In the United States Court of Federal Claims

No. 00-746V
Filed: October 1, 2008
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FINN HOPKINS, a minor, by his parents and natural guardians, GREG HOPKINS and HELEN HOPKINS,	* * * * * * * * * * * * * * * * * *	**Motion for Review of Special Master's Decision; National Vaccine Compensation Act, 42 U.S.C. §§ 300aa-1 – 300aa-34.**
Petitioners,		
v.		
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,		
Respondent.		
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Clifford J. Shoemaker, Shoemaker and Associates, Vienna, Virginia, for the petitioner.

Lisa A. Watts, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for the respondent. With her were **Jeffrey S. Bucholtz**, Acting Assistant Attorney General; **Timothy P. Garren**, Director; **Vincent J. Matanoski**, Acting Deputy Director; and **Catharine E. Reeves**, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

O P I N I O N

HORN, J.

PROCEDURAL HISTORY AND FINDINGS OF FACT

[1] This opinion was issued under seal on October 1, 2008. Petitioner and respondent were given the opportunity to propose redactions to the opinion, but did not propose redactions. The opinion, therefore, is unsealed without redactions.

On December 11, 2000, Greg and Helen Hopkins, acting on behalf of their son, Finn Hopkins, filed a petition seeking compensation under the National Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1 – 300aa-34 (2000) (Vaccine Act). Petitioners allege that their son suffered from bilateral sensorineural hearing loss ("SNHL") as a result of receiving the haemophilus influenzae B ("HIB"), diphtheria-pertussis-tetanus ("DPT") and oral polio ("OPV") vaccines on December 10, 1998. Also on December 11, 2000, these same individuals, this time acting on behalf of their other child, Ruby Hopkins, filed a separate claim, also for bilateral sensorineural hearing loss as a result of the HIB, DTP and OPV vaccinations, likewise received on December 10, 1998. Chief Special Master Gary Golkiewicz chose to hold a single hearing for both children and to issue a single decision in the two separately filed cases. According to the Chief Special Master, he and the petitioners in both of the cases were in agreement on how to proceed.

The Chief Special Master held a factual hearing on September 27, 2004, at which both parents testified as fact witnesses. The Chief Special Master issued a factual determination on February 9, 2005. Finn Hopkins v. Sec'y of HHS, No. 00-746 (Fed. Cl. Spec. Mstr. Feb. 9, 2005). In his Factual Determination regarding Finn, prior to taking the expert testimony, the Chief Special Master found that:

> Petitioners' testimony provides no persuasive evidence of the onset of Finn's hearing loss occurring following the December 10, 1998 vaccinations. Accordingly, from the undersigned's viewpoint, it will be virtually impossible to demonstrate an appropriate temporal relationship between the vaccinations and Finn's injury. While petitioners reserve the right to an expert hearing in this case, the court cautions them that given the factual finding regarding onset of Finn's injury, establishing entitlement will be a herculean effort.

Subsequently, the Chief Special Master heard expert testimony and received documentary evidence. In addition to the summary contained in this opinion, a more extensive presentation of the facts of Finn's medical history is found in the Chief Special Master's Decision on Remand. On August 10, 2007, after reviewing the record, including the testimony of fact and expert witnesses and the submitted documentary evidence, the Chief Special Master issued a single opinion denying entitlement to both Finn and his sister, Ruby, for whom a separate claim had been filed, also by the parents. Ruby Hopkins and Finn Hopkins ex rel. Greg and Helen Hopkins v. Sec'y of HHS**,** Nos. 00-745 and 00-746, 2007 WL 2454038 (Fed. Cl. Aug. 10, 2007). Petitioners filed a motion for review of the Chief Special Master's decision on September 9, 2007. The final single opinion issued by the Chief Special Master stated that: "Throughout the presentation of these cases, the two cases had been treated essentially as one." Based on the decision to treat the two cases together, the Chief Special Master also indicated, "the presentation of the two cases are so intertwined through the expert testimony, it makes eminent sense to resolve the cases through one opinion."

This court recognizes that combining the two cases might produce ease, speed and cost reduction. Moreover, from petitioners' point of view, combining the cases would enable the petitioners to use Ruby's case to bolster Finn's case. This court, however, disagreed with the decision to treat the two cases, which put at issue distinct, medical facts of two separate physical beings of different ages, as one entity. Although the Chief Special Master acknowledged some differences between Ruby and Finn in his single opinion, upon reading the opinion of the Chief Special Master, this court was concerned that too much information had been merged and too little consideration given to possible different conclusions. Therefore, on October 16, 2007, this court remanded the two separately filed cases to the Chief Special Master for separate consideration of each child's case. In doing so, this court noted, regarding the two separate cases, that "while the facts [of the two cases] share some similarities, they are not identical," and "that separate opinions should have been issued in each case." This court also directed that, "[a]s part of the remand consideration, the [Chief] Special Master shall give consideration to whether sufficient facts exist in the current record to enable him to reach an independent conclusion as to each child." The Chief Special Master also was instructed that if he did not hold further hearings, he "should indicate his reasons for doing or not doing so in his final opinion."

