

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

Filed: October 15, 2015

* * * * *		PUBLISHED
DWAYNE COZART and MICHELE	*	
HAMILTON, as representatives of the	*	
Estate of C.A.C.,	*	No. 00-590V
	*	
Petitioners,	*	
	*	Chief Special Master Dorsey
v.	*	
	*	
SECRETARY OF HEALTH	*	Motion for Reconsideration in Light
AND HUMAN SERVICES,	*	of Additional Evidence; Vaccine
	*	Rule 10(e)(1); Manifest Injustice.
Respondent.	*	
	*	
* * * * *		

Ronald Craig Homer, Conway, Homer & Chin-Caplan, PC, Boston, MA, for petitioners.  
Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for respondent.

**ORDER DENYING PETITIONERS’ MOTION FOR RECONSIDERATION**<sup>1</sup>

Petitioners, Dwayne Cozart and Michele Hamilton (“petitioners” or the “Cozarts”) filed a petition under the National Childhood Vaccine Injury Act (“Vaccine Act” or the “Program”),<sup>2</sup> as the representatives of the estate of their son, C.A.C, alleging that C.A.C. “experienced an adverse reaction to [his October 19, 1998] inoculations which resulted in his death on October 19, 1998.” Petition at 1. Petitioners filed an amended petition alleging that as a result of the administration of the hepatitis B (“Hep B”), Diphtheria-Tetanus-acellular-Pertussis (“DTaP”), inactivated polio (“IPV”), and haemophilus influenzae (“Hib”) vaccines on October 19, 1998, C.A.C. died on October 19, 1998. Amended Petition at 1, filed Oct. 24, 2011. Respondent recommended

<sup>1</sup> In accordance with the Vaccine Rules, each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b); 42 U.S.C. § 300aa-12(d)(4)(B)(2012). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be redacted.

<sup>2</sup> The National Vaccine Injury Act comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-1 et. seq. (“Vaccine Act”). Individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

against awarding compensation to petitioners. See Respondent’s Report, filed July 15, 2013, at 13.

On June 30, 2015, following a hearing, the undersigned issued a decision denying compensation to the Cozarts, finding that petitioners had failed to provide preponderant evidence that the vaccinations C.A.C. received on October 19, 1998, caused his death. Cozart v. Sec’y of Health & Human Servs., No. 00-590, (June 30, 2015) (“Original Decision”). In reaching that decision, the undersigned found that petitioners failed to set forth a reliable medical theory explaining how the vaccines could have caused the alleged injury. Specifically, the undersigned found that petitioners failed to provide preponderant evidence that vaccines have been identified as an exogenous stressor implicated in the Triple Risk Model. The undersigned also found that petitioners failed to show that vaccines cause cytokines to produce an abnormal brainstem serotonin response or otherwise act in a manner that causes or contributes to Sudden Infant Death Syndrome (“SIDS”) as petitioners’ experts postulated. In finding that petitioners failed to prove the second prong of the Althen<sup>3</sup> test, a “logical sequence of cause and effect showing that the vaccination was the reason for the injury,” the undersigned found that there was no evidence that C.A.C. suffered from symptoms in the manner postulated by petitioners’ experts that would support a finding that the cytokines played a role in the child’s death. Based in part on a statement made by a nurse to paramedics, the undersigned found preponderant evidence that the child was lying on his face, either in the prone or side position, both positions which are strongly associated with SIDS. As such, the undersigned found that C.A.C. satisfied the Triple Risk Model of SIDS without the need to consider a speculative risk factor such as the vaccines. Thus, the undersigned found that petitioners were not entitled to compensation.

On July 21, 2015, petitioners filed a motion for reconsideration (“Motion for Reconsideration”) of the Original Decision. This motion was granted to the extent that the motion requested that the Original Decision be vacated. See Order dated July 28, 2015. A decision determining whether petitioners were entitled to any additional relief (a substantive change in outcome) was deferred until respondent responded to the Motion for Reconsideration.

