

OFFICE OF SPECIAL MASTERS

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LAURA MALLOY,	*	
by her mother and next friend,	*	
JAN MALLOY,	*	
	*	
	*	No. 99-0193V
Petitioner,	*	PUBLISHED
	*	
v.	*	
	*	
SECRETARY OF THE DEPARTMENT OF	*	
HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Ronald Homer, Boston, MA, for petitioner.
Glenn MacLeod, Washington, DC, for respondent.

Edwards, Special Master

DECISION ON ENTITLEMENT

Petitioner, Jan Malloy (Ms. Malloy), as mother and next friend of her daughter, Laura Malloy (Laura), seeks compensation under the National Vaccine Injury Compensation Program (Program).¹ Ms. Malloy alleges that Laura suffers “profound right ear hearing loss” that is related to a measles-

¹ The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-1 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

mumps-rubella (MMR) immunization that she received on August 23, 1996. Petition (Pet.) at 1. The special master directed the substantive factual and medical development of the petition. Because the parties dispute few material facts, the special master convened a hearing limited to medical expert testimony. Edward J. O'Rourke, M.D. (Dr. O'Rourke), testified for Ms. Malloy. Roland D. Eavey, M.D. (Dr. Eavey); Raoul L. Wientzen, Jr., M.D. (Dr. Wientzen) and Burton Zweiman, M.D. (Dr. Zweiman), testified for respondent.

BACKGROUND

Laura was born on December 5, 1984. Petitioner's exhibit (Pet. ex.) 3 at 2. She is a twin. *See, e.g.*, Pet. ex. 3 at 43. Throughout Laura's childhood and into Laura's adolescence, physicians from Hazelton Children's Medical Associates, in Hazelton, Pennsylvania, provided pediatric care to Laura, *see generally* Pet. ex. 3, including treatment for typical ailments like ear infections, *see, e.g.*, Pet. ex. 3 at 3, 9, 11, and upper respiratory infections. *See, e.g.*, Pet. ex. 3 at 5, 8, 11, 13, 15-18, 20, 22-24. Although her mother was "terrified" apparently of vaccines, Pet. ex. 3 at 4, Laura received eventually a full complement of routine vaccinations between 1985 and 1989. Pet. ex. 3 at 1. In particular, Laura received an initial MMR immunization on July 10, 1986. *Id.*; *see also* Pet. ex. 3 at 9. Except for "redness" and "inflammation" at the vaccination site following a diphtheria-pertussis-tetanus (DPT) vaccination on May 4, 1989, Laura tolerated well her vaccinations. Pet. ex. 3 at 16.

On May 22, 1996, Laura presented to Robert W. Childs, M.D. (Dr. Childs), at Hazelton Children's Medical Associates. Pet. ex. 3 at 27. Laura reported that she had experienced a "headache" for five days. *Id.* Dr. Childs "confirm[ed] rhinorrhea" with an "occ[asional] assoc[iated] cough." *Id.* In addition, Laura reported that she had experienced "dizziness" for three days. *Id.* Dr. Childs described the "dizziness" as "episodic." *Id.* Dr. Childs performed blood pressure testing. *Id.* Dr. Childs performed also a neurological examination. *Id.* Dr. Childs determined that the neurological examination was "totally w[ithin]n[ormal]l[imits]." *Id.* Dr. Childs concluded that Laura was suffering "prob[able] vestibulitis," or "poss[ible] cerebellitis," from a "viral illness." *Id.*; *see also* Pet. ex. 3 at 78. Dr. Childs prescribed "Antivert" and "Tyl[enol]." Pet. ex. 3 at 27. Dr. Childs instructed Laura to return to Hazelton Children's Medical Associates if her dizziness increased. *Id.*

Dr. Childs "did not hear from" Laura again until August 23, 1996, when Dr. Childs evaluated Laura for a "regular sixth-grade physical." Pet. ex. 3 at 73; *see also* Pet. ex. 3 at 28. During the examination, Laura did not recount any "further problems with dizziness." Pet. ex. 3 at 73. Dr. Childs noted "early puberty, a functional heart murmur and multiple dental fillings and caps." *Id.*; *see also* Pet. ex. 3 at 28. Dr. Childs characterized the remainder of Laura's examination as "fine." Pet. ex. 3 at 28; *see also* Pet. ex. 3 at 73. Laura received a second MMR immunization. Pet. ex. 3 at 1, 58, 73, 78.

On September 7, 1996, Laura presented to Jennifer M. Trella, M.D. (Dr. Trella), at Hazelton Children's Medical Associates. Pet. ex. 3 at 28; *see also* Pet. ex. 8 at ¶ 8. Laura related that her right

ear felt “blocked.” Pet. ex. 3 at 28; *see also* Pet. ex. 3 at 73, 78. Laura indicated that she had experienced some “hearing loss” in her right ear, too. Pet. ex. 3 at 28. Laura recounted that she had been “congested” for over one week. *Id.*; *see also* Pet. ex. 3 at 73, 78. In addition, Laura recounted that she had experienced “h[ead]/a[che] [and] dizziness since” the previous day. Pet. ex. 3 at 28; *see also* Pet. ex. 3 at 73, 78. Further, Laura recounted that she had vomited “green mucous” during the morning on September 7, 1996. Pet. ex. 3 at 28.

Dr. Trella noted Laura’s previous history of “vestibulitis.” Pet. ex. 3 at 28. Upon examining Laura, Dr. Trella observed that Laura’s right “T[ympanic]M[embrane]” was “erythematous, bulging [and] immobile.” *Id.*; *see also* Pet. ex. 3 at 73, 78. Dr. Trella commented that Laura’s “neuro[logical]” system was “intact.” Pet. ex. 3 at 28. Dr. Trella concluded that Laura had suffered an upper respiratory infection that was “resolving.” *Id.* Dr. Trella concluded also that Laura was suffering “R[ight]O[titis]M[edia].” *Id.* Dr. Trella prescribed “Augmentin” and “Antivert.” *Id.*; *see also* Pet. ex. 3 at 73, 78. Dr. Trella advised Laura to “call back” as needed. Pet. ex. 3 at 28.