The Chief Special Master did not hold additional hearings or take any additional evidence. On December 14, 2007, the Chief Special Master issued two Decisions on Remand, one for Ruby Hopkins and one for Finn Hopkins. Neither decision contained substantive changes to the original single opinion. The primary difference between the original and the Remand Decision was that the Chief Special Master's discussion and conclusion were segregated into two separate opinions, one for Ruby and one for Finn. In fact, in the Chief Special Master's Remand Decision, he specifically wrote, "[t]he undersigned notes for the convenience of the court and the parties that in issuing this separate decision for Finn Hopkins, no substantive changes were made to the undersigned's initial Decision [the Joint Decision issued earlier]." Finn Hopkins v. Sec'y of HHS, No. 00-746, slip op. at 3 (Fed. Cl. Spec. Mstr. Dec. 14, 2007). In the case of Finn Hopkins, discussed in this opinion, the Chief Special Master concluded that based on the record, Finn was not entitled to compensation under the Vaccine Act. On January 7, 2008, petitioners filed a Motion for Review of the December 14, 2007 Remand Decision

Finn was born on May 15, 1997. Finn had been seen in November 1997, at the Emergency Care facility at Elmendorf Air Force Base, Alaska, for a fever and bulging fontanel. At that time, he was diagnosed with mild otitis media. On June 1, 1998, Finn was diagnosed with sinusitis. On December 10, 1998, Finn received the haemophilus influenzae type B ("HIB"), diphtheria-tetanus-pertussis ("DTP"), and oral polio ("OPV") vaccinations at Elmendorf Air Force Base.[2] After returning from a family vacation to

[2] Due to an aversion to vaccines, referring to them as "toxins made from diseases," Mr. and Mrs. Hopkins chose not to have Finn vaccinated as an infant. Mrs. Hopkins agreed that vaccines are normally administered to infants in their first year at two, four and six

Thailand, Finn was evaluated by John Caeton, M.D., on March 8, 1999, for a possible viral respiratory infection. In Finn's medical record, Dr. Caeton noted that his "TMs [tympanic membranes] look gray," his nose was "not draining," and his pharynx and lungs were "negative." In his diagnosis, the doctor concluded that Finn was suffering from an upper respiratory infection, for which Finn's parents were advised to give him over-the-counter medication.

Approximately two weeks later, on March 23, 1999, Finn was evaluated by audiologist Joyce F. Sexton at Northern Hearing Services, Inc., in Anchorage, Alaska. Ms. Sexton evaluated Finn at the request of his parents because he was not talking clearly and he seemed to be slow in acquiring new words. Also, his sister, Ruby, recently had been diagnosed with a hearing loss of unknown etiology and his parents wanted to determine if hearing was any concern for Finn. Subsequently, on April 1, 1999, an audiologist performed Otoacoustic Emissions Testing (OAE). She noted the "[r]esults of the OAE tests showed no emissions for either ear suggesting abnormal cochlear function." It was recommended, however, that Finn be examined by an Ear, Nose and Throat (ENT) specialist to rule out any medical concerns which may be affecting Finn's hearing.

On May 11, 1999, Finn was evaluated at the Alaska Native Medical Center. At the Center, it was concluded that Finn's results suggested "the presence of a moderate sensorineural hearing loss in the Left ear and a moderately severe sensorineural hearing loss in the Right ear." The Center recommended the parents follow-up with the Elmendorf Air Force Base ENT program. On May 13, 1999, Finn was evaluated by Randall Ow, M.D., at the Elmendorf Otorhinolaryngology (ENT) Clinic. The diagnostic assessment by Dr. Ow was "probable hereditary hearing loss."

A Vaccine Adverse Event Reporting System (VAERS) form dated June 14, 1999, signed by Dr. Thad L. Woodward of the Alaska Center for Pediatrics, indicated Finn's hearing loss was first noticed following his December 10, 1998 vaccinations. The "adverse event onset" is unclear on the form, but appears to be either April 2 or April 12, 1999. Later, in a report dated August 20, 1999, Dr. Woodward concluded, "no genetic origin or other cause of their [Finn and Ruby's] hearing loss have been discovered. He also wrote, "[i]t is certainly curious that both children have developed bilateral hearing loss within a short period of time after receiving a DPT vaccine, and although I do not personally believe that this is the likely cause of the coincidental hearing loss, we do not have any other explanation."