Petitioners seek reconsideration of the undersigned’s Original Decision on Althen Prongs One and Two in light of additional evidence, a medical article by Kashiwagi et al.<sup>4</sup> that petitioners filed in support of their Motion for Reconsideration. The parties’ additional arguments have been considered. For the reasons discussed below, the Motion for Reconsideration is DENIED.

## **I. Facts and Procedural History**

The Original Decision sets forth detailed facts about C.A.C.’s medical history. A synopsis of these facts is that C.A.C. was born on August 17, 1998. At his two week well-child

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<sup>3</sup> Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005)

<sup>4</sup> Pet. Ex. 49 (Kashiwagi Y, et al., Production of inflammatory cytokines in response to diphtheria-pertussis-tetanus (DPT), haemophilus influenza type b (Hib), and 7-valent pneumococcal (PCV7) vaccines, 10 Hum Vaccine Immunother 3, 677-85(2014)).

visit, he was noted to be developing normally. At his two month well-child visit, the pediatrician again noted that C.A.C. was a well-child. He received the Hep B, DTaP, IPV and Hib vaccinations during this visit (at approximately 10:15 a.m.). After this visit, C.A.C. was taken to his babysitter's home. The babysitter put the child down for a nap. At approximately 2:57 p.m., emergency medical services were dispatched to the babysitter's house after receiving a report that C.A.C. was unresponsive. When the Fire Department Emergency Medical Services ("EMS") arrived, C.A.C. was pulseless and apneic. CPR was performed and C.A.C. was intubated and given epinephrine. He was taken to the Charlton Methodist Hospital. Upon arrival, C.A.C. still had no pulse and was asystolic.

The emergency room physician, Dr. Joe Tsou, documented that C.A.C. had a rectal temperature of 94.7 degrees, indicating that "significant time had elapsed since the time of arrest." Pet. Ex. 8 at 7. Dr. Tsou performed a physical exam and noted "coffee ground vomitus around [the] mouth," congested chest, distended abdomen, and paleness. Id. at 8. Resuscitative efforts were not successful and C.A.C. was pronounced dead at 15:47 (3:47 p.m.). Id. at 7.

An autopsy was performed which revealed "posterior lividity [that was] partially fixed" and "lividity of the right side of the face with blanching over the pressure areas." Pet. Ex. 9 at 19. Lividity was also seen on the right ear and neck. Pet. Ex. 12 at 17. The internal examination revealed petechiae in the lungs with moderately congested parenchyma of the lung. Pet. Ex. 9 at 20. A chest x-ray showed a right pneumothorax. Id. A microscopic examination of the thymus revealed an increase in "Hassall's corpuscle." Id. at 4. The "[h]istologic sections of [the] medulla at multiple levels reveal[ed] scant arcuate nuclei neurons bilaterally." Id. at 5. Dr. Holley, who performed the autopsy, noted that "[a]rcuate nucleus hypoplasia has been reported in association with infants dying of SIDS." Id. at 6. The toxicology reports were normal. Id. The medical examiner concluded that the child's death should be classified as SIDS. Id. "This category is used when complete autopsy, investigation and additional studies fail to yield a definite cause of death. Although there was a recent immunization, a connection to the death could not be established." Id.

The Cozarts filed their petition on October 2, 2000. They filed an expert report from Dr. Douglas Miller, a neuropathologist, on August 6, 2012, and an expert report from Dr. James Oleske, an immunologist, on December 11, 2013. Respondent filed an expert report from Dr. Hart Lidov, a neuropathologist, on April 20, 2013. On June 21, 2013, respondent filed an expert report from Dr. Christine McCusker, an immunologist. A hearing was held on September 25-26, 2014, during which Drs. Miller and Oleske testified for petitioners, and Drs. McCusker and Lidov testified for respondent.

Following the conclusion of the hearing and submission of briefs, the undersigned found that petitioners were not entitled to compensation, because petitioners failed to provide preponderant evidence that the vaccinations C.A.C. received on October 19, 1998, caused his death. Petitioners filed a Motion for Reconsideration of the Original Decision on July 21, 2015. That motion was granted to the extent that it vacated the Original Decision. Respondent filed a response to the Motion for Reconsideration on August 12, 2015. Petitioners filed a Reply brief on August 26, 2015. The Motion for Reconsideration is now ripe for ruling.

