

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Nos. 00-745V and 00-746V

Filed: August 10, 2007

(Reissued for Publication on August 16, 2007)¹

RUBY HOPKINS, a minor, by her parents *
and natural guardians, GREG HOPKINS *
and HELEN HOPKINS, *

Petitioners, *

v. *

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

Respondent. *

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

Petitioners, *

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.

¹This Decision was originally entered by the court on August 10, 2007 as an unpublished decision. The reissuance of this decision *shall not affect the time for filing a motion for review pursuant to Vaccine Rule 23.*

DECISION²

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

On December 11, 2000, petitioners filed two separate petitions pursuant to the National Vaccine Injury Compensation Program³ (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. 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.

Initially, both cases 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 in each case. 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 individual Factual Determinations for Finn and Ruby. 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 ___”]) and 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 Ruby, the parents’ credible testimony established from their perspective that Ruby’s hearing loss was not noticed until “the night of January 1, 1999,” approximately three weeks following her immunizations. Ruby slip op. at 12. The timing of Finn’s 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 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.

² 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.

³ 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.

Subsequently, petitioners continued to pursue both claims, Ruby's as well as Finn's. 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 cases are now ripe for decision. After considering the entire records for both Ruby and Finn, the undersigned concludes that petitioners are not entitled to compensation. The undersigned's reasoning follows. However, before discussing the cases, an explanation is necessary for why one decision is being issued to resolve the two individual cases.

Throughout the presentation of these cases, the two cases have been treated essentially as one. The siblings received the same vaccinations on the same day and are currently suffering from the same injury - SNHL. The respective experts agree that whatever caused the hearing loss in Ruby, caused the hearing loss in Finn. See Transcript of April 14, 2006 Hearing ("Tr.1 at ___") at 138; Transcript of May 11, 2006 Hearing ("Tr.2 at ___") at 35. Thus, the medical theories are the same for both Ruby and Finn, the cause is the same and the doctors' conclusions are the same for each. The only difference is that petitioners' experts ascribe causation to the vaccines, while respondents' experts disagree and argue that a genetic cause is to blame. Given that the petitioners presented the same medical theories for Ruby and Finn, the parties filed and discussed the same medical literature for both cases and the presentation of the two cases are so intertwined through the expert testimony, it makes eminent sense to resolve the cases through one opinion.

II. FACTUAL BACKGROUND

The following is a condensed version of the undisputed facts for Ruby Hopkins.⁴

Ruby was born on November 23, 1994. On December 28, 1995, Ruby first visited A. John Caeton, M.D., with a diagnosis of Bronchiolitis. P Ruby Ex. 2 at 4.⁵ On March 3, 1996, Ruby again saw Dr. Caeton. Id. Her parents reported that they had just returned from a vacation in Mexico, and that Ruby had been sick for about 10-12 days, with symptoms of cough and congestion over the past two days and occasional fevers as high as 105.6 degrees. Id. Dr. Caeton's impression was "Suspect pneumonia. Also Otitis." Id.

Ruby next returned to Dr. Caeton on July 19, 1996 for a daycare physical and to start her

⁴These facts are taken from the undersigned's February 9, 2005 unpublished Factual Determination rendered in Ruby's case.

⁵ Citations to the record for Ruby and Finn will be made by first referencing the party submitting the information, respondent or petitioner, and then to whose case, Ruby's or Finn's. Thus, a record submitted by petitioner in Ruby's case will be cited as "P Ruby Ex. ___."

immunizations. Id. She received Tetramune⁶ and OPV vaccinations. On November 11, 1996, Dr. Caeton spoke with Ruby's father regarding episodes of vomiting and diarrhea, with intermittent fever to 104.5 degrees. P Ruby Ex. 2 at 2. Dr. Caeton's impression was that Ruby had a viral gastroenteritis. Id. On January 8, 1997, Ruby visited Dr. Caeton for bilateral conjunctivitis. Id.

A "Deployment/Travel Medicine Questionnaire," dated December 9, 1998, identifying Ruby as a patient, notes proposed recreational travel to Thailand. P Ruby Ex. 3 at 22. Various vaccinations were required for travel to that country, and Ruby was referred to the immunization clinic. Id. On December 10, 1998, Ruby received the HIB/DTP and OPV vaccines at the Elmendorf Air Force Base ("AFB"). P Ruby Ex. 3 at 26, 28.

A treatment note, dated January 4, 1999, from the pediatric clinic at Elmendorf AFB indicates that Ruby was seen for "perceived hearing loss." P Ruby Ex. 3 at 23. An examination revealed "clear and mobile" tympanic membranes ("TM") and an audiology consultation was recommended. Id. On January 11, 1999, Ruby again received the OPV and Tetramune vaccines. Id. at 27, 29.

On January 12 and 18, 1999, Ruby underwent a complete audiological evaluation by Northern Hearing Services. P Ruby Ex. 3 at 82-84. In a summary from this evaluation, it is noted that Ruby's parents reported that "[t]hey had notice over the past few months that Ruby seemed to respond inconsistently, but they weren't sure at first if it was just 'selective hearing.'" P Ruby Ex. 3 at 82. Results of pure tone air and bone conduction testing revealed a mild to possibly severe SNHL in her right ear, and moderate, possibly severe SNHL in her left ear. Id. It was recommended that Ruby undergo a follow-up evaluation by an Ear, Nose and Throat ("ENT") physician. P Ruby Ex. 3 at 83.

On January 20, 1999, Ruby was evaluated by Donald Endres, M.D., at an ENT clinic. P Ruby Ex. 3 at 78-79. Dr. Endres described Ruby as being "recently diagnosed with sensorineural hearing loss bilaterally." P Ruby Ex. 3 at 78. He noted that Ruby had no family history of congenital or syndromic deafness, other than a maternal aunt with mild palsy and some hearing loss associated with that condition. Id. at 79. Dr. Endres could not find anything in Ruby's history or physical examination pointing to a specific syndromic cause for this deafness. Id.

Randall Ow, M.D., examined Ruby on January 22, 1999. P Ruby Ex. 3 at 17. Dr. Ow noted that parents noted hearing loss recently and "child has noted l[eft] ear (doesn't work)." Id. He also noted "2 y[ear] H[istory] of ? H[earing]L[oss]." Id. A physical examination of Ruby's ears was normal. Id. Dr. Ow noted that Ruby's bilateral hearing loss was probably congenital and ordered further consultations and testing when the family returned from Thailand. Id.

⁶Tetramune contains diphtheria and tetanus toxoids, pertussis vaccine, adsorbed and haemophilus b conjugate vaccine. R Ruby Rule 4 Report at 2, n.3.

On March 8, 1999, Ruby had a check-up with A. John Caeton, M.D. P Ruby Ex. 2 at 2. Dr. Caeton noted that Ruby had received immunizations in December; in January her parents began noticing that her hearing seemed diminished; and a hearing evaluation approximately one month ago revealed almost total hearing loss in her left ear and significant loss in the right ear. Id.

On May 14, 1999, Ruby underwent a follow-up comprehensive hearing evaluation with Dr. Ow. P Ruby Ex. 3 at 71-72. Dr. Ow noted that detailed questioning of Ruby's parents revealed a family history of deafness on the maternal side. Specifically, "the grandmother's brother apparently was deaf as a child," and there was a maternal uncle with hearing loss before age 20, as well as a maternal sister who has cerebral palsy with mild hearing loss. Id.

Dr. Ow reported that audiometry and otoacoustic emission testing confirmed a moderately severe SNHL in the right ear, and severe SNHL in the left ear. Id. He noted Ruby's parents' suspicion that her hearing loss may be related to the DPT/HIB vaccination performed in December 1998." Id. at 72. However, Dr. Ow felt that "in light of the significant family history of probable hereditary hearing loss, i[t] seems more likely that the child's condition represents a progressive hereditary sensorineural hearing loss." Id. Dr. Ow recommended further evaluation by a geneticist and a pediatric otolaryngologist. Id.

On June 24, 1999, Ruby's blood was drawn for a deafness DNA screen. P Ruby Ex. 3 at 61. A report from this testing revealed that while "[n]o mutations were detected in the CX26 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, Ruby and her brother, Finn, were evaluated by Phillip Massengill, M.D., an otolaryngologist at the Madigan Army Medical Center. P Ruby Ex. 3 at 73-74. Dr. Massengill noted that Ruby's family history was negative for any type of genetic hearing loss. Id. at 73. He also reported that her parents feel that the hearing loss was associated temporally with her immunizations. Id.

On July 23, 1999, Ruby and Finn underwent a comprehensive clinical genetics evaluation by Mark J. Stephan, M.D. P Ruby Ex. 3 at 75-77. Dr. Stephan reported that Ruby's parents state she babbled and began speaking words at the normal age and they considered her expressive speech to be completely normal at age two years. Id. at 75. Ruby's parents decided to postpone immunizations until she and her brother were older. Id. On December 10, 1998, Ruby received her second DPT immunization. Id. On January 1, 1999, Ruby's father noted that while she was lying in bed with her head turned on her right side, she did not respond to his voice. Becoming suspicious that Ruby was not hearing well from her left ear, her father had her sit up. She then answered his question appropriately. Id. After testing confirmed bilateral SNHL, Ruby was fitted with hearing aids in May 1999 and began two months of speech therapy. Id. Dr. Stephan concluded that both Ruby and Finn suffered from bilateral SNHL. Id. at 77. 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 Ruby Ex. 3 at 76. 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 Ruby’s parents in the event they contemplated having more children. Id. at 77. 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.

The following is a condensed version of the undisputed facts for Finn Hopkins.⁷

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. 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 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

⁷These facts are taken from the undersigned’s February 9, 2005 unpublished Factual Determination rendered in Finn’s case.

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 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

⁸Tympanometry 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).

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 even 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 Ruby was filed as P Ruby Ex. 33; his expert report for Finn was filed as P Finn Ex. 35. Dr. Creagan's CV was filed as P. Ruby Ex. 32 and 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 Ruby and 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 Ruby's and 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 Ruby and Finn's hearing loss. Id. at 46. In addition to the hearing loss being immune mediated, both Ruby and Finn were 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 Ruby and 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 Ruby and 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 Ruby was filed as P Ruby Ex. 15. For Finn, Dr. Tornatore’s report 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 reports. See P Ruby Ex. 15; P Finn Ex. 16. Dr. Tornatore testified that the vaccine caused the hearing loss in both Ruby and 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 these cases 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 these cases - “[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 these cases “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 Ruby’s case as R Ruby Ex. E, and his supplemental report was filed as R Ruby Ex. F. His CV was filed as R Ruby Ex. G. Dr. Raymond testified without objection, Tr.1 at 190, as an expert in pediatric neurology and clinical genetics. His opinion was consistent with Ruby’s treating doctors that Ruby’s hearing loss was genetically based, specifically autosomal recessive nonsyndromic hearing loss. R Ruby Ex. E at 3. Addressing the timing of Ruby’s hearing loss, Dr. Raymond wrote in his report and testified consistent thereto that “Ruby’s language abilities demonstrate that her hearing loss followed the development of language. It does not document more precisely the timing of her decline in hearing. Based upon experience, her hearing loss appears to have been gradual enough to allow

behavioral compensation. The coincidental discovery of her hearing loss in the month following her second vaccination does not demonstrate that it was causal.” R Ruby Ex. E at 4.

Dr. Raymond’s expert report was filed in Finn’s case as R Finn Ex. E, and his CV was filed at Ex. F. Much of the discussion in Dr. Raymond’s report for Finn is essentially the same as his discussion of Ruby’s case. Dr. Raymond’s 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 reports were filed, for Ruby at R Ruby Ex. A, and for Finn at R Finn Ex. A. Dr. Mankarious’ CVs were filed at R Ruby Ex. B and R Finn Ex. B respectively. Dr. Mankarious’ opinion and discussion of the two cases are essentially the same. Her 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 both Finn and Ruby had a pre-existing “mild sensorineural hearing loss” prior to their immunizations. R Ruby Ex. A at unnumbered page 2; R Finn Ex. A at unnumbered page 2. Dr. Mankarious testified consistently with these reports. As discussed below, the undersigned relied heavily on Dr. Mankarious in resolving these cases.

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 Ruby’s and Finn’s injuries, a so-called “off-Table” case.

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).

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., 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
(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

¹⁰(...continued)

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. Mstr. Oct. 31, 1999).

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 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.”). Ruby’s and Finn’s cases are measured against these standards.

C. Analysis

The records for these two cases are voluminous. They contain over 80 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 these cases. However, for purposes of deciding Ruby's and Finn's cases, 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 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 these cases. Then where is the disagreement?

The central issue for resolution of these cases revolves around the issue of timing - when did Ruby and Finn begin to lose their 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 these cases. Respondent argues through their experts that there is really no reliable way to time the onset of Ruby's or 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 there is no evidence that Ruby and Finn had normal hearing prior to vaccination); Tr.2 at 21 (Dr. Mankarious testifying that "you can't state that the hearing loss was identified at a specific time" for either Ruby or 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

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

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.

Tr.2 at 15-16.

hearing problems prior to the vaccination as evidenced by Ruby's and Finn's normal expressive speech. Coupling the evidence of normal speech 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 both Ruby's and Finn's cases.

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 Ruby and Finn. On these critical interpretive issues, the 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 Ruby Ex. 15 (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 Ruby Ex. BBBB in Ruby's cases and R Finn Ex. AAAA in Finn's. 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

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

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 31-33 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 Ruby and 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 clear and critical defects.

In the final analysis, these cases fail 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 Ruby's 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

RUBY HOPKINS

A summary of Dr. Tornatore's opinion regarding Ruby's hearing loss is as follows:

[S]he was given the vaccine, which is bacterial antigen. There is an immune response to the antigen, and you have the autoimmune component in the appropriate time period, so that three weeks would be right. You would develop an immune response in the ear, and then hearing loss becomes manifest.

Tr.1 at 124. Underlying this opinion is the "sudden loss" of hearing, Tr.1 at 121, as noted by the parents and by three speech and language professionals. Id. at 122. However, a close scrutiny of the records and Dr. Tornatore's interpretation of those records does not support the "sudden loss" of hearing that is critical to his opinion.

Dr. Tornatore first cites to various hearing tests performed following the January 1999

immunizations that confirmed Ruby's hearing loss, but also noted that Ruby's expressive and acquired language was normal. See Tr.1 at 118-122. Thus, in March 1999, Ruby was seen by Linda Simpson who wrote "Ruby's speech and language development appear to be age appropriate which is consistent with her having had better hearing thresholds than obtained today." P Ruby Ex. 9 at 18 (duplicated at P Ruby 3 at 67). On April 2, 1999, Ruby's "language skills appeared to be within normal limits." Id. at 52. A May 1999 report found Ruby able to produce "all the age appropriate sounds." Id. at 70. From these reports, Dr. Tornatore draws the conclusion that "if she had longstanding hearing loss, one would have anticipated seeing some changes in some of these parameters." Tr.1 at 119. For further support, Dr. Tornatore referenced an April 2, 1999 Individual Education Program (IEP) for Ruby. The evaluation found Ruby's "language skills appeared to be within normal limits." P Ruby Ex. 9 at 52. Dr. Tornatore referenced a May 13, 1999 evaluation which indicated that Ruby's test scores show "typical receptive language skills for her age." Tr.1 at 119 (citing P Ruby Ex. 9 at 70). Dr. Tornatore buttressed this conclusion by referencing letters from the speech pathologist. Janice Boyt wrote in June 1999 that "Ruby's articulation and language skills seemed to indicate that her hearing loss skills was fairly recent." P Ruby Ex. 30; but see Evaluation at P Ruby Ex. 9 at 47 (Ms. Boyt stated Ruby "appears to use some lip reading skills to improve her language comprehension." This is an indication of compensating for a hearing deficiency.); see also Tr.1 at 196; Tr.2 at 61. Dr. Tornatore also relied upon the letter submitted by Joyce Sexton, an audiologist. P Ruby Ex. 31. This letter was written on March 8, 2005 after the factual hearing was conducted in this case. Ms. Sexton writes in pertinent part that "Ruby's hearing loss is of such severity that she could not have acquired normal speech and language skills (which she did have at the age of diagnosis) if her hearing loss was congenital. Ruby's hearing loss had to have been of sudden onset, there is no other explanation." Id. at 2.¹³ Based upon the parents observations and the records and letters

¹³ 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 January 1999 evaluation reveals none of the conclusions reached in her 2005 letter. Compare P Ruby Ex. 9 at 14-15 with R Ruby Ex. 31 ("It was explained [to the parents] that the
(continued...)

from the speech professionals, Dr. Tornatore concluded that “there had to have been a period of good language acquisition; otherwise, [Ruby] wouldn’t be where she is, which is normal for her age.” Tr.1 at 122.

However, under questioning from respondent’s counsel, Dr. Tornatore conceded a critical point that undermined significantly the basis for his conclusion. First, he was asked whether he disagreed with medical literature that says one can experience up to a three decibel hearing loss and still acquire normal speech. Tr.1 at 158. In answering, Dr. Tornatore first makes several misstatements about the speech pathologist, saying that she noted that it would be “extremely unusual” that Ruby would acquire language skills with this hearing loss and that “the only way” Ruby would have acquired this language is with normal hearing. A review of the record reveals that the speech pathologist did not say this. It is clear from the later discussion that Dr. Tornatore is referencing Ms. Linda Simpson. See Tr.1 at 159. Ms. Simpson merely stated that “Ruby’s speech and language development appear to be age appropriate, which is consistent with her having had better hearing thresholds than those obtained today.” P Ruby Ex. 9 at 18. This is not a statement by Ms. Simpson that Ruby’s hearing loss was “extremely unusual” or that “the only way that she could have language at that level was if she had had normal hearing.” Tr.1 at 158. Those are Dr. Tornatore’s words, which appear grossly unjustified. Dr. Tornatore then stated that the speech pathologist “is saying, if she had 40 decibel or greater hearing loss, she wouldn’t have been able to make those particular sounds.” Tr.1 at 158-59. When challenged about the reference to 40 decibels, Dr. Tornatore could provide no reference. Thus, the undersigned re-asked the question: “the question is, could she have had some hearing loss up to 40 decibels and still acquire normal speech?” Dr. Tornatore responded “**Well, I can’t say no. Sure.**” Tr.1 at 160 (emphasis added).

This is a critical concession because it is consistent with respondent’s experts’ opinions that congenital hearing loss can begin at any age and even the most astute observers will not detect it. Thus, simply relying on normal speech as the indicator of timing is improper because one can have hearing loss and develop normal speech. As Dr. Mankarious explained: “It is widely known that children with mild sensorineural hearing loss, and that is defined as up to 40 decibels or as low as 48 decibels, can develop normal speech.” Tr.2 at 13. Dr. Tornatore reluctantly conceded that point. Tr.1 at 160. When questioned as to how he knows whether or not Ruby had mild hearing loss prior to vaccination, Dr. Tornatore relied upon Ms. Simpson’s finding of age appropriate speech and language skills. Tr.1 at 156. However, Dr. Tornatore then exaggerated the testing results to defend his opinion stating that Ruby’s tests showed “significant” hearing loss that “was not present up to that point” and extrapolated from those statements the conclusion that “otherwise, she would not have acquired the speech and language skills that she had.” Tr.1 at 156. However, the undersigned can find no record from 1999 that says Ruby’s hearing loss was “significant,” and as Dr. Mankarious said and Dr. Tornatore agreed, one can have hearing loss and still develop normal speech and language. As Dr. Raymond noted

¹³(...continued)
cause of Ruby’s hearing loss may not be determined”)

in his expert report “there is no objective evidence that [Ruby] had normal hearing prior to vaccination and her abilities including speech reading present by the time of evaluation suggest a longer period of deterioration.” R Ruby Ex. F at 4; see also Tr.1 at 220; Tr.2 at 21-22. Neither the records cited by Dr. Tornatore, nor his testimony, undercut Dr. Raymond’s statement, which is supported by Dr. Mankarious’ persuasive testimony. Thus, the ineluctable conclusion to be reached is that you cannot determine based merely upon speech and language testing performed **at a later point in time** when the hearing loss began.

Faced with this admission that Ruby could have hearing loss and still acquire normal speech, Dr. Tornatore shifted to the parents for support.¹⁴ Dr. Tornatore stated that the parents noted a sudden loss of hearing and “these parents . . . are well trained.” Tr.1 at 161. But, as is unfortunately typical of Dr. Tornatore’s testimony, after making a strong statement of the parents knowledge and observations to support one opinion, he backs off of the statement in response to another question. Thus, in response to the undersigned’s question, Dr. Tornatore stated that “if there was a subtle hearing loss, I would hope the parents, who are special-ed trained, might have picked it up. Maybe not, but I have the **sneaking suspicion** they would have been aware of this, given that they picked up these things pretty quickly thereafter.” Tr.1 at 163 (emphasis added). It must also be noted that Dr. Tornatore’s initial statement of reliance on the “well trained” parents conflicts with his statement in his supplemental report that “the moderate loss of function could easily be missed by even the most attentive parent.” P Finn Ex. 34.¹⁵ Since Dr. Tornatore concedes that one can have moderate hearing loss, up to 40 decibels, and still develop normal speech, he is unable to rely solely on the paraclinicians’ findings of normal speech as an indicator

¹⁴ The undersigned found in Ruby’s Factual Determination that from the “parents’ perspective” Ruby’s hearing loss was not noticed until the night of January 1, 1999. Based upon the information provided by the experts, it is clear that the “parents’ perspective” is not a reliable determinate of when Ruby’s hearing loss began.

¹⁵ Dr. Mankarious testified:

The literature is replete with articles demonstrating that parents cannot identify mild sensorineural hearing loss in their children. And although with all due respect to Mr. and Ms. Hopkins, they are special education teachers, but we don’t know what kind of special education teachers they are. And I think it’s unlikely that they’re special education teachers who deal with children who are hard of hearing and have specific knowledge of the association between hard of hearing and language delay. So, you know, they may specialize in motor disorders or they may specialize in, you know, something else, autism, or something else altogether. So I think that really has to be called into question that specifically the children lost their hearing at the time of the vaccination. I don’t think anybody can say that with certainty.

Tr. 2 at 22.

of an acute onset of hearing loss. See Tr.1 at 161. Faced with that realization that a critical support has been undermined, Dr. Tornatore pins his “hope[s]” on the parents - that they “might have” picked up on subtle hearing loss, and relies on a “sneaking suspicion” that they would have. However, this “hope” and “sneaking suspicion” is belied by his own words that even the “most attentive parent” “could easily” miss the signs of moderate hearing loss. P Finn Ex. 34; see also P Ruby Ex. 3 at 82 (parents reported that “[t]hey had noticed over the past few months that Ruby seemed to respond inconsistently, but they weren’t sure at first if it was just ‘selective hearing’”). On that point, Drs. Raymond and Mankarious agree fully with Dr. Tornatore. Standing alone, Dr. Tornatore’s factual basis is at best highly questionable. Measured against the testimony of Dr. Mankarious, see infra at page 24-25, Dr. Tornatore’s testimony crashes under the weight of questionable assumptions.

FINN HOPKINS

As Dr. Tornatore noted, the timing issue is far more 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 the same “two prongs” - the paraclinical professionals and the parents’ observations - for his factual information.¹⁶ 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 11.¹⁷

¹⁶ 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.

¹⁷ On July 28, 2006, petitioners filed along with their posthearing brief several exhibits. See P Ruby Ex. 37-41 and 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. (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.”

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 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

¹⁷(...continued)

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 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 Ruby’s and 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).

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, 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 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; R Ruby Ex. E (Ruby’s “compensation for her profound hearing loss also argues that the onset did not occur acutely, but rather gradually allowing her to develop lip reading abilities.”); P Ruby Ex 9 at 47 (“It was noted [by the speech pathologist] during the evaluation that Ruby makes excellent eye contact and appears to use some lip reading skills to improve her language comprehension”). 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. Neither Ruby nor Finn was tested for hearing loss prior to immunization.¹⁸ 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 Ruby’s and Finn’s hearing loss is unknown. Accordingly, both Ruby and Finn 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 Ruby’s and 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 Ruby’s and Finn’s hearing loss was the environmental cue. See Tr.1 at 117.

Relying upon medical literature submitted by respondent, Dr. Tornatore contended that

¹⁸ If there was documented testing of normal hearing prior to vaccination, the result in these cases could have changed. See Tr.2 at 38.

hearing loss “usually” has an environmental trigger, and in Ruby’s case “the only environmental cue is the vaccine issued three weeks prior. So we have a logical sequence of causing events.” Tr.1 at 117. 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 Ruby 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 Ruby Ex. OOO. 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 Ruby Ex. PPP. 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 Ruby’s and 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

at170. 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 exhibit 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 32 (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 Ruby and Finn diagnosed, consistent with Drs. Raymond and Mankarious, a genetic cause for their hearing loss. Dr. Ow, while recognizing the parents' concern over the relationship between the vaccines and hearing loss, 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. Similarly, Dr. Ow's diagnostic assessment of Finn was "prob[able] hereditary hearing loss." P Finn Ex. 1 at 9.

On July 23, 1999, Ruby and Finn underwent a comprehensive clinical genetics evaluation

by Mark J. Stephan, MD. P. Ruby Ex. 3 at 75-77; P. Finn Ex. 1 at 104-106. Dr. Stephan's impression was that "this represents an autosomal recessive nonsynchronous auditory deficit in the siblings." P. Ruby Ex. 3 at 77; 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.¹⁹ 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.

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 Ruby and 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 Ruby and 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. [Ruby and Finn] saw at least three otolaryngologists and there was no treatment or even offering them of steroids.

Tr.2 at 51. Dr. Mankarious summarized these cases succinctly in stating:

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

¹⁹Dr. 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.

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 Ruby and Finn with a genetic cause. Critically important, as Dr. Mankarious noted, is that they did not diagnose or treat Ruby and 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 Ruby and 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 these cases, 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 these cases. 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 Ruby and 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 Ruby and 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 Ruby and Finn in these cases. 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 Ruby 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 Ruby 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 Ruby and Finn’s cases and the important lack of information of “familial occurrence.” Tr.1 at 196. Most importantly, however, Ruby and 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 Ruby’s and Finn’s immunizations and their hearing loss.²⁰

²⁰ Dr. Mankarious’ testimony raised the question of whether Ruby’s hearing loss was significantly aggravated by the vaccine. She testified that Ruby experienced a “precipitous []” drop in her hearing following her immunizations. Tr.2 at 22, 58. However, it is clear from the totality of Dr. Mankarious’ testimony that she does not believe that the vaccine played any role in Ruby’s hearing loss. She stated, for example, that “if Ruby lost her hearing three weeks after the vaccinations it’s more likely to have been a spurious even[t] with poor timing, enough to bring the vaccine into question, but it’s probably not related to the vaccine.” Tr.2 at 22-23; see also id. at 58-59 (such a “precipitous” drop is seen in cases of mild or no hearing loss). Dr. Raymond’s testimony (continued...)

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-

²⁰(...continued)

clearly and convincingly ascribed no causative role to the immunization. See Tr.1 at 195-196. Dr. Tornatore's sole mentioning of the possibility of significant aggravation was in response to a question from the undersigned. Tr.1 at 162. There simply is insufficient evidence in this record to support a finding of significant aggravation.

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 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 exhibit 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 both of these cases, as the vaccine is the environmental trigger that ties his medical theory to both Ruby and 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 Ruby's and Finn's injuries were caused-in-fact by the vaccinations they received. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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