Laura’s “dizziness” persisted. Pet. ex. 3 at 36; *see also* Pet. ex. 3 at 73; Pet. ex. 8 at ¶¶ 9-10. On September 13, 1996, Dr. Childs evaluated Laura. Pet. ex. 3 at 29. Laura reported that “her ear still felt blocked.” Pet. ex. 3 at 73; *see also* Pet. ex. 3 at 29, 78. Laura reported also “slight pain behind the right auricle.” Pet. ex. 3 at 73; *see also* Pet. ex. 3 at 29. A nurse performed “a hearing test.” Pet. ex. 3 at 73. The nurse “could not elicit any response from the right ear.” *Id.*; *see also* Pet. ex. 3 at 59.

Although Dr. Childs remarked that Laura was “still sl[ightly] congested,” and although Dr. Childs observed that Laura’s right ear was still “abn[orma]l,” Dr. Childs depicted Laura’s examination as “totally w[ithin]n[ormal]l[imits].” Pet. ex. 3 at 29 (emphasis in original). Dr. Childs was perplexed by Laura’s condition. *See id.* Dr. Childs instructed Laura to “finish” the course of “a[n]ti[b]iotic” that Dr. Trella had prescribed on September 7, 1996. Pet. ex. 3 at 29. Dr. Childs requested Laura to provide a “P[rogress]R[eport]” on September 16, 1996, or “sooner” if she exhibited “[increased] evidence of vestibulitis.” *Id.* Dr. Childs planned to “continue” antibiotic therapy if Laura’s “congestion” had not resolved. *Id.* In addition, Dr. Childs planned a “B[rainstem]A[uditory]E[voked]R[esponse]s” test if Laura’s right ear remained “blocked.” *Id.*

On September 16, 1996, Dr. Childs referred Laura to Linda M. Farley (Ms. Farley), an audiologist, “for complete audiologic testing.” Pet. ex. 3 at 73; *see also* Pet. ex. 2 at 1. In her recitation of the chronology of Laura’s condition, Ms. Farley indicated that Laura described being “off balance” or “dizzy at times,” as if the room were “spinning,” before she suffered “sudden right ear hearing loss” in early September 1996. Pet. ex. 2 at 1. According to Ms. Farley, Laura did not present with any potential contributory “history,” such as “recurrent ear infections as a younger child,” trauma or “congenital deafness.” *Id.*

Ms. Farley conducted an “[o]toscopic exam.” Pet. ex. 2 at 1. Ms. Farley determined that Laura’s tympanic membranes were “intact,” with “good TM mobility” on the right side and on the left side. *Id.* Ms. Farley concluded that Laura’s “middle ear status” was “normal.” *Id.*

Ms. Farley conducted also a formal “[a]udiological [e]valuation.” Pet. ex. 2 at 1-2. Ms. Farley determined that “[p]ure air tone and bone conduction thresholds” revealed “[p]rofound sensori-neural hearing loss across all tests frequencies” in Laura’s right ear. Pet. ex. 2 at 1. Ms. Farley commented that “[a]coustic reflexe[s] (stapedial contraction)” were “absent” in Laura’s “right ear[,] as expected” for Laura’s “type of” hearing loss. *Id.* Ms. Farley recommended additional, significant “otological evaluation,” including “M[agnetic]R[esonance]I[maging], E[lectro]N[ystagmo]G[ram], and complete work-up for retrichochlear involvement, inner ear disorder and C[entral]N[ervous]S[ystem] disorder.” *Id.*

Also on September 16, 1996, Dr. Childs referred Laura to Jang-Huei Jang, M.D. (Dr. Jang), an Ear, Nose, Throat (ENT) specialist. *See* Pet. ex. 3 at 35; Pet. ex. 5 at 5; Pet. ex. 8 at ¶¶ 11-12. Dr. Childs expressed concern about “[v]iral demyelination of” Laura’s right “auditory nerve.” Pet. ex. 3 at 35. According to Dr. Jang, Laura’s “ear, nose, and throat examination was essentially negative except” for accumulated “wax” in Laura’s “right ear” that Dr. Jang “removed.” Pet. ex. 5 at 5; *see also* Pet. ex. 5 at 1. Based upon the results of Laura’s audiological testing, Dr. Jang diagnosed “right sudden sensori-neural hearing loss.” Pet. ex. 5 at 5; *see also* Pet. ex. 5 at 1. Dr. Jang recommended an “MRI of [the] head” and an ENG with a “fistula test” to “r[ule]/o[ut] labrynthitis [versus] ruptured round or oval window.” Pet. ex. 5 at 1; *see also* Pet. ex. 5 at 5.

On September 17, 1996, Ms. Malloy telephoned Hazelton Children’s Medical Associates. Pet. ex. 3 at 35. She posed apparently questions about the relationship between Laura’s August 23, 1996 MMR immunization and Laura’s hearing loss. *Id.* She indicated that “Dr. Jang’s books list

MMR as” a cause of “sudden deafness.” *Id.* She requested a “2nd opinion.” *Id.* Dr. Childs advised Ms. Malloy to “wait” pending the completion of “tests.” *Id.*

Laura underwent an MRI on September 18, 1996. Pet. ex. 5 at 3. The MRI was “[w]ithin [n]ormal [l]imits,” revealing “no evidence for a[n] acoustic neuroma.” *Id.*; *see also* Pet. ex. 5 at 5. Laura underwent also an ENG on September 18, 1996. Pet. ex. 2 at 3. The “Fistula Test” was “[n]ormal” on Laura’s “right” side. *Id.* However, the ENG revealed “[s]pontaneous left beating positional nystagmus with mild left Directional Preponderance.” *Id.*; *see also* Pet. ex. 5 at 5. In addition, the ENG revealed a “slight Right Canal Paresis.” Pet. ex. 2 at 3. The ENG results were “[c]onsistent with [a] peripheral vestibular disorder such as vestibular neuronitis.” *Id.*

On September 20, 1996, Laura presented again to Dr. Childs. Pet. ex. 3 at 29. Laura reported that she could hear “a little” in her right ear. *Id.* Dr. Childs discussed at length with Ms. Malloy the “pathogenesis/prognosis” of Laura’s “condition.” *Id.* Dr. Childs related that he had consulted an ENT specialist at Children’s Hospital of Philadelphia. *Id.* According to Dr. Childs, the specialist indicated that the “immediate cause” of sudden sensorineural hearing loss “is almost always unclear.” *Id.* While the specialist postulated apparently several potential etiologies, such as “genetic” conditions or trauma, “incl[uding] pressure from O[titis]M[edia],” the specialist informed Dr. Childs that sudden sensorineural hearing loss is “very unlikely to be” related to a virus, “incl[uding] MMR.” *Id.*

During the September 20, 1996 examination, Dr. Childs appreciated a “[m]inor ongoing low grade” upper respiratory infection. Pet. ex. 3 at 29. Dr. Childs prescribed for at least six weeks an antibiotic as “prophylaxis.” *Id.*; *see also* Pet. ex. 7 at 71. In addition, Dr. Childs “provided” a prescription for a “Medrol Dosepak” and for a course of adult aspirin as recommended apparently by Dr. Jang. Pet. ex. 3 at 29; *see also* Pet. ex. 3 at 73. Dr. Childs noted that “[approximately] 15%” of patients on a similar “regimen” of steroid therapy and of aspirin therapy “recover significant hearing.” Pet. ex. 3 at 29.

Dr. Childs planned to monitor Laura’s progress for four to six weeks. Pet. ex. 3 at 29. Then, Dr. Childs contemplated a “C[omputed]T[omography]” scan of Laura’s “inner ear” to investigate any “evidence of a congenital malformation of the cochlear.” *Id.* Depending upon the result of the CT scan, Dr. Childs envisioned “simple surgery.” *Id.* However, Dr. Childs cautioned that any surgery would not likely restore Laura’s hearing. *Id.*

On September 25, 1996, Ms. Farley conducted “a repeat audiological evaluation” of Laura’s sensorineural hearing loss. Pet. ex. 2 at 4. Ms. Farley noted that after a “week” of “steroid therapy with aspirin,” Laura reported that she was able to hear “words over the telephone but not very clear from the right ear.” *Id.* In addition, Laura reported “some roaring sound in the right ear” that Ms. Farley attributed either to Laura’s hearing loss or to “the aspirin.” *Id.* Audiological testing confirmed “significant improvement” in Laura’s right ear. *Id.* Laura exhibited “[m]ild/moderate low tone loss” and “severe mid to high tone loss.” *Id.* Ms. Farley recommended another audiological evaluation within two weeks, “especially if” Laura continued “steroid therapy.” *Id.*

Complaining of “pain” in her “r[igh]t ear,” Laura presented to Dr. Childs on October 11, 1996. Pet. ex. 3 at 30. Laura’s “P[hysical]E[xamination]” was “totally” normal, except for “[m]inor ongoing nasal congestion.” *Id.* (emphasis in original). Dr. Childs scheduled Laura for a CT scan of her “inner ear” and for a “repeat audiol[ogical] eval[uation]” on October 16, 1996. *Id.*

Laura underwent a “C[omputed]A[xial]T[omography] scan” of her “temporal bones” on October 16, 1996. Pet. ex. 3 at 72. The scan was “normal.” *Id.* The radiologist stated specifically that there were “[n]o soft tissue densities in the regions of either round or oval windows.” *Id.*

Also on October 16, 1996, Ms. Farley conducted a third “audiological evaluation” of Laura’s sensorineural hearing loss. Pet. ex. 2 at 6. While Laura indicated that she was not certain if she had experienced “any significant improvement with her overall hearing,” she mentioned that she noticed that “the roaring sound” was diminished “at times.” *Id.* Audiological testing confirmed greater “improvement” in Laura’s right ear, “especially in the lower frequencies.” *Id.* Laura exhibited “severe mid to high frequency nerve loss.” *Id.* Ms. Farley recommended another “audiometric evaluation” within “one month to determine stability of right ear thresholds in the absence of steroid/aspirin therapy.” *Id.* In addition, Ms. Farley recommended a “hearing aid evaluation after medical clearance.” *Id.*

Although Dr. Childs understood from conversations with “consultants” that Laura’s sensorineural hearing loss was “not compatible with hearing loss that has been rarely associated with MMR administration,” Dr. Childs referred Laura to the Division of Pediatric Otolaryngology at St.

Christopher's Hospital for Children, in Philadelphia, Pennsylvania, because of Ms. Malloy's concern that Laura's "MMR booster may be involved" with Laura's sensorineural hearing loss. Pet. ex. 7 at 71. Ellen S. Deutsch, M.D. (Dr. Deutsch), an Assistant Professor of Otorhinolaryngology and of Pediatrics, evaluated Laura in late October 1996. See Pet. ex. 6. Dr. Deutsch noted that an October 24, 1996 "audiogram" revealed "mild low frequency sensorineural hearing loss sloping abruptly to profound mid to high frequency loss" in Laura's right ear. Pet. ex. 6 at 2; see also Pet. ex. 6 at 1. Dr. Deutsch stated that the "etiology" of Laura's "right sensorineural hearing loss of sudden onset" was "not obvious." Pet. ex. 6 at 2. Dr. Deutsch considered that Laura's sensorineural hearing loss "could possibly be related to the MMR vaccine." *Id.* However, Dr. Deutsch remarked that "the cause" for Laura's hearing loss "may be impossible" to determine. *Id.* Nevertheless, after conferring with "Infectious Disease" staff at St. Christopher's Hospital for Children, Dr. Deutsch suggested "filing a vaccine adverse event report to the CDC." *Id.* In addition, Dr. Deutsch suggested that the Malloy "family" pursue "the possible association between the vaccine and the hearing loss" through "an Infectious Disease specialist." *Id.*

In November 1996, Dr. Childs completed a Vaccine Adverse Event Reporting System (VAERS) report about Laura's "MMR booster" and Laura's "severe hearing loss." Pet. ex. 3 at 78. Also, Dr. Childs continued his investigation of the association between Laura's MMR booster and Laura's hearing loss. See Pet. ex. 3 at 31. Dr. Childs contacted "Sarah Long" (Dr. Long) at "St. Chris I.D." *Id.* During the discussion, Dr. Childs "assured [Dr. Long] that Laura did not seem to have measles/mumps encephalitis." *Id.* Dr. Childs indicated that while Dr. Long "acknowledge[d] the temporal relationship" between Laura's MMR booster and Laura's hearing loss, Dr. Long was

not aware of the “phenomenon” of hearing loss following a “booster” immunization. *Id.* (emphasis in original). In addition, Dr. Childs contacted John H. Dossett, M.D. (Dr. Dossett), Chief, Division of Pediatric Infectious Diseases at Hershey Medical Center in Hershey, Pennsylvania. *Id.*; *see also* Pet. ex. 3 at 80. According to Dr. Childs, Dr. Dossett promised to have an assistant “do a literature search” regarding MMR vaccine and hearing loss. Pet. ex. 3 at 31; *see also* Pet. ex. 3 at 80.