## II. Analysis

### a. Standards for Reconsideration

Vaccine Rule 10(e), which governs motions for reconsideration, provides, “[e]ither party may file a motion for reconsideration of the special master’s decision within 21 days after the issuance of the decision . . . .” Vaccine Rule 10(e)(1). A party seeking reconsideration “must support the motion by a showing of extraordinary circumstances which justify relief.” Fru-Con Constr. Corp. v. United States, 44 Fed. Cl. 298, 300 (1999). The motion for reconsideration “must be based ‘upon manifest error of law, or mistake of fact, and is not intended to give an unhappy litigant an additional chance to sway the court.’” Prati v. United States, 82 Fed. Cl. 373, 376 (2008) (quoting Fru-Con Constr. Corp., 44 Fed. Cl. at 300).

“A court may grant such a motion when the movant shows ‘(1) that an intervening change in the controlling law has occurred; (2) that previously unavailable evidence is now available; or 3) that the motion is necessary to prevent manifest injustice.’” System Fuels, Inc. v. United States, 79 Fed. Cl. 182, 184 (2007), quoting Amber Resources Co. v. United States, 78 Fed. Cl. 508, 514 (2007). Granting such relief requires “a showing of extraordinary circumstances.” Caldwell v. United States, 391 F.3d 1226, 1235 (Fed. Cir. 2004) (citation omitted), cert. denied, 546 U.S. 826, 126 S.Ct. 366, 163 L.Ed.2d 72 (2005). Special masters have the discretion to grant a motion for reconsideration if to do so would be in the “interest of justice.” Vaccine Rule 10(e)(3).

Petitioners do not claim that there has been an intervening change in the law, nor do they contend that there is new evidence that was unavailable at the time the undersigned issued the Original Decision. Petitioners also admit that while the additional evidence offered with their motion was available at the time the case was litigated, it “did not seem relevant until the special master filed her decision,” and therefore was not previously filed. Motion for Reconsideration at 2. Thus, in order to prevail on their Motion for Reconsideration, petitioners must demonstrate that the denial of their motion would result in manifest injustice. See Hall v. Sec’y of Health & Human Servs., 93 Fed. Cl. 239, 251 (2010), aff’d 640 F.3d 1351 (Fed. Cir. 2011). As noted by other special masters, there is little case law interpreting Vaccine Rule 10(e)(3) beyond the conclusion that it is within the special master’s discretion to decide what the “interest of justice” is in a given case. See Krakow v. Sec’y of Health & Human Servs., No 03-632V, 2010 WL 5572074, at \*3 (Fed. Cl. Spec. Mstr. Jan. 10, 2011) (granting reconsideration of motion to dismiss case for failure to prosecute).

### b. Petitioners’ Motion for Reconsideration

#### i. Petitioners’ Review of the Original Decision

In requesting reconsideration of the Original Decision, petitioners note that the undersigned found that they had not presented preponderant evidence under Althen Prongs One and Two. Petitioners state that it is unclear whether the undersigned found that they had met their burden under Althen Prong Three, which will be discussed more fully below.

With regard to petitioners' argument that the undersigned did not consider the record as a whole and simply rejected petitioners' arguments and chose to accept the opinions of respondent's experts, the undersigned must address these statements. This case involves a very tragic situation, and the undersigned considered all evidence presented by the parties in reaching her decision. All the evidence and testimony presented in this case was carefully reviewed and analyzed, and the undersigned did not reach her conclusion lightly. After all the evidence was analyzed and weighed in accordance with the applicable legal standards, it became clear to the undersigned that the evidence presented by petitioners could not meet their legal burden, and thus, entitlement was denied.

Because this case involves significant issues that may have broader implications, the undersigned granted petitioners' request to reconsider her decision in light of petitioners' statement that they had additional evidence to present that they believed the undersigned should consider. This motion was not granted to allow petitioners a second chance to reargue their case.

For the reasons set forth below, the undersigned finds that petitioners' arguments in support of their Motion for Reconsideration are not persuasive. The additional evidence that petitioners presented is not new evidence; rather, it is an article that was available to petitioners at the time this case went to hearing. The argument that petitioners did not deem this article relevant until the undersigned issued her decision is not proper grounds for reconsideration of the undersigned's decision. Even if petitioners had presented this article at a time when the undersigned could have taken it into consideration in reaching her decision, it would not have changed the outcome. Thus, petitioners' motion for reconsideration is DENIED.

## **ii. Althen Prong One**

### **1. Vaccines as Extrinsic Risk Factors of the Triple Risk Model**

In the Motion for Reconsideration, petitioners first claim that they have demonstrated a reliable medical theory causally connecting C.A.C.'s vaccinations and his death. Motion for Reconsideration at 5. In doing so, petitioners concede that "vaccines have not been scientifically proven to be an extrinsic risk factor in the Triple Risk Model." Id. Petitioners argue, however, that requiring scientific certainty is not a requirement of proving a reliable medical theory. This statement is correct. Scientific certainty is not a requirement of proving a reliable medical theory, and the undersigned did not analyze petitioners' claim according to that standard. In reaching her conclusion on Althen Prong One, the undersigned found that petitioners failed to show that their interpretation of the Triple Risk Model, as it relates to vaccines, is a sound and reliable medical theory. The undersigned noted that petitioners did not present any evidence demonstrating that vaccines were identified as exogenous stressors implicated in the Triple Risk model. Both of petitioners' experts agreed that there were no other medical professionals who have opined that vaccinations operate similar to infections which are identified as exogenous stressors for the purpose of the Triple Risk model. Nowhere in her opinion did the undersigned state or require petitioners to prove with scientific certainty that vaccines are an extrinsic risk factor in the Triple Risk model. Indeed, one of the reasons petitioners' arguments failed on Althen Prong One is because there was little to no evidence presented to support their position, other than the testimony of Drs. Oleske and Miller. "An expert opinion is no better than the

soundness of the reasons supporting it.” Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). A special master does not need to credit “expert opinion testimony that is connected to the existing data or methodology ‘only by the ipse dixit of the expert,’ or where ‘there is simply too great an analytical gap between the data and the opinion proffered.’ ” Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 61 (2011) (quoting Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010)).

## **2. Vaccinations versus Infections and Inflammatory Processes**

In their Motion for Reconsideration, petitioners state that “the one piece of evidence purportedly lacking (evidence typically not required in Vaccine Program proceedings) is evidence that the cytokines produced by vaccination are the same or similar to the cytokines produced by infections.” Motion for Reconsideration at 10. Petitioners’ theory of causation is fully detailed in the Original Decision, but a summary is provided here.

Petitioners’ theory of causation is based on the Triple Risk Theory developed by Dr. Hannah Kinney and her colleagues. Drs. Miller and Oleske explained that the Triple Risk Theory involves “a vulnerable infant, who during a critical time, encounters external stressor(s), resulting in death.” Id. According to this theory, the infant is vulnerable due to a defective serotonergic (“5-HT”) system. Id. at 10. At autopsy, C.A.C. was found to have hypoplasia of the arcuate nucleus of his brain. Id.; Pet Ex. 4 at 12-13. If an infant has a defective 5-HT system, the ability to arouse in hypoxic conditions will be compromised. According to petitioners’ theory

[i]f the increased cytokine production secondary to mild infection or inflammatory process (such as vaccination) is superimposed on this vulnerable infant, her ability to respond or arouse is further compromised. In this regard, the evidence is clear that cytokines such as IL-1 $\beta$  have an inhibitory effect on 5-HT neurons, meaning that cytokine interaction with 5-HT neurons will decrease their firing and thereby dampen the arousal response.

Pet. Post-Hearing Brief at 13.

In order for petitioners’ theory to succeed, petitioners would need to demonstrate that the activation of an immune response to a vaccination is similar to that of an infection. Petitioners argue that the evidence in this case “clearly demonstrates that a mild infection or a mild inflammatory process can be external risk factors in SIDS.” Motion for Reconsideration at 7. Petitioners further state that the evidence “shows that vaccinations trigger the immune system and promote the production of pro-inflammatory cytokines. In this regard, then, vaccinations clearly meet the definition of a ‘mild inflammatory process’ as described in the filed evidence.” Id. at 8.

The evidence does not support this assertion. First, infections have been identified as exogenous stressors for the Triple Risk Model. Vaccinations have not. As Dr. McCusker testified, there are important similarities and differences between an immune response to an infection and an immune response to a vaccination. Tr. 138. One important difference is that an

infection is a live organism that has the ability to replicate in the body and cause a severe immune reaction. A live virus will infect a cell directly and the virus within the cell will begin to replicate. What begins as a few infected cells can quickly become thousands of infected cells. The vaccines C.A.C. received, on the other hand, are composed of particulate killed organisms, i.e., pieces of organisms. Administered alone, these particles may not elicit much of an immune response beyond a local reaction. Adjuvants are added to vaccines to elicit a greater immune response from the body to protect an individual who may later be exposed to the live virus. Dr. Oleske, petitioners' immunologist, testified that vaccines try to mimic what infections do in the body "without the profound negative effects of natural infection." Tr. at 12. He explained that vaccinations elicit "an adequate response that allows a protective immune response, without overwhelming complications." Tr. at 15.

Regarding the timing of an immune response from a vaccination, the experts had differing opinions. Dr. Oleske testified that when a vaccination is administered into the body, there is a local inflammatory response at the site of the injection. The local response becomes systemic "in that fairly short period of time ... [a]nd in the case of what we've been talking about, SIDS, that inflammatory response circulates very rapidly through the body to the central nervous system, and in the arcuate nucleus in a vulnerable infant..." Tr. 74. Dr. McCusker, on the other hand, testified that when studies were conducted to look "at the pattern of the way the immune response occurs, it actually stays quite local for a significant period of time." Tr. 140. For example, if a vaccine is administered in the thigh, the initial activation event would occur in "the thigh, and then it would lead up to the draining lymph node in the groin on that side, and it takes a significant ... in the studies where they have looked at this, it actually takes a significant amount of time..." Id. Dr. McCusker testified that "in terms of looking at activation of immune responses in general, you are talking about several hours for the pro-inflammatory activation to ramp itself up, and then you're talking about several days for the dissemination of that information beyond the regional lymph node." Tr. at 141. Dr. McCusker did state, however, that there may be signs and symptoms of the pro-inflammatory response occurring in the six to twelve hours after administration of the vaccine, but in "the initial few hours, [the immune response] is very local" as has been reported in the medical literature. Id. When asked whether there was any evidence of an inflammatory process occurring in C.A.C. at the time of his death, Dr. Oleske responded that the "pathology showed that [C.A.C.] had a negative area in the brain that has been linked to that type of death [SIDS]." Id. at 40. But other than C.A.C.'s death, Dr. Oleske stated that there was no other pathological evidence of an inflammatory process occurring. Id.

The undersigned also notes that the evidence submitted in this case identifies common infections that have been associated with SIDS death, including upper respiratory tract infections and gastrointestinal infections, two types of infections that can affect the breathing mechanics of an infant from either congestion or reflux. Tr. at 197, 252. While not confined to just these types of infections, Dr. McCusker is the only expert who provided an opinion explaining how these infections might contribute to SIDS deaths. Vaccinations do not act in the same way as these infections because vaccinations do not interfere with the mechanics of breathing. Tr. 170-71.

### 3. Petitioners' Additional Evidence – Kashiwagi et al., Article

Assuming that petitioners are able to succeed in providing preponderant evidence that vaccinations act similar to infections, the next step would be to provide preponderant evidence that the cytokines released in response to a vaccination act in the same way as cytokines released in response to an infection or an inflammatory process. In support of this proposition and in support of their Motion for Reconsideration, petitioners introduced exhibit 49, an article by Kashiwagi<sup>5</sup> et al. published in March 2014, to demonstrate that the DTaP and Hib vaccinations, which C.A.C. received, led to the production of cytokines IL-1 $\beta$ , IL-6 and TNF- $\alpha$ , which are the same cytokines that are produced by infection. These are the same cytokines that petitioners theorize are implicated in their interpretation of the Triple Risk Model. Motion for Reconsideration at 11. Upon review of this article, the undersigned notes that the purpose of the Kashiwagi study was to compare levels of inflammatory cytokines<sup>6</sup> in the serum of 61 vaccine recipients with febrile reactions and 18 recipients without febrile illness within 24 hours of vaccination. There was no significant difference between the two groups except that the cytokine G-CSF was elevated in individuals with a febrile illness. The significance of this finding was not determined. In fact, the authors state as follows:

Vaccine-specific innate inflammatory responses are clearly important, and have not been sufficiently investigated regarding cytokine production using difference vaccines. . . . “

Id. at 678. The study was not designed to examine the effects of cytokines in the brain following vaccination. Of interest, however, is the authors' report that cytokine production begins six hours after stimulation. Id. at 679. The authors state that, “when a vaccine is administered through an intramuscular or subcutaneous route, the antigen is transported from the muscle tissue to the regional lymph nodes, where immune responses occur.” Id. This supports Dr. McCusker's testimony at hearing. See Tr. at 141.

The undersigned does not take issue with petitioners' argument that vaccinations result in a cytokine release, and that some of these cytokines are the same cytokines that are released in response to infection. It is petitioners' argument about how the cytokines produced in response to a vaccination have a negative effect on the brain and 5-HT system that is not persuasive.

To carry that argument, petitioners needed to show how cytokines produced in response to a vaccination appear in the brain, and lead to the death of an infant. But, petitioners' theory fails because it is based on an outdated theory of the role of cytokines in the brain and on the 5-HT system. The current and persuasive understanding of cytokines, as discussed by respondent's experts, shows that the cytokines in the brain identified by petitioners' experts do not cause a pathologic event. Tr. 183

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<sup>5</sup> Pet. Ex. 49 (Kashiwagi Y, et al., Production of inflammatory cytokines in response to diphtheria-pertussis-tetanus (DPT), haemophilus influenza type b (Hib), and 7-valent pneumococcal (PCV7) vaccines, 10 Hum Vaccine Immunother 3, 677-85(2014)).

<sup>6</sup> The cytokines include IL-1 $\beta$ , IL-4, IL-6, IL-10, IL-12, IFN- $\gamma$ , M1P-1, TNF- $\alpha$ , PGE2, and G-CSF.

To explain how the role of cytokine expression and its effect on the brain has evolved, Dr. McCusker testified that in 2003, immunologists were researching SIDS deaths and were beginning to study the role of cytokines in the brain. Those early studies showed that the pro-inflammatory cytokine, IL-1 $\beta$ , was present in the brains of SIDS infants. The question, at the time, was whether this inflammation was involved in or contributed to sudden infant death. Petitioners' theory is premised on the idea that the cytokine expression in the SIDS brain causes inflammation and SIDS death in a vulnerable infant. Tr. 38, 55, 85. The current research demonstrates that the brain regularly produces pro-inflammatory cytokines as part of a normal, regulatory process. The existence of these cytokines is not an indication that the brain is constantly inflamed. Tr. 159. Dr. McCusker explained that to further investigate this observation, a study was performed where a large amount of the cytokine IL-6 was introduced in the brain of piglets. In these animal models, it was found that the overexpression of IL-6 did not have a significant effect on respiration and the 5-HT system. The study demonstrated that there was some small effect, but it did not appear to be significant and did not negatively affect respiration.<sup>7</sup> Similar to IL-6, IL-1 $\beta$ , another cytokine identified in petitioners' theory to have a negative impact on the 5-HT system, was also found to be expressed normally in brain cells. Tr. 165, 171-72; Pet. Ex. 35.<sup>8</sup> Dr. McCusker testified that these cytokines are likely being upregulated in the brain cells of SIDS infants because the brain has identified a stressor. Tr. 167. Thus, the cytokines are an indicator of stress and not a cause or contributor. Dr. Miller admitted that the literature he presented in support of his theory of a negative effect of cytokines on the brain, was literature only discussing the expression of cytokines, not the effect. He stated that he was not aware of any data on the effect of these cytokines. Tr. at 365-66.

In discussing the articles cited by petitioners' experts regarding the role of cytokines, Dr. McCusker repeatedly demonstrated that the information upon which petitioners' theory is based is outdated. New information and a greater understanding of the role of cytokines is available and respondents' experts provided a detailed discussion on the current understanding. Petitioners' experts did little to dispute this information. Thus, the undersigned found that petitioners had not presented preponderant evidence to both set forth a reliable medical theory and logical sequence of cause and effect, i.e., Althen Prongs One, and Two which is discussed more fully below.

### iii. Althen Prong Two

In the Motion for Reconsideration, petitioners stated that they have "provided a wealth of evidence of sudden infant death syndrome occurring shortly after vaccinations, including the same vaccinations received by C.A.C." Motion for Reconsideration at 6. However, temporal association alone is not evidence of causation. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

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<sup>7</sup> Resp. Ex. A. Tab 11 at 4-5; A. Vege et al., Are Elevated Cerebrospinal Fluid Levels of IL-6 in Sudden Unexplained Deaths, Infectious Deaths and Deaths Due to Heart/Lung Disease in Infants and Children Due to Hypoxia?, 87 Acta Paediatrica 819, 819-24 (1998).

<sup>8</sup> Brambilla et al., Interleukin-1 inhibits firing of serotonergic neurons in the dorsal raphe nucleus and enhances GABAergic inhibitory postsynaptic potentials, 26 Eur J Neurosci 1862-69 (2007).

Next, petitioners state that the undersigned held that “petitioners offered no evidence that ‘peripheral cytokines released in response to the vaccines . . . communicated with the central nervous system[.]’” This statement is only partially accurate. Quoting from the Original Decision, the undersigned stated “that petitioners did not offer preponderant evidence demonstrating that the peripheral cytokines released in response to the vaccines administered to C.A.C. communicated with the central nervous system to invoke an abnormal brain response in the manner described by Dr. Oleske and Dr. Miller.” (emphasis added). In a footnote, the undersigned noted that respondent’s expert, Dr. McCusker, agreed that there is communication between the peripheral body and the central nervous systems, and that cytokines played a role in the communication. But, Dr. McCusker did not agree with petitioners’ experts’ contention that cytokines played a pathological role. Petitioners argue that the undersigned required them to present direct evidence of communication between the cytokines produced by vaccination and the peripheral system. This argument is wholly misplaced. Nowhere in the Original Decision did the undersigned require petitioners to present direct evidence of their theory.

Next, in response to the undersigned’s finding that there is no clinical evidence that cytokines played a role in C.A.C.’s death, petitioners take issue with the fact that the undersigned referenced Dr. Oleske’s testimony that C.A.C. experienced a cytokine storm. Petitioners argue that a “cytokine storm was not discussed in either of petitioners’ expert reports,” and that it was “not a concept embraced as a cause of SIDS in the medical literature.” Motion for Reconsideration at 14. Nonetheless, petitioners agree that Dr. Oleske used the terminology “cytokine storm” during his testimony at hearing. Petitioners argue, however, that “Dr. Oleske clearly did not mean cytokine storm in the traditional sense and his use of language should not be used to import a different meaning to his testimony. Rather, he referred to the evidence showing a hypertuned or exaggerated cytokine response in SIDS death.” Motion for Reconsideration at 15. Essentially, what petitioners have asked the undersigned to do is to speculate on the meaning of Dr. Oleske’s testimony and to assign a meaning to his testimony that he did not provide. The undersigned cannot, and will not, speculate in a manner that is contrary to the direct testimony provided by petitioners’ own experts. If petitioners took issue with the testimony of their expert, they had ample opportunity to clarify the record, either during the hearing on direct, or redirect questioning, or even in their post-hearing brief. Petitioners failed to do so, and a motion for reconsideration is an improper method to explain or further clarify an expert’s testimony at hearing. Even if the undersigned were to accept petitioners’ suggested interpretation of Dr. Oleske’s testimony regarding a cytokine storm, it would not change the outcome of this Motion for Reconsideration or the Original Decision. The undersigned would still find that C.A.C. did not exhibit any clinical signs that cytokines played a causal role in his death.

It is also important to note that in the Original Decision, the undersigned found that C.A.C. fit the Triple Risk Model without need to consider a speculative risk factor, such as vaccines. The child was found in the prone or side position, exogenous risk factors that, alone, would satisfy the Triple Risk Model. It was for these additional reasons that the undersigned concluded that petitioners failed to provide preponderant evidence of a logical sequence of cause and effect showing that C.A.C.’s vaccinations caused his death.

#### iv. Althen Prong Three

Petitioners state that they were unclear whether the undersigned found that they met their burden on Althen Prong 3. To clarify, in the Original Decision, and the undersigned found that there was a temporal relationship between C.A.C.'s vaccinations and his death. But without a plausible medical theory and logical sequence of cause and effect upon which to base a finding regarding Althen Prong 3, the undersigned simply could not find that petitioners met their burden on this prong. The temporal relationship is not enough. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (holding "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury"). The undersigned only noted in the Original Decision that the child's death took place at a point in time that would warrant consideration of the vaccinations as the potential cause of the child's injury.

#### c. Summary

Petitioners' medical theory is reliant on the proposition that the vaccinations are exogenous stressors. Petitioners have failed to demonstrate, by a preponderance of the evidence, that the vaccinations act similarly to the other exogenous stressors that have been identified for the Triple Risk Model. As is set forth in the Original Decision, petitioners and their experts have failed to identify any medical professional who has identified vaccinations as exogenous stressors or to even postulate that vaccinations may act as exogenous stressors in the Triple Risk Model. Even if petitioners were successful in providing evidence that vaccinations produced cytokine effects in the brain similar to that of infections, petitioners' theory still fails because they have not shown that the cytokines have a negative impact on the brain that would lead to SIDS death.

Petitioners' additional evidence, exhibit 49, the Kashiwagi article, has been reviewed and considered. The undersigned finds that it does not change the reasoning or conclusion of the Original Decision. Thus, even considering this additional evidence, the undersigned finds that there is no manifest injustice by denying petitioners' Motion for Reconsideration.

The undersigned must also note that in many similar SIDS cases heard by special masters in the Vaccine Program (and upheld on review), entitlement was denied to petitioners because of the lack of sufficient proof of causation. See generally Doe/11 v. Sec'y of Health & Human Servs., \_\_\_ F.3d \_\_\_ (Fed. Cir. 2010)(the court upheld special master's decision that a death labeled "SIDS" was not caused by a hepatitis B vaccine); Nordwall v. Sec'y of Health & Human Servs., No. 05-0123v, 2008 WL 857661 (Fed. Ct. Cl. Spec. Mstr. Feb. 19, 2008)(special master held that SIDS death of an infant was not due to a vaccine, but rather "positional asphyxia"); Waterman v. Sec'y of Health & Human Servs., No. 13-960v, 2015 WL 4481244 (June 30, 2015)(aff'd on appeal)(special master denied entitlement in a SIDS case finding that petitioners did not prove that their child suffered an encephalopathy prior to his death); Sanchez v. Sec'y of Health & Human Servs., No. 11-651V, 2013 WL 4476750 (Fed. Cl. July 26, 2013)(special master held that petitioner failed to prove that vaccinations caused SIDS death); Bigbee v. Sec'y of Health & Human Servs., No. 06-663V, 2012 WL 1237759, at \*49 (Fed. Cl. Mar. 22, 2012)(special master held that petitioners failed to produce preponderant evidence that the vaccines caused the child's death); Heller v. Sec'y of Health & Human Servs., No. 96-797V,

1998 WL 408612(Fed. Ct. Cl. Spec. Mstr. June 22, 1998)(special master held that studies did not show a causal link and that petitioner failed to demonstrate a causal relationship between DPT vaccine and child's SIDS death).

**III. Conclusion**

For the aforementioned reasons, the undersigned hereby DENIES petitioners' Motion for Reconsideration. The Original Decision will be reinstated and considered filed as of today's date, October 15, 2015.

**IT IS SO ORDERED.**

s/Nora Beth Dorsey  
Nora Beth Dorsey  
Chief Special Master