On June 24, 1999, a deafness DNA screen was performed on Finn to test for mutations in the CX26 gene, which is associated with deafness. The results indicated that "[n]o mutations were detected in the CX26 gene," but that "[t]his is still consistent with a clinical diagnosis of autosomal recessive nonsyndromic deafness (ARNSD)

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months of age, according to the Department of Health and Human Services Center for Disease Control and Prevention guidelines.

attributable to the CX 26 (or DFNB1) locus because the test does not detect all possible mutations."

A letter to Dr. Mark J. Stephan from Dr. Richard Smith on September 17, 1999, however, indicated that after completing an analysis of the Connexin 26 gene, "[t]he father and both hearing-impaired children [Ruby and Finn] carry the M34T mutation in Connexion [sic] 26." The letter concluded that in Dr. Smith's opinion deafness is not "due to mutations in Connexion [sic] 26." He also stated, however, "the history is still consistent with a clinical diagnosis of autosomal recessive non-syndromic hearing loss due to mutations in another gene."

On July 20, 1999, Finn was evaluated for bilateral sensorineural hearing loss by Phillip Massengill, M.D., at an ENT Clinic at the Madigan Army Medical Center in Tacoma, Washington. In his report, Dr. Massengill noted that there was no known etiology for the hearing loss. He also indicated that Finn "is too young to document progressive hearing loss at this point." He further noted that Finn's parents were concerned the hearing loss could have been the result of his recent vaccinations and that Finn "was thought to have normal hearing by his parents prior to the vaccinations." Dr. Massengill noted that while he found no known etiology for the hearing loss, the risks and benefits of immunizations and temporal association of possible medical reactions from immunizations were discussed with the parents.

On July 23, 1999, Finn and his sister Ruby received a clinical genetics evaluation by Dr. Stephan. With respect to Finn, the doctor noted, "he did not have any unusually toxic reaction to the vaccine during the week following the vaccine." In evaluating Finn's family history, Dr. Stephan determined that Finn's mother's auditory evaluation "detected a very mild auditory deficit in the high frequency ranges only." Dr. Stephan also noted that Mrs. Hopkins's sister suffered from minor cerebral palsy and had a "minor auditory deficit." In addition, it was noted that Mrs. Hopkins has one "paternal uncle who has hearing loss secondary to mastoiditis at age 4 as well as noise trauma" and "another paternal uncle with hearing loss associated with multiple bouts of otitis media." It was also noted that Mrs. Hopkins "has a maternal uncle who had adult onset hearing loss and is also visually impaired." Greg Hopkins, however, had a normal hearing test, with Dr. Stephan noting that Finn's grandfather "has hearing loss of adult onset secondary to artillery noise," but petitioners' expert, Dr. Raymond, indicated that no audiograms or evaluations were produced and, therefore, there is "no evidence that this hearing loss is also not genetic." Dr. Stephan ultimately concluded Finn suffered from "[b]ilateral sensorneural [sic] hearing deficit." With regard to Finn's parents' concern that his hearing loss might be related to the immunizations received in December 1998, Dr. Stephan noted that the condition "represents an autosomal recessive non-syndromic auditory deficit," and that there were "no other previous reports of hearing loss developing after a DPT immunization . . . ." He further noted that Dr. Mary Fairchok of Pediatric Infectious Diseases also was not aware of any such reports or cases correlating DPT immunizations and hearing loss.

On September 9, 1999, Finn's medical records indicate he was evaluated by Bruce T. Hewett, M.D. The medical record states: "genetic testing preliminary pos [sic] for genetic mutation for neurological hearing loss." In a letter dated September 17, 1999 from Dr. Smith to Dr. Stephan, Dr. Smith states:

> The father and both hearing-impaired children [Finn and his older sister Ruby] carry the M34T mutation in Connexin 26. Although the pathologic significance of this mutation has been debated in the literature, it is our opinion that the mutation represents a benign polymorphism and is not disease causing. Based on this interpretation, it is our opinion that your family does not have deafness due to mutations in Connexin 26. However, the history is still consistent with a clinical diagnosis of autosomal recessive non-syndromic hearing loss due to mutations in another gene.

DISCUSSION

When reviewing a special master's decision, the assigned judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); see also Rules of the United States Court of Federal Claims (RCFC) App. B (Vaccine Rules), Rule 27. The legislative history of the Vaccine Act states that, "[t]he conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those cases in which a truly arbitrary decision has been made." H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 512-13, 517, reprinted in 1989 U.S.C.C.A.N. 1906, 3115, 3120.

Regarding the standard of review, in Markovich v. Sec'y of HHS, the United States Court of Appeals for the Federal Circuit wrote, "Under the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of HHS, 477 F.3d 1353, 1355-56 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 92 (2007); see also Bazan v. Sec'y of HHS,

539 F.3d 1347, 1350 (Fed. Cir. 2008); Althen v. Sec'y of HHS, 418 F.3d 1274, 1277 (Fed. Cir. 2005).

As described by the Federal Circuit in Althen:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of HHS, 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 127 S. Ct. 2909 (2007).

Petitioners, on behalf of Finn Hopkins, claim that as a result of HIB, DPT and OPV vaccinations on December 10, 1998, Finn suffered post-vaccinal bilateral sensorineural hearing loss (SNHL), and that a petitioner is entitled to compensation for an off-Table injury, with conditions and symptoms not listed on the Vaccine Injury Table. Under the off-Table theory of recovery, a petitioner is entitled to compensation if he can demonstrate by a preponderance of the evidence (42 U.S.C. § 300aa-13(a)(1)(A)), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table (42 U.S.C. § 300aa-14(a) and 42 C.F.R. § 100.3), but which was caused by a vaccine that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also Althen v. Sec'y of HHS, 418 F.3d at 1278; Hines ex rel. Sevier v. Sec'y of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

Since Finn's condition does not meet the requirements of a presumptively on-Table, vaccine-related condition, to prove entitlement for an off-Table injury, petitioners must:

> prove causation-in-fact. Grant [v. Sec'y of HHS], 956 F.2d [1144,] 1147-48 [(Fed. Cir. 1992)]. [The United States Court of Appeals for the Federal Circuit has] held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm."

Bazan v. Sec'y of HHS, 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)). A "'substantial factor' standard requires a greater showing than 'but for' causation. Bazan v. Sec'y of HHS, 539 F.3d 1351 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole

or predominant cause of her injury, just that it was a substantial factor." Bazan v. Sec'y of HHS, 539 F.3d 1351.

When proving eligibility for compensation for an off-Table injury under the Vaccine Act, petitioners may not rely on their testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." See 42 U.S.C. § 300aa-13(a)(1).

The petitioners must prove their case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of HHS, 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of HHS, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). Decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress in which "close calls" are resolved in favor of injured claimants." Althen v. Sec'y of HHS, 418 F.3d at 1280. The Althen court further noted that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Id. (citing Knudsen v. Sec'y of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994)).

In a comprehensive discussion, the court in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e.,"evidence in the form of scientific studies or expert medical testimony[.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect

> showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of HHS, 418 F.3d at 1278 (brackets added); see also Pafford v. Sec'y of HHS, 451 F.3d at 1355; Capizzano v. Sec'y of HHS, 440 F.3d 1317, 1324 (Fed. Cir. 2006). Evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. Id. at 1326. If a petitioner satisfies the Althen burden and meets all three prongs of the Althen test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen v. Sec'y of HHS, 35 F.3d at 547 (alteration in original; citation omitted).

Medical Theory Causally Connecting Vaccination and Injury

In this case, expert reports were filed and live testimony was taken from the experts. The first prong of the Althen test requires a petitioner to demonstrate a "medical theory causally connecting the vaccination and the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278. The Chief Special Master found that the experts agreed that, "genetics play a significant role in SNHL cases." However, accepting a general statement that it is possible for vaccines (not specific vaccines) to cause hearing loss, regarding this first prong in his Decision on Remand, the Chief Special Master wrote that, "the medical theory of how the vaccine could plausibly cause the alleged injury was not contested; the experts agreed that an autoimmune process can result in hearing loss."[3] Therefore, the petitioners met the first prong of the Althen test.

Proximate Temporal Relationship

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, a "proximate temporal relationship between the vaccination and the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of

[3] However, later in the remand decision, the Chief Special Master wrote that both "Dr. Raymond and Dr. Mankarious were also adamant that the vaccines involved in this case do not cause hearing loss," specifically citing Dr. Mankarious' statement, "[n]obody has hearing loss from those four vaccines. Not even in the medical literature." If, in fact, the Chief Special Master accepted the testimony of respondent's experts, Drs. Raymond and Mankarious as reliable, and more credible than, the expert opinion of the petitioners, then, perhaps, the Chief Special Master should have concluded that the first prong of Althen was not met. Regardless, as is discussed below, petitioners fail to carry their burden and cannot substantiate their claim.

HHS, 451 F.3d at 1358. The Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Sec'y of HHS, when it noted that "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Id.

The Chief Special Master identified "timing," in other words, "when did Finn begin to lose his hearing," as the "central issue for resolution of this case." After reviewing the available evidence, the Chief Special Master concluded in his Remand Decision that, "the petitioners failed to establish this key factual predicate – the timing of onset – which requires a finding against petitioners in Finn's case."

In the record, there was no specific time identified for Finn's hearing loss. The Chief Special Master, therefore, based his Remand Decision for this factor on expert opinion, insisting that the credibility of the experts was "unusually important." Among the difficult issues identified on the issue of timing, the Chief Special Master identified the following: determining hearing loss in children is extremely difficult because a child can develop normal speech with as much as a 40 decibel deficit. The Chief Special Master did not accept petitioner's expert, Dr. Creagan, because he never treated children, was not an expert in genetics and vaccinology and did not consider him to be impartial. The Chief Special Master stated, "the undersigned was not impressed with Dr. Creagan and gave virtually no weight to his testimony." The Chief Special Master also rejected the testimony of the petitioners' expert, Dr. Carlo Tornatore, stating: "because the foundational facts for Dr. Tornatore's opinions, the appropriate timing for the onset of the hearing loss is rejected."

In reviewing the testimony of the experts, the Chief Special Master turned his attention primarily to petitioners' expert, Dr. Tornatore, and respondent's expert, Dr. Mankarious, having dismissed petitioners' expert, Dr. Creagan, from his consideration. Although impressed by the testimony of respondent's expert, Dr. Raymond, the Chief Special Master relied most heavily on the testimony of Dr. Mankarious. The Chief Special Master found significant credibility gaps between petitioner's expert, Dr. Tornatore, and respondent's expert, Dr. Mankarious.

In Finn's case, the Chief Special Master found that Finn had not been tested for hearing loss prior to immunization. He also found "there are no medical records documenting normal hearing prior to the immunizations" and "the onset of Finn's hearing loss is unknown." The Chief Special Master also found that:

> Petitioners attempted to show no prior hearing loss through contemporaneous speech and language tests performed following the immunizations, and letters from those paraclinicians written five years later. However, Drs. Mankarious and Raymond effectively and convincingly showed that the information does not establish the onset date for the hearing loss. As discussed above, relying heavily upon the

> testimony of Drs. Mankarious and Raymond, the undersigned finds that the onset of Finn's hearing loss is unknown. Accordingly, petitioner failed to establish the critical temporal relationship between their[4] hearing loss and immunizations, and thus, failed to establish that the vaccines in-fact caused their hearing loss.

With regard to the proximate temporal relationship prong of the Althen test, as applied to Finn, petitioners argue that the experts, for both petitioners and respondent, testified that whatever caused the hearing loss in Ruby also caused the hearing loss in Finn. Petitioners, therefore, argue that if Ruby established causation, the same causation finding should be applied to Finn. Following the factual hearings, however, while allowing a proximate temporal relationship in Ruby's case,[5] the Chief Special Master had indicated it would be "virtually impossible" for Finn to meet this Althen test.

With respect to Finn, regardless of the outcome on the timing issue and the third Althen test in his sister Ruby's case, the questions raised in Finn's case are different. Under the Althen tests used to establish entitlement for an off-Table injury, a petitioner must demonstrate by a preponderance of the evidence all three prongs of the Althen test, including "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d at 1278. The record, including the testimony of the experts, establishes that Finn's hearing was not tested prior to his vaccination when he was just over 18 months old. Moreover, according to the testimony of the experts, Drs. Raymond, Tornatore and Mankarious, there is great difficulty in determining hearing loss in young children.

In his Decision on Remand, the Chief Special Master, after receiving the expert testimony, rejected the testimony of petitioners' experts and accepted that of respondent's experts. One of petitioners' experts, Dr. Creagan, stated during his testimony, "I think there is a lot of evidence that [Finn] had normal hearing in December [1998] and no evidence to suggest he had abnormal hearing. The problem is that the evidence is less abrupt and definitive on when we had onset of hearing loss and the degree of progression. . . . The onset was delayed because he had never had Tetramune before, and Ruby had."

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[4] Despite the remand, the Chief Special Master continued to refer to the two children, Ruby and Finn, together. Especially with respect to the issue of timing, the two cases of children of different ages present different factual profiles.

[5] Following a factual determination hearing, the Chief Special Master issued his determination on Ruby: "Ruby's parents, Greg and Helen Hopkins, provided clear, convincing and consistent testimony that . . . supported their statements that Ruby's hearing loss was not apparent until after her December 10, 1998 vaccinations." However, also respecting Ruby, the Chief Special Master reversed himself on the timing issue after hearing expert testimony.

Petitioners' other expert, Dr. Tornatore, relied upon the clinical professionals who had evaluated Finn and the family's observations to support his conclusions regarding Finn. Dr. Tornatore stated that, "Finn was noted by his parents to have changes, as well as his grandmother, in his ability to hear and to dance and to do certain things, albeit not as nearly well characterized as Ruby . . . ." Regarding the clinical professionals' observations, despite describing it as "the least helpful letter," Dr. Tornatore cited an April 1, 2005 letter from Lisa Owens, a Speech-Language Pathologist, who observed "[g]iven his [Finn's] moderate-to-severe hearing loss, it's unusual that Finn would use some of these high-frequency, acquired sounds, that is, as he should, while having trouble with other easier sounds unless he had heard these sounds before." Dr. Tornatore also relied on an April 1, 2005 letter from Patty Hoffman, an elementary school Speech Pathologist, who observed:

> His [Finn's] expressive language skills were typical of a child 24 to 28 months of age. This indicates a language delay of 4 to 8 months. It is interesting to note that the amount of delay (i.e., 4 to 8 months) mirrors the approximate time frame between when Finn incurred the hearing loss and when he was fitted with aides [sic] and began receiving early intervention services (i.e., about 6 months).

Based on this information, Dr. Tornatore reasoned that since Finn was 36 months at the time of testing, and had language skills of a 24-28 month old, that his language delay was 4-8 months, which would date back to the approximate time of the vaccinations. The Chief Special Master, however, found in his opinion, "the factual basis for Dr. Tornatore's opinion was highly questionable . . . even before Dr. Mankarious testified."

In response to petitioners' claim that Finn's vaccinations preceded his hearing loss, the government's witness, Dr. Mankarious, stated in her opinion that Finn most likely had hearing loss before the vaccinations based on the fact that "by the time he had his speech evaluation done he was already speech-delayed." This, she concluded, indicated that it was "most likely he has had hearing loss through a large portion of his time of speech acquisition." Regarding Dr. Tornatore's testimony estimating the time of onset, Dr. Mankarious remarked:

> I read the previous testimony and that was a big misunderstanding in the previous testimony. The delay had nothing to do with how long he had been without his hearing. You can't extrapolate that because he's four to eight months behind where he should be, that means he's had a hearing loss for four to eight months. The two have nothing to do with each other.
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> It only means that at the time he was tested he was four to eight months behind where he should have been, but he may have had a very severe loss and yet he's a smart boy and therefore . . . he could have been 12 months behind.

Later, during her testimony, Dr. Mankarious further stated:

> . . . I was a little horrified when I went through the transcript that people were trying to calculate when his hearing loss occurred based on how many months he was delayed. That's such false thinking. I really need to bring this out very strongly.
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> How far a child is delayed based on a hearing loss has so much to do with the skill set of that child, and it has nothing to do with when the hearing loss actually occurred. I shouldn't say it has nothing to do. That has some effect, but the child may be very visual or may not be very visual.
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> [T]here's so many factors that play into how – or not how, but at what age range a child is at when they do the testing. It has really nothing to do with – you can't translate that data and backdate, well, if he's four to eight months behind where he should be that means the hearing loss should have been four to eight months ago. They have nothing to do with each other.

The Chief Special Master found Dr. Mankarious to have "vastly superior training, experience and knowledge," and Dr. Tornatore to have a "lack of the same." The Chief Special Master concluded that, "[w]hat is clear from Dr. Mankarious' testimony is that the factual predicate for Dr. Tornatore's opinion was not factual, but consisted of snippets of information put forth as facts." The Chief Special Master also wrote, "Dr. Tornatore had neither the requisite knowledge nor experience to determine whether the snippets of information fit together to form a true picture or whether they were pieces of a puzzle that will never fit together." The Chief Special Master, therefore, stated that he "accepts Dr. Mankarious' discussion and explanation of all aspects of hearing loss over Dr. Tornatore's." Regarding petitioners' other expert, Dr. Creagan, the Chief Special Master indicated that Dr. Creagan's "testimony regarding the timing of the onset was pure speculation."

The Chief Special Master then noted that "there are no medical records documenting normal hearing prior to the immunizations" and that "Drs. Mankarious and Raymond effectively and convincingly showed that the information does not establish the onset date of hearing loss." The Chief Special Master ultimately concluded that "the onset of Finn's hearing loss is unknown." Unlike in the case of Ruby, this court agrees.

Logical Sequence of Cause and Effect

The second prong of the Althen test requires petitioners to demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of HHS, 418 F.3d at 1278; see also Pafford v. Sec'y of HHS, 451 F.3d at 1355. The relationship between the various prongs of the Althen test can be complex. In Capizzano v. Sec'y of HHS, the United States Court of Appeals for the Federal Circuit noted:

> There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Capizzano v. Sec'y of HHS, 440 F.3d at 1327.

In his Remand Decision, the Chief Special Master also found that petitioners had failed to establish the logical sequence of cause and effect for Finn. On this issue, the Chief Special Master once again relied heavily on a balancing of expert testimony. The Chief Special Master found petitioners' expert, Dr. Tornatore, to lack credibility, paid less attention to petitioners' expert, Dr. Creagan, but found respondent's experts, Drs. Raymond and Mankarious, significantly more credible. Such a determination, as to the credibility of the experts, is within the purview of the Chief Special Master, who, when determining entitlement to compensation, must weigh expert testimony on causation, since the Vaccine Act states, "[t]he special master or court may not make such a finding based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-12(a). Direct proof, however, is not required. See Althen v. Sec'y of HHS, 418 F.3d at 1280.

Petitioners argue that "the vaccinations were the reason for the injury" and that the "[p]etitioner ha[d] normal hearing prior to vaccination." Petitioners also argue that the Chief Special Master incorrectly "faulted petitioner for failing to meet the requirements of Prong II (logical sequence of cause and effect)," when, in fact, the petitioners "have shown a logical sequence of cause and effect," showing that the vaccinations were the reason for the injury.

In Capizzano, the United States Court of Appeals for the Federal Circuit found "'[a] logical sequence of cause and effect' means what it sounds like--the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury. 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1)." Capizzano v.

Sec'y of HHS, 440 F.3d at 1326. The logical sequence can be supported by reputable medical or scientific explanation, or otherwise stated, evidence in the form of scientific studies or expert medical testimony. See Althen v. Sec'y of HHS, 418 F.3d at 1278 (quoting Grant v. Sec'y of HHS, 956 F.2d at 1148); see also Devonshire v. Sec'y of the HHS, 76 Fed. Cl. 452, 454 (2007). In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause of the injury, but also a substantial factor in bringing about the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278 (quoting Shyface v. Sec'y of HHS, 165 F.3d at 1352-53).

The Chief Special Master described petitioners' case as relying on the testimony of petitioners' expert, Dr. Tornatore, when he tried to link Finn's autoimmune reaction, which resulted in hearing loss, to an environmental trigger or cue, in Finn's case, the vaccine administered three weeks earlier. As stated by the Chief Special Master, "[t]he need for an environmental trigger was a key component of Dr. Tornatore's opinion – it was the core of Dr. Tornatore's logical sequence of cause and effect linking the vaccines to Ruby's and Finn's hearing loss." Dr. Tornatore himself described the genetic disposition plus an environmental trigger as "a background curve for all of my thinking."

In his Remand Decision, the Chief Special Master noted how Dr. Tornatore, citing to the medical literature, concluded that if a child with normal hearing, but with a genetic predisposition for hearing loss, receives an additional environmental trigger, that trigger can push the individual over to deafness. Although the record is not definitive, there is evidence from a treating physician, Dr. Ow, of a "hereditary hearing loss." Moreover, both Finn's father and paternal grandfather have this mutation; Finn's father evidenced no hearing loss, whereas the adult hearing loss attributed to his grandfather resulted from either genetics or artillery exposure.

This court, however, is unpersuaded by Dr. Tornatore's argument that the variation acted as a trigger to a genetic predisposition. There is no evidence in the record that Finn had normal hearing prior to the vaccination, including that he was not tested prior to the vaccination. Similarly, petitioner's assertion regarding Finn's father and paternal grandfather does not support the petitioners' cause of action theory because the record contains no information as to whether either of Finn's forbearers received the HIB, OPV and DPT vaccinations. The triggering mechanism proposed by Dr. Tornatore as the explanation for the hearing loss in Finn is not sufficiently documented to carry the petitioners' burden by a preponderance of the evidence.

Dr. Tornatore relied on a number of medical articles, including one titled "Mitochondrial Deafness Mutations Reviewed." Dr. Tornatore testified that the article demonstrated, "if you have a mitochondrial mutation, and then there is an environmental agent that's given, you may then become deaf . . . ." Dr. Tornatore also referred to other selections from the medical literature during his testimony, including an article titled, "How to Identify Gene-Environmental Interactions," as evidence that "environment is a critical part in determining what may happen to you depending on your genetic background." Another article titled "Gene-Environment Interaction: A Central Concept in

Multifactoral Diseases," was used by Dr. Tornatore to conclude that the article supported the proposition that, "even though you have the gene, that's not what determines whether you're going to have it. What determines is if there is that gene plus something else that then pushes you over," and that "drug intake" is a factor to which genes can act as response modifiers. Or, stated otherwise, Dr. Tornatore testified: "even if you have the genetic predispostion, this diagram [in the article] shows that in some cases the environmental agent pushes you over to deafness."

The Chief Special Master dismissed the testimony and articles cited by Dr. Tornatore as not involving the vaccines administered to Finn. In fact, the Chief Special Master severely criticized Dr. Tornatore's credibility on multiple grounds including Dr. Tornatore's "straying from the facts, overstating information to support a point or subtly changing language to strengthen his position." Finn Hopkins v. Sec'y of HHS, slip op. at 25. The Chief Special Master concluded, "[i]n summary, Dr. Tornatore's testimony and, thus, his credibility, is severely damaged by his advocacy, his piecemeal use of medical literature, his imprecise interpretation of the same literature and frequent use of unsupported assumptions." The Chief Special Master also discredited petitioners' other experts on this prong of the Althen test, based on their lack of relevant credentials and their testimony. He found that Dr. Creagan's testimony was "unhelpful," adding "nothing" to the central issue and, that it was "not impartial" or "objective."

While rejecting testimony by petitioners' experts, the Chief Special Master chose to rely on the testimony of respondent's experts, Drs. Mankarious and Raymond, finding the professional experience and testimony of respondent's experts far more relevant and credible. With regard to Dr. Tornatore's conclusions, Dr. Mankarious, respondent's expert, stated:

> I find that amazing that could be proposed. I see patients all the time with genetic hearing loss and there is usually never a triggering factor. There's never an illness, there's never head trauma, there's never a vaccine, there's never an ear infection that triggers the hearing loss. The hearing loss is usually spontaneous with no known inciting event, and so that's what I see on a daily basis. Nor has there ever been a triggering agent written of in the literature for genetic hearing loss such as a connexon [sic] 26 mutation.

The Chief Special Master also cited to respondent's expert, Dr. Raymond, questioning Dr. Tornatore's extrapolation from the article on mitochondrial deafness. Dr. Raymond testified that the "article is completely and specifically dealing with mitochondrial mutations," and those mutations "are the only ones that I'm aware of specifically where an environmental trigger has been clearly demonstrated to be the cause of the hearing loss." Ultimately, the Chief Special Master found Dr. Mankarious' and Dr. Raymond's testimony to undermine the testimony of Dr. Tornatore and led him, as the fact finder, to rule in favor of the respondent on the second prong of the Althen test.

In addition, the Chief Special Master noted that the United States Court of Appeals for the Federal Circuit has instructed special masters that, "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" See Capizzano v. Sec'y of HHS, 440 F.3d at 1326 (quoting Althen v. Sec'y of HHS, 418 F.3d at 1278). In this regard, Dr. Endres, Dr. Ow, Dr. Massengill and Dr. Stephan, each treating physicians for Finn, chose not to correlate the hearing loss with the vaccines (even though suggested by the parents). However, the majority of these doctors in their notes specifically noted that heredity, rather than environment, was or might be the probable cause for Finn's hearing deficiency. Similarly, Dr. Mankarious testified as to the family history of hearing loss as indicative of a non-vaccine induced reason for Finn's hearing loss.

The Chief Special Master also found the medical literature presented to the court provided no evidence that the vaccines administered to Finn caused SNHL. Moreover, both Drs. Raymond and Mankarious "were adamant that the vaccines involved in this case do not cause hearing loss." In addition, the only medical article which discussed the vaccines administered to Finn was found by the Chief Special Master to be based on a fact pattern significantly different than the one before him.

Based on all of the evidence presented, the Chief Special Master concluded that petitioners had not successfully proved a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen v. Sec'y of HHS, 418 F.3d at 1278. This court has carefully reviewed the record and the decision issued by the Chief Special Master and concludes that his decision regarding the second Althen prong was not arbitrary or capricious, despite his perhaps overly zealous discrediting of Dr. Tornatore. The Chief Special Master acted within his discretion by giving Drs. Raymond's and Mankarious' testimony greater weight than that of Drs. Tornatore and Creagan. See Whitecotton v. Sec'y of HHS, 81 F.3d 1099, 1108 (Fed. Cir.) ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence"), reh'g and reh'g en banc denied (Fed. Cir. 1996); Sword v. Sec'y of HHS, 44 Fed. Cl. 183, 188 (1999) ("Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to [his or her] own conclusions."). The petitioners have failed to prove their case by a preponderance of the evidence in this off-Table, vaccine injury case.

CONCLUSION

In the case of Finn, the court notes that the petitioners are unable to meet the third prong of the Althen test regarding establishing a proximate temporal relationship, given his age and the fact he had not been tested prior to the vaccinations. Finn's age makes the onset of a hearing loss difficult to prove. How to measure the alleged

hearing loss in a less than totally verbal, young child may be an almost impossible burden of proof for Finn. However, Finn does not prevail on all the other Althen grounds. Accordingly, upon a review of the record in the above-captioned case, including the transcript, exhibits to the record, the filings submitted by the parties, and the decisions issued by the Chief Special Master, including his Decision on Remand, the court affirms the decision of the Chief Special Master denying compensation to the petitioners on behalf of Finn.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge