.R.M.'s nap. Dr. Miller stated that the timeframe from vaccination to death was medically acceptable and that in his opinion the risk would be increased for two to three days after receiving a vaccination. Dr. Miller noted similarities between his previous opinions provided in SIDS cases and I.R.M.'s SUDC, but did not directly relate to the situation in this case, because of factors present in infants (under the age of one) that are not present with three-year olds. Dr. Miller also stated that he was not an immunologist, did not include any opinions about cytokine reaction to vaccination in his pre-hearing report and that he had not filed any literature in support of his theory concerning cytokine reaction to vaccination.

Petitioners also relied on testimony provided by Dr. Marcel Kinsbourne, who prepared two reports and testified at the hearing. Dr. Kinsbourne is board certified in pediatrics and his credentials were summarized by the Chief Special Master, who stated:

> Dr. Kinsbourne is board certified in pediatrics. He received his medical degree in England, and he has been licensed to practice medicine in North Carolina since 1967. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. His clinical experience includes serving as a senior staff physician in Ontario from 1974 to 1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981 to 1991, although (as noted in other cases) many years have passed since he regularly saw patients. He is on the editorial board of several journals that deal with the brain, such as *Brain and Cognition* and *Brain Research*.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *7 (emphasis in original; internal citations omitted). Chief Special Master Corcoran questioned Dr. Kinsbourne's experience and expert report and testimony, writing:

> Cross-examination of Dr. Kinsbourne established a number of reasons to question the degree to which his professional qualifications and experience (especially at present) made him a good "fit" to opine on the issues in contention. Specifically, he admitted (a) having no hospital-based clinical practice for approximately 25 years, (b) that he only occasionally sees patients on referral, (c) that he had not treated a seizure or evaluated its cause in that entire period, and (d) that his focus since ceasing to regularly see patients had been on teaching (mainly as a professor of psychology

> teaching neuroscience to graduate psychology students), although he argued that he nevertheless frequently considered issues pertaining to neurology and the brain. He similarly acknowledged that he lacked training and expertise in immunologic matters generally, and the study of cytokines specifically, deferring on such issues to Petitioner's [sic] third expert, Dr. Levin.

Id. (internal citations omitted).

Dr. Kinsbourne pointed out that I.R.M. had been feeling fine before he received the vaccine but that he felt sluggish afterwards. Dr. Kinsbourne ultimately provided contradictory opinions, in which Dr. Kinsbourne changed his opinion from aligning with Dr. Levin's opinion that brain swelling caused I.R.M.'s death to more closely align with Dr. Miller's opinion concerning a brain abnormality. The Chief Special Master also noted that on cross-examination Dr. Kinsbourne could not explain why previous vaccinations had not triggered a seizure. According to the Chief Special Master's decision, Dr. Kinsbourne's testimony largely rests on the theory that the flu vaccine is generally capable of causing injury, a theory which Dr. Kinsbourne tried to support with reference to T. Togashi et al., Influenza-Associated Acute Encephalopathy in Japanese Children in 1994-2002, 103 Virus Res. 75–78 (2004) (Togashi). The Chief Special Master, however, stated:

> But Dr. Kinsbourne admitted that he did not contend that I.R.M. had suffered an encephalopathy, and Togashi's authors say nothing about vaccines being potentially causal of any injury process associated with encephalopathy—in fact, they reached the *opposite* conclusion. [citing the Togashi article] ("[t]he best way to avoid this severe complication is no doubt prevention by influenza vaccination"). Dr. Kinsbourne also claimed that Cox [R. Cox et al., *Influenza Virus: Immunity and Vaccination Strategies. Comparison of the Immune Response to Inactivated and Live, Attenuated Influenza Vaccines,* 59 Scand. J. Imm. 1-15 (2004) (Cox)] observed increased levels of similar cytokines after vaccination, although that article does not squarely address post-vaccination cytokine levels, focusing instead on antibody levels. Cox at 5–7.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *9 (emphasis in original; internal citations omitted) (brackets added). The Chief Special Master also found other "deficiencies" with Dr. Kinsbourne's opinion, because Dr. Kinsbourne stated that he did not know "whether it's well known or not" that Flumist causes seizures regardless of mechanisms, that he could not identify literature addressing the possibility and that the Togashi study involved wild flu virus-induced fever and not vaccines.

Petitioners' third and final expert was Dr. Alan Levin. The Chief Special Master summarized Dr. Levin's credentials as:

> Dr. Levin has a master's degree in biochemistry and received his medical degree from the University of Illinois in 1964. Dr. Levin also received a juris doctor from Golden Gate University in San Francisco in August 1995 and currently practices law. He is board certified in allergy, immunology, and clinical pathology. His CV lists numerous publications and states these

> publications are primarily in the subjects of immunology, immunopathology, cancer biology and treatments.
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> Dr. Levin claimed as well to have done research on immunologic issues, but "mostly for the Vaccine Court"—suggesting he deems work on petitions as an expert to be akin to research into the background medical or scientific question. He is not board certified in neuropathology, however (unlike Drs. Miller and Harris), and deferred to Dr. Miller on issues in this case relevant to pathology (while maintaining he did have some up-to-date expertise with pathologic issues).
>
> As with Dr. Kinsbourne, Respondent devoted some cross-examination time to highlighting issues with Dr. Levin's expert qualifications. In particular, Dr. Levin graduated from law school 25 years ago, and appears largely since that time to have been a practicing attorney rather than immunologist or pathologist (although the clients he had represented often have brought claims that impinge on the kinds of medical and scientific issues litigated in the Vaccine Program). He is not the primary physician for any patients today, even though he does see a few patients every month, and (as noted above) has kept up to date his medical licenses. He also has not published any medical academic articles for over 20 years.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *10 (capitalization in original) (internal citations omitted).

Dr. Levin posited that the Flumist vaccine had strong immune system-stimulating properties, but unlike Dr. Kinsbourne's initial report, Dr. Levin did not refer to it as a cytokine storm. The Chief Special Master noted that Dr. Levin's reports filed prior to Dr. Miller's report did not state that seizure would have caused I.R.M.'s death, but rather that, "[t]he most probable diagnosis is respiratory arrest secondary to cerebral edema." Dr. Levin stated in his testimony, however, that I.R.M.'s hippocampal abnormality did not make him susceptible to cerebral edema, but rather that it made I.R.M. "susceptible to seizure," and that cerebral edema "probably" postdated any seizure. Dr. Levin also testified that the Flumist vaccine's administration through I.R.M.'s nose rather than his arm distinguished Flumist from other vaccinations, because of "[t]he proximity to the brain." Dr. Levin referenced the Fischer article as support for the contention that "the response is much more vigorous when you put it in the nose." Chief Special Master Corcoran also noted that Dr. Levin could not identify which cytokines were necessary to spark a cerebral edema. In support of his opinion, Dr. Levin cited an article by A. Vezzani et al., Il-1 Receptor/Toll-like Receptor Signaling in Infection, Inflammation, Stress and Neurodegeneration Couples Hyperexcitability and Seizures, 25 Brain, Behavior and Imm. 1281–89 (2011) (Vezzani). The Chief Special Master noted that the Vezzani article says nothing about the ability of vaccines to cause seizures and focuses on cytokines already present in the central nervous system rather than cytokines entering the central nervous system.

