

In the United States Court of Federal Claims

No. 13-611V

(Filed Under Seal: July 3, 2018)

(Reissued: July 18, 2018)¹

CHASE BOATMON and MAURINA
CUPID, parents of J.B., deceased,

Petitioners,

v.

SECRETARY OF
HEALTH AND HUMAN SERVICES,

Respondent.

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* National Childhood Vaccine

* Injury Act; Review of Special

* Master's Decision Granting

* Relief for Sudden Infant Death

* Syndrome; Application of

* Althen Test; Assessment of

* Expert Testimony.

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Joseph Pepper, with whom was *Ronald C. Homer*, Conway Homer, P.C., Boston, Massachusetts, for Petitioners.

Thomas G. Ward, Deputy Assistant Attorney General, Torts Branch, Civil Division, with whom were *Chad A. Readler*, Acting Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Catharine E. Reeves*, Deputy Director, *Kathryn A. Robinette* and *Lara A. Englund*, Trial Attorneys, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C. for Respondent.

OPINION AND ORDER

WHEELER, Judge.

This vaccine case is before the Court on Respondent's motion for review of the Special Master's entitlement decision in Boatmon v. Sec'y of Health & Human Servs., No. 13-611V, 2017 WL 3432329 (Fed. Cl. Spec. Mstr. July 10, 2017). The case focuses on the relationship, if any, between vaccines and Sudden Infant Death Syndrome (SIDS), a condition causing unexpected death, leaving families devastated and looking for answers.

¹ Pursuant to Rule 18(b) of the Court's Vaccine Rules, this opinion and order was initially filed under seal. As required under the Rules, each party was afforded 14 days from the date of issue, until July 17, 2018, to object to the public disclosure of any information furnished by that party. Neither party submitted any proposed redactions.

The Special Master found that Petitioners Chase Boatmon and Maurina Cupid, the child's parents, were entitled to compensation under the Vaccine Act because they had shown that vaccines were a substantial cause of their child J.B.'s SIDS-related death. The Court has carefully reviewed the parties' briefs and the court record, and heard oral argument on June 5, 2018. For the reasons explained, the Court finds as a matter of law that the Special Master erred in ruling for Petitioners, and in finding that Petitioners had met their burden of proof as established by applicable statutes and case law. The Court therefore grants the Respondent's motion for review and reverses the Special Master's entitlement decision below, vacating the judgment and dismissing the Petition.

Background²

J.B. was born on April 7, 2011, four weeks premature but otherwise without notable health difficulties. He received his first hepatitis B vaccination at one week. At his two-week well-baby visit J.B. appeared healthy, with normal growth and development. His subsequent well-baby visits were scheduled to account for the fact that he was born four weeks prematurely, and he had his two-month visit with his pediatrician around four months after his birth, on July 22, 2011. He was noted to be a "well child" with normal growth and development, and received first diphtheria, tetanus and pertussis (DTaP), inactivated polio (IPV), pneumococcal conjugate (PCV), rotavirus, and hepatitis B (Hep B) vaccinations at that visit.

On September 2, 2011, J.B. had his four-month well baby visit, almost five months after his birth. The pediatrician described him as "healthy appearing and cooperative ... well-nourished and well developed." His chest and lungs were normal. He had no fever, nasal congestion, or cough. He met developmental milestones for a four-month old, and he was given his second round of vaccinations, again DTaP, IPV, PCV, rotavirus, and Hep B. His father stated in an affidavit that later in the day J.B. seemed quiet and withdrawn, and during the evening he had a fever. Early the next morning, at 4:00 a.m., his parents gave him Advil and he went to sleep on his back. When he woke up a few hours later, he was distant, very quiet, and would not eat. He began running a fever again and was given more Advil at 8:00 a.m. In the early afternoon his father put him down for a nap on his back with his head to the right. His father then left the house and his mother checked on him twice. The second time, about 50 minutes after the start of his nap, his mother found that J.B. was unresponsive. She reported that he was on his right side with his head turned. She also stated that his nose and mouth were not covered.

J.B.'s mother called 911 and attempted CPR. A policeman arrived very quickly, about three minutes after the call, and finding that J.B. had no pulse or breath, began performing chest compressions until Emergency Services arrived. Efforts at resuscitation

² Drawn from the Special Master's Decision or where noted, from filed Exhibits.

were unsuccessful and J.B. was pronounced dead at the hospital on September 3, 2011, at 4:01 p.m.

The medical examiner's Report of Investigation includes a summary of a reenactment done by the Suffolk County Police Department with J.B.'s parents five days after his death. Med. Records at 3, Dkt. No. 6-9. Using a doll, the investigator noted that the father placed the doll on its back and put a blanket across the midsection. The autopsy report observed that photographs of the reenactment show a crib with soft blankets and a flat soft pillow. The autopsy found a "well nourished, well developed infant male" with no detected abnormalities that could cause death: "Given the absence of findings and the reported sleeping position in a child with no anatomic or microscopic significant findings, it is felt that the cause of his death is best classified as sudden infant death syndrome (SIDS)."

Petitioners filed their vaccine petition on August 27, 2013, alleging that J.B.'s death was the result of the vaccinations he received the day before his death. Petitioners later filed medical records and the expert report of Dr. Douglas Miller, a neuropathologist, together with the medical literature exhibits cited in his report. Respondent filed responsive expert reports of Dr. Brent Harris, a neuropathologist, and Dr. Christine McCusker, a pediatric immunologist, with medical literature, in opposition to Petitioner's claims. The Special Master conducted an entitlement hearing at which all three experts testified on August 6 and 7, 2015.

As noted by the Special Master, SIDS is defined as "the sudden death of an infant under one year of age which remains unexplained after a thorough case investigation, including performance of a complete autopsy, death scene investigation, and review of the clinical history." SIDS occurs during sleep or transitions between sleep and waking, and is the leading cause of infant mortality in the United States. Cardiorespiratory failure is emphasized.

Medical researchers have attempted to understand the cause of such devastating deaths. Beginning in 1994, Dr. Hannah Kinney, a neuropathologist at Harvard, and her colleagues have developed and refined the "Triple Risk Model" as a hypothesis to explain the causes of SIDS. That model proposes that infants are at risk of SIDS when three factors occur simultaneously: the child (1) is in a critical development period, usually defined as under six months old, (2) has an underlying vulnerability, and (3) encounters an externally caused stressor.

As the research has developed into underlying vulnerabilities leading to SIDS, Dr. Kinney's team and others have focused increasingly on brainstem abnormalities affecting response to cardiorespiratory difficulties. In this connection, the role of cytokines has been studied and debated, and was a key focus of the dispute in this case. Cytokines are "communication proteins" whereby "a signal is transmitted to the receptive cell inducing

a response affecting behavior and function of the recipient cell.” McCusker Report at 2, Dkt. No. 30-1. The third factor, externally caused stressors, includes being placed in a prone or in a side sleeping position; found face-down or head covered; sleeping on an adult mattress, couch, or playpen; soft bedding; bed-sharing, and upper respiratory tract infection. Experts for both parties agreed that Dr. Kinney’s work has not included vaccinations among external stressors. The finding that SIDS infants were often in a face-down or prone position inspired the “Back-to-Sleep” campaign encouraging parents to place infants to sleep on their back, and this practice has reduced the incidence of SIDS by about 50 percent.³ Research continues to seek answers for the remaining fatalities.

Summary of Expert Testimony

Petitioner’s Expert Dr. Miller

Petitioners’ expert, Dr. Douglas Miller, is a board-certified neuropathologist who has been practicing and teaching neuropathology at major U.S. medical centers for about thirty years. Miller Report at 2, Dkt. No. 21-1. He practices at the University of Missouri School of Medicine and provides neuropathology consulting services including forensic autopsy services to counties throughout Missouri. He stated that he had reviewed a “considerable number of SIDS autopsies” in his career. After reviewing the medical records in this case, he concurred with the medical examiner’s finding that J.B.’s death was due to SIDS. He further opined, based on the evidentiary record and on medical literature submitted with his report, that it is “medically plausible” that J.B.’s death was “related” to the vaccinations he received the day before his death, and that in fact the vaccinations “may represent a substantial contributing factor.” In his report he stated that he reached this conclusion from medical literature “suggesting a mechanism for SIDS involving cytokine-induced abnormalities of neurotransmitter function in the brainstem leading to respiratory arrest.” Id. at 2. While he noted that the autopsy in this case was “seriously deficient” because it failed to examine the part of the brain critical to his theory that J.B.’s brainstem was abnormally developed, he stated that “the setting is suspicious” for such a defect. Id. at 7. Characterizing vaccinations as an external stressor under the Triple Risk Model, he argued that some literature shows that vaccines are “triggers for systemic cytokine release” and that the cytokines impair the response to breathing difficulties by a sleeping infant with an abnormal brainstem. Id. at 6.

Respondent’s Expert Dr. McCusker

Dr. Christine McCusker is Division Director of Pediatric Allergy, Immunology and Dermatology at Montreal Children’s Hospital, McGill University Health Center and is a pediatric immunologist and director of the Clinical Immunology Lab. McCusker CV, Dkt. No. 32-7. In her report, she reviewed the literature and disputed Dr. Miller’s opinion that

³ Trachtenberg et al., Risk Factor Changes for Sudden Infant Death Syndrome After Initiation of Back-to-Sleep Campaign, 129 Pediatrics 630 (2012), Dkt. No. 31-4.

vaccinations played a substantial role in causing J.B.'s death by provoking release of destructive cytokines. McCusker Report, Dkt. No. 30-1. She argued that the cytokines released as part of the immune response at the site of the inoculation are "transient and tightly regulated." She further stated that cytokines have been shown to be expressed by cells of the brain and help maintain normal brain function. In a situation of distress such as that which occurs with SIDS, "it is reasonable to hypothesize" that "cytokines involved in neuroprotection would be released in an attempt to 'save' the system" rather than attack the system. Id. at 3. She also argued that increased cytokines would most likely promote rather than inhibit arousal. She added that Dr. Kinney's external stressors (part of the Triple Risk Model) such as sleeping position, bedding, and upper respiratory infection are related to interference with the mechanical ability to breathe, not to a neurochemical effect such as that posited by the Petitioner's expert. Id. at 5. She also reviewed the epidemiological literature specifically looking at SIDS and vaccination and found that "[m]ore recent well designed publications ... increase the strength of evidence against a causal association for SIDS and vaccines." Id. at 8. Other case studies were also discussed as not supportive of Petitioners' arguments. She concluded from the literature that cytokines play an important role in sleep and arousal, and that they can induce fever as well as create more frequent arousal. She does not accept Petitioners' claim that vaccine-induced cytokines reduce the capacity for arousal in brain-impaired infants leading to SIDS. Id.

Respondent's Expert Dr. Harris

Dr. Brent Harris is an anatomic/neuropathologist (board-certified in both). Harris Report at 1, Dkt. No. 29-1. He has practiced in prominent academic medical centers and is currently an Attending Pathologist and Associate Professor in Neurology and Pathology and Director of Neuropathology at Georgetown University Medical Center. He is also a neuropathology consultant for the Washington, D.C. Chief Medical Examiner, the National Institutes of Health, Howard University Hospital, the Washington, D.C. Veterans Administration Hospital, and the American International Pathology Laboratory. In the last three years he reviewed more than 50 pediatric autopsies, the majority of which were SIDS cases. Harris Report, Dkt. No. 29-1. Dr. Harris reviewed the medical records and literature in this case and disagreed with Dr. Miller's opinion that J.B.'s death was linked to his vaccinations. Id. at 6. He saw no conclusive evidence "generally agreed upon in the medical community and in the medical literature" that links vaccination and SIDS. He stated that the Triple Risk Theory is "well-reasoned and generally accepted," although it has yet to be proven, and also that it does not suggest a link with vaccinations. Id. Dr. Harris concluded that there were no pathological findings in J.B.'s medical records that indicate a vaccine related death. Id. at 7.

The Althen Standards

Petitioners seek recovery in this case for an “off-Table” injury, that is, an injury caused by a vaccine other than those injuries listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). In off-Table injuries, claimants must show causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A); see also Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010). The U.S. Court of Appeals for the Federal Circuit summarized the claimant’s evidentiary burden associated with off-Table cases in Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), holding that the claimant must establish by preponderant evidence:

- (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 proximate temporal relationship between vaccination and injury.

These three burden of proof factors are now commonly referred to as the three Althen prongs.

The Special Master’s Decision

The Special Master found in this case that Petitioners had established all three prongs required by the Althen test. With respect to Prong One, he first found that even though the autopsy did not examine J.B.’s brainstem, the infant must have had a defective brainstem because the Kinney studies had found such defects in about 75 percent of SIDS cases studied. Boatmon, 2017 WL 3432329, at *32. He went on to conclude that Petitioners had shown “a reasonable and reliable theory of vaccine causation” where cytokines produced by vaccination can act “as an extrinsic stressor in a baby with a brainstem deficit under the Triple Risk Model.” Id. at *38. As to Prong Two, requiring a “logical sequence of cause and effect” showing vaccination was the reason for J. B.’s death, the Special Master dismissed as unlikely other possible external stressors such as formula feeding, side sleeping and soft bedding argued by Respondent’s expert as likely causes of his death. He then found that “[t]he cause and effect between the vaccines, the cytokines triggered by the vaccines, and their co-occurrence with other intrinsic and/or extrinsic risk factors in the presence of a defective or underdeveloped brainstem seems likely to have produced the perfect storm that resulted in J.B.’s death.” Id. at *41. The Special Master also found that Petitioners had established the timeliness requirement of Prong Three. He reasoned that death on the day following vaccination was consistent with causation: “vaccine-induced cytokines are likely to be active in close proximity to the stimulating event.” Id. at *42.

Standard for Review

This Court has jurisdiction to review decisions of the special masters in accordance with provisions of the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-12(e)(1) - (2). Under those provisions, this Court will only set aside findings of fact or conclusions of law found to be “arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.” 42 U.S.C. § 300aa-12(e)(2)(B). With respect to findings of fact, the special masters have broad discretion to weigh evidence and make factual determinations. As to questions of law, the legal rulings made by a special master in connection with a vaccine claim are reviewed de novo, under a “not in accordance with the law” standard. Following this distinction, “[t]he allocation of the burdens of proof under the Vaccine Act is a legal issue subject to de novo review.” Heinzelman v. Sec’y of Health & Human Servs., 98 Fed. Cl. 808, 812 (2011); see also Whitney v. Sec’y of Health & Human Servs., 122 Fed. Cl. 297, 304-05 (2015).

Discussion

In the Motion for Review, Respondent argues that the Special Master applied too low a standard when evaluating Petitioner’s burden of proof in this case. Respondent also notes that in reaching his conclusions the Special Master ignored the decisions in four recent SIDS cases, in all of which the Special Masters rejected a similar if not identical theory presented by Dr. Miller, who testified on behalf of Petitioners using the same medical literature presented in the instant case. Further, Respondent maintains that the Special Master impermissibly found, based on statistical evidence alone, that J.B. had a defective brainstem making him vulnerable to vaccines under the Special Master’s extension of the Triple Risk Theory.

The four decisions by three different Special Masters addressing the question of vaccine causation in SIDS deaths were issued in 2015 and 2016. See Jewell v. Sec’y of Health & Human Servs., No. 11-138V, 2016 WL 5404165 (Fed. Cl. Spec. Mstr. Aug. 29, 2016); Copenhaver v. Sec’y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), review denied, 129 Fed. Cl. 176 (2016); Lord v. Sec’y of Health & Human Servs. No. 12-255V, 2016 WL 806818 (Fed. Cl. Spec. Mstr. Feb. 9, 2016); Cozart v. Sec’y of Health & Human Servs., No. 00-590V, 2015 WL 6746616 (Fed. Cl. Spec. Mstr. Oct. 15, 2015), review denied, 126 Fed. Cl. 488 (2016). These cases uniformly found that the evidence presented by Dr. Miller to prove his theory of vaccine causation was not persuasive. For example, in Copenhaver, the Special Master found Respondent’s expert, Dr. McCusker, to be a “superb witness” and better qualified to discuss cytokines because of her cytokine research, her expertise in immunology, and her status as a board-certified pediatrician. Copenhaver, 2016 WL 3456436, at *11,*13. He also found that none of the medical articles submitted “reliably demonstrate that vaccines increase the risk of SIDS.” Id. at *3. And he found that Petitioners improperly used assumptions rather than facts to fill gaps in knowledge about their case. Id. at *16.

Similarly, in Cozart a different Special Master found Petitioners had failed to prove a “sound and reliable” medical theory as required by Althen Prong One because they did not show how the Triple Risk Model relates to vaccines. They also could not point to any other medical professionals aside from their own two experts, who shared their opinion about vaccines and SIDS. Id. at *17. In their response to Respondent’s Motion for Review in the present case, Petitioners were not able to cite a single Vaccine Program opinion finding that vaccinations had caused SIDS.

A Special Master is not bound to follow the opinions of other Special Masters; however, when issuing an opinion extending vaccine causation to previously uncharted areas, a clear explanation would be expected, if not critical. The Special Master here made no acknowledgement of the other cases reaching opposite conclusions and made no attempt to distinguish the instant case from any of the others. Here, even though extension of the Triple Risk Theory to vaccine causation has not been advanced by Dr. Kinney or her colleagues, nor has it been accepted by any other medical authorities outside those testifying in the Vaccine Program, the Special Master describes Petitioners’ theory to be “reasonable and persuasive.” Boatmon, 2017 WL 3432329, at *40.

This departure from the conclusions of other Special Masters can only be explained by improper application of the standard of proof required in vaccine cases. While scientific certainty is not required to establish causation under the Vaccine Act, the theory must be supported by a “sound and reliable” medical or scientific explanation. Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). In Moberly, 592 F.3d at 1322, the Federal Circuit noted that a Petitioner must provide a “reputable medical or scientific explanation” for causation, and that this standard requires more than mere “plausibility,” which is “not the statutory standard.” In the case at bar, the theory embraced by the Special Master has not been accepted by any other experts in the field of SIDS research. The Moberly Court cited with approval the standards for assessing expert reliability set forth in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). Among the Daubert considerations is whether the theory at issue has been subjected to peer review and publication. Id. at 593. With respect to Petitioners’ burden of proof, the Special Master in this case has applied a standard so low as to constitute clear error.

Loss of a child in a sudden and seemingly senseless manner can only be described as heartbreaking. For this reason research to find clear answers must continue, and premature unsupported conclusions cannot be relied upon. In this case, having found that Petitioners failed to satisfy Althen Prong One, the Court also finds that they have not presented a persuasive basis for finding that the vaccinations caused J.B.’s death, as required under Althen Prong Two. For this reason, the Court hereby GRANTS the motion for review, REVERSES the ruling on entitlement, and VACATES the decision of the Special Master. The Clerk is directed to dismiss the Petition and to enter Judgment for Respondent.

IT IS SO ORDERED.

s/Thomas C. Wheeler
THOMAS C. WHEELER
Judge