EXHIBIT 4
DATE 3/31/21
HB 702

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 10, 2017

CHASE BOATMON & MAURINA CUPID, *parents of* J.B., *deceased*,	*	PUBLISHED DECISION
	*	No. 13-611V
Petitioners,	*	Special Master Gowen
v.	*	Entitlement Decision; Diphtheria-Tetanus-acellular Pertussis (DTaP) Vaccine; Inactivated Polio Vaccine (IPV); Haemophilus Influenzae (HiB) Vaccine; Pneumococcal Conjugate (PCV) Vaccine; Rotavirus Vaccine; Sudden Infant Death Syndrome (SIDS).
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer & Joseph M. Pepper, Conway, Homer P.C., Boston, MA, for petitioners.
Lara A. Englund & Ryan M. Pyles, United States Department of Justice, Washington, DC, for respondent.[1]

RULING ON ENTITLEMENT[2]

On August 27, 2013, Chase Boatmon and Maurina Cupid ("petitioners"), as the representatives of the estate of their deceased minor child, J.B., filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or the "Program"),[3] 42 U.S.C. § 300aa-10 *et. seq.* (2012). Petitioners allege that as a result of receiving vaccinations for

[1] Mr. Homer is petitioners' attorney of record, while his colleague Mr. Pepper appeared at the entitlement hearing. Similarly, for respondent, Ms. Englund has always been the attorney of record, but Mr. Pyles appeared at the entitlement hearing.

[2] Because this decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the website of the United States Court of Federal Claims, pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012). The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the decision is posted on the court's website, each party has 14 days to file a motion requesting 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). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website. *Id.*

[3] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3705, codified as amended, 42 U.S.C. §§ 300aa-1 to -34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

Diphtheria-Tetanus-acellular Pertussis ("DTaP"), inactivated polio ("IPV"), haemophilus influenzae ("HiB"), Pneumococcal Conjugate ("PCV"), and Rotavirus vaccinations on September 2, 2011, J.B. passed away from Sudden Infant Death Syndrome ("SIDS") on September 3, 2011. *See* Petition (ECF No. 1); Amended Petition (ECF No. 15).

After carefully analyzing and weighing all of the evidence and testimony presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioners have met their legal burden. Petitioners have put forth preponderant evidence that the vaccines J.B. received on September 2, 2011 actually caused or substantially contributed to his death from Sudden Infant Death Syndrome. Furthermore, respondent has failed to put forth preponderant evidence that J.B.'s death was in fact caused by factors unrelated to the vaccines. Accordingly, petitioners are entitled to compensation.

I. BACKGROUND

A. Procedural History

Petitioners filed a petition for compensation pursuant to the Vaccine Act on behalf of their deceased minor son, J.B., on August 27, 2013. Petition (ECF No. 1). They filed an amended petition on February 6, 2014. Amended Petition (ECF No. 15). Petitioners filed the expert report of Dr. Douglas C. Miller, a neuropathologist, along with the medical literature referenced in his report, on May 20, 2014. Exhibit 13, 14 (ECF No. 21).[4]

On September 9, 2014, respondent filed a Rule 4(c) report advising against compensation. Rule 4(c) Report (ECF No. 28). That same day, he filed an expert report and medical literature referenced therein from Dr. Brent Harris, a pathologist. Exhibit A (ECF No. 29). Respondent also filed an expert report and medical literature from Dr. Christine T. McCusker. Exhibit C (ECF Nos. 30-32). Petitioners filed a supplemental report from Dr. Miller on November 10, 2014. Exhibit 16 (ECF No. 35). Extensive and detailed medical literature was submitted in support of all of the expert reports.[5]

At numerous stages of this case, the undersigned encouraged the parties to pursue the possibility of an informal resolution and/or to consider mediation. *See, e.g.*, Order filed December 9, 2014 (ECF No. 37). The parties ultimately did not settle the case. An entitlement hearing was held on Thursday, August 6, and Friday, August 7, 2015, in Washington, D.C. Dr. Miller testified on behalf of petitioners, and Dr. Harris and Dr. McCusker testified for respondent. The case was well tried and involved detailed expert testimony from both sides. *See*

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[4] On October 14, 2014, petitioners refiled the medical literature cited in Dr. Miller's report, highlighting the specific portions being relied upon to support causation. Petitioners' Notice of Refiling Documents (ECF No. 34).

[5] I have read and digested all of the literature submitted in this case and will reference numerous but not all articles in the course of this opinion. However, all articles have been considered in coming to a conclusion in this case. More recent articles, particularly those by the same authors or groups, are referenced more frequently because they incorporate, build upon, and update the earlier literature. Petitioners and Dr. Miller filed Exhibits 13-A through 13-V and Exhibits 14 through 21. Respondent and Dr. Harris filed Exhibits A-1 through A-6. Respondent and Dr. McCusker submitted Exhibits C-1 through C-20 and Exhibits D through G.

(emphasis added). In this scenario, "if the infant's ventilator response to the progressive hypoxia and hypercapnia during the apnea is depressed, and if the hypoxic gasping and/or arousal mechanism is abnormal, oxygen lack from uninterrupted apnea results. Ultimately, death occurs *within minutes to hours*." *Id.* (emphasis added).

Respondent filed the article by Trachtenberg et al., which emphasized that they could find no positive correlations between risk factors or risk clusters but it appeared that any combination of risks together increased the odds of SIDS. The fact that most infants have at least two extrinsic risk factors suggests that SIDS occurs as a result of the occurrence of multiple factors and rarely just one.[42] The Kashiwagi article[43] filed by petitioners suggests that vaccines provoke an inflammatory cytokine response similar to that provoked by a mild infection. Petitioners theorize that these cytokines travel to the brainstem and further suppress the function of the already impaired medullary 5-HT system in a subset of SIDS infants.

a. Cytokines, Mild Infection and Vaccines

Relevant to this case, in a 2009 article in the New England Journal of Medicine, Kinney and Thach stated, "A causal role for mild infection in sudden infant death is suggested by reports that in approximately half of SIDS cases, the infants have a seemingly trivial infection around the time of death, as well as mild tracheobronchial inflammation, altered serum immunoglobulin or cytokine levels and the presence of microbial isolates at autopsy. In infants who die unexpectedly of infection, the given organism may precipitate a lethal cytokine cascade or toxic response."[44] The question arises as to whether the cytokine response stimulated by vaccination can have the same effect as a mild or trivial infection in a baby who presumably has a defect in the medullary 5-HT system.

The role of cytokines stimulated by either mild infection or by vaccination is central to petitioners' theory in this case. Approximately 50% of SIDS babies have been found in multiple studies to have had mild or even "trivial" infections, primarily of the upper respiratory tract at the time of death. In this case, J.B. was documented the prior day as being healthy with patent nares, normal turbinates, and clear chest, but during the 28 hours after the vaccine he was reported to have a fever, which is generated by cytokine signaling. He also was distant, quiet, and would not eat, according to his parents. The case raises the issue of whether inflammatory cytokines stimulated by the innate response to the vaccines triggered the fever and his fussiness, and ultimately suppressed his 5HT system sufficiently so that he could not process the carbon dioxide in his system. The question of whether inflammatory cytokines stimulated by the innate response to the vaccine could have been the trigger that led to his death was central to the testimony and much of the literature submitted by the parties particularly in light of the clear medical evaluation on the day of the vaccination and a fever within hours afterward.

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[42] Trachtenberg, Kinney, et al. (2012), Exhibit C-11 at 7.

[43] Kashiwagi Y et al., *Production of Inflammatory Cytokines in Response to Diphtheria-Pertussis-Tetanus (DPT), Haemophilus Influenzae Type B (Hib) and 7-Valent Pneumococcal (PC7) Vaccines*, 10 Hum. Vacc. Immunother. 677 (2014), Exhibit 17.

[44] Kinney & Thach (2009), Exhibit A-4 at 2.

As Dr. Kinney and her colleagues explained in 2011: "Cytokines orchestrate immune responses to microbial invasion and other insults and coordinate these responses with those of other physiological systems, including the autonomic nervous system, in the protection of the organism against tissue injury. They also mediate sickness behavior, including fever, anorexia, excessive sleepiness, blunted arousal, deep rest respiration, and lowered heart rate, which is thought to protect the organism during systemic illness by dampening excessive metabolic demands and thereby speeding repair and recovery - a form of homeostasis."[45] "Cytokines determine this sickness behavior by binding to endogenous cytokine receptors on neuronal populations in the hypothalamus and/or brainstem that mediate respiration, autonomic function, satiety, sleep, and arousal." *Id.* at 190. The cytokines which act within the brain in response to tissue injury are produced by astrocytes, and endothelial cells, microglia, *and/or peripheral immune cells* which enter the brain in response to binaural signals of tissue damage." *Id.* (emphasis added). During infection, peripherally produced IL-6 may cross the blood brain barrier and bind to IL-6 receptors on 5 HT neurons that mediate homeostasis in response to the infectious stressor and potentially mediate sickness behavior. *Id.* at 191. The role of pro-inflammatory cytokines in the pathology of SIDS is thought by multiple authors to be a potentially critical factor in tipping the molecular balance in the underdeveloped brainstem leading to death in infants in the vulnerable time period. IL-1β, IL-2, and IL-6 are pro-inflammatory cytokines that have been studied in connection with SIDS leading to theories about their potentially neuro-modulatory role in SIDS babies.

Kadhim et al. described a distinct cytokine profile in a SIDS brain in a study comparing SIDS brains with non-SIDS brains. The non-SIDS brains were from infants who died of known causes, including AIDS, cirrhosis of the liver, mononucleosis, purulent meningitis, and congenital heart disease with post-operative acidosis-shock. He found an over-expression of interleukin 1β in arcuate and dorsal vagal nuclei in all SIDS victims. In arcuate nuclei, high levels of interleukin 1β were detected in 17/17 SIDS brains vs. only 1 of 6 non-SIDS brains.[46] In dorsal vagal nuclei, interleukin 1β was also detected in high levels in 17 of 17 SIDS brains vs. only 2 of 7 non-SIDS brains. *Id.* Kadhim found a "region-specific pattern of cytokine expression in [the arcuate and dorsal vagal nuclei] of SIDS brains compared to non-SIDS brains." *Id.* at 1259. Kadhim theorized: "cytokines could exert neuromodulatory effects. Infectious inflammatory conditions and injury to the brain could up regulate pro inflammatory cytokines and produce functional alteration ... Cytokine/neurotransmitter interactions could therefore modify vital CNS functions." *Id.* Kadhim et al. further concluded that IL-1 causes prolonged apnea and depresses respiration, and that the brain appears to be less effective than the peripheral nervous system in inducing IL-1 antagonists to control IL-1 action.

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[45] Kinney et al. (2011), Exhibit 13-F at 189.

[46] Kadhim, H. et al., *Distinct Cytokine Profile in SIDS Brain: A Common Denominator in a Multifactorial Syndrome?*, 61 Neurol. 1256 (2003), Exhibit 13-L at 1256.

Health Choice

Lessons from the Lockdown

Why are so many fewer children dying?

A White Paper from Health Choice

By Amy Becker and Mark Blaxill

June 18, 2020

6. **Net effect in life-years.** Every untimely death is tragic. But if one considers life-years lost, the premature death of an infant carries more weight than the premature death of someone whose life expectancy is 5 years or less. And whereas the median age at death of, say, a Minnesotan dying of Covid19 is 83, the typical life expectancy of that senior citizen absent Covid19 might be just 2-3 more years. By comparison, when an infant in lockdown avoids a death, the potential impact in life years saved can rise to 80 years or more.

When one measures the net effect of life years either lost or gained during the pandemic and associated lockdowns, the net result across age groups is unexpectedly mixed. (5)

Figure 17: Average Life Expectancy per Age Cohort

Under 1 year	78.2
1-4 years	76.5
5-14 years	69.5
15-24 years	59.7
25-34 years	50.3
35-44 years	41.0
45-54 years	32.4
55-64 years	23.5
65-74 years	15.9
75-84 years	9.3
85 years and over	2.5

Not surprisingly, excess deaths are highest in the oldest seniors where life expectancy is the lowest. Combining the excess deaths with life expectancy by age group (with an adjustment for the quality of those life-years) shows the toll of the pandemic: about 540,000 life-years lost among those 65 and older. (3) (5) (6)

By comparison, the reduction in expected deaths is highest in infants, where the life expectancy benefits are the greatest. Compared to expectations, the lives of over 200 infants per week were saved during the month of May. Combining the number of lives saved in infants and children aged 1-4, demonstrates a smaller but comparably large and beneficial effect: roughly 145,000 life-years saved among children under 5.

Figure 18: Quality-Adjusted Life-Years (QALY) Saved or Lost by US Age Group During COVID-19 Pandemic Feb 1 - May 16, 2020	
Under 1 Year	110,358
1-4 Years	13,729
5-14 years	14,590
15-24 Years	15,352
Age <25 Life Years Saved	**154,029**
25-34 years	(53,678)
35-44 years	(115,648)
45-54 years	(68,264)
55-64 years	(234,432)
65+ Life Years Lost	**(540,077)**
65-74 years	**(341,519)**
75-84 years	**(172,317)**
85 years and over	**(26,240)**

Noting the surprising effect of the lockdown on infants and children under 5 does nothing to negate the tragic effect of the pandemic on the elderly. It does, however, raise a question: why are so many fewer children dying?

7. **Causation**? When infants die, the cause is frequently some form of congenital condition or birth defect. Sadly, accidents and homicides are frequent causes as well. There are however, frequent cases in which previously healthy infants die unexpectedly. These deaths are usually classified as "Sudden Infant Death Syndrome" or SIDS. According to the CDC, SIDS deaths are one of the two largest causes of death among infants aged 1 month to 1 year. (7)

Figure 19: Postnatal Infant Causes of Death, 2017 (aged 1 month - 1 year)

Cause	IMR*
Congenital Malformation	0.32
SIDS	0.32
Accidents	0.31
Circulatory Complications	0.09
Homicide	0.07

*Deaths per 1000 live births

We have no specific data on the trend in SIDS deaths during the pandemic. We have, however, heard anecdotal reports from emergency room (ER) doctors suggesting some have observed a decline in SIDS. One doctor who says he might see 3 cases of SIDS in a typical week has seen zero cases since the pandemic and associated lockdowns began.

What has changed during this period that might have such an effect? Are infant deaths not being recorded? Are parents taking better care of their families while working remotely and their children are not going to school? There are many possible hypotheses about the infant death decline.

One very clear change that has received publicity is that public health officials are bemoaning the sharp decline in infant vaccinations as parents are not taking their infants into pediatric offices for their regular well-baby checks. In the May 15 issue of the CDC Morbidity and Mortality Weekly Report (MMWR), a group of authors from the CDC and Kaiser Permanente reported a sharp decline in provider orders for vaccines as well as a decline in pediatric vaccine doses administered. (8) These declines began in early march, around the time infant deaths began declining.

Dear Legislators: Our family is Native American living in Billings. My 4th child, Kaleo Dale NoRunner passed away May 14th 2016, a day after receiving his first vaccinations that were also delayed for his age. He was 3 months and 22 days old.

- Kaleo was included in the statistics presented to the Supreme Court to have SIDS added to vaccine inserts as a reaction in 2017.
- Research dug up during that trial did in fact prove that SIDS is higher in vaccinated babies.

I lost my son in a matter of minutes. I was laying with him cuddling, giving him nose kisses & he was smiling at me and holding my finger. He began to doze off to sleep. Within minutes he was blue and limp. He went to ER with faint heartbeat but could not be saved.

This picture was taken by a dear friend who was with us at the ER after our son passed away and she captured this very raw picture. **I can feel my pain in this picture. We spent hours with Kaleo after he passed. Just me and my husband. It was so hard to leave him there and not bring him home ever again.**

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