Respondent's experts were Dr. Brent Harris and Dr. Christine McCusker. Dr. Harris, a pediatric neuropathologist, prepared an expert report and testified at the hearing for respondent. Dr. Harris concurred with some of the approach offered by Dr. Miller,

agreeing with Dr. Miller's conclusions that I.R.M. had a brain abnormality and that I.R.M. had suffered from previously un-diagnosed seizures, but noting that it was not possible to tell when these previous seizures had occurred, because the slide of I.R.M.'s gliosis was "not an entirely specific finding." Dr. Harris stated that "having the hippocampal malformation was sufficient to cause seizures in and of itself." Dr. Harris also stated that sleep position was often an initiating factor in children's seizures, because sleep position affects breathing and compromises airways. Dr. Harris found it likely that I.R.M. died earlier in the nap, which would explain the evidence of subsequent edema.

Respondent's second expert was Dr. Christine McCusker, a pediatric immunologist who prepared an expert report and testified at the hearing. Dr. McCusker stated that Flumist could not have started a seizure in I.R.M. based on proinflammatory cytonkines. Dr. McCusker's credentials were summarized by the Chief Special Master, as follows:

> Dr. Christine McCusker earned a master's degree in Molecular Virology in 1988, followed by an M.D. in 1993, at McMaster University, in Hamilton, Ontario. She served as a pediatric resident at Montreal Children's Hospital, McGill University, from 1993 to 1996. Then, she was then a clinical fellow in allergy and immunology at McGill University from 1996 to 1999. Dr. McCusker is board certified in pediatrics. She is currently the division director of pediatric allergy, immunology, and dermatology at the Montreal Children's Hospital at McGill University Health Center and is the director of the Clinical Immunology Lab. She also conducts research on developmental immunology, vaccines and immunology, and serves on the boards of several journals.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *15 (internal citations omitted).

The Chief Special Master found Dr. McCusker to be particularly persuasive, writing, "[b]ut this case turned mostly on questions of *pathology* and *immunology*—and on the latter topic, Dr. McCusker was a far more qualified immunologist than Dr. Levin, and provided testimony I found significantly more persuasive." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *31 n.44 (emphasis in original). In summarizing her opinion, the Chief Special Master wrote:

> Dr. McCusker's opinion in this case was rooted in some core contentions about cytokines and the roles they play in the human immune response. Dr. McCusker stressed that cytokines—proteins released by immune system cells to perform communications tasks—were not "one thing." Rather, they have many different functions, and more than 80 have been identified. Cytokines are often lumped together with chemokines, but Dr. McCusker maintained that the latter perform a distinguishable function (by acting as "addressants" that instruct other cells where to go, as opposed to travelling to such other cells *themselves* to deliver information, as cytokines do).
>
> Because of the functional importance and power of cytokines, the immune system tightly regulates their release. IL-1β, for example (which Dr.

> McCusker deemed a common cytokine), is as quickly released as it is controlled, with excess amounts inactivated after being picked up by a "decoy receptor." As a result, Dr. McCusker maintained, cytokines act rapidly and over short distances in the body, with their dissemination and circulation ultimately limited. She specifically disputed the concept that cytokines themselves regularly "travel" from a peripheral site of vaccination to places like the brain, or that they could cause edema there. Rather (and using the example of cytokines implicated in "sickness behavior" after vaccination), cytokines responsible for fever accomplish this most often by causing peripheral nerves at the site of vaccination to communicate signals to the brain (specifically the hypothalamus), "instructing" such CNS [Central Nervous System] locations to initiate a fever in response to an infection. Even in the circumstances of a true "cytokine storm" (which even Dr. Levin discounted as having occurred in this case) featuring uncontrolled cytokine circulation, few cytokines would still travel into the brain.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *16 (emphasis and capitalization in original) (brackets added; internal citations omitted). Dr. McCusker also rejected petitioners contention that proinflammatory cytokines regularly permeate the blood-brain barrier following vaccinations, and also disagreed with the petitioners' experts' assignment of certain conditions to the vaccine, noting that several of the symptoms could be explained by the method of administrating the vaccine.[5] Dr. McCusker also acknowledged that cytokines could be upregulated for a one or two day period following vaccination, but disputed the amount of elevation. Moreover, Dr. McCusker acknowledged that fever or malaise could be induced by vaccines, but she disputed Dr. Levin's argument that Flumist would generally induce fever, particularly in a short time frame, and noted that that to her knowledge the incidence of fever would be no higher than a placebo version of a vaccine. Dr. McCusker disputed the impact of cytokines on a brain malformation and denied that a brain edema would be induced by cytokines, noting that the type of cytokines do not cause inflammation. If such were true, then Dr. McCusker noted that I.R.M. would have suffered reactions or seizures earlier in his life, stating:

> And in this case, this child had several vaccines. This child had several infections. And at each one of those infections, these same series of events would have occurred. And you would have anticipated that if he was sensitive to the point that it would induce a seizure, [sic] that his seizures would have become much more apparent much sooner, just based on the odds.

[5] As indicated in the Chief Special Master's decision, "[s]ome such symptoms might be specific to the vaccine's method of administration; thus, in Dr. McCusker's understanding, people receiving Flumist vaccine often reported a runny nose, consistent with the vaccine's intranasal administration (and this is the response she would usually expect to see if excess cytokine upregulation were at issue)." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *17.

Dr. McCusker also addressed Flumist specifically, noting that its application method through the nose rather than the arm provokes a "not as virulent" response in the immune system. To this she cited a direct study on Flumist's immunogenicity by M. Barria et al., Localized Muscosal Response to Intranasal Live Attenuated Influenza Vaccine in Adults, J. Infectious Diseases 207:115–24 (2013) (Barria). The Chief Special Master wrote concerning the Barria study and Dr. McCusker's opinion that:

> More relevant to this case, Barria observed no change in serum cytokine profiles (in comparison to the impact of a wild viral infection) or concentrations between the date of the vaccine's administration and three days later. IL-1β, the cytokine most identified herein by Petitioners' experts as causal, barely varied in amounts from before to after vaccination—and was in fact the least prevalent of the *eleven* specifically-measured cytokines. Thus, Barria's authors concluded—contrary to a central contention of Petitioners' experts—that the Flumist LAIV [live, attenuated, influenza vaccine] did not produce a notable systemic immune response (evidenced by increased cytokines or antibodies). This kind of finding was, Dr. McCusker suggested, a basis for questioning the overall efficacy of Flumist (when coupled with other evidence establishing that the localized immune response that a LAIV like Flumist did provide was *itself* not all that effective).

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *18 (emphasis in original; capitalization in original) (brackets added; internal citations omitted). Dr. McCusker also provided an opinion on SUDC, and stated that the primary risk factors were sleep and sleep position, with the potential for some suggestion of febrile seizures based on prior "unwitnessed" seizures.

On May 8, 2020, the Chief Special Master ruled in favor of respondents, finding that the petitioners had not presented a plausible theory of causation, that petitioners had not "persuasively established with reliable science" that the Flumist vaccine "was in particular likely to further increase the seizure risk due to its stimulation of the innate immune system" and that the record before the Chief Special Master did not support the conclusion that I.R.M.'s death was caused by a vaccine. The Chief Special Master found I.R.M.'s case of SUDC analogous to a SIDS case, although he noted that the two are different and that the SIDS "triple risk" analysis had no direct application to the case under review. The Chief Special Master held that:

> **I thus do *not* conclude that the many SIDS cases going against petitioners in the Vaccine Program compelled the same result herein**. The fact that I held a hearing in this case, *despite* my concerns about the similarity of this case to the prior SIDS determinations, and have written a lengthy decision evaluating the arguments asserted, should underscore the degree to which I have tried to give Petitioners' claim a fair shot at success.
>
> Nevertheless - this claim, like the prior SIDS cases, relies on the theory that vaccine-induced cytokine interference with the brain in some way has pathologic, and ultimately fatal, outcomes under circumstances involving very young children that otherwise remain mysterious to medical science.

> And in such comparable cases, special masters have repeatedly noted that existing medical and scientific evidence does not reliably support the contention that cytokines *cause* such processes - as opposed to appear in *response* to an ongoing pathogenic process caused by something else. It was for such reasons that the Federal Circuit in *Boatmon* termed the causation theory therein offered as merely "plausible"—and therefore insufficient to meet the preponderant test. *Boatmon[v. Sec'y of Health & Human Servs.],* 941 F.3d [1351,] 1360 [(Fed. Cir. 2019)]. My decision below reasonably takes such parallel analyses into account.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *27 (emphasis in original) (brackets added; footnote omitted). The Chief Special Master also addressed prior SIDS related vaccine cases as it related to the experts in this case. He stated:

> Special masters have had numerous opportunities to evaluate whether vaccines can cause unexplained death via SIDS in infants younger than I.R.M. They have almost never found so, and their determinations have been consistently upheld on appeal. *See, e.g., Cozart v. Sec'y of Health & Human Servs.*, No. 00–590V, 2015 WL 6746616, at *1 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), *mot. for review den'd*, 126 Fed. Cl. 488 (2016); *Nunez v. Sec'y of Health & Human Servs.*, No. 14-863V, 2019 WL 2462667, at *1 (Fed. Cl. Spec. Mstr. Mar. 29, 2019), *mot. for rev. den'd*, 144 Fed. Cl. 540 (Fed. Cl. 2019), *appeal docketed*, No. 20-1021 (Fed. Cir. Oct. 8, 2019). Those prior cases also uniformly featured Drs. Miller and McCusker—underscoring the parallel nature of the present claim. *See, e.g., Cozart*, 2015 WL 6746616, at *9–11. Their views have been evaluated and demeanors considered time and time again—but Respondent has always prevailed.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *26 (emphasis in original).

The Chief Special Master was unconvinced by petitioners' experts Dr. Levin and Dr. Kinsbourne and found the causation theory provided by Dr. Miller, to be unsupported. The Chief Special Master stated:

> Petitioners' experts shifted their causation theory somewhat over the course of the proceedings. Although Drs. Kinsbourne and Levin initially pointed to brain edema triggered by vaccination as causal, at hearing they maintained that (1) a child with a hippocampal abnormality like I.R.M. was susceptible to seizure, (2) the conditions of sleep made seizure more likely under such circumstances, (3) a seizure experienced while sleeping could result in unexplained death, and (4) the Flumist vaccine was in particular likely to further increase the seizure risk due to its stimulation of the innate immune system. While items (1) to (3) were persuasively established with reliable science (and largely not contested by Respondent's experts), the fourth element of the theory, and the component most critical to Petitioners' success, was not.

> Both sides' primary pathologists (Drs. Miller and Harris) were credentialed and credible, and they agreed that a hippocampal malformation was likely associated with childhood seizures—especially during sleep. They also concurred that literature on SUDC ties these factors together (although, as Dr. Harris noted, in many SUDC cases a seizure-induced fatality was, or appeared to have been, preceded by seizures that went unrecognized—and therefore such cases would closely align with SUDEP, but for the absence of a prior epilepsy diagnosis). But there is little to no direct evidence that any vaccine, let alone the Flumist vaccine, could cause or contribute to this process, nor could any of Petitioners' experts speak from their own experience, whether from patient treatment or research, to bulwark this point.

Id. *28 (capitalization in original) (internal citations omitted; footnotes omitted). Further, Chief Special Master Corcoran wrote:

> Coloring the scientific and medical unreliability of theories offered in this case are deficiencies in the qualifications and testimony of two of the three experts who testified for Petitioners. Drs. Kinsbourne and Levin lacked testimonial credibility in important regards. Dr. Kinsbourne, for example, has no demonstrated research or treatment expertise in the matters in dispute, and he relies on neurology expertise that has not been honed or refined, whether by clinical practice or research, for nearly *30 years*. This is a criticism that has been lodged— reasonably—against him repeatedly in the Vaccine Program. *See, e.g.*, *Pope v. Sec'y of Health & Human Servs.*, No. 14-078V, 2017 WL 2640503, at *21 n.29 (Fed. Cl. Spec. Mstr. May 1, 2017). Although Dr. Kinsbourne may have a facility (drawn from his many prior turns as a Vaccine Program expert) in speaking to neurology topics with clarity and confidence, he is not *compelling or persuasive* in so doing—especially to the degree his statements are either not grounded in reliable science or do not arise from his own direct medical expertise or recent work. The mere fact he has experience as a pediatric neurologist does not render him a helpful expert in *all* cases involving a pediatric neurologic injury.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *31 (emphasis in original). Moreover, the Chief Special Master acknowledged in his decision that he found respondent's experts to be more credible and persuasive, as follows:

> Petitioners' post-hearing brief notes (perhaps in the hope of vouching for his expertise) that Dr. Kinsbourne was the "only" neurologist who testified in this case—a true fact as far as it goes. But this case turned mostly on questions of *pathology* and *immunology*—and on the latter topic, Dr. McCusker was a far more qualified immunologist than Dr. Levin, and provided testimony I found significantly more persuasive. *See also Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 3456436, at *1 (Fed. Cl. Spec. Mstr. May, 31, 2016) (finding that Dr. McCusker was more credible than Dr. Miller), *mot. for review denied*, 129 Fed. Cl. 176 (Fed. Cl. 2016). In addition, the neurologic issues posed in this

> case related to the hippocampal abnormality, an issue that both sides largely agreed upon, disputing only the immunologic impact of the vaccine at issue, and Dr. Kinsbourne has no specific demonstrated expertise on that topic that would suggest his statements are deserving of extra weight. In any event, special masters are never bound to accept *any* expert's statements as gospel—especially an expert who sees no patients, conducts no research bearing on the subject of his testimony, and cannot demonstrate otherwise any particular specialization in the relevant topic, as here.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *31 n.44 (emphasis in original) (internal citations omitted). In his conclusion, the Chief Special Master wrote:

> The circumstances of this case are truly tragic. The Martins's desire to identify the medical reason for the loss of their son is wholly understandable—as is their good faith basis for contending that the flu vaccine might have been involved, given the temporal proximity of its administration theory, and I cannot otherwise grant an award of damages simply because an injury occurred close-in-time to a vaccination. Thus, for the reasons stated above, I must deny entitlement in this case.

Id. at *35.

On June 8, 2020, petitioners timely filed a Motion for Review of the Chief Special Master's Decision in the United States Court of Federal Claims. Petitioners argue that the Chief Special Master erred by increasing the burden of proof in requiring petitioners to "supply direct evidence of a biological mechanism of causation." Petitioners argue that:

> The special master made it very clear that he does not accept an association between a vaccine and an injury established by reliable medical opinion. He will only accept direct proof of causality. His analysis searches for direct proof. The question he finds important is not can Flumist upregulate cytokines, but rather which cytokines, when and how many? The question he finds important is not can cytokines cross the blood-brain barrier but again, which cytokines, when and how many? The question he finds important is not can cytokines either reduce the seizure threshold or directly trigger a seizure, but rather which cytokines would, how many would be needed, how would they cross the blood-brain barrier, what would they do once they got in, and how long would the brain need to be exposed to them for a seizure to occur? Even if there is some indication on one question, unless all questions are answered, Petitioners lose.
>
> The Special master is asking the wrong questions. He is asking the equivalent of the who, what, when, where and how of a criminal investigation. But special masters are not to scour the evidence with the aim of meeting the standard of a laboratorian. To demand causation proven with scientific certainty, as this special master has done, goes against the very basic tenets of Vaccine Program law.

Petitioners argue that support by medical opinion is enough, rather than causation in fact. In addition, petitioners argue that the Chief Special Master erred in finding that the vaccine was not a substantial factor in bringing about I.R.M.'s death. Moreover, petitioners argue that the Chief Special Master's decision not to find that I.R.M. had suffered from "malaise" as a result of the vaccine was in error, because the Chief Special Master ruled that "it is equally likely based on this record that I.R.M. merely felt tired." Petitioners argue:

> "Given the importance of this fact [referring to I.R.M.'s feeling of tiredness on the day of his death] to Petitioners' theory of causation, the special master, under *Althen* [Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1277 (Fed. Cir. 2005)] and *Walther* [Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)], should have decided the issue in favor of Petitioners. Given that there is no direct scientific evidence regarding Flumist and seizures, Petitioners must rely on circumstantial evidence. The fact that I.R.M. was suffering from malaise within the hours before he had a seizure and died, is very relevant to the causation theory."

(capitalization and emphasis in original) (brackets added).

In response, respondent asserts that the Chief Special Master's finding that petitioners failed to establish that Flumist caused I.R.M.'s death was not arbitrary and capricious, because the Chief Special Master's decision was "strongly supported by the evidence in the record." Respondent further argues:

> First, it was undisputed that I.R.M. did not have a fever. The Chief Special Master found Dr. McCusker's testimony about cytokines and fever credible. The Chief Special Master also found that Dr. Kinsbourne's and Dr. Levin's testimony "did not merit significant weight." He further found that Dr. Miller's opinions regarding the "theoretical impact of Flumist on a child with a possible susceptibility to seizure" was unreliable and outside the scope of Dr. Miller's area of expertise. In short, the only credible testimony about immunologic pathways came from Dr. McCusker.

(capitalization in original) (internal references omitted). Respondent argues that credibility determinations regarding expert testimony are appropriate. Respondent also argues that petitioners misconstrues the Chief Special Master's decision in suggesting that "the fact issue relating to causation is in equipoise" and that, therefore, the Chief Special Master must rule in favor of the petitioners. Respondent states:

> While the Chief Special Master stated it was a "reasonable inference to associate I.R.M.'s pre-nap condition with what thereafter transpired," that is, I.R.M.'s death, he did not find that the pre-nap condition, or malaise, resulted from the vaccine or an inflammatory response to the vaccine. Moreover, he also found it "equally likely based on this record" that the malaise was because I.R.M. "merely felt tired." Ultimately, the Chief Special Master found "there is weak evidence here that I.R.M. was experiencing a proinflammatory reaction to Flumist due to cytokine upregulation as of the morning of his death." Based on the Chief Special Master's findings and

> discussion of this particular fact, the evidence of any connection between the vaccine and I.R.M.'s malaise most certainly was not in "equipoise."

(internal citations omitted). Respondent also argues that the issue is moot even if evidence were in equipoise, because petitioners bear the burden of proof and equipoise is not preponderance of evidence. Respondent also states:

> Specifically, as noted, I.R.M. did not exhibit a fever, which "greatly undermin[ed] the contention that IL-1β, which is associated with fever, was upregulated by Flumist – even assuming it *could be*, a conclusion that Dr. McCusker effectively rebutted." (emphasis in original). I.R.M. displayed "no other post-vaccination symptoms even within 24 hours" of vaccination. Moreover, I.R.M. slept for two nights, without incident, before his nap on September 26, undermining petitioners' theory that sleeping "interacted negatively with his receipt of Flumist." Additionally, the Chief Special Master found that the record supported an "alternative explanation for the immediate trigger of I.R.M.'s death that petitioners did not rebut," namely, I.R.M.'s sleep position and evidence of regurgitation (vomit). This evidence suggested that I.R.M. experienced respiratory failure, which "would be sufficient to trigger seizure in a child with the hippocampal abnormality I.R.M. possessed."

(brackets in original) (internal citations omitted). Respondent concluded its reply by rejecting petitioners' assertion that Chief Special Master Corcoran had elevated petitioners' burden of proof. Respondent argues that the Chief Special Master simply found instead that, "for reasons he soundly discussed at length, 'important sections of [petitioners' causation] chain of opinion were medically/scientifically unreliable.'" (brackets in original).

D I S C U S S I O N

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (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 conclusions 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) (2018). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In Markovich v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also K.G. v. Sec'y of Health & Human Servs., 951 F.3d 1374, 1379 (Fed. Cir. 2020); Oliver v. Sec'y of Health & Human Servs., 900 F.3d 1357, 1360 (Fed. Cir. 2018) (citing Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1375-76 (Fed. Cir. 2016)); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master's findings were arbitrary or capricious.'" (brackets in original) (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))); W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355 (Fed. Cir. 2013); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir. 2008); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277; Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. 445, 458 (2019); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992). The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard . . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Health & Human Servs., 970 F.2d at 871 n.10; see also Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1345) (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence,

or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder") reh'g and reh'g en banc denied (Fed. Cir. 2012); Morgan v. Sec'y of Health & Human Servs., 148 Fed. Cl. 454, 470-71 (2020). "[T]he special masters have broad discretion to weigh evidence and make factual determinations." Dougherty v. Sec'y of Health & Human Servs., 141 Fed. Cl. 223, 229 (2018).

> With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was "arbitrary and capricious."

Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B).

Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the Special Master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

> As noted by the United States Court of Appeals for the Federal Circuit:
>
> > Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366-67 (modification in original) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363;

Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The United States Court of Appeals for the Federal Circuit has explained that the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (modification in original) (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363); see also K.G. v. Sec'y of Health & Human Servs., 951 F.3d at 1379 ("With respect to factual findings, however, we will uphold the special master's findings of fact unless they are clearly erroneous." (citing Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278)); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1338).

The United States Court of Appeals for the Federal Circuit has explained that:

> A petitioner can establish causation in one of two ways. Id. [Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1341] If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. Andreu[ex rel. Andreu] v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact.

Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379 (citing Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1374); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467-68 (2012); Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011).

For petitioners to establish a *prima facie* case in a vaccine case, decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress, in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280; see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), cert. denied, 566 U.S. 956 (2012); Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009) ("In Althen, however, we expressly rejected the Stevens test, concluding that requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act." (modification in

original)); La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 198 (2013) ("Causation-in-fact can be established with circumstantial evidence, i.e., medical records or medical opinion."), aff'd, 746 F.3d 1344 (Fed. Cir. 2014). The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280 (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356.

When proving eligibility for compensation under the Vaccine Act in a off-Table case,, such as the one filed petitioners, petitioners may not rely on their testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). A petitioner who meets his or her burden is entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. 672, 680 (2016) (citing 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995)). "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379; de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353).

Petitioner also must prove causation-in-fact in a off-Table injury. See Grant v. Sec'y of Health & Human Servs., 956 F.2d at 1147-48. The United States Court of Appeals for the Federal Circuit has held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "'a substantial factor in bringing about the harm.'" de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a) (1965)); see also Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1361 (citing Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1321); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 ("To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (citing Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)). A Judge of the United States Court of Federal Claims has

explained the relationship between "but-for" causation and "substantial factor" in Deribeaux ex rel. Deribeaux v. Secretary of Health & Human Services:

> The de Bazan [v. Sec'y of Health & Human Servs., 539 F.3d at 1351] court defined but-for causation as requiring that "the harm be attributable to the vaccine to some nonnegligible degree," and noted that, although substantial is somewhere beyond the low threshold of but-for causation, it does not mean that a certain factor must be found to have definitively caused the injury. Id. [de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351] Accordingly, a factor deemed to be *substantial* is one that falls somewhere between causing the injury to a non-negligible degree and being the "sole or predominant cause." Id.
>
> This definition of substantial—somewhere between non-negligible and predominant—is applicable to respondent's burden to prove a sole substantial factor unrelated to the vaccine. Accordingly, a respondent's burden is to prove that a certain factor is the only *substantial* factor—one somewhere between non-negligible and predominant—that caused the injury.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 105 Fed. Cl. 583, 595 (2012), aff'd, 717 F.3d 1363 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (emphasis in original).

In order to recover under the Vaccine Act, a petitioner "must show, by a preponderance of the evidence, 'that the injury or death at issue was caused by a vaccine.'" Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379; (quoting Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1341 (citing 42 U.S.C. §§ 300aa–11(c)(1), –13(a)(1))); see also Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1361; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355-56 ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or condition.'" (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); see also Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1355, 1359 (Fed. Cir. 2019); Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1360; La Londe v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011). "Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at

1322); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines v. Sec'y of Health & Human Servs., 940 F.2d at 1525.

While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Human Servs., 88 Fed. Cl. 473, 439 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379). The United States Supreme Court has explained that:

> Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 562 U.S. 223, 228-29 (2011) (footnotes omitted); see also Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 F. App'x 435 (Fed. Cir. 2012).

The Federal Circuit in Althen v. Secretary of Health & Human Services defined a three-prong test by which a petitioner can meet his or her burden to establish causation in a off-Table injury case:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). 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[.]" Grant [v. Sec'y of Health & Human Servs.], 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface[v. Sec'y of Health & Human Servs.], 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant[v. Sec'y of Health & Human Servs.], 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [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 vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (first three sets of brackets in original); see also Boatmon v. Sec'y of Health & Human Servs., 941 F.3d at 1354-55; Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1361; Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); Faup v. Sec'y of Health & Human Servs., 147 Fed. Cl. at 458; C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that provide "objective confirmation" of medical plausibility. See id. at 1278, 1279-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. at 358. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Health & Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health & Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549. The Federal Circuit in Knudsen stated further:

> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP [diphtheria-tetanus-pertussis vaccine] and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. 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 [petitioner's] injury or that the [petitioner'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. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549 (brackets added).

The Federal Circuit also has indicated that:

> Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (omission in original).

Regarding the use of epidemiological evidence in a case in which causation is at issue, the United States Court of Appeals for the Federal Circuit has found that a Special Master may consider epidemiological evidence in determining causation. See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 ("Although Althen[v. Secretary of Health & Human Services,] and Capizzano[v. Secretary of Health & Human Services] make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." (brackets added)); see also Grant v. Sec'y of Health & Human Servs., 956 F.2d at 1149 ("These epidemiological studies are probative medical evidence relevant to causation."); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280.

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). In Capizzano v. Secretary of Health & Human Services, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1)-13(a)(1) (2006)); see also Cozart v. Sec'y of Health & Human Servs., 126 Fed. Cl. 488, 498 (2016). The Federal

Circuit has found that treating physicians' opinions can help satisfy the second prong of the Althen test:

> Such testimony is "quite probative" since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." Id. [Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326] (citations and internal quotation marks omitted); see also Althen[v. Sec'y of Health & Human Servs.], 418 F.3d at 1279–80 (noting that the Vaccine Act provides for the use of "medical opinion as proof" of causation); Zatuchni v. Sec'y of Health & Human Servs., 69 Fed. Cl. 612, 623 (Fed. Cl. 2006) (relying heavily on the testimony of treating physicians in concluding that Vaccine Act causation had been established).

Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1375 (first set of brackets in original); see also Paluck v. Sec'y of Health & Human Servs., 786 F.3d at 1385 (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1375 (finding "the special master erred in disregarding contemporaneous statements from K.P.'s [petitioners' minor child] treating physicians regarding the cause of his neurodegeneration" and "[a]s we explained in Andreu, 'treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (brackets added)).

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health & Human Services, when the court noted that "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in Althen because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358 (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326). The Pafford court further explained,

> [i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the

> presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Id. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352. Determining what constitutes a medically appropriate timeframe, thus, is linked to the petitioner's theory of how the vaccine can cause petitioner's injury. See id.; see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. 175, 186 (2017); Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542 (2011).[6]

According to the court in Capizzano v. Secretary of Health & Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. See Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen [v. Secretary of Health & Human Services, 418 F.3d at 1278] prongs cannot overlap to satisfy another prong." (brackets added)). If a petitioner satisfies the Althen test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 547 (brackets in original; quotation omitted).

The Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict).

> "Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder."

Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870 n.10); see also Rich v. Sec'y of Health & Human

[6] As noted above, n a footnote, Chief Special Master Corcoran indicated, "[m]y opinion almost wholly turns on the first two *Althen* prongs, so I do not also include an extended discussion of Petitioners' success at demonstrating that the timeframe for alleged onset in this case was medically acceptable. " Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *26 n.32.

Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("So long as those findings are 'based on evidence in the record that [is] not wholly implausible,' they will be accepted by the court." (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363 (alteration in original))).

Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009) (brackets added); see also Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010)], he [or she] cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (brackets added) (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

With regard to the Special Master's weighing of evidence when testimony conflicts with contemporaneous medical records, a Special Master generally should afford contemporaneous medical records greater weight than conflicting testimony offered after the fact. See Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) ("It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")), aff'd, 968 F.2d 1226 (Fed. Cir.) reh'g denied, (Fed. Cir. 1992). This is because medical records, created contemporaneously with the events they describe are presumed to be accurate and complete. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

In the case currently under review, petitioners claim they are entitled to compensation for an alleged a off-Table injury claim, which means petitioners "may seek compensation by proving causation-in-fact." Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1379 (citing Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1374). Petitioners must meet the three Althen prongs to prove causation-in-fact. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Boatmon v. Sec'y of Health & Human Servs., 941 F.3d at 1354-55; Oliver v. Sec'y of Health & Human Servs., 900 F.3d at 1361. The Chief Special Master denied petitioners' claim on the basis that petitioners had failed the Althen test. As the Chief Special Master stated in footnote 32 of his decision:

> My opinion almost wholly turns on the first two *Althen* prongs, so I do not also include an extended discussion of Petitioners' success at demonstrating that the timeframe for alleged onset in this case was medically acceptable. *K.L. v. Sec'y of Health & Human Servs.*, No. 12-312V, 2017 WL 1713110, at *16 (Fed. Cl. Spec. Mstr. Mar. 17, 2017), *mot. for rev. denied*, 134 Fed. Cl. 579 (Fed. Cl. 2018). I do note, however, that although the timeframe from vaccination to I.R.M.'s tragic death was consistent with Petitioners' theory (and particularly was within the two-to-three day time period in which *some* proinflammatory cytokines produced in response to

> Flumist might upregulate via an innate immune response), Petitioners did *not* preponderantly demonstrate (a) that this actually occurred in I.R.M.'s case after the administration of Flumist, or (b) that the one cytokine most referenced by Petitioners' experts, IL-1β, *is* upregulated after Flumist administration at all, let alone in sufficient quantities to be pathologic.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *26 n.32 (emphasis in original).

Before this court, petitioners argue that the Chief Special Master improperly raised the burden of proof from requiring petitioners to provide a medically reliable theory to requiring "direct evidence of a biological mechanism of causation." Under the test articulated in Althen v. Secretary of Health & Human Services: "Concisely stated, [petitioners'] burden is to show by preponderant evidence that the vaccination brought about [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 vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Boatmon v. Sec'y of Health & Human Servs., 941 F.3d at 1354-55. The Chief Special Master's analysis considered the persuasiveness and reliability of petitioners' experts' causation theory. The Chief Special Master also noted that the weight of the expert testimony in the record did not establish that the petitioners' causation theories were plausible or reliable. The Chief Special Master's decision also noted that petitioners' theories were similar to other theories found unsupported in similar cases. See Nunez v. Sec'y of Health & Human Servs., No. 14-863V, 2019 WL 2462667, at *1 (Fed. Cl. Spec. Mstr. Mar. 29, 2019), mot. for rev. den'd, 144 Fed. Cl. 540 (2019), appeal docketed, No. 20-1021 (Fed. Cir. Oct. 8, 2019); Cozart v. Sec'y of Health & Human Servs., No. 00–590V, 2015 WL 6746616, at *1 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), mot. for review den'd, 126 Fed. Cl. 488 (2016). In both Nunez and Cozart, two different Special Masters heard testimony from two of the same experts as in the above captioned case, Dr. Miller and Dr. McCusker. In both Nunez and Cozart, as in this case, Dr. Miller, presented his theory proposing that vaccines increased cytokines which then crossed the blood-brain barrier into the central nervous system, and in both cases Dr. McCusker rebutted Dr. Miller's theory. See Nunez v. Sec'y of Health & Human Servs., 2019 WL 2462667, at *1; Cozart v. Sec'y of Health & Human Servs., 2015 WL 6746616, at *1; In both cases the Special Masters found Dr. McCusker persuasive and rejected Dr. Miller's theory on the grounds that it was not medically reliable, thus reaching the same conclusion as reached by Chief Special Master Corcoran in the case currently before this court. See Nunez v. Sec'y of Health & Human Servs., 2019 WL 2462667, at *1; Cozart v. Sec'y of Health & Human Servs., 2015 WL 6746616, at *1. In sum, in the case brought by the Martin petitioners on behalf of their son, Chief Special Master Corcoran considered respondent's experts to be more credible than petitioners' experts in the area of immunology. While the Chief Special Master found that Dr. Miller's theory of a brain abnormality was plausible, he did not find Dr. Miller's theory of increased cytokines serving as a trigger to induce a seizure to be reliable as opposed to Dr. McCusker's testimony and the above referenced rulings in similar cases.

Special Masters are and entitled to and expected to weigh conflicting opinions provided by experts and the decisions issued by the Special Masters are owed a significant amount of deference. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict); Waterman v. Sec'y of Health & Human Servs., 123 Fed. Cl. 564, 571 (2015) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d at 961) ("As the Federal Circuit has stated, 'Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process.'"). Regarding petitioners' experts Dr. Levin's and Dr. Kinsbourne's testimony and expert opinions, the Chief Special Master noted that, in addition to both doctors' lack of recent experience, after reading Dr. Miller's report, both doctors modified their expert opinions to coincide with Dr. Miller's causation theory, which contributed to Chief Special Master Corcoran's finding that Dr. Levin and Dr. Kinsbourne were unpersuasive.[7] Moreover, the Chief Special Master concluded that he found respondent's experts to be more credible and persuasive in refuting the theories of petitioners' experts. The Chief Special Master stated:

> But this case turned mostly on questions of *pathology* and *immunology*—and on the latter topic, Dr. McCusker was a far more qualified immunologist than Dr. Levin, and provided testimony I found significantly more persuasive. *See also Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 3456436, at *1 (Fed. Cl. Spec. Mstr. May, 31, 2016) (finding that Dr. McCusker was more credible than Dr. Miller), *mot. for review denied*, 129 Fed. Cl. 176 (Fed. Cl. 2016). In addition, the neurologic issues posed in this case related to the hippocampal abnormality, an issue that both sides largely agreed upon, disputing only the immunologic impact of the vaccine at issue, and Dr. Kinsbourne has no specific demonstrated expertise on that topic that would suggest his statements are deserving of extra weight.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *31 n.44 (emphasis in original).

[7] The Chief Special Master stated in his decision, "the causation theory offered herein is scientifically unreliable, especially in light of the unpersuasive testimony offered by two of Petitioners' three experts." Special Master Corcoran also indicated, "[c]oloring the scientific and medical unreliability of theories offered in this case are deficiencies in the qualifications and testimony of two of the three experts who testified for Petitioners. Drs. Kinsbourne and Levin lacked testimonial credibility in important regards." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *1, *31.

The Chief Special Master found that the opinions presented by respondent's experts directly refuted the petitioners' experts' theory linking the vaccine to the seizure, to which petitioners' experts provided inadequate responses, and there was a noticeable and convincing difference in the specificity of the arguments raised by Dr. McCusker when compared to the generality of the causation theory offered by Dr. Miller as part of his report and testimony. This difference in specificity between respondent and petitioners' experts also is reflected in the respective experts' use of medical literature as support. Dr. Miller did not cite any literature in support of his contentions. Dr. Levin and Dr. Kinsbourne relied on literature which largely focused on vaccines in general and not on Flumist in particular. Petitioners' experts could not point to any literature suggesting that peripheral cytokines could stimulate a seizure. In contrast, respondent's expert Dr. McCusker cited the Barria article, which directly addressed the Flumist vaccine and found that Flumist did not increase the one cytokine named by petitioners' experts. The Chief Special Master summarized the inability of petitioners' experts and the petitioners' experts' medical literature to account for whether "the Flumist vaccine was in particular likely to further increase the seizure risk due to its stimulation of the innate immune system." The Chief Special Master stated:

> But there is little to no direct evidence that any vaccine, let alone the Flumist vaccine, could cause or contribute to this process, nor could any of Petitioners' experts speak from their own experience, whether from patient treatment or research, to bulwark this point.
>
> Petitioners instead attempted to support this aspect of their theory by connecting several indirect items of proof (of course a valid means of establishing entitlement in the Program). But important sections of this chain of opinion were medically/scientifically unreliable. The most significant insufficient element was the lack of evidence pertaining to the direct or initial pathologic capacity of cytokines. As noted above, the inability to preponderantly establish this particular causal element has resulted in the dismissal of *all* prior SIDS claims. In addition, I [Chief Special Master Corcoran] have on many occasions considered whether the transient upregulation of cytokines attributable to the innate immune system's initial response to a vaccine can be pathologic, but have consistently found this contention could not be substantiated with reliable scientific or medical evidence.
>
> For example, Kashiwagi[8]—an article mentioned by both sides at hearing – is an item of literature I have discussed at length in other decisions. *See, e.g.*, *Dean v. Sec'y of Health & Human Servs*., No. 13-808V, 2017 WL 2926605, at *17 (Fed. Cl. Spec. Mstr. June 9, 2017) (DTaP and Hib vaccines did not cause child's neurologic deficits). Kashiwagi only observes the transient upregulation of *some* proinflammatory cytokines (not including

[8] Referring to Y. Kashiwagi et al., Production of Inflammatory Cytokines in Response to Diphtheria-Pertussis-Tetanus (DPT), Haemophilus Influenzae Type B (Hib), and 7-valent Pneumococcal (PCV7) Vaccines, 10 Human Vacc. & Immunotherapeutics, 3:677-85 (2014).

> IL-1β)—not that they are also pathogenic. It also did not test *any* version of the flu vaccine, LAIV [Live Attenuated Influenza Vaccine] or otherwise. Kashiwagi thus does not stand for the conclusion that the expected and intended effect of immune stimulation caused by vaccination can turn pathologic. Togashi is similarly unpersuasive as proof for Petitioners' causation theory. Not only did it involve an injury not alleged herein (acute encephalopathy), but it did not firmly conclude whether cytokines were initially causal, or merely contributed to an ongoing pathologic process attributable to a direct wild flu virus infection (and the article ultimately concluded that vaccination was the best means of preventing the infection—directly contrary to the proposition that vaccination herein instigated a pathologic process).
>
> In addition, some elements of Petitioners' cytokine-related arguments confuse association for causal effect, even though evidence cited for those arguments has scientific reliability. Fischer [W. Fischer et al., *Live Attenuated Influenza Vaccine Strains Elicits a Greater Innate Immune Response Than Antigenically-Matched Seasonal Influenza Viruses During Infection of Human Nasal Epithelial Cell Cultures,* 32 Vaccine 15:1761–67 (2014)], for example, makes scientifically-reliable points about how LAIVs function. And articles like Vezzani *do* credibly suggest that certain proinflammatory cytokines, including IL-1β, are associated with seizure, and their findings are consistent with the arguments of Petitioners' experts about neuron excitability and seizure threshold generally. But such literature also says little to nothing about peripheral stimulation of cytokines or their inevitable passage into the CNS—as opposed to cytokine generation *within* the brain or in *response* to existing seizure. These articles also do not establish that Flumist specifically would be expected to generate the particular proinflammatory cytokines identified by Petitioners' experts—while other literature persuasively demonstrates it would *not. Compare* Fischer at 7 *with* Barria at 118, 120.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *28-29 (emphasis in original) (brackets added; footnotes omitted). The Chief Special Master noted, regarding the reference to SIDS and Dr. Miller's testimony:

> One issue coloring the entirety of Dr. Miller's testimony was the question of whether opinions he has offered in prior Vaccine Program cases (along with existing scientific and medical literature relevant therein) involving SIDS had any bearing herein. On the one hand, Dr. Miller was careful to state that the present claim is (from a literal standpoint) "not a SIDS case," given that I.R.M. was three when he received Flumist, whereas the SIDS classification applies only to infants who die before the age of one. The theory that a vaccine could cause SIDS also is based on the notion that "medullary abnormalities" present in infant brains, when combined with other factors, could precipitate unexplained death, factors not bearing on the death of a three-year-old (whose brain development is more advanced). It was for this

> reason, Dr. Miller explained, that he mostly did not file literature relevant to SIDS that would have supported certain aspects of his opinion herein.
>
> At the same time, however, Dr. Miller admitted there were "similarities" between the kind of causation theory he has offered numerous times in SIDS cases and the present matter. In particular, he acknowledged that he had previously opined about the role of cytokines in causing SIDS by impacting brain structures, but that such contentions had been generally rejected (with the exception of one case that, at least as of the time of his testimony, was on appeal).

Id. at *6 (capitalization in original). Given the petitioners' expert discussion of SIDS and SIDS cases, it was reasonable for Chief Special Master Corcoran to refer to, and consider any similarities, to SIDS cases. Notably, the Chief Special Master also discussed in depth the one decision in which a Special Master found for petitioner in SIDS case and relied on Dr. Miller's testimony. See Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351. In citing to the United States Court of Appeals for the Federal Circuit's 2020 decision in Boatmon v. Secretary of Health & Human Services, 941 F.3d 1351, the Chief Special Master noted:

> In only one instance has a special master found for a petitioner in a SIDS case—but that determination was reversed by the Court of Federal Claims, with the Federal Circuit affirming the reversal. *Boatmon*, 941 F.3d at 1353. In so ruling, the Federal Circuit found that Dr. Miller's theories about the purported role cytokines could play in causing or contributing to a SIDS death (theories paralleling the arguments offered in this case) were not supported with sufficient reliable science, relying less on establishing how cytokines would function as opposed to the fact that cytokines were *present* in association with certain brain injuries, or could cross the blood-brain barrier under specific circumstances. The *Boatmon* claimants also could not substantiate the more fundamental contention—that vaccines could play *any* role in the SIDS "triple risk" model.

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *26 (emphasis in original) (internal citations omitted). The Chief Special Master also referred to "several decisions in which special masters have found that a vaccine could induce an initial seizure in an infant or very young child." Id. at *27. The Chief Special Master stated:

> Most commonly, they have reached such conclusions after the child experienced a fever in response to the vaccine. *See*, *e.g.*, *Graves v. Sec'y of Health & Human Servs.*, 109 Fed. Cl. 579 (Fed. Cl. 2013) (summarizing that petitioners were entitled to compensation when a Prevnar vaccine caused their daughter to suffer from seizures after experiencing a fever). In effect, these findings stand for the proposition that the innate immune response to vaccination, and not a specific adaptive-autoimmune process (in which specific components of the vaccine interact with self structures [sic], or otherwise induce seizure) can produce a fever which triggers an initial seizure, thereby propelling the child into a chain of ever-more-damaging seizures thereafter. *Fuller v. Sec'y of Health & Human Servs.*,

> No. 15-1470V, 2019 WL 7576382, at *18 (Fed. Cl. Spec. Mstr. Dec. 17, 2019).

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *27 (emphasis in original) (footnote omitted).

In his decision the Chief Special Master also discussed additional reasons for finding petitioners' theory to be implausible, and wrote:

> Beyond the above, there are numerous other insufficiencies in the scientific reliability of the portion of Petitioners' causation theory relating to cytokines. Petitioners' experts did not persuasively establish that cytokines generated in response to Flumist would (a) likely travel into the CNS, or (b) from outside the blood-brain barrier stimulate a response within, or (c) upregulate in sufficient amounts (and type) to impact a child with a hippocampal abnormality and thereby further lower his seizure threshold. At best, some of the literature filed post-hearing by Petitioners establishes the different ways cytokines can travel into the brain. This does not establish that the receipt of a LAIV means it is more *likely* that this will occur, or that it will *inherently* occur in the absence of some coterminous infectious or disease process that encourages blood-brain barrier breach.

Id. at *30 (emphasis in original) (footnote omitted).

As explained by the Federal Circuit in Knudsen, a finding of causation "must be supported by a sound and reliable medical or scientific explanation." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994); see also Simanski v. Sec'y of Health & Human Servs., 671 F.3d at 1384. Chief Special Master Corcoran concluded petitioners' theory of causation was unreliable and unsupported, and determined that petitioners did not meet the criteria under the Althen first prong. "While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly ex rel. v. Sec'y of Health & Human Servs., 592 F.3d at 1324. This court finds that the Chief Special Master's decision to deny entitlement to petitioners was rational and not capricious when he determined that the theory presented by petitioners' experts was not supported by scientific theory and evidence. See Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d at 548-49.

Petitioners also argue that the Chief Special Master erred in not finding that I.R.M.'s malaise was a result of the vaccine. The Chief Special Master noted that "Petitioners point to I.R.M.'s apparent pre-nap malaise as evidence of their theory at work. This is the sole evidence they can muster on this point, but it does not strongly support their theory." Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *32. Chief Special Master Corcoran continued:

> It is certainly a fair point to observe that vaccines can present transient symptoms reflecting an immune response is occurring (although Dr.

> McCusker's points about the *kinds* of cytokines that a LAIV would produce, along with the low likelihood that Flumist would generate certain proinflammatory cytokines stressed as causal herein, such as IL-1β, were not rebutted). And the statements of Mrs. Martin and her babysitter do suggest I.R.M. was not feeling well right before he napped. It is a reasonable inference to associate I.R.M.'s pre-nap condition with what thereafter transpired.

Id. (emphasis in original). The Chief Special Master, however, noted,

> malaise is .a somewhat nonspecific condition, especially for a young child, and it is equally likely based upon this record that I.R.M. merely felt tired. More significantly, it is undisputed that I.R.M. was *not* running a fever prior to his nap on September 26th, thus greatly undermining the contention that IL-1β [a pro-inflammatory cytokine], which is associated with fever, was upregulated by Flumist—even assuming it *could be*, a conclusion that Dr. McCusker effectively rebutted. And I.R.M. displayed no other post-vaccination symptoms even within 24 hours of receiving Flumist (the period of time in which arguably cytokine production would at least have begun to peak, if Fischer or Kashiwagi are relied upon).

Id. (emphasis in original) (footnote omitted). The record before the Chief Special Master regarding I.R.M.'s activities and heath in the days following the administration of I.R.M.'s Flumist vaccine do not show evidence of symptoms apart from his apparent feeling tired on the morning of his death on September 26, 2014. Otherwise, he was observed as being active and playful following his vaccination on September 24, 2014, and the day after. He had no signs of fever. There is nothing linking the Flumist vaccine to I.R.M.'s "malaise" on the morning of his death other than the fact that it occurred two days after I.R.M.'s receipt of the vaccine. In sum, the preponderance of the evidence in the record of the lack of physical evidence, the inadequacy of the expert testimony presented by petitioners and the more persuasive testimony of respondent's experts does not support petitioners' allegation that the Flumist vaccine triggered I.R.M.'s seizure and caused his death. The Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. Petitioners failed to meet this requirement because they did not provide a logical sequence linking the vaccine as the cause of I.R.M.'s death by a preponderance of the evidence. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. The Chief Special Master's conclusion that petitioners had failed to meet the criteria to establish entitlement to compensation under the Vaccine Program was reasonable, not arbitrary, and not capricious.

Moreover, although the Chief Special Master noted that the burden of proof never shifted to respondent, his decision also notes the existence of an alternative cause of I.R.M.'s death, as follow:

> This is not a case in which the burden to prove alternative cause ever shifted to Respondent—and if it had done so, I would not on this record be able to conclude that the evidence for such an explanation preponderates for Respondent, since the record ultimately does not permit me to identify a likely cause of I.R.M.'s death. But I can and did consider this contrary confounding evidence when evaluating Petitioners' success in carrying their overall *Althen* burden. *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[o]ur decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the "factors unrelated" defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question").

Martin v. Sec'y of Health & Human Servs., 2020 WL 4197748, at *33 n.46 (brackets in original).

Regarding the issues identified in the motion for review to this court and described in the Chief Special Master's decision, the Chief Special Master gave cogent reasons for rejecting petitioners' theory and claim. Petitioners "must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); see also Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1525. While scientific certainty is not required, a Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness[es]." Moberly ex rel. Moberly ex rel. v. Sec'y of Health & Human Servs., 592 F.3d at 1324. Petitioners' experts did not present a reliable medical theory linking the vaccine to the death of I.R.M. and the preponderance of evidence did not demonstrate that the vaccine caused I.R.M.'s death. As such, petitioners have failed to meet all of the prongs under the Althen test, because petitioners did not present "a medical theory causally connecting the vaccination and injury" and did not "show a logical sequence of cause and effect." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278.

C O N C L U S I O N

Petitioners have not demonstrated that Chief Special Master Corcoran acted arbitrarily and capriciously when he found that petitioners' claim did not entitle them to compensation under the Vaccine Compensation program. Therefore, the petitioners' Motion for Review is **DENIED**. The Clerk of the Court shall enter **JUDGMENT** consistent with this Opinion.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge