

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 00-746V
Filed: December 14, 2007

NOT TO BE PUBLISHED

FINN HOPKINS, a minor, by his parents *
and natural guardians, GREG HOPKINS *
and HELEN HOPKINS, *

Petitioners, *

Entitlement; Expert Credibility;
Hearing Loss; Treating Doctors

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

Clifford J. Shoemaker, Shoemaker & Associates, Vienna, Virginia, for Petitioners.

Lisa A. Watts, United States Department of Justice, Washington, D.C., for Respondent.

DECISION ON REMAND¹

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

On December 11, 2000, petitioners filed two separate petitions pursuant to the National

¹ Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" decision will be available to the public. Id.

Vaccine Injury Compensation Program² (hereinafter referred to as “the Program” or “Act”) alleging that their son, Finn, and their daughter, Ruby, suffered bilateral sensorineural hearing loss (“SNHL”) as a result of haemophilus influenzae type B (“HIB”), diphtheria-tetanus-pertussis (“DTP”), and oral polio (“OPV”) vaccinations received on December 10, 1998. Ruby’s case was docketed as case number 00-745V, and Finn’s case was docketed as case number 00-746V. On March 1, 2004, respondent filed his Rule 4 Report in each case contesting the sufficiency of the evidence and recommending that compensation be denied to both Finn and Ruby.

On August 10, 2007, the undersigned issued a single Decision denying compensation in both Ruby’s and Finn’s cases. Ruby Hopkins and Finn Hopkins v. Sec’y of Dept. of Health & Human Servs., Nos. 00-745V and 00-746V (Fed. Cl. Spec. Mstr. Aug. 10, 2007), reissued for publication on August 16, 2007. Hopkins ex rel. Hopkins v. Sec’y of Dept. Of Health & Human Servs., No. 00-745V and No. 00-746V, 2007 WL 2454038 (Fed. Cl. Spec. Mstr. Aug. 10, 2007). Following petitioners’ filing of timely Motions for Review, the Honorable Marian Blank Horn remanded the cases to the undersigned “for separate consideration of each child’s case.” Order filed October 16, 2007. In addition, Judge Horn directed that the undersigned consider conducting an additional hearing if the current record does not contain sufficient facts “to enable him to reach an independent conclusion as to each child.” Id. If no additional hearing is conducted, “the Special Master should indicate his reasons for doing or not doing so in his final opinion.” Id.

The undersigned has reviewed the entire record of this case and concludes that the current record contains sufficient factual and medical information to resolve fairly and individually the cases of Ruby and Finn Hopkins. Most importantly for purposes of this Remand, the undersigned assures the reviewing judge, that even though a single Decision was utilized initially to resolve the two cases, throughout the development of the records in the two cases, including the three hearings that were conducted, the involved medical experts, the parties’ lawyers and the undersigned were focused not only on the global medical issue of the relationship of hearing loss to vaccines, but also on the application of those medical principles to the individual cases of Ruby and Finn.³ Critically, the undersigned discussed with the parties the development of the record to reduce redundant testimony on overlapping medical issues, while ensuring individual attention to Ruby’s and Finn’s cases. The parties were in full agreement.

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

³ The August 10 Decision contains, in hindsight, a poor choice of words that could be interpreted to indicate that individual consideration of Ruby’s and Finn’s cases was not given. The Decision reads “[t]hroughout the presentation of these cases, the two cases have been treated essentially as one.” Hopkins, 2007 WL 2454038, at 2. Because of the overlapping medical theories of the case and the common discussion of the overarching medical issues, the development of the two cases was to a great extent handled essentially as one. However, at all times and at every step in the process, the parties and the undersigned were careful to apply any global medical discussion to the facts of the individual cases, that is Ruby’s and Finn’s specific circumstances.

While much of the discussion with the parties on how to most efficiently develop the records in these cases was conducted off of the record, the transcript of the April 14, 2006 Hearing⁴ does contain a summary of those discussions. It states:

THE COURT: . . .

Now, we discussed briefly off of the record with counsel as to how we're going to proceed today because we have three experts who are going to testify in both cases, and we have a lot of overlapping medical information and discussions. What we're going to do is we are going to take the experts in turn. The experts are going to testify to the general medical principles that apply to both cases, and then, at the appropriate time, at counsel's lead, they will separate their testimony and talk specifically about the individual cases, Finn and Ruby, whichever order you're going to take them in. That was per the agreement of the parties. We will also have one transcript, which we will then file in both cases. . . .

Tr. 1 at 4.⁵ Again, the undersigned assures the reviewing court that the parties and the undersigned developed the records in Ruby's and Finn's cases with an eye to both the overarching medical issue and the application of those medical principles to the individual cases of Ruby and Finn. Accordingly, the records contain individual discussions of the factual issues involved in both cases, and individual factual rulings were issued. See Ruby Hopkins v. Sec'y of Dept. of Health & Human Servs., No. 00-745V (Fed. Cl. Spec. Mstr. Feb. 9, 2005 [hereinafter "Ruby slip op. at ____"]; Finn Hopkins v. Sec'y of Dept. of Health & Human Servs., No. 00-746V (Fed. Cl. Spec. Mstr. Feb. 9, 2005). Likewise, the expert reports and expert testimony addressed the general medical principles involved in the case, but also addressed the individual situations of both Ruby and Finn and applied the general medical principles to the specific factual circumstances of each case. Accordingly, the undersigned is completely satisfied that the parties had every opportunity to present complete evidence in support of their respective positions in both Ruby's and Finn's cases and that the records contain the necessary information to render decisions in both cases.

Lastly, the 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. Again, after considering the record of the case and the court's Remand, the undersigned firmly believes that full consideration was given to the individual facts and circumstances of Finn's case and thus no changes are necessary.

⁴ Three Hearings were held in this case, and thus there are three transcripts. The first Hearing conducted on September 27, 2004 dealt solely with the factual issues. That transcript is referenced once in this decision. The subsequent two Hearings involved the experts and are extensively cited herein. The transcript of the April 14, 2006 Hearing will be cited as "Tr. 1 at ____"; and the transcript of the May 11, 2006 Hearing will be cited as "Tr. 2 at ____".

⁵ Inadvertently, the transcripts were not filed in both cases. The Clerk's office corrected that error on December 12, 2007.

Initially, this case presented factual issues that required resolution prior to addressing the medical causation issues presented. A factual hearing was conducted on September 27, 2004 addressing the factual issues presented. See Transcript of September 27, 2004 Hearing. At that hearing, petitioners, Greg and Helen Hopkins, testified as fact witnesses. On February 9, 2005, the undersigned issued a Factual Determination for Finn. Finn Hopkins v. Sec’y of Dept. of Health & Human Servs., No. 00-746V (Fed. Cl. Spec. Mstr. Feb. 9, 2005 [hereinafter “Finn slip op. at ___”]). In summary, the undersigned found that in the case of Finn, the timing of his hearing loss was problematic. The parents testimony disclosed “no clear demarcation when Finn’s hearing loss began” given that the parent’s concern about Finn arose from his sister’s, Ruby’s, hearing loss problem. Finn slip op. at 11. Accordingly, the undersigned concluded that “the exact timing or even a reasonable approximation of the onset of Finn’s hearing loss is unknown.” Id.

Subsequently, petitioners continued to pursue Finn’s case. Expert reports were filed by petitioners, followed by responsive expert reports from respondent. Live testimony was taken from the experts at an April 14, 2006 Hearing, and at a telephonic Hearing conducted on May 11, 2006. The parties filed post-Hearing briefs. The case is now ripe for decision. After considering the entire record, the undersigned concludes that petitioners are not entitled to compensation. The undersigned’s reasoning follows.

II. FACTUAL BACKGROUND

The following is a condensed version of the undisputed facts for Finn Hopkins.⁶

Finn was born on May 15, 1997. An Elmendorf Air Force Base (“AFB”) Emergency Care & Treatment record notes that Finn was seen for a viral illness, with symptoms of fever and bulging fontanelle at six months of age in November 1997. P Finn Ex. 1 at 15.⁷ At this time, Finn’s ears were examined and noted to be “mild, red but no significant/obvious OM [otitis media].” Id. On June 1, 1998, Finn visited his pediatrician with a one month history of cough and sinus congestion. Id. at 14. Finn was diagnosed with clinical sinusitis, with his pediatrician noting that RAD (reactive airway disease) should be considered if the cough persists. Id.

A “Deployment/Travel Medicine Questionnaire,” dated December 9, 1998, identifying Finn as a patient, notes proposed recreational travel to Thailand. P Finn Ex. 3 at 22. Various vaccinations were required for travel to that country, and Finn was referred to the immunization

⁶ These facts are taken from the undersigned’s February 9, 2005 unpublished Factual Determination rendered in Finn’s case.

⁷ Citations to the record for Finn will be made by first referencing the party submitting the information, respondent or petitioner, and then to the case name, Finn. Thus, a record submitted by petitioner in Finn’s case will be cited as “P Finn Ex. ___.”

clinic. Id. On December 10, 1998, Finn received the HIB/DTP and OPV vaccines at the Elmendorf Air Force Base (“AFB”). P Finn Ex. 3 at 26, 28.

A treatment note of A. John Caeton, M.D., dated March 8, 1999, reports that Finn was seen for a, possibly viral, upper respiratory infection with intermittent fever over the past several days. P Finn Ex. 11. Finn was noted to be combative and hard to examine. Id. Dr. Caeton examined Finn and reported that his TMs looked “gray,” his nose was not draining and his pharynx and lungs were “negative.” Id. Linear markings on Finn’s back were noted to be the apparent stings from a jellyfish he received on the family’s recent trip to Thailand. Id. Dr. Caeton prescribed over the counter treatments as needed for Finn’s upper respiratory infection. Id.

On March 23, 1999, Finn’s hearing was evaluated by audiologist, Ms. Joyce F. Sexton, at his parent’s request because: “1. His speech was difficult to understand and he seemed to be slow in acquiring new words [and] 2. His sister has recently been diagnosed with a hearing loss of unknown etiology and his family wanted to determine if hearing was any concern for Finn.” P Finn Ex. 8 at 47, 49. It was noted that Finn’s history included “not talking clearly - babbles, jargon, seems to hear (parents notice) picked up a few new words on vacation.” Id. at 49. On examination, Finn’s TMs were clear and tympanometry was normal.⁸ Id. Otoacoustic (“OAE”) emissions testing was unable to be performed on Finn because he was so active during the evaluation. Id. However, during a visit on April 1, 1999, Finn’s OAE testing was completed on Finn while he was asleep. Id. at 47. This testing revealed no emissions for either ear suggesting abnormal cochlear function. Id. It was recommended that Finn be examined by an ENT to rule out any medical concerns that could be affecting his hearing. Id. On May 11, 1999, Finn underwent additional audiometric testing at the Alaska Native Medical Center. P Finn Ex. 1 at 18-19. This testing showed a moderate SNHL in Finn’s left ear and moderately severe SNHL in the right ear. Id. at 19. It was recommended that Finn follow-up with the Elmendorf AFB ENT program. Id.

On May 13, 1999, Finn was evaluated by Randall Ow, M.D. at the Elmendorf AFB Otorhinolaryngology Clinic. P Finn Ex. 1 at 9. It was noted that Finn had a sibling with suspected progressive bilateral SNHL. Id. It was further noted that Finn does try to speak, but used to dance to music and now does not. Id. The diagnostic assessment was “prob[able] hereditary hearing loss.” Id. Finn was referred to TRICARE for amplification studies, speech therapy and periodic audiometric evaluations. Id.

On June 24, 1999, Finn’s blood was drawn for a deafness DNA screen. P Finn Ex. 1 at 79. A report from this testing revealed that while “[n]o mutations were detected in the CX26

⁸ Tympanometry is the indirect measurement of the compliance (mobility) and impedance of the tympanic membrane and ossicles of the middle ear; it is done by subjecting the tympanic membrane to different levels of air pressure. DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1779 (27th Ed. 1988).

gene[,] this is still consistent with a clinical diagnosis of autosomal recessive nonsyndromic deafness (ARNSD) attributable to the CX26 (or DFNB1) locus because this test does not detect all possible mutations.” Id.

On July 20, 1999, Finn and his sister, Ruby, were evaluated by Phillip Massengill, M.D., an otolaryngologist at the Madigan Army Medical Center. P Finn Ex. 1 at 63-68. Dr. Massengill reported that Finn’s family history was negative for any type of genetic hearing loss and that there is no known etiology for his SNHL. Id. at 63. Dr. Massengill also noted Finn’s parents felt he had normal hearing prior to receiving the December 1998 vaccinations. Id.

On July 23, 1999, Finn and Ruby underwent a comprehensive clinical genetics evaluation by Mark J. Stephan, M.D. P Finn Ex. 1 at 104-106. Dr. Stephan reported that Finn’s parents reported that Finn seemed normally responsive to sounds and developed about twenty words in expressive speech by approximately nineteen months of age. Id. at 104. On December 11, 1998, Finn received a DPT immunization from the same vaccine batch as his sister. Id. His parents reported no unusually toxic reaction to the vaccine during the week following administration. Id. On May 11, 1999, Finn was diagnosed with SNHL and fitted with hearing aids. Id.

Dr. Stephan concluded that Finn suffered from bilateral SNHL. P Finn Ex. 1 at 106. His impression was that “this represents an autosomal recessive non-syndromic auditory deficit in the siblings.” Id. Dr. Stephan added that he knew “of no other previous reports of hearing loss developing after a DPT immunization.” Id.

Dr. Stephan noted a family history of auditory deficit. P Finn Ex. 1 at 105. Specifically, he reported that Ms. Hopkins’ auditory evaluation detected a very mild auditory deficit in the high frequency range only. Id. Further, Ms. Hopkins reported a paternal uncle with hearing loss associated with multiple bouts of otitis media as well as a maternal uncle with adult onset hearing loss. Id. Mr. Hopkins reported that his father suffers hearing loss of adult onset second to artillery noise. Id. Dr. Stephan noted that he discussed autosomal recessive inheritance with Finn’s parents in the event they contemplated having more children. Id. at 106. He explained that the risk of Finn or Ruby having children with a hearing impairment will depend on the history of hearing impairment in their future spouses. Id.

A VAERS report submitted for Finn by Thad L. Woodard, M.D. of Alaska Center for Pediatrics indicates that Finn suffered SNHL, which was first noticed after his December 11, 1998 vaccination. P Finn Ex. 3 at 6. The adverse event onset date is illegible. Id. On August 20, 1999, in a subsequent letter to VAERS, Dr. Woodard reported that genetic evaluations of both siblings have been completed and no genetic origin has been discovered. P Finn Ex. 3 at 18. Although he did not believe that the DPT vaccine is the likely cause of the “coincidental hearing loss,” Dr. Woodard noted that “we do not have any other explanation.” He went on to state that it is his “understanding that about 50% of genetic causes of hearing loss can be documented by current genetic testing which leaves approximately 50% with a presumed genetic origin.” Id.

A medical record, dated September 9, 1999, from Bruce T. Hewett, M.D., at the Elmendorf AFB pediatric clinic notes, “genetic testing preliminary pos [sic] for genetic mutation for neurological hearing loss.” P Finn Ex. 1 at 57. A note on October 7, 1999 reports that Dr. Hewett “discussed hearing mutation genetic results” and arranged for a teleconference to be held with Dr. Stephan. Id. at 53.

III. DISCUSSION

A. Summary of The Experts’ Positions

Dr. Creagan

Dr. Creagan’s expert report for Finn was filed as P Finn Ex. 35. Dr. Creagan’s CV was filed as P. Finn Ex. 33. Dr. Creagan is board certified in emergency medicine. After conducting extensive voir dire, respondent’s counsel objected to Dr. Creagan being offered as an expert in genetics and vaccinology, but did not object to him being offered as an expert in the field of emergency medicine. Tr.1 at 34. Dr. Creagan’s opinion was based upon his review of Finn’s medical records and his review of the relevant medical literature. P. Posthearing at 6. During the hearing, the undersigned stated that Dr. Creagan undoubtedly was qualified to review and discuss the medical literature, but had serious doubts as to his giving an opinion on the role of vaccines as the cause of Finn’s hearing loss. Tr.1 at 35-36.

In short, Dr. Creagan testified that vaccines are designed to evoke an immune response and that immune mechanisms can cause hearing loss. Tr.1 at 38. Vaccines produce cytokines, cytokines produce hearing loss. Id. at 54. He believes the vaccine stimulated an abnormal immune response and caused Finn’s hearing loss. Id. at 46. In addition to the hearing loss being immune mediated, Finn was genetically susceptible to hearing loss which was triggered by the vaccine. Id. at 58.

At this point, the undersigned will discuss Dr. Creagan’s qualifications and why it is not necessary to discuss his testimony or written opinion. As noted above, Dr. Creagan is not board certified in otolaryngology or neurology. He has never treated or diagnosed children with SNHL. Tr.1 at 16-36. While the undersigned agreed that as a medical doctor, Dr. Creagan has the training to review and discuss the medical literature, he does not have the training, experience, or qualifications to ascribe the cause of the children’s hearing loss to their vaccinations. His testimony reflected this lack of relevant knowledge. Moreover, Dr. Creagan’s testimony is unhelpful to the proceedings because, as will be discussed later, the experts agreed on the key issues in the medical literature *i.e.*, the medical theory of autoimmune response and genetics. The remaining issue was the temporal relationship. Dr. Creagan’s testimony adds nothing to this determination because the crux of his testimony was the medical theory to which there is no disagreement. His testimony regarding the timing of onset was pure speculation. Id. at 52-62.

Finally, the undersigned gives little weight to Dr. Creagan's testimony because he was not an objective medical expert witness. According to the American Academy of Emergency Medicine, of which Dr. Creagan was a Fellow from 1997 to 2004, the medical expert has a duty to the court in which he must "impartially assist the Court . . . on relevant matters within the expert's area of expertise; [and] not advocate for the party who engages him or her as an expert witness" American Academy of Emergency Medicine Position Statements, available at <http://www.aaem.org/positionstatements/ethicalexpert.php> (last visited Jul. 24, 2007). Clearly, Dr. Creagan was an advocate for petitioners. In his expert report, Dr. Creagan states "we have injury and damaged lives" with regard to Finn. P Finn Ex. 35 at 13. He then goes on to state that if the Vaccine Program does not compensate petitioners he "will be very willing to support claims against the system that did cause them great harm in the next appropriate venue." Id. Further, during the hearing Dr. Creagan referred to what happened to Finn as a "tragedy." Tr.1 at 38. Dr. Creagan's testimony and opinion was not impartial, not within his area of expertise, and not objective. The undersigned was not impressed with Dr. Creagan and gave virtually no weight to his testimony.

Dr. Tornatore

Dr. Tornatore's expert report for Finn was filed as P Finn Ex. 16, and his supplemental report was filed as P Finn Ex. 34. His CV can be found attached to his expert report. See P Finn Ex. 16. Dr. Tornatore testified that the vaccine caused the hearing loss in Finn. He explained in his testimony that the medical theory is an "autoimmune-mediated hearing loss." Tr.1 at 98. Dr. Tornatore reviewed the medical literature submitted by the parties and showed how this literature supported his theory that a vaccine can cause an autoimmune reaction which can lead to the loss of hearing. See Tr.1 at 98-114. While Dr. Tornatore recognized that there could be a genetic component to the loss, based upon the submitted literature, he contended that the hearing loss is triggered by an environmental component. See Tr.1 at 111-114;117. Accordingly, in this case the vaccine operates as the environmental trigger, and thus, "we have a logical sequence of causing events." Tr.1 at 117. Lastly, based upon the parents' testimony and the letters submitted from three therapists, there is an appropriate time frame present for an autoimmune process in this case - "[p]robably between two and three weeks because there has to be some processing of the antigen." Tr.1 at 124. In summary, Dr. Tornatore stated that the acuteness of the hearing loss in this case "really speaks to an environmental cue. The only thing that changed in their environment was the vaccination, and that's a very reasonable environmental cue that makes sense in this context." Tr.1 at 125.

Dr. Raymond

Dr. Raymond's expert report was filed in Finn's case as R Finn Ex. E, and his CV was filed at Ex. F. Dr. Raymond's supplemental report was filed as R Ruby Ex. F, but was not filed in Finn's case. Dr. Raymond testified without objection, Tr.1 at 190, as an expert in pediatric neurology and clinical genetics. His opinion was consistent with Finn's treating doctors that Finn's hearing loss was genetically based, specifically autosomal recessive nonsyndromic hearing

loss. R Finn Ex. E at 3. Addressing the timing of Finn’s hearing loss, Dr. Raymond wrote in his report and testified consistent thereto that there is no objective evidence of Finn’s hearing loss until he undergoes hearing testing four months following his immunizations. R Finn Ex. E at 8. Dr. Raymond concludes that “[i]t is my opinion within a reasonable degree of medical certainty that Finn Hopkins is a boy with autosomal recessive nonsyndromic hearing loss and that neither his disease nor subsequent course were caused by the immunizations received.” R Finn Ex. E at 10.

Dr. Mankarious

Dr. Mankarious’ expert report was filed for Finn at R Finn Ex. A. Dr. Mankarious’ CV was filed at R Finn Ex. B. Dr. Mankarious’ opinion and conclusions are that “[t]here are no known cases of sensorineural hearing loss due to DPT, oral polio or HiB vaccines;” that the family history “is much more closely associated with an autosomal, recessive genetic mutation responsible for hearing loss;” and that it is likely that Finn had a pre-existing “mild sensorineural hearing loss” prior to their immunizations. R Finn Ex. A at unnumbered page 2. Dr. Mankarious testified consistently with her report. As discussed below, the undersigned relied heavily on Dr. Mankarious in resolving this case.

B. Legal Standard

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.⁹

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Petitioners do not allege a table injury. Thus, petitioners must prove that the vaccine caused-in-fact Finn’s injuries, a so-called “off-Table” case.

To demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Sec’y of Dept. of Health & Human Servs., 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Sec’y of Dept. of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Sec’y of Dept. of Health & Human Servs.,

⁹ A preponderance of the evidence standard requires a trier of fact to “believe that the existence of a fact is more probable than its nonexistence before the [special master] may find in favor of the party who has the burden to persuade the [special master] of the fact’s existence.” In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J. concurring) (quoting F. James, CIVIL PROCEDURE, 250-51 (1965)). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984).

956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, “[petitioners must] show a medical theory causally connecting the vaccination and the injury.” Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Sec’y of Dept. of Health & Human Servs., 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Sec’y of Dept. of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Sec’y of Dept. of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Sec’y of Dept. of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by “[a] reputable medical or scientific explanation” which is “evidence in the form of scientific studies or expert medical testimony.” Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.¹⁰ See also H.R. Rep. No.

¹⁰ The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also cautioned about rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication “does *not* necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” Daubert, 509 U.S. at 594. However, the Supreme Court’s only guidance to lower courts in determining the reliability of a novel proposition is that

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Althen, 418 F.3d at 1280 (“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.”); see also, Gall v. Sec’y of Dept. of Health & Human Servs., No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec.

(continued...)

99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

While petitioners need not show that the vaccine was the sole or even predominant cause of the injury, petitioners bear the burden of establishing “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. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation”)); Hodges, 9 F.3d at 960. Finally, petitioners do not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

In Althen v. Sec’y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioner’s burden is to produce “preponderant evidence” demonstrating: “(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 the vaccination and injury.” The Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Id. at 1281. The Federal Circuit concluded that to support petitioners theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioners submit “objective confirmation,” such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec’y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter “Capizzano III”]. Moreover, the Federal Circuit stated, “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.

The Federal Circuit affirmed Althen’s three-part test in Capizzano III and most recently in Pafford v. Sec’y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). The panel

¹⁰(...continued)
Mstr. Oct. 31, 1999).

in Pafford, however, explained that the three prongs in Althen “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford, 451 F.3d at 1355. Fairly interpreted, the Pafford court held that it is petitioner’s burden to rule out other competing possible causes of the injury in establishing that the vaccine was the “but-for cause of the harm.” Id. at 1355, 1357; see also Althen at 1281. (“[T]he elimination of other causes [] is merely a recitation of this court’s well-established precedent.”). But see, Walther v. Sec’y of Dept. of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (“[W]e conclude that the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes when the other evidence on causation is sufficient to establish a prima facie case.”).

However, the legal requirement that a petitioner support her proposed causation theory with a “sound and reliable medical or scientific explanation” is undisturbed. Knudsen, 35 F. 3d 543, 548 (Fed. Cir. 1994); see also Grant, 956 F.2d at 1148 (“A reputable or scientific explanation must support this logical sequence of cause and effect.”). Thus, when considering the evidence in a case, the special master is to “consider all relevant and reliable evidence, governed by the principles of fundamental fairness to both parties.” Vaccine Rule 8(c); see also DeBazan at n12 (“A special master assuredly should apply the factors enumerated in Daubert in addressing the reliability of an expert witness’s testimony regarding causation.” citing Terran v. Sec’y of Dept. of Health & Human Servs., 41 Fed. Cl. 330, 336 (1998)); Campbell v. Sec’y of Dept. of Health & Human Servs., 69 Fed. Cl. 775, 781. (Althen’s requirement of a “reputable medical or scientific explanation” “[l]ogically [] requires a special master to rely on reliable medical or scientific evidence”); Manville v. Sec’y of Dept. of Health & Human Servs., 63 Fed. Cl. 482, 491 (Fed. Cl. 2004) (“Daubert adequately serves the gatekeeping function for analysis of the admissibility of evidence; once evidence has passed that test, the trier of fact’s process, simply, is to determine the probativeness of that evidence.”). Finn’s case is measured against these standards.

C. Analysis

The record for this case is voluminous. It contains over 40 medical articles discussing very difficult issues pertaining to hearing loss, autoimmune processes and genetics. There was much discussion, debate and disagreement regarding the proper interpretation and application of those articles to this case. However, for purposes of deciding Finn’s case, it is unnecessary to delve deeply into those disputes. That is because the experts agreed on several of the key issues covered in the submitted medical literature. In fact, what is usually the primary and most contentious issue in vaccine causation-in-fact cases - 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. See Tr.1 at 98, 198, 226; Tr.2 at 16.¹¹ Also, the experts agreed

¹¹ Dr. Mankarious explained autoimmune inner ear disease as the following:

(continued...)

that genetics play a significant role in SNHL cases. See Tr.1 at 111-13,117, 191-95; Tr.2 at 9. These two areas of agreement eliminate the need to discuss a substantial portion of the medical literature and testimony submitted in this case. Then where is the disagreement?

The central issue for resolution of this case revolves around the issue of timing - when did Finn begin to lose his hearing. This is a critical element of the Federal Circuit's test of causation - "a showing of a proximate temporal relationship between the vaccination and injury[]" Althen, 418 F.3d at 1278, and is the crux of the dispute in this case. Respondent argues through his expert that there is really no reliable way to time the onset of Finn's hearing loss. Timing is problematic because the experts agreed that one can suffer from as much as a 40 decibel hearing deficit and still acquire normal speech. See Tr.1 at 160; Tr.2 at 13. Thus, in children, the accurate determination of when the hearing loss began is extremely difficult. See Tr.1 at 220-221 (Dr. Raymond stating that based upon the records he could not "time when Finn's hearing loss came about."); Tr. 2 at 21. (Dr. Mankarious testifying that "you can't state that the hearing loss was identified at a specific time" for Finn); see also P Finn Ex. 34 (Dr. Tornatore stating that "[h]earing loss in an 18 month old can never be precisely timed to an inciting event given that the moderate loss of function could easily be missed by even the most attentive parent.") Petitioners on the other hand argue that there is no indication of hearing problems prior to the vaccination. Coupling the lack of hearing loss evidence with literature supporting the need for an environmental trigger to activate the genetic predisposition for hearing loss, petitioners argue that the only environmental trigger in this case is the vaccination. However, in the final analysis, it is the undersigned's determination that petitioners failed to establish this key factual predicate - the timing of onset - which requires a finding against petitioners in Finn's case.

Prior to discussing the timing issue, the undersigned notes that the credibility of the experts is unusually important in these particular cases; unusual in the sense that what looks to be a straightforward factual determination, actually turns on critical information provided by the experts. Thus, the experts' explanations and interpretations of information contained in the medical records were determinative of the issue of whether one can determine more probably than not when the hearing loss occurred in Finn. On these critical interpretive issues, the

¹¹(...continued)

Autoimmune inner ear disease is a term that was originally proposed by Brian McCabe in 1979. He's also from the University of Iowa. He found a population of patients who had antibodies directed against a specific inner ear protein which he called the 68 kilodalton protein and this was a protein that was only isolated from the inner ear. The term has evolved now to include all forms of hearing loss which are thought to be immune-mediated or have an inflammatory/autoimmune basis and we often make the diagnosis when a patient responds to steroid therapy rather than actually have a serologic or blood test that can be used to identify it.

undersigned found Dr. Mankarious' testimony vastly superior.¹² In contrast, the undersigned gave far less weight to Dr. Tornatore's testimony, and gave virtually no weight to Dr. Creagan's.

In deciding vaccine cases, the undersigned avoids as much as possible resolving cases based upon a straight comparison of the experts' training and experience, but instead hews toward weighing the strength of the explanation and support put forth by the expert, *i.e.*, the reliability. See Terran, 41 Fed. Cl. 330, 336. However, in this case, the disparity between the experts, primarily Dr. Tornatore and Dr. Mankarious, in terms of knowledge, training, research and experience, is so great that the undersigned was persuaded beyond any doubt to find any disputed issues of SNHL in favor of respondent based upon Dr. Mankarious' testimony.

There is no doubt that Dr. Tornatore is a qualified neurologist. See Tr.1 at 94-6; see also P Finn Ex. 16 (CV attached to expert report.) However, when asked about his experience with SNHL, Dr. Tornatore responded that he has diagnosed one case in a child during his nearly 20 year professional career. Tr.1 at 151-52. The contrast with Dr. Mankarious is striking. Dr. Mankarious' updated CV was filed as R Finn Ex. AAAA. She is a board-certified otolaryngologist, and specializes in pediatric otolaryngology, for which there is no board certification. Tr.2 at 6. She explained that otolaryngology is the study of ear, nose and throat disorders. Id. She sees an estimated 300-400 children with hearing loss per year, and sees these children multiple times over the years for return treatments. Id. at 7. Dr. Mankarious is currently an assistant professor of otology and laryngology at the Harvard School of Medicine and the Massachusetts Eye and Ear Infirmary. Id. at 6. The disparity on paper between Dr. Mankarious and Dr. Tornatore was manifest in the quality of their testimony. As will be discussed further, Dr. Tornatore's testimony was of dubious quality. Dr. Mankarious on the other hand evinced a clear and deep understanding of the medicine at issue, which she explained and supported with examples from her hands-on research and clinical experience with patients. Overall, Dr. Mankarious' testimony was marked by the self-confidence expected from someone with superior knowledge and experience. That superiority was noted by the undersigned and duly credited.

This credibility gap based upon a CV comparison became a cavern with Dr. Tornatore's testimony. As will be discussed later, see pages 24-26 infra, putting credentials aside, the undersigned was not impressed with the quality of Dr. Tornatore's testimony in this case. Dr. Tornatore opined on how the vaccines caused the hearing loss in Finn. In doing so, he used highly selective pieces of medical literature and factual information from each case to support his opinion. Dr. Tornatore is undoubtedly a well-trained quality physician; however he can be, in the undersigned's experience, at times, a questionable expert. In supporting his opinion, he weaves together one questionable piece of evidence together with another to create a piece of medical tapestry that to the untrained eye -the undersigned's - appears superficially enticing. But while the untrained eye detects potential flaws in the fabric, the trained eye of Dr Mankarious uncovers

¹² The undersigned was also impressed with the testimony of Dr. Raymond. However, the most weight was given to Dr. Mankarious' testimony.

clear and critical defects.

In the final analysis, this case fails because the foundational facts for Dr. Tornatore's opinions, the appropriate timing for the onset of the hearing loss is rejected. Without those foundational facts, Dr. Tornatore's opinion must fail. Mahaffey v. Sec'y of Dept. of Health & Human Servs., 2003 WL 22424989 at *5 (Fed. Cl. Spec. Mstr. May 30, 2003) (holding that the "case fail[ed] for a lack of a factual predicate for the medical opinion"). In addition, the undersigned finds that even if the appropriate temporal relationship was established, petitioners failed to establish a logical sequence of cause and effect between the vaccinations and Finn's hearing loss. Finally, the undersigned finds the testimony of Drs. Tornatore and Creagan to be of dubious quality and thus, finds their testimony not credible. Each of these findings will be discussed in turn.

1. Timing of Onset

As Dr. Tornatore noted, the timing issue is problematic for Finn. Tr.1 at 125. As Dr. Tornatore agreed, detecting hearing loss in an 18-month old is "hard to tell" because their speech and language skills are in the formative stages. Id. To establish the factual predicate for his opinion, Dr. Tornatore relied upon "two prongs" - the paraclinical professionals and the parents' observations - for his factual information.¹³ Regarding the parents, Dr. Tornatore noted that following the vaccinations "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 nearly as well characterized as Ruby. . . ." Tr.1 at 126. This is the extent of Dr. Tornatore's testimony regarding his reliance upon the parents for support for the timing of onset. Id. The undersigned notes that the parents' testimony was rejected in the factual ruling. Finn slip op. at 11.¹⁴

¹³ Dr. Tornatore offered a third "prong," that this is a case of challenge-rechallenge. Tr.1 at 125. See Capizzano I, 2004 WL 1399178 at *2 ("rechallenge cases are such strong proof of causality that it is unnecessary to determine the mechanism of cause-it is understood to be occurring"). He later conceded that he was incorrect. Tr.1 at 141.

¹⁴ On July 28, 2006, petitioners filed along with their posthearing brief several exhibits. See P Finn Ex. 39-43. These filings consisted of affidavits from Ruby's and Finn's maternal grandmother, an audiologist's report of Helen Hopkins (Ruby's and Finn's mother), and a statement from Patty Hoffman, a speech pathologist. It is inappropriate for petitioners to submit these exhibits as part of their posthearing memorandum. The evidentiary record in this case was closed after the testimony of respondent's expert, Dr. Mankarious, on May 11, 2006. The purpose of posthearing briefing is for the parties to wrap up all of the evidence presented in this case, not to submit new evidence.

Petitioners submit this evidence, apparently, to rebut Dr. Mankarious' testimony regarding petitioners' family history of hearing loss. See P. Posthearing Reply at 6. Petitioners argue that the affidavits from Helen Hopkins' mother is "evidence that removes the very underpinnings of Dr. Mankarious' opinion." Id. Presumably, petitioners are arguing that Dr. Mankarious' opinion about a genetic basis for hearing loss is based solely on the family history. This is not what Dr. Mankarious testified to, and petitioners' reference to the quote from page 35 of Transcript 2 (incorrectly cited by petitioners as page 33) in petitioners' brief in support of this is in fact the opposite. Dr. Mankarious testified that her

(continued...)

Thus, Dr. Tornatore moved to discussing the three paraclinicians. See Tr.1 at 126. The first is an e-mail from Cynthia Ryan dated April 4, 2005. P Finn Ex. 27. Dr. Tornatore did not discuss this e-mail. The note is of questionable utility as there is minimal discussion and concludes with the general finding that “[m]ost children” who experience hearing loss from birth demonstrate “large delays in both expressive and receptive language.” Id. Since Dr. Tornatore did not discuss this e-mail, it cannot be given weight in considering his opinion. The second letter Dr. Tornatore relied upon is the April 1, 2005 letter from Lisa Owens, Speech-Language Pathologist/Audiologist. P Finn Ex. 28; the same letter is replicated at P Finn Ex. 31. However, when questioned by the undersigned regarding the utility of the letter, given that Ms. Owens qualified her statements with “may,” - as in “This may suggest that he had heard these sounds and may have a progressive or later onset hearing loss” - Dr. Tornatore concluded that “I think this is the least helpful letter . . .” Tr.1 at 128. Thus, the factual support Dr. Tornatore offered for Finn’s case that began with the parents’ testimony and the support of three paraclinicians, was quickly reduced to one paraclinician, since the undersigned had previously rejected the parents’ testimony regarding Finn, Finn slip op. at 11, and Dr. Tornatore effectively eliminated two of the three paraclinicians by not discussing one and conceding that the other was the “least helpful.”¹⁵

The one remaining letter Dr. Tornatore relied on was from Patty Hoffman, an Elementary School Speech Pathologist, dated April 1, 2005. P Finn Ex. 29. Based upon her assessment of

¹⁴(...continued)

opinion in this case “is based upon the fact **partially** that Helen Hopkins and her sister have genetic hearing loss . . .” Id. (emphasis added). Dr. Mankarious’ opinion was also based upon numerous other factors. See R. Posthearing brief at 18 n. 9. It should be also noted that Dr. Mankarious’ opinion is consistent with Finn’s treating doctors.

Finally, it is unnecessary to discuss and address the contents of these untimely filings because the undersigned’s decision is not based upon a finding of a genetic cause. Moreover, petitioners failed to meet their burden under the Act, and therefore, the burden to prove a factor unrelated never shifted to respondent. Thus, it is not necessary to discuss whether respondent met his burden to prove an alternate cause. See Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994); see also Walther v. Sec’y v. Health & Human Servs., 485 F.3d 1146, 1152-53 (Fed. Cir. 2007).

¹⁵ Dr. Mankarious raised serious issues regarding these letters. She stated:

I think that they’re fairly suspicious to me the way that the information is being presented. It’s as if it’s being presented in preparation for a legal case. The speech pathologists don’t usually try to ascribe causation, nor do they usually try to ascribe the timing of the loss. They simply make an assessment, determine where the child is in relationship to where they should be and then make recommendations for environmental improvements or speech and language services. They usually do not so clearly try to prepare an opinion as if it’s going to a legal case and these speech pathologists have done that. So they’re somewhat suspicious that the family has somehow befriended them and tried to get them to write on their behalf, which is fine, but you just have to take it with a grain of salt. This is not the typical speech pathology report.

Tr.2 at 63; see also id. at 65. There is support for Dr. Mankarious’ concerns. Reviewing Joyce Sexton’s March and April 1999 evaluation reveals none of the conclusions reached in her 2005 letter. Compare P Finn Ex. 8 at 47 with R Finn Ex. 32.

Finn's testing, Ms. Hoffman offered this critical observation:

In general, his receptive 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., 4-8 months) mirrors the approximate time frame between when Finn incurred the hearing loss and when he was fitted with aides and began receiving early intervention services (i.e., about 6 months).

Id. at 5. Since Finn was 36 months at the time of the testing, and had language skills of a 24-28 month old, Dr. Tornatore reasoned that his language delay was 4-8 months. Dr. Tornatore takes this "interesting" observation that the 4-8 month delay in language "mirrors the approximate time frame" when Finn lost hearing and was fitted with hearing aides and draws the conclusion that "what they are pointing out here is there was a six-month delay." Tr.1 at 134. The undersigned was extremely skeptical of Dr. Tornatore's use of Ms. Hoffman's data, and expressed that skepticism. Tr.1 at 134-140. For example, the undersigned questioned the use of a range of months to pinpoint the date of onset with the vaccination. Dr. Tornatore responded that "we have to **assume** that when he got his hearing aids is when he starts acquiring language correctly" and since he got his hearing aids in June, 4-8 months takes you back to November (before the vaccination) or to December/January (the dates of the vaccinations). Tr.1 at 137 (emphasis added).

How does Dr. Tornatore determine if the hearing loss was before or after the vaccination? Easy, Dr. Tornatore stated: "we go back to Ruby, [Finn's older sister] if we accept that her hearing loss was acute because she had no loss - hers was very clear, the abrupt onset - if we accept both children had a hearing loss, and both of them had the same etiology for it . . ." Tr.1 at 137-38. Thus, Dr. Tornatore's opinion is based upon the correctness of utilizing the range of language delay 4-8 months as coincident with one's hearing loss and adds in Ruby's "acute" hearing loss and the "abrupt onset" to determine that the timing for Finn's hearing loss was the same. Dr. Tornatore presented no evidence to support this supposition and in fact made no effort in his testimony to explain or defend this use of the data. Thus, when the undersigned queried why we should accept Dr. Tornatore's thesis, his response was "as the previous articles showed, there has to be a trigger that causes the hearing loss, and here we have the clear trigger in the sister, and in the brother we have to assume whatever the triggers are, whatever the genetic background is, that they are comparable. **Again, I'm trying to use the data that we have to get us back to that November-December-January timeframe.**" Tr.1 at 139 (emphasis added). This bootstrapping argument strikes the undersigned as highly questionable expert testimony. Dr. Mankarious' highly credible testimony also rejected Dr. Tornatore's opinion.

The factual basis for Dr. Tornatore's opinion was highly questionable to the undersigned even before Dr. Mankarious testified. Dr. Tornatore relied upon the parents' testimony despite the fact that he recognized that even with their special education training they may or may not pick up on a subtle hearing loss. Tr.1 at 163. And he relied on their testimony regarding Finn's loss of hearing despite the fact that the undersigned rejected that testimony. Finn slip op. at 11.

The other factual information taken from the paraprofessionals was just as questionable. Ms. Ryan was not discussed by Dr. Tornatore and Ms. Owens was seen as the “least helpful.” Tr.1 at 128. That left Ms. Hoffman’s letter which the undersigned suspected Dr. Tornatore was misusing or extrapolating far too much from in reaching his conclusions. The undersigned’s suspicions were confirmed through Dr. Mankarious’ testimony.

Dr. Mankarious stated that we do not know if Finn’s sister, Ruby, had hearing loss before the vaccine. Tr.2 at 36. However, Finn most likely had hearing loss prior to the immunizations based upon the fact that “by the time he had his speech evaluation done he was already speech-delayed.” Id. Dr. Mankarious confirmed what the undersigned suspected - that it was improper for Dr. Tornatore to extrapolate from Ms. Hoffman’s report “that because he’s four to eight months behind . . . that means that he’s had a hearing loss for four to eight months.” Tr.2 at 36. She stated that she was a “little horrified” reading the transcript of Dr. Tornatore’s testimony calculating when the hearing loss occurred based upon how many months Finn was delayed. Tr.2 at 60. As Dr. Mankarious explained and emphatically stated “[t]he two have nothing to do with each other.” Tr.2 at 37. She explained that

That’s such false thinking. I really need to bring this out very strongly. 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 is 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. If he’s not very visual he’ll have an increased delay. He’ll be at the two-year level rather than closer to three year. If he has a lot of visual queues, in this case he was homeschooled so there isn’t going to be a lot of background noise, those two things would make him further advanced in his speech and language skills. So there’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.**

Tr.2 at 60-61 (emphasis added). As stated earlier, based upon Dr. Mankarious’ vastly superior training, experience and knowledge, and Dr. Tornatore’s lack of the same, the undersigned accepts Dr. Mankarious’ discussion and explanation of all aspects of hearing loss over Dr. Tornatore’s.

Dr. Mankarious explained from her clinical experience that a number of factors influence how delayed someone will be with a mild hearing loss. At this point it bears repeating that all of the experts, including Dr. Tornatore, agreed that one can have a mild hearing loss and still have normal speech. Dr. Mankarious stated that the degree of hearing loss affects the degree of one’s language skills. Other factors include the child’s cognitive ability, how many visual cues are used to compensate for the hearing loss, and, if homeschooled, the lack of competing background

noise. Tr.2 at 61; see also Tr.2 at 13, 37. What 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. However, 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.

Conclusion on Timing of Onset

In Pafford, the Federal Circuit found that "the Special Master's requirement for strong temporal evidence is consistent with the third prong of the *Althen* test: demonstrating a proximate temporal relationship between the vaccination and the injury." Pafford, 451 F.3d at 1358. The timing issue is especially critical here because the experts, including Dr. Tornatore, recognize the difficulty in detecting hearing loss in a young child. This is further complicated by the fact that "you can be born with completely normal hearing and develop hearing loss at any point in your life." Tr.2 at 11; see also Tr.1 at 203. One cannot predict when the hearing loss will occur. Tr.2 at 13. The fact that one can have mild hearing loss and still develop normal speech makes the detecting of onset of hearing loss without testing virtually impossible. That detection is complicated by the ability of children to compensate for their hearing loss by the use of other faculties. Finn was not tested for hearing loss prior to immunization.¹⁶ Thus, there are no medical records documenting normal hearing prior to the immunizations. Petitioners attempted to show no prior hearing loss through contemporaneous speech and language tests performed **following** the immunizations, and letters from those paraprofessionals 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 hearing loss and immunizations, and thus, failed to establish that the vaccines in-fact caused their hearing loss.

2. Logical Sequence of Cause and Effect

Even if petitioners had established the temporal relationship between Finn's hearing loss and immunizations, the undersigned would find that a logical sequence of cause and effect was not established. Such failure would also necessitate a finding against petitioners. The second part of the three-part test enunciated in Althen is that it is petitioners' burden to produce "preponderant evidence" demonstrating "(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. The link Dr. Tornatore relied upon to tie the medical theory of an autoimmune reaction to Finn's hearing loss was the environmental cue. See Tr.1 at 117.

¹⁶ If there was documented testing of normal hearing prior to vaccination, the result in these cases could have changed. See Tr.2 at 38.

Relying upon medical literature submitted by respondent, Dr. Tornatore contended that hearing loss “usually” has an environmental trigger, and in Finn’s sister’s case, Ruby’s, “the only environmental cue is the vaccine issued three weeks prior. So we have a logical sequence of causing events.” Tr.1 at 117. Dr. Tornatore stated that we have to “assume” that Finn had a comparable environmental trigger. Tr. 1 at 139. However, once again, Dr. Tornatore is overreading the medical literature to support his end result--the literature simply does not say all that Dr. Tornatore purports. Dr. Mankarious found Dr. Tornatore’s testimony on this point “amazing.” Tr.2 at 20.

Dr. Tornatore referenced respondent’s Finn Ex. AA discussing mitochondrial deafness and quoted a sentence on page 267 of that article which says that “a combination of environmental, mitochondrial, and nuclear factors can push a cell over a threshold” Tr.1 at 112. After discussing this sentence, Dr. Tornatore concluded that “so even if you have the genetic predisposition; this diagram shows that in some cases the environmental agent pushes you over to deafness.” Id. Obviously, the article stated that it was a “combination” of factors, but Dr. Tornatore concluded without explanation that it was the environmental component alone that is responsible.

Dr. Tornatore referenced two additional articles to show “that there are very strong genetic environmental relationships.” Tr.1 at 112. The first article, entitled “How to identify gene-environmental interactions in a multifactorial disease: CHD as an example,” did not involve deafness. R Finn Ex. NNN. Dr. Tornatore’s interpretation of the article is that “they are saying here that environment is a critical part in determining what may happen to you depending on your genetic background.” Tr.1 at 113. Finally, Dr. Tornatore referenced “Gene-environment interaction: a central concept in multifactorial diseases.” R Finn Ex. OOO. Dr. Tornatore referenced from the abstract the following:

There is now accumulating evidence that most of the susceptibility genes for common diseases do not have a primary aetiological role in predisposition to disease, but rather act as response modifiers to exogenous factors such as stress, environment, disease, drug intake.

Id. Dr. Tornatore took from the quoted language that “so even through 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.” Tr.1 at 113. The 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 Finn’s hearing loss. See Tr.1 at 117.

Dr. Raymond questioned Dr. Tornatore’s extrapolation from R Finn Ex. AA to the circumstances of this case stating that “this article is completely and specifically dealing with mitochondrial mutations.” Tr.1 at 206. Dr. Raymond later stated the individuals with mitochondrial 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.” Tr.1 at

212. Dr. Tornatore's rebuttal was unhelpful and unpersuasive: "just because it's on the mitochondria doesn't mean that the same thing couldn't happen in a gene elsewhere." Tr.1 at 170. Dr. Raymond is far more qualified to speak to this issue.

Dr. Mankarious was more forceful addressing Dr. Tornatore's testimony regarding the need for an environmental trigger. She 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 26 mutation.

Tr.2 at 20.

The need for an environmental trigger was Dr. Tornatore's link between the accepted medical theory--autoimmune response and the onset of hearing loss, *i.e.*, the logical sequence of cause and effect. While Dr. Tornatore insists that "there has to be a cause for the hearing loss," Tr.1 at 141, respondent's Finn Ex. U referenced by Dr. Tornatore found that out of 100 hearing impaired children, the causes for 55 of those children was unknown. Tr.1 at 142. Finally, when the undersigned questioned Dr. Tornatore about his assertions that an environmental trigger is needed, Dr. Tornatore did his version of the testifying two-step before finally stating that "as I previously stated, the evidence is that **most** of the genes" are triggered by an environmental factor. Tr.1 at 168-69 (emphasis added). See discussion, *infra* page 26 (Dr. Tornatore's varying interpretations for the need for an environmental trigger). Unfortunately, that is not what Dr. Tornatore said previously and is not supported by the submitted literature and most importantly is not supported by Dr. Mankarious. Petitioners failed to establish by preponderant evidence the need for an environmental cue for triggering hearing loss. The environmental cue was the lynchpin for Dr. Tornatore's opinion that the vaccines were the logical cause of Ruby's and Finn's hearing loss. Without the environmental cue, petitioners failed to show a logical sequence of cause and effect for Ruby's and Finn's hearing loss.

The Federal Circuit has instructed the 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.'" Capizzano, 440 F.3d at 1326. The treating doctors for Finn diagnosed, consistent with Drs. Raymond and Mankarious, a genetic cause for their hearing loss. While noting his sibling's "suspected progressive" SNHL, Dr. Ow's diagnostic assessment of Finn was "prob[able] hereditary hearing loss." P Finn Ex. 1 at 9.¹⁷

¹⁷ Dr. Ow, while recognizing the parents' concern over the relationship between the vaccines and hearing loss, (continued...)

On July 23, 1999, Finn underwent a comprehensive clinical genetics evaluation by Mark J. Stephan, MD. P. Finn Ex. 1 at 104-106. Dr. Stephan's impression was that "this represents an autosomal recessive nonsynchronic auditory deficit in the siblings." P. Finn Ex. 1 at 106. Dr. Stephan also states that "I know of no other previous reports of hearing loss developing after a DPT immunization and neither is Dr. Mary Fairchok of Pediatric Infectious Disease aware of any such reports or cases." Id.

Lastly, Dr. Stephan referred the cases to Dr. Richard Smith.¹⁸ Dr. Smith's conclusion was that "the history is . . . consistent with a clinical diagnosis of autosomal non-syndromic hearing loss due to mutations in another gene." P Ruby Ex. 1 at 60.¹⁹

As Dr. Raymond stated in responding to the question of what impact the treating doctors had on his opinion:

Those clinicians . . . are individuals who evaluated these children, who evaluate individuals with hearing loss, and felt, look, this complete saga is consistent with what we see in autosomal, recessive, nonsyndromic hearing loss.

Tr.1 at 199.

It is also important to note that the treating doctors did not believe that Finn suffered from an autoimmune process: petitioners' theory of how the vaccines caused the hearing loss. Not only did the treating doctors not mention such a process, more importantly they did not treat Finn for such a process. As Dr. Mankarious noted the treatment for autoimmune disorders is steroid treatment. Tr.2 at 31. Dr. Mankarious opined that "the fact that nobody else offered them steroids suggests that nobody else believed that this is an immune-mediated hearing loss." Tr.2 at 27. While defending her opinion that the hearing loss was due to a genetic cause, she stated that the family history of hearing loss is a meaningful factor for

the other physicians as well because nobody treated them with steroids. [Finn] saw at least three otolaryngologists and there was no treatment or even offering them of steroids.

Tr.2 at 51. Dr. Mankarious summarized this case succinctly in stating:

¹⁷(...continued)

felt that "in light of the significant family history of probable hereditary hearing loss, i[t] seems more likely that [Ruby's] condition represents a progressive hereditary sensorineural hearing loss." P Ruby Ex. 3 at 71-72.

¹⁸ Dr. Mankarious testified that she was a "disciple of Richard Smith for [her] pediatric otolaryngology fellowship. [Dr. Smith] was also part of [her] residency as well." Tr.2 at 6.

¹⁹ This exhibit was not filed in Finn's case but clearly references "both hearing-impaired children." P Ruby Ex. 1 at 60.

This is a very simple case. I see this every day. Multiple siblings within the same family affected. The mother is affected and the father has an M34T mutation. I see this all the time and nobody really calls into question the vaccine as the source of that hearing loss. So it's not the vaccine that's the issue it's just that this family's case presentation is very standard for what I see and would call a genetic hearing loss. I would not even have offered steroids to the children, given the family history. And also in support of that all the other treating physicians, all the other otolaryngologists, nobody offered the children steroids either.

Tr.2 at 26.

As the Federal Circuit has noted, and Drs. Mankarious and Raymond agreed, treating doctors offer a unique perspective on the history, assessment, and treatment of a disorder. This information can be critical to ascribing a causative role. The treating doctors had the history of the parents' concern about the vaccines' role, the lab data and other medical information before them, and they diagnosed Finn with a genetic cause. Critically important, as Dr. Mankarious noted, is that they did not diagnose or treat Finn for an autoimmune cause. In the face of this information, and in the absence of cogent information to the contrary, an effort to re-diagnose Finn several years after the fact must be accorded less weight than the contemporaneous medical records of their treating doctors. See DeRoche v. Sec'y of Dept. of Health and Human Servs., 2002 WL 603087 (Fed. Cl. Spec. Mstr. Jun. 6, 2002). More recently, in Capizzano v. Sec'y of Dept. of Health and Human Servs., 2006 WL 3419789 at *15 (Fed. Cl. Spec. Mstr. Nov. 8, 2006) [hereinafter "Capizzano IV"], the undersigned found that "[i]f as in this case, the treating doctors provide a consistent clinical picture that comports with the experts' medical theory, the treating doctors' opinions are as the Federal Circuit determined, 'quite probative'" (quoting Capizzano III, 440 F.3d 1317, 1326 (Fed. Cir. 2006)). In this case, the treating doctors viewed the case as respondent's experts, ascribing causation not to the vaccine but to a genetic cause. As Dr. Mankarious stated, autoimmune inner ear disease is very rare in children. She stated that her experience is consistent with that proposition, stating that "I have thousands of patients with hearing loss and only one with true autoimmune inner ear disease." Tr.2 at 30.

However, both Dr. Raymond and Dr. Mankarious were also adamant that the vaccines involved in this case do not cause hearing loss. Tr.2 at 18; Tr.1 at 210. As Dr. Mankarious stated, "we do not see hearing loss from those vaccines. So although you can speculate that there may be an association[,] in reality that doesn't exist. Nobody has hearing loss from those four vaccines. Not even in the medical literature. Not just in my practice, but not even in the medical literature." Tr.2 at 19.

Petitioners did reference several articles filed by respondent that discussed hearing loss following a number of vaccines, none of which were involved in this case. Dr. Tornatore referenced R Finn Ex. J. Dr. Tornatore read the title into the record, but mistakenly inserted "Hib B" for "hepatitis B vaccination." Tr.1 at 104. This is a critical error because Finn received the

Hib vaccination, they did not receive the hepatitis B. In any event, the article is not supportive of petitioners because it covered a different vaccination. Likewise, Dr. Tornatore referenced an article discussing the measles live virus vaccine. Tr.1 at 104. That vaccine is not at issue in this case. Dr. Tornatore conceded the critical difference between the live virus and the killed virus vaccines involved in Finn's cases. Tr.1 at 105. He also referenced another article discussing the hepatitis B vaccination and finally the mumps vaccination; neither of which was administered to Finn in this case. Tr.1 at 105-106.

The only literature discussing a vaccine given in the cases at issue was a case report involving a case from 1974. See R Finn Ex. MM. Dr. Tornatore conceded that it is the only literature discussing the vaccines at issue in this case. Tr.1 at 178. In that case, two days following the immunization the child became dizzy, had vertigo, could not stand properly and then "notice[d] loss of hearing and tinnitus in the right ear." See R Finn Ex. MM at 1. While Dr. Tornatore found support from this one case report, Tr.1 at 107-08, Drs. Raymond and Mankarious convincingly questioned its meaningfulness. Dr. Mankarious noted that this is an "anecdotal case report, it's incomplete in the sense that the investigators did not do family history, nor did they even do a patient history of previous hearing loss or a vestibular disorder" Tr.2 at 24-25. Dr. Raymond also noted the dissimilarities between the case report and Finn's case and the important lack of information of "familial occurrence." Tr.1 at 196. Most importantly, however, Finn exhibited no acute associated events as seen in the case report i.e., no vertigo or other signs of encephalopathy. Id. at 197. With such signs, Dr. Raymond "might have changed [his] opinion." Id. at 214.

The Federal Circuit recognized in Capizzano that:

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, 440 F.3d at 1327. That is the case at hand. Dr. Tornatore attempted to establish a logical sequence of cause and effect by showing that an environmental cue was necessary to trigger the genetic predisposition. That effort failed for the reasons discussed above. In addition, the cumulative weight of other evidence - the treating doctors' diagnoses, the treating doctors' treatment regimen, and the lack of any other reliable support for Dr. Tornatore's opinion - overwhelmingly militates in favor of rejecting a logical sequence of cause and effect between Finn's immunizations and their hearing loss.

Dr. Tornatore Was Not A Credible Witness

Lastly, the undersigned feels compelled to elaborate on Dr. Tornatore's credibility. Dr. Tornatore is clearly an able and accomplished physician; he is not, at least at times, a good

expert. The undersigned would like to give him the benefit of the doubt and attribute this to being overzealous in testifying for petitioner. For example, when pressed about his use of facts, Dr. Tornatore stated “we have to make a herculean effort to try to get this timing right.” Tr.1 at 131; see also Tr.1 at 139 (“I’m trying to use the data that we have to get us back to that November-December-January timeframe.”) Instead of objectively assessing medical information and based upon that information giving an unvarnished opinion, Dr. Tornatore takes it upon himself to advocate. This is not the role of an expert. See Kelley v. Sec’y of Dept. of Health & Human Servs., 2005 WL 1125671 at *7, No. 02-223V (Fed. Cl. Spec. Mstr. Mar. 17, 2005) (“As stated by the American Medical Association (‘AMA’): ‘The medical witness must not become an advocate or a partisan in the legal proceeding.’ AMA COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, Code of Medical Ethics (2002-2003 ed.), at 9.07 ‘Medical Testimony.’” Dr. Tornatore, however, appeared to make every effort, no matter how thinly supported, to advocate petitioner's position. It was unhelpful testimony for the court and ultimately unhelpful to petitioner”). While Dr. Tornatore’s motivation is irrelevant, the effect is not. The decision maker requires objective analysis of the relevant medicine as applied to the facts in the case. Unfortunately, Dr. Tornatore is caught far too often giving questionable slanted interpretations which leads the undersigned to question the reliability of the testimony and thus finding Dr. Tornatore not credible.

The undersigned has commented unfavorably on Dr. Tornatore’s efforts in the past. Kelley, 2005 WL 1125671 at *7; *7 n.13 (“While he is clearly well qualified, his testimony strayed from accepted medical principals into speculative, argumentative, and unsupported statements. The undersigned suspects that Dr. Tornatore misunderstood his role. [] In order to make ‘his’ case, Dr. Tornatore ignores the medical records and creates facts which support his assertions which, in themselves, are not based on his clinical practice or knowledge”). In fairness, Dr. Tornatore learned from that chastising and gave quality testimony (thus leading the undersigned to conclude that it is Dr. Tornatore’s misunderstanding of his role that negatively affects his testimony in a given case). This record is replete with examples of Dr. Tornatore straying from the facts, overstating information to support a point or subtly changing language to strengthen his position. Some examples follow.

Dr. Tornatore all too frequently makes statements that he lets stand until he is challenged. One of the most egregious in this case was stating that Finn’s case is an example of a challenge-rechallenge case. Tr.1 at 125. This is critical because proof of challenge-rechallenge is tantamount to finding causation. See Capizzano I, 2004 WL 1399178 at *2. However, when the undersigned questioned Dr. Tornatore about his statement, he merely replied that “[i]t may not be a rechallenge” Id. at 141. That is an unacceptable declaration and retraction about a critical causation issue. Challenge-rechallenge, and its causation significance, is a principle that is well known to anyone practicing and testifying in the Vaccine Program and is not subject to misunderstanding. Dr. Tornatore’s attempt to characterize Finn’s case as a challenge-rechallenge is simply credibility shattering.

In another example, in response to the undersigned's question whether a person with a moderate hearing loss would not acquire speech, Dr. Tornatore responded "Sure. I think that's common sensical." Tr.1 at 130. However, later when asked by the undersigned whether Finn's sister, Ruby, could "have had some hearing loss up to 40 decibels and still acquire normal speech?", Dr. Tornatore responded "Well, I can't say no. Sure." Id. at 160. Those responses are irreconcilable.

And one final example, and one of the most egregious for an expert, is the strengthening of language to give greater meaning to a factor in the causation opinion - in this case the need for an environmental trigger for the hearing loss, which Dr. Tornatore says is the vaccine. As stated earlier, Dr. Tornatore referenced respondent's Finn Ex. AA discussing mitochondrial deafness and quoted a sentence on page 267 of that article which says that "a combination of environmental, mitochondrial, and nuclear factors can push a push a cell over a threshold" Tr.1 at 112. Dr. Tornatore concluded from this that "[s]o even if you have the genetic predisposition, this diagram shows that in **some** cases the environmental agent pushes you over to deafness." Id. (emphasis added). This is critical to Dr. Tornatore's opinion in this case, as the vaccine is the environmental trigger that ties his medical theory to Finn; it is the core of the logical sequence of cause and effect. Tr.1 at 117; see also Althen, 418 F.3d at 1278. However, what began with a diagram showing "in **some** cases the environmental agent," Tr.1 at 112 (emphasis added), evolved to "[y]ou **have to have** something else in the environment that triggers the response. Tr.1 at 114 (emphasis added). This latter changed to "there **tends to usually be** an environmental cue," Tr.1 at 117 (emphasis added), to once again intensifying to "there **has to be** a trigger that causes the hearing loss." Tr.1 at 139 (emphasis added); see also id. at 154, 164. On cross-examination, the testimony came full circle when Dr. Tornatore stated that respondent "submitted the article to show . . . that environmental influences **can** cause deafness in somebody who has the appropriate genetic mutation." Tr.1 at 170 (emphasis added). Such subtle, but critical, shifts in language are unacceptable.

In 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, see Tr.1 at 136, 148, 154, 156, as a basis for his opinions. This creates a level of distrust that ultimately undermines his testimony.

IV. CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that petitioners are not entitled to compensation under the Vaccine Act. Petitioners failed to

prove by a preponderance of the evidence that Finn's injuries were caused-in-fact by the vaccinations he received.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master