

In the United States Court of Federal Claims

No. 05-136V

(Filed Under Seal: May 5, 2017)

(Reissued for Publication: May 23, 2017)¹

LAURA HOLT, parent of
A.H.T., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

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* Vaccine Act; Motion for Review;
* Vaccine Triggering Preexisting
* Disease; Weighing Expert Testimony;
* Treating Physician Testimony; Althen
* Causation Factors.
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Alexis B. Babcock, with whom were *Benjamin C. Mizer*, Principal Deputy Assistant Attorney General, as well as *Rupa Bhattacharyya*, Director, *Vincent J. Matanoski*, Deputy Director, and *Catharine E. Reeves*, Assistant Director, Torts Branch, Civil Division, U.S. Department of Justice, Washington, D.C., for Respondent.

OPINION AND ORDER DENYING PETITIONER’S MOTION FOR REVIEW

WHEELER, Judge.

On June 24, 2015, then-Chief Special Master Denise K. Vowell issued a decision denying compensation to Petitioner Laura Holt (on behalf of her daughter, A.H.T.) under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*

¹ On May 5, 2017, the Court filed this opinion under seal and directed the parties to submit any proposed redactions within fourteen days pursuant to Appendix B, Rule 18(b) of the Court of Federal Claims. Neither party has proposed any redactions. Therefore, the Court reissues its opinion in full.

(“Vaccine Act”). Ms. Holt has filed a motion for review of the Chief Special Master’s decision. In her motion for review, Ms. Holt primarily challenges the Chief Special Master’s evidentiary findings. She also argues that the Chief Special Master applied the wrong burden of proof in this case. The bar for disturbing evidentiary findings is quite high, and the Court finds that Ms. Holt has not met it. Similarly, the Court finds that the Chief Special Master properly evaluated Ms. Holt’s claims under the Vaccine Act. Accordingly, Ms. Holt’s motion for review is DENIED.

Background²

A. Summary of Medical History

A.H.T. was born at home in 2002 after a normal pregnancy. Dec. at 7. Her primary care physician, Dr. Rhonda Buttleman, saw A.H.T. five days later. Id. at 9. At that time, A.H.T. was nursing well and had gained ten ounces. Id. at 7. During the visit, Dr. Buttleman administered A.H.T.’s first hepatitis B vaccine, which is at issue in this case. Id. After the visit, A.H.T. developed problems with constipation, and she cried more often and more intensely than other newborns. Id. She also had problems sleeping and breastfeeding. Id. Despite these issues, A.H.T. appeared to be developing normally for the first fifteen to seventeen months of her life. Id. at 8. Neither Dr. Buttleman nor the family practice physician, Dr. Richard Hefner, recorded any concerns about A.H.T.’s development during this time period. Id. at 9. As a result of A.H.T.’s gastrointestinal issues and crying, Dr. Hefner diagnosed her with colic when she was about five months old, and a pediatric gastroenterologist diagnosed her with mild constipation and mild gastroesophageal reflux when she was six months old. Id.

Dr. Hefner evaluated A.H.T. again in September 2003. Id. at 10. During that visit, he noticed that A.H.T. was not using two-word phrases, which indicated a possible language delay. Id. When A.H.T. still exhibited signs of a speech delay six months later, Dr. Hefner referred her to the state’s early intervention program. Id. A.H.T. participated in several early intervention therapies, and the Chief Special Master examined the records from those therapy sessions in detail. See id. at 11–13. Alternative medicine providers supplied some of these early intervention treatments. Id. at 12–14. A.H.T. underwent a neurodevelopmental evaluation in early 2005, after which Dr. Gail Williams diagnosed her with a regulatory disorder and “central nervous system dysfunction, as manifested by toe walking and decreased muscle tone.” Id. at 15 (citation omitted). Still, A.H.T. did not meet the criteria for autism because of her “better developed social skills” and “clear evidence of joint attention.” Id. (citation omitted).

² The Court takes the facts in this Background section from the Chief Special Master’s Decision, which will be referred to herein as “Dec.” The Court will address Ms. Holt’s disagreement with portions of that Decision later in this Opinion.

A.H.T. was diagnosed with a bipolar disorder, depression, learning disability, central auditory processing disorder, and insomnia in 2009 (she had also experienced unrelated medical issues). Id. at 16. Beginning in June 2010, A.H.T. received treatment for her sleeping issues, and her sleep improved. Id. at 16–17. Finally, A.H.T. underwent mitochondrial testing in August 2011, and Dr. John D. Shoffner diagnosed her with a probable mitochondrial disorder. Id. at 77–78.

B. Procedural History

Ms. Holt originally brought this action on January 21, 2005, alleging that A.H.T.’s vaccine had caused her to develop an autism spectrum disorder (ASD). The case was subsequently stayed pending the outcome of the Omnibus Autism Proceeding (OAP). See Dkt. No. 4. On September 22, 2011, Ms. Holt filed an amended petition in which she removed all references to ASD.³ See Am. Pet, Dkt. No. 19. She now claims that A.H.T.’s vaccination “significantly aggravated an underlying mitochondrial disorder,” and that this disorder caused an “encephalopathic event.” Dec. at 3 (citing Am. Pet. ¶¶ 15–16).

The Chief Special Master held a hearing in this case on February 13–15, 2013. During that hearing, Dr. Francis Kendall and Dr. Phillip DeMio testified for Ms. Holt, and Dr. Max Wiznitzer and Dr. Shawn McCandless testified for the Government. The parties then submitted post-hearing briefs.

In a comprehensive 104-page decision issued on June 25, 2015, Chief Special Master Vowell denied compensation to Ms. Holt. She found scant evidence that an illness can trigger or aggravate an underlying genetic disease such as a mitochondrial disorder. Id. at 102. She further found that A.H.T. did not have an encephalopathic event because there was no reliable evidence that she developed a fever or autistic regression after vaccination. Id. A.H.T. also did not lose skills, and had many normal months of development after vaccination. Id. As a result, the Chief Special Master found that A.H.T. had not suffered an injury after vaccination, and Ms. Holt was not entitled to compensation. Id. at 103.

Ms. Holt filed a motion for review in this Court on July 25, 2015. See Dkt. Nos. 98, 99. The Government responded on August 24, 2015. Judge Victor J. Wolski of this Court held oral argument on Ms. Holt’s motion on October 28, 2015. On March 29, 2017, this case was reassigned to Judge Wheeler pursuant to Rule 40.1(c) of the Court of Federal Claims (“RCFC”), where it remains ripe for decision. See Dkt. No. 110.

³ The decisions in the OAP cases found no causal link between vaccinations and ASD. See Dec. at 3–5 (citing cases). As the Chief Special Master noted, Ms. Holt’s case appears to be part of a “trend by some former OAP petitioners to re-characterize their children’s diagnoses as something other than ASD, in an attempt to render irrelevant the impressive body of evidence produced in the OAP test cases establishing that vaccines are exceedingly unlikely to be responsible for ASD.” Id. at 4.

Discussion

Ms. Holt takes issue with the Chief Special Master’s factual findings and legal conclusions. In particular, Ms. Holt argues that the Chief Special Master erroneously concluded that A.H.T. did not have a fever after her vaccination. She further argues that the Decision improperly characterizes A.H.T.’s mitochondrial dysfunction and improperly attacks the credibility of A.H.T.’s parents. Ms. Holt also alleges that the Chief Special Master accorded too much weight to the Government’s experts, and not enough weight to two of A.H.T.’s treating physicians. Finally, Ms. Holt argues that the Chief Special Master applied the incorrect burden of proof. The Court will address these allegations in turn.

A. Standard of Review

Under the Vaccine Act, 42 U.S.C. § 300aa-12(e)(1)–(2), this Court may review decisions of the Special Masters if a party timely requests such review. The Court reviews the Special Master’s legal conclusions *de novo*, but will not disturb the Special Master’s factual findings unless those findings are arbitrary and capricious. Munn v. Sec’y of Health & Human Servs., 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). In practice, the “arbitrary and capricious” standard grants broad deference to the “weighing of evidence by the trier of fact.” Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000). “[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” Id. This Court grants the Special Master such deference on factual findings because “[w]eighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and . . . the special masters have that responsibility in Vaccine Act cases.” Moberly v. Sec. of Health & Human Servs., 592 F.3d 1315, 1325 (Fed. Cir. 2010).

B. The Chief Special Master’s Factual Findings Were not Arbitrary and Capricious

1. The Chief Special Master Reasonably Found That A.H.T. did not Develop a Fever or Encephalopathy After Vaccination

Ms. Holt argues that the Chief Special Master disregarded testimony about A.H.T.’s post-vaccination fever and accorded too much weight to the absence of any fever-related notes in the treating physician’s records. See Pet. Mem. at 6–10, Dkt. No. 99. Ms. Holt points to the testimony of fact witnesses—mainly of A.H.T.’s parents—to show that the physician in question, Dr. Buttleman, kept inaccurate records. Id.

Even if this were true, however, the Court finds that the Chief Special Master did not rely exclusively on Dr. Buttleman’s records. For example, Ms. Christy Holt could not recall any concern A.H.T.’s parents had about a post-vaccination fever. Dec. at 66. Ms.

Holt and her husband also offered different testimony as to how high A.H.T.’s fever was, as well as how many calls they placed to Dr. Buttleman. Id. Further, the Chief Special Master cites Ms. Holt’s journal, in which Ms. Holt recorded more minor symptoms that A.H.T. was experiencing around the time of the alleged fever. See Dec. at 67–68. In fact, Ms. Holt did not mention a post-vaccination fever in her journal—or to anyone—until after her visit with Dr. Shoffner in 2010. Id. at 67. This coincidence is significant, as Dr. Shoffner authored “an article about the incidence of fever in autistic regressions in children with mitochondrial disorders.” Id. at 68. Further, expert testimony showed that a fever in a newborn baby would be extremely concerning and could require hospitalization. See Dec. at 62–63 (recounting testimony on fevers in neonates). The combination of these factors led the Chief Special Master to conclude that A.H.T. did not develop a fever after vaccination. Id. at 68.

The Court finds that the Chief Special Master has articulated facts that show a rational basis for her conclusion that A.H.T. did not suffer a post-vaccination fever. Therefore, under the great deference this Court gives the Special Masters on such factual findings, the Court finds that the Chief Special Master’s fever-related finding was not arbitrary and capricious.

Furthermore, the Chief Special Master reasonably found that A.H.T. did not suffer encephalopathy after her vaccination. The Decision cites Dr. McCandless, one of the Government’s experts, who testified that a neonate experiencing an encephalopathic event “would be unlikely to have a period of normalcy for five days and then ‘crash and burn’” the way A.H.T. allegedly did. Id. at 90. Similarly, the child would be unlikely to appear normal a week or two after the alleged encephalopathic event (as A.H.T. did). Id. In contrast, Ms. Holt’s expert, Dr. Kendall, “dodged” many questions “about typical presentations” of encephalopathic events. Id. Further evidence, such as neuroimaging scans, failed to corroborate A.H.T.’s encephalopathic event as well. Id. at 90–91; 99. Therefore, the Chief Special Master’s finding that A.H.T. did not suffer an encephalopathic event was not arbitrary and capricious.

2. The Chief Special Master’s Findings Concerning A.H.T.’s Mitochondrial Dysfunction Were not Arbitrary and Capricious

First, the parties seem to disagree on whether there is a meaningful difference between a mitochondrial “dysfunction” and a mitochondrial “disorder.” The Court finds that there is a difference. The Chief Special Master relied primarily on the testimony of Dr. McCandless, one of the Government’s experts, to reach the same conclusion. Id. at 31. According to Dr. McCandless, “primary mitochondrial disease [is] a set of clinical abnormalities that directly result from mitochondrial dysfunction.” Id. “When dysfunction of the mitochondria is observed in a laboratory setting, there must be some evidence that the dysfunction also causes an identifiable clinical finding or symptom before the patient can be characterized as having a mitochondrial disease or disorder.” Id. In other words,

“dysfunction” refers to a condition in which a patient’s mitochondria function abnormally. A patient is said to have a “disorder” only if this abnormal functioning causes symptoms.⁴

Second, the Chief Special Master properly and exhaustively examined both expert testimony and A.H.T.’s medical records to conclude that A.H.T. had a mitochondrial dysfunction, but merely a possible—not probable—mitochondrial disorder. See id. at 69–99. The Chief Special Master heard testimony about the Nijmegen scoring system, which is the primary test used to diagnose mitochondrial disorders. Id. at 75–76. She then addressed seeming inconsistencies in Dr. Shoffner’s diagnosis. Id. at 77–82. Dr. Shoffner had first diagnosed a “possible” mitochondrial disorder, but later changed his diagnosis to “probable.” Id. at 99. In particular, the Chief Special Master focused on the “exercise intolerance” factor, which appeared to play an outsized role in Dr. Shoffner’s change of diagnosis from “possible” to “probable.” Id. This factor was telling, as A.H.T.’s parents appear to be the only source for accounts of A.H.T.’s exercise intolerance. There are no medical records that corroborate it. Id. Furthermore, Ms. Holt’s later testimony about A.H.T.’s exercise appeared to contradict any indication of exercise intolerance. Id. at 82. As a result, it was not arbitrary and capricious for the Chief Special Master to conclude that A.H.T. did not suffer exercise intolerance, and to find a possible, rather than probable, mitochondrial disorder as a result. See id. at 99.

C. The Chief Special Master Gave Appropriate Deference to A.H.T.’s Treating Physicians

The Special Masters must weigh and evaluate medical evidence. Weighing medical evidence often necessarily involves weighing the credibility of the medical professionals who offer it. While the Special Master “may not ‘cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review,’” she may nevertheless determine how much credibility to lend expert testimony and the testimony of treating physicians. Moberly, 592 F.3d at 1325 (quoting Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009)). “Assessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert’s opinion.” Moberly, 592 F.3d at 1325–26. The Special Masters may use the framework set out in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593–94 (1993), to determine the weight to which expert testimony is entitled. Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). The Court finds that the Chief Special Master made her credibility determinations on the basis of the treating physicians’ testimony and supporting evidence. As such, her weighing of their testimony is not improper “cloaking” of an erroneous legal standard (which would require *de novo* review), and the Court will review her determinations for an abuse of discretion.

⁴ Petitioner’s counsel appeared to agree with this basic definition at oral argument, albeit with the words “dysfunction” and “disorder” reversed. See Oral Arg. Tr. at 40 (Dkt. No. 112).

Treating physicians are often entitled to deference because, having evaluated their patient, they are able to determine whether “a logical sequence of cause and effect shows that the vaccination was the reason for the injury.” Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citation omitted). For this reason, the Chief Special Master did not “entirely reject[]” the records of two of A.H.T.’s treating physicians, Drs. Levinson and DeMio.⁵ Dec. at 19. Nevertheless, she could not “credit their statements about the connection between A.H.T.’s vaccination and her subsequent medical and behavioral problems.” Id. Essentially, the Chief Special Master believed that Drs. Levinson and DeMio were alternative medicine providers who “espouse[d] junk science.” Id. at 18. Furthermore, they both treated A.H.T. years after the vaccination at issue in this case. As a result, the Chief Special Master did not give Drs. Levinson and DeMio the deference she might have accorded to more conventional treating physicians who made contemporaneous observations after vaccination.

In her Decision, the Chief Special Master first examined Dr. Andrew Levinson. Id. at 20. Dr. Levinson did not testify at the hearing, but Ms. Holt used his treatment records as evidence in her case. Dr. Levinson treated A.H.T. in 2010 and 2011—long after her hepatitis B vaccination. Id. at 20. The Chief Special Master found that Dr. Levinson’s records contained no diagnosis of A.H.T. Id. Dr. Levinson had mentioned that A.H.T. was responding to a treatment for a mitochondrial disorder, but he did not describe the treatment. He also lacked training in “immunology, oxidative stress, or mitochondrial disorders.” As such, the Chief Special Master reasonably gave little weight to his records in her Decision.

Similarly, Dr. DeMio only treated A.H.T. approximately three years after her vaccination. Id. at 23 n.63. The Chief Special Master notes that Dr. DeMio has “no formal specialized training in metabolic diseases or in any of the several areas (pediatrics, immunology, neurology, or gastroenterology)” on which he testified. Id. at 21. Dr. DeMio seemed to base all testimony about the events after A.H.T.’s vaccination on statements that A.H.T.’s parents made years after the fact. Id. at 23. Finally, the Chief Special Master also rested her credibility determination on Dr. DeMio’s actual testimony, which she quoted at length. See id. at 22. Dr. DeMio spoke in vague and conclusory statements, and it was reasonable on balance for the Chief Special Master to assign little weight to his testimony.

D. The Chief Special Master Applied the Correct Burden of Proof

The Chief Special Master’s decision rests largely on her factual finding that A.H.T. did not suffer an injury after her hepatitis B vaccination. Logically, this finding also means

⁵ The Chief Special Master “fully credited” the testimony and records of Drs. Buttlerman and Hefner. Dec. at 19.

that Ms. Holt has failed to carry her burden of proof under the Vaccine Act. Under the Vaccine Act, a petitioner in a vaccine case may show she is eligible for compensation by either (1) demonstrating that she suffered an injury listed on the Vaccine Injury Table within the required time period after a vaccination covered by the Vaccine Act; or (2) demonstrating that a covered vaccine was a cause-in-fact of her injury. 42 U.S.C. § 300aa-11(c)(1)(C). Here, Ms. Holt does not allege a Table injury. Rather, she alleges that A.H.T.'s hepatitis B vaccination on April 4, 2002 "significantly aggravated an underlying mitochondrial disorder, causing manifestation of ASD or a similar neurological disorder." Dec. at 3. As noted above, the Chief Special Master properly found that A.H.T. had not suffered an aggravation of an underlying mitochondrial disorder. Still, even if A.H.T. had suffered such an injury, Ms. Holt would need to show that the vaccination caused it.

Causation in fact is a legal conclusion subject to *de novo* review. To establish causation in fact, a petitioner must show, by a preponderance of the evidence, that the vaccination caused her injury by providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Courts refer to these requirements as the "Althen prongs."

Under the first Althen prong, the petitioner must produce a "biologically plausible" and "reputable" medical theory. See Andreu, 569 F.3d at 1375. The Chief Special Master properly found that Ms. Holt had not done so. Dr. Kendall, Ms. Holt's expert, was not able to point to evidence suggesting that vaccinations (possibly accompanied by fever) can trigger underlying genetic diseases. See Dec. at 35, 102.⁶ Further, Dr. McCandless testified that the articles Dr. Kendall submitted did not support the petitioner's case. Id. at 39–41. As the Chief Special Master noted, Ms. Holt's medical theory appears to be based on little more than the *ipse dixit* of Dr. Kendall. Id. at 103. Therefore, Ms. Holt did not show a medical theory causally connecting A.H.T.'s vaccination and injury.

Under the second Althen prong, the petitioner must put forth a logical sequence of cause and effect showing that the vaccination caused the injury. Logically, Dr. Kendall's theory would require a preexisting mitochondrial disorder or dysfunction, a fever, and evidence linking A.H.T.'s vaccination to the onset of her mitochondrial disorder symptoms. As noted above, A.H.T. may have a mitochondrial dysfunction, but has merely a "possible" mitochondrial disorder. Furthermore, A.H.T. did not have a fever after

⁶ Dr. Kendall cited the Shoffner paper, Pet. Ex. 68, but the paper has numerous flaws. For example, the paper did not explain its authors' methodology, and "did not clearly indicate when mitochondrial disease was diagnosed in the patients." Dec. at 41–42. The paper also noted, "In our patients with mitochondrial disease and autism spectrum disorders, the vaccines did not appear related to the neurological regression." Id. at 43.

vaccination. There is no evidence—aside from Dr. Kendall’s testimony, which is unsupported by the scientific literature petitioner cited before the Chief Special Master—that links the hepatitis B vaccination to A.H.T.’s alleged mitochondrial disorder symptoms. As such, Ms. Holt did not satisfy the second Althen prong.

Finally, a petitioner must show a proximate temporal relationship between vaccination and injury. Here, Ms. Holt argues in her motion for review that A.H.T. suffered an encephalopathic event shortly after her hepatitis B vaccination that caused later developmental delays. Pet. Mem. at 9. As noted above, there is no evidence that any encephalopathic event occurred. Furthermore, A.H.T. developed normally after the alleged encephalopathic event and only experienced developmental delays much later. See Dec. at 91. This pattern of development is inconsistent with neonatal encephalopathy, and it is therefore extremely unlikely that such an encephalopathic event occurred. Id. Without an encephalopathic event, there can be no proximate temporal connection between the vaccination and A.H.T.’s injury, so Ms. Holt has also failed to satisfy the third Althen prong.⁷

In sum, Ms. Holt has failed to show both an injury and causation under the Vaccine Act.

Conclusion

The Court finds that the Chief Special Master’s factual findings and weighing of expert testimony were not arbitrary and capricious, and further finds that the Chief Special Master reached the correct legal conclusion under the Vaccine Act and Althen. Accordingly, Petitioner’s motion for review is DENIED.

IT IS SO ORDERED.

s/Thomas C. Wheeler
THOMAS C. WHEELER
Judge

⁷ Ms. Holt also argues that the Chief Special Master required her to produce scientific evidence showing a causal relationship between the hepatitis B vaccination and A.H.T.’s injuries. See Pet. Mem. at 14. The Court disagrees. The Chief Special Master specifically notes that she did not require epidemiological evidence. Dec. at 41–42 n.84. Furthermore, there is a difference between requiring epidemiological evidence and weighing expert testimony. As noted above, the Court finds that the Chief Special Master properly weighed expert testimony here.