Dr. Dossett wrote to Dr. Childs on November 19, 1996, enclosing “some papers” about “MMR and Deafness.” Pet. ex. 3 at 80. Noting “a background incidence of acute onset, idiopathic, Sensori-neural hearing loss,” Dr. Dossett offered that he could not “be sure whether there is a correlation” between Laura’s MMR immunization and Laura’s hearing loss. *Id.* Although he did not recite his understanding about the chronology of Laura’s condition, Dr. Dossett expressed his view that the “proximity of [Laura’s] hearing loss and the MMR vaccination seems too close for there to be a causal relationship.” *Id.* But, Dr. Dossett stated that he “would be more likely to interpret a causal relationship if [Laura’s] hearing loss had started 8-10 days or more after [Laura] received the MMR.” *Id.* After reviewing Dr. Dossett’s letter, Dr. Childs appended a memo exclaiming that Laura’s hearing loss “did occur” within the period that Dr. Dossett cited. *Id.* (emphasis in original).

On December 30, 1996, Ms. Farley conducted another audiological evaluation of Laura’s sensorineural hearing loss. Pet. ex. 2 at 8. According to Ms. Farley, Laura had not experienced a “difference in her hearing” since the October 16, 1996 evaluation. *Id.* Ms. Farley commented that Laura appeared to be “adapting very well in listening situations.” *Id.* Audiological testing revealed

“[s]table right ear severe mid to high frequency sensori-neural hearing loss.” *Id.* Ms. Farley conducted also “[a] hearing aid evaluation.” *Id.* Ms. Farley concluded that Laura derived some “benefit” from “amplification.” *Id.*

Laura continues to suffer “right ear sensorineural hearing loss.” Pet. ex. 16 at 1; *see also* Pet. ex. 19.

THE MEDICAL TESTIMONY

Dr. O’Rourke²

Dr. O’Rourke opined that Laura’s August 23, 1996 MMR immunization, particularly “the mumps component,” is the “most likely cause of” Laura’s unilateral sensorineural hearing loss. Tr. at 6-7; *see also* Tr. at 10, 20-22, 25-26. Dr. O’Rourke elaborated that he presumed that Laura suffered an “acute viral infection” of her inner ear from the MMR immunization, rather than “some

² Dr. O’Rourke is an Assistant Professor of Pediatrics at Harvard Medical School. Pet. ex. 13. In addition, he is an Associate in Medicine, Division of Infectious Diseases, at Children’s Hospital in Boston, Massachusetts. Transcript (Tr.), filed February 26, 2002, at 5; *see also* Pet. ex. 13. Dr. O’Rourke stated that he works now predominantly “on international medicine” at Harvard Medical International, an adjunct of Harvard Medical School. Tr. at 5. He is board-certified in pediatrics and in pediatric infectious diseases. Pet. ex. 13.

unusual immunologic reaction” to the MMR immunization, leading to unilateral sensorineural hearing loss. Tr. at 26; *see also* Tr. at 42, 55. Dr. O’Rourke stated that he based his opinion upon the “biological plausibility” that wild viruses cause hearing loss, Tr. at 7-9; *see also* Tr. at 14, 16-17, 21, 25, 54-55; the fact that Laura received “a live viral vaccine,” Tr. at 8; *see also* Tr. at 14, 22; the “temporal association” between Laura’s August 23, 1996 MMR immunization and the onset of Laura’s unilateral sensorineural hearing loss, Tr. at 9; *see also* Tr. at 12, 19-20, 22; and the absence of another “etiology” for Laura’s unilateral sensorineural hearing loss. Tr. at 9-10; *see also* Tr. at 14-16, 20, 22.

Dr. O’Rourke asserted that “there’s no question” in the medical community that the wild mumps virus and the wild measles virus can cause hearing loss. Tr. at 16-17; *see also* Tr. at 7, 9, 21, 25. Indeed, Dr. O’Rourke maintained that “at least one” case report demonstrates that physicians have “isolated” the wild mumps virus “from the ear of a patient who went acutely deaf during a mumps infection.” Tr. at 8-9; *see also* Tr. at 21, 24-26, 42, 55. According to Dr. O’Rourke, hearing loss related to an infection from wild mumps virus or from wild measles virus may occur “without other dramatic symptoms,” such as an “encephalitis.” Tr. at 21; *see also* Tr. at 7.

Dr. O’Rourke testified that he “builds on” the biologically-proven association between the wild mumps virus, the wild measles virus and hearing loss to render an opinion regarding a biologically-plausible association between MMR vaccine and hearing loss. Tr. at 8. While Dr. O’Rourke described MMR vaccine as an “excellent attenuated” vaccine, he stressed that MMR vaccine is nonetheless “a live viral vaccine.” Tr. at 8; *see also* Tr. at 14, 22. Thus, Dr. O’Rourke

argued that “vaccine[-]strain” virus can infect “in occasional cases” the same body “tissues that are infected by the wild[-]type virus.” Tr. at 53-55; *see also* Tr. at 8, 14, 21-22, 25. As an example, Dr. O’Rourke cited “parotitis.” *See* Tr. at 8, 21-22, 53, 55. Dr. O’Rourke explained that the wild mumps virus “targets” usually the “[parotid] gland.” Tr. at 8; *see also* Tr. at 21-22, 53, 55. And, Dr. O’Rourke claimed that parotitis has become “one of the recently recognized minor complications of MMR vaccination.” Tr. at 8; *see also* Tr. at 21-22, 53, 55. Dr. O’Rourke advanced as a “corollary” that since MMR vaccine “can cause a parotitis, which is a relatively common” consequence of mumps, MMR vaccine “could also cause unilateral deafness, which is an uncommon complication of natural mumps infection.” Tr. at 8; *see also* Tr. at 22, 55.

Moreover, Dr. O’Rourke posited that the “association of MMR vaccination with sudden onset of hearing loss” is “reasonably documented,” estimating that medical literature contains “half a dozen or ten” case reports. Tr. at 17-18; *see also* Tr. at 35. Yet, Dr. O’Rourke conceded that all of the case reports involve a first MMR immunization rather than a second MMR immunization. Tr. at 35-36. Nevertheless, Dr. O’Rourke implied that because the recommendation to administer “[t]he second MMR immunization” has existed only “since [] the early ‘90s,” the medical community has not had sufficient time to examine the “issue of hearing loss in association with the second MMR” immunization. Tr. at 35. In addition, Dr. O’Rourke challenged the proposition that a study like the population-based surveillance conducted in Finland could identify MMR-related sensorineural hearing loss in children if the study did not include prevaccination auditory screening and postvaccination auditory screening to “detect a hearing loss above baseline.” Tr. at 43-44. Regardless, Dr. O’Rourke asserted that “immunity wanes.” Tr. at 27. Thus, Dr. O’Rourke insisted

that people can “be infected” by “measles or mumps after apparently successful vaccination.” *Id.*; *see also* Tr. at 28. Dr. O’Rourke speculated also that as “a host” ages, the “host” may be “more susceptible to certain types of complications” from reexposure to a vaccine. Tr. at 29.

According to Dr. O’Rourke, the interval between exposure to the wild mumps virus or the wild measles virus and the onset of symptoms ranges from “a little bit less than two weeks to a little bit more than three weeks.” Tr. at 11. Dr. O’Rourke suggested that “bioreplication” of the attenuated virus in MMR vaccine “may speed up” because administration of MMR vaccine bypasses “the respiratory tract” where the wild virus incubates “before spreading.” Tr. at 12. Thus, Dr. O’Rourke estimated that the interval between administration of MMR vaccine and the onset of symptoms ranges from “a week or ten days” to “two[-]and[-]a[-]half or three weeks.” Tr. at 25.

Dr. O’Rourke reviewed Laura’s medical history. Dr. O’Rourke discounted the significance of Laura’s May 1996 “acute episode of dizziness,” resulting in a diagnosis of “probable vestibulitis and probable cerebellitis” and prompting a trial of Antivert, as potential evidence of “middle [sic] ear disease.” Tr. at 29-35. Dr. O’Rourke explained that because Laura’s “neurological exam was entirely negative,” Laura’s “dizziness” was likely just part of a “vague symptom complex” rather than “vertigo, which is a more specific symptom associated with the middle [sic] ear.” Tr. at 32-35; *see also* Tr. at 29, 47, 49-50. Thus, in Dr. O’Rourke’s view, Laura was entirely “well” before her August 23, 1996 MMR immunization. Tr. at 5; *see also* Tr. at 30, 32, 34.

Likewise, in Dr. O'Rourke's view, Laura was well until "approximately two weeks" after her August 23, 1996 MMR immunization, when she experienced "onset of symptoms which were" eventually "recognized to be" symptoms "associated with hearing loss." Tr. at 5-6; *see also* Tr. at 10-14, 37-41, 51. Dr. O'Rourke proclaimed that because he was "not impressed with the diagnostic evaluation" that Dr. Trella performed on September 7, 1996, Tr. at 41, *see also* Tr. at 52, he was "quite unconvinced" that Laura had suffered "an upper respiratory tract viral illness" between August 23, 1996, and September 7, 1996. Tr. at 51. Dr. O'Rourke explained that Dr. Trella did not describe any symptom, except congestion, that "suggests" an upper respiratory infection. Tr. at 39-40; *see also* Tr. at 51; *but see* Tr. at 14 (accepting counsel's representation that Laura exhibited symptoms of an upper respiratory infection preceding September 7, 1996, Dr. O'Rourke related broadly the symptoms to immunization), 45 (Dr. O'Rourke agreed that Laura's reported symptoms are consistent with an upper respiratory infection). Moreover, Dr. O'Rourke asserted that upper respiratory infections are not "particularly common" in September. Tr. at 51. Thus, Dr. O'Rourke indicated that Laura's congestion between August 23, 1996, and September 7, 1996, may have represented instead "allergic rhinitis." Tr. at 51-52. In addition, Dr. O'Rourke maintained that Dr. Trella "was simply wrong" when she concluded on September 7, 1996, that Laura exhibited "acute otitis media." Tr. at 13; *see also* Tr. at 10-11. Dr. O'Rourke explained that Dr. Trella did not note that Laura complained of "ear pain," a hallmark of "a bulging tympanic membrane." Tr. at 12-13. Dr. O'Rourke explained also that because "the half-life of middle ear effusion after a true acute otitis media is about three weeks," Tr. at 13, "it's quite unlikely" that an acute otitis media would resolve completely in "seven days." Tr. at 11; *see also* Tr. at 13, 40. Yet, Dr. O'Rourke stated, Dr. Childs described Laura's right ear as "totally normal" on September 13, 1996. Tr. at 11; *see also* Tr. at 13,

40. Thus, Dr. O'Rourke speculated that because Laura presented with "hearing loss" on September 7, 1996, Dr. Trella assumed merely that Laura exhibited acute otitis media. Tr. at 10-11. Regardless, Dr. O'Rourke advanced that even though Laura did not undergo her first formal hearing evaluation until September 13, 1996, her "hearing loss was, in fact, present" on September 7, 1996. Tr. at 13-14. And, according to Dr. O'Rourke, the temporal relationship between the administration of Laura's August 23, 1996 MMR immunization and the onset of Laura's hearing loss "is pretty much exactly" the interval that he "would predict" for hearing loss following MMR immunization based upon "standard incubation period numbers." Tr. at 19-20; *see also* Tr. at 9, 12, 22.

Dr. O'Rourke maintained that Laura's symptoms on September 7, 1996, were not "particularly compatible with" other viruses that have been implicated in hearing loss. Tr. at 41. In addition, Dr. O'Rourke offered that two otolaryngologists who conducted "standard," but "complete," evaluations of Laura's hearing loss did not identify any "anatomic cause" for Laura's hearing loss. Tr. at 15-16; *see also* Tr. at 20, 22. Dr. O'Rourke agreed that there exists a "large category" of cases involving "hearing loss in children" that is labeled "idiopathic." Tr. at 36-37; *see also* Tr. at 20. Moreover, Dr. O'Rourke acknowledged that the two otolaryngologists' conclusions that Laura's hearing loss was "idiopathic" were "reasonable." Tr. at 16. Nevertheless, Dr. O'Rourke insisted that Laura's August 23, 1996 MMR immunization remains "the most plausible" explanation for Laura's hearing loss. Tr. at 20; *see also* Tr. at 21-22.

Dr. Eavey³

Distinguishing sensorineural hearing loss related to congenital rubella syndrome, Tr. at 72, Dr. Eavey testified that he rejects essentially the medical community's "dogma" that viruses can cause sensorineural hearing loss. Tr. at 60; *see also* Tr. at 72, 82, 85, 90, 104, 108, 131. According to Dr. Eavey, the literature regarding the association between viruses and sensorineural hearing loss is "old," Tr. at 85; *see also* Tr. at 70, 72, and "particularly weak." Tr. at 60; *see also* Tr. at 69-70, 103, 108, 118-19. Moreover, Dr. Eavey asserted that a comprehensive study of "secondary effects" from MMR immunization in Finland did not identify sensorineural hearing loss as a complication of immunization. Tr. at 143-45; *see also* Tr. at 69-70, 129.

In Dr. Eavey's view, Laura exhibited "some kind of inner ear disorder" in May 1996, Tr. at 62-66; *see also* Tr. at 83, 119-23, 132-33, that heralded the onset of her unilateral sensorineural hearing loss in September 1996. Tr. at 141; *see also* Tr. at 63-64, 66, 83, 119-20, 132-34. Dr. Eavey noted that during Laura's May 1996 examination, Dr. Childs performed a test "to rule out a really common kind of dizziness" Tr. at 62. Dr. Eavey said that the test result was "normal." *Id.* In addition, Dr. Eavey noted that Dr. Childs diagnosed "vestibulitis." Tr. at 63; *see also* Tr. at 120,

³ Since 1981, Dr. Eavey has served as Director of ENT Pediatric Services at Massachusetts Eye and Ear Infirmary, an adjunct of Harvard Medical School. Respondent's exhibit (R. ex.) C at 2. However, Dr. Eavey testified that he practices primarily "pediatric otology," or "the pediatric ear." Tr. at 57. In addition, since 1981, Dr. Eavey has held several academic appointments at Harvard Medical School. R. ex. C at 1. He is board-certified in pediatrics and in otolaryngology. *Id.*

122. Dr. Eavey explained that the “vestibular system” controlling balance “is also called” the labyrinth, referring to the inner ear. Tr. at 120; *see also* Tr. at 63-64. Further, Dr. Eavey noted that Dr. Childs prescribed “Antivert,” a medication that is “used to treat inner ear disorders.” Tr. at 62-63; *see also* Tr. at 120. Dr. Eavey acknowledged that Dr. Childs did not attempt “extensively to define” the source of Laura’s vestibulitis in May 1996. Tr. at 120. Dr. Eavey acknowledged also that Laura’s vestibulitis in May 1996 resolved. *See, e.g.*, Tr. at 67, 121-23. But, Dr. Eavey maintained that children present occasionally with general “inner ear problems.” Tr. at 120. And, Dr. Eavey insisted that patients with inner ear disorders “usually have episodes” of dizziness that vary in frequency and in duration, rather than constant dizziness. Tr. at 67; *see also* Tr. at 121. Finally, Dr. Eavey noted that Laura’s September 1996 ENG showing that Laura’s “balance system [was] not working well” demonstrated “objectively” a “problem” with Laura’s “inner ear.” Tr. at 63-64. Thus, Dr. Eavey asserted that he cannot “intellectually totally disconnect” the similarities between Laura’s clinical presentation in May 1996 and Laura’s clinical presentation in September 1996. Tr. at 64; *see also* Tr. at 63, 119-20, 132-33.

In the alternative, Dr. Eavey suggested that Laura may have suffered a “bacterial labyrinthitis” that led to her unilateral sensorineural hearing loss from an “ear infection” in September 1996. Tr. at 141; *see also* Tr. at 66, 83. Dr. Eavey stressed that Dr. Trella’s “description of [Laura’s] ear drum” as “red” and “bulging” on September 7, 1996, was not “middle of the road.” Tr. at 65; *see also* Tr. at 141. Thus, Dr. Eavey accepted Dr. Trella’s diagnosis of “otitis media,” representing “pus in the middle ear.” Tr. at 65; *see also* Tr. at 141. And, Dr. Eavey remarked that Laura experienced her sensorineural hearing loss in the same ear that was infected. Tr. at 81. While

Dr. Eavey admitted readily that labyrinthitis with hearing loss from an ear infection is “very uncommon,” he asserted that the phenomenon is “a lot more plausible than” hearing loss from “a vaccine.” Tr. at 66; *see also* Tr. at 83, 141.

Dr. Wientzen⁴

Dr. Wientzen testified that he accepts the “very commonly[-]held principle” that viruses can cause sensorineural hearing loss.⁵ Tr. at 177; *see also* Tr. at 159-60. However, Dr. Wientzen insisted that an association between MMR vaccine and sensorineural hearing loss has “never been proven.” Tr. at 160; *see also* Tr. at 148, 150, 159. Regardless, Dr. Wientzen asserted that in the significant majority of cases, the second dose of “a live attenuated vaccine” like MMR vaccine will not “produce the same kind and number of consequences” as the first dose. Tr. at 151; Tr. at 173-75. Thus, Dr. Wientzen opined that Laura’s sensorineural hearing loss is not related to Laura’s “second MMR” immunization. Tr. at 148-49; *see also* Tr. at 161. Rather, Dr. Wientzen maintained that “the illness that is responsible for Laura’s” sensorineural hearing loss preceded Laura’s August 23, 1996

⁴ Dr. Wientzen is a Professor of Pediatrics at Georgetown University School of Medicine. Tr. at 146; R. ex. K at 1. He serves as Vice Chairman, Department of Pediatrics, and as Chief, Division of Pediatric Infectious Diseases, at Georgetown University Medical Center. Tr. at 146-47; R. ex. K at 1. He is board-certified in pediatrics and in pediatric infectious diseases. Tr. at 147; R. ex. K at 1.

⁵ Respondent should examine the utility of presenting medical experts who offer conflicting testimony about general medical issues. The practice does not assist the special master.

MMR immunization. Tr. at 148; *see also* Tr. at 157-58, 161, 163-65. In the alternative, Dr. Wientzen maintained that Laura's "suppurative otitis media" in September 1996 "could have caused" Laura's sensorineural hearing loss. Tr. at 164-65; *see also* Tr. at 149.

Dr. Wientzen advanced that in order for a virus to cause "damage" like sensorineural hearing loss, the virus "needs to get into the blood, grow in the blood, and then affect a target organ." Tr. at 151; *see also* Tr. at 169, 174. Dr. Wientzen estimated that 98 per cent of children who receive an MMR immunization at age 16 months develop sufficient antibodies to "become immune" to mumps, measles and rubella. Tr. at 151; *see also* Tr. at 170. Dr. Wientzen stated that the children develop also "a clone of T[-]cells" that "carry the immune memory of" the antigens in the MMR vaccine. Tr. at 172; *see also* Tr. at 175. According to Dr. Wientzen, the "immune response" that T[-]cells generate "amnesticly" to a second MMR immunization is "very rapid," Tr. at 175, *see also* Tr. at 172, and "direct," Tr. at 172, preventing the propagation of viremia. Tr. at 174; *see also* Tr. at 151-53. Dr. Wientzen urged that because there is no viremia following a second MMR immunization, the potential consequences of a second MMR immunization are not similar to the potential consequences of a "non-vaccine primary infection" or to the potential consequences of an initial MMR immunization. Tr. at 174; *see also* Tr. at 151-53, 169. Moreover, Dr. Wientzen posited that "accumulated data" establish that the "amnestic response" following exposure to a second MMR immunization is not associated with "serious adverse effects." Tr. at 173-74. Dr. Wientzen explained that if the "amnestic response" were associated with "serious adverse effects," then the bulk of "bad" reactions would occur after a second MMR immunization instead of after an initial MMR immunization. *Id.*

Dr. Wientzen concurred that “the incubation period for side effects” from an MMR immunization is between seven days and 14 days after administration. Tr. at 169; *see also* Tr. at 154, 167. However, Dr. Wientzen asserted that Laura’s “clinical symptomatology” on September 7, 1996, did not represent manifestations of a “vaccine-related complication.” Tr. at 154; *see also* Tr. at 167-69, 177. Challenging Dr. O’Rourke’s interpretation of Laura’s condition on September 7, 1996, Dr. Wientzen contended that Laura suffered clearly an upper respiratory illness and otitis media. *See* Tr. at 162; *see also* Tr. at 154-56, 169. Indeed, Dr. Wientzen declared that the interpretation of Laura’s condition on September 7, 1996, is not subject to “valid debate.” Tr. at 155; *see also* Tr. at 162. Dr. Wientzen explained first that the process of diagnosing otitis media is not “an arcane part of the science of pediatrics.” Tr. at 155. Rather, Dr. Wientzen remarked that the process of diagnosing otitis media in older children who “don’t struggle, cry, [or] fight” like infants or toddlers is “very easy.” Tr. at 155-56. Dr. Wientzen explained next that 20 per cent of otitis media cases will resolve “one week into antibiotic therapy,” particularly if the child is older since “the anatomy is bigger.” Tr. at 156-57. According to Dr. Wientzen, the MMR vaccine does not cause “respiratory symptoms.” Tr. at 177; *see also* Tr. at 154, 167. In addition, according to Dr. Wientzen, while otitis media is “very common complication of wild measles infection,” Tr. at 166, otitis media has never been identified as a complication of the MMR vaccine. Tr. at 154.

In Dr. Wientzen’s view, Laura’s “episode of dizziness” or “vestibulitis” in May 1996 marked the “clinical beginning of” some “process” leading to Laura’s sensorineural hearing loss in September 1996. Tr. at 148; *see also* Tr. at 161, 163-65. Dr. Wientzen stated that in his experience, children present rarely with “a complaint of dizziness” resulting in a diagnosis of “vestibulitis.” Tr.

at 157. As an example, Dr. Wientzen offered that he has “prescribed Antivert” no “more than two to three times in a 25-year career.” *Id.* Thus, Dr. Wientzen implied that Laura’s description of symptoms in May 1996 must have been “very convincing” for Dr. Childs to be “suspicious” enough of an “inner ear” disorder to prescribe Antivert. *Id.* And, Dr. Wientzen submitted that Laura’s description of dizziness in May 1996 and Laura’s description of dizziness in September 1996 is “extremely internally consistent.” Tr. at 158; *see also* Tr. at 161.

Although not his “primary thinking in the case,” Dr. Wientzen suggested that Laura’s “suppurative otitis media” in September 1996 is “another reason” for Laura’s sensorineural hearing loss. Tr. at 164-65; *see also* Tr. at 149. Dr. Wientzen acknowledged that otitis media causes predominantly temporary “conductive hearing loss.” Tr. at 163. But, Dr. Wientzen said that “a toxic or infective inner ear infection” from otitis media “can cause” also sensorineural hearing loss. Tr. at 164-65; *see also* Tr. at 149.

Dr. Zweiman⁶

⁶ Dr. Zweiman is currently Emeritus Professor of Medicine and Neurology at the University of Pennsylvania Medical Center. Tr. at 179; R. ex. I at 2. From 1974 to 1998, Dr. Zweiman served as Chief of the Allergy and Immunology Section in the Department of Medicine at the University of Pennsylvania School of Medicine. R. ex. I at 2. He is board-certified in internal medicine, in allergy and immunology and in diagnostic laboratory immunology. *Id.*

Dr. Zweiman disputed Dr. O'Rourke's interpretation of some of Laura's symptoms preceding Laura's unilateral sensorineural hearing loss. *See* Tr. at 184-85. Based upon his experience directing a hospital's "Allergy Unit," Dr. Zweiman opined that "nasal congestion alone" is not consistent with "acute seasonal allergic rhinitis or Hay Fever." Tr. at 184-85. Rather, Dr. Zweiman indicated that he would expect "repetitive sneezing, itching [and] eye symptoms" to accompany nasal congestion related to "pollen and acute seasonal allergic rhinitis." Tr. at 185. Thus, Dr. Zweiman offered that in the absence of other indicia of "an allergic reaction," Laura's nasal congestion was "at least as likely" to represent "an upper respiratory infection." *Id.*

Stating that he is "not an infectious disease specialist," Dr. Zweiman declined to comment upon the Institute of Medicine's conclusion that it is biologically plausible that wild mumps can cause sensorineural hearing loss. Tr. at 192. Nevertheless, Dr. Zweiman insisted that one cannot "extrapolate" that a "wild virus" and a "vaccine virus" act similarly. Tr. at 193; *see also* Tr. at 180. According to Dr. Zweiman, a wild virus is different from an attenuated vaccine virus. Tr. at 180, 193.

Moreover, Dr. Zweiman testified that an attenuated vaccine virus does "not behave the same way in somebody who has had a previous dose" of the vaccine. Tr. at 180. Dr. Zweiman said that an immunologically sound person who receives an attenuated virus vaccine will mount an immunological response to the vaccine. Tr. at 185. Indeed, Dr. Zweiman maintained that even if an immunologically sound person who has received an attenuated virus vaccine does not "make big quantities of antibodies" to the vaccine, *id.*, or even if an immunologically sound person's immunity

to the vaccine has waned, Tr. at 186, the person will have still “a population of” certain “memory T[-]cells” from the “prior immunologic encounter.” Tr. at 185. Dr. Zweiman asserted that “memory T[-]cells” provoke “a very rapid secondary immune response” when an immunologically sound person who has received an attenuated virus vaccine is exposed again to the vaccine. Tr. at 186. Dr. Zweiman elaborated that the “secondary immune response” will “contain the virus” in the vaccine, preventing likely the “virus” from “enter[ing] the central nervous system.” *Id.* Dr. Zweiman noted that there is no evidence that Laura has “any underlying immune deficiencies.” Tr. at 185. Thus, Dr. Zweiman doubted that Laura could have suffered unilateral sensorineural hearing loss from a viral invasion of her central nervous system related to her second MMR immunization. Tr. at 186; *see also* Tr. at 180-81.

THE STATUTORY SCHEME

Ms. Malloy may pursue potentially three legal theories. Ms. Malloy may present what is commonly referred to as a Table case. The Act contains the Vaccine Injury Table that lists vaccines covered by the Act and certain injuries and conditions that may stem from the vaccines. § 300aa-14. If Ms. Malloy establishes by the preponderance of the evidence that following an August 23, 1996 MMR immunization, Laura suffered the onset of an injury listed on the Table for MMR vaccine, within the time period provided by the Table, then Ms. Malloy is entitled to a presumption that the

vaccine caused the injury. §§ 300aa-11(c)(1)(C)(i); 300aa-13(a)(1)(A).⁷ Respondent may rebut the presumption of causation if respondent establishes by the preponderance of the evidence that the injury was “due to factors unrelated to the administration of” a vaccine. § 300aa-13(a)(1)(B); *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994).

In the alternative, Ms. Malloy may show based upon traditional tort standards that Laura’s August 23, 1996 MMR immunization caused actually a condition that is listed on the Table for MMR vaccine, but that occurred outside the period provided in the Table, § 300aa-11(c)(1)(C)(ii)(II); or that Laura’s August 23, 1996 MMR immunization caused actually a condition that is not listed on the Table for MMR vaccine. § 300aa-11(c)(1)(C)(ii)(I). Thus, to prevail under an actual causation theory, Ms. Malloy must demonstrate by the preponderance of the evidence that (1) “but for” the administration of Laura’s August 23, 1996 MMR immunization, Laura would not have been injured, and (2) Laura’s August 23, 1996 MMR immunization was a “substantial factor in bringing about” Laura’s injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). According to the United States Court of Appeals for the Federal Circuit, Ms. Malloy’s burden is “heavy.” *Whitcotton v. Secretary of HHS*, 81 F.3d 1099, 1102 (Fed. Cir. 1996). The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove legal cause. *Grant v. Secretary of HHS*,

⁷ The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g., Thornton v. Secretary of HHS*, 35 Fed. Cl. 432, 440 (1996); *see also 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 meet the preponderance of the evidence standard. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff’d*, 73 F.3d 381 (Fed. Cir. 1995).

956 F.2d 1144 (Fed. Cir. 1992); *see also Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, Ms. Malloy must establish “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” *Grant*, 956 F.2d at 1148. Ms. Malloy must support the logical sequence of cause and effect with a “sound and reliable” medical explanation. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994)(citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993)). “The analysis undergirding” the medical explanation must “fall within the range of accepted standards governing” medical research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Special masters apply routinely a two-part test to analyze actual causation cases. *See, e.g., Crockett v. Secretary of HHS*, No. 94-0015V, 1997 WL 702559 (Fed. Cl. Spec. Mstr. Sept. 30, 1997); *Housand v. Secretary of HHS*, No. 94-0441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996); *Guy v. Secretary of HHS*, No. 92-0779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994). First, special masters determine if a specific vaccine *can* cause a specific injury. *See, e.g., Crockett v. Secretary of HHS*, No. 94-0015V, 1997 WL 702559 (Fed. Cl. Spec. Mstr. Sept. 30, 1997). Then, special masters determine if the vaccine more likely than not *did* cause the injury in the individual case. *Id.* The evidence in a case “must affirmatively demonstrate that the injury. . . was caused by the vaccine.” *Grant*, 956 F.2d at 1147-48 (quoting H.R. REP. No. 908, 99th Cong., 2nd Sess., pt. 1, at 15 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6356)(emphasis omitted); *see also Hodges v. Secretary of HHS*, 9 F.3d 958, 961 n.4 (Fed. Cir. 1993)(“That the DPT vaccine may cause death is not proof that it did in a particular case.” (quoting *Hodges v. Secretary of HHS*, No.

90-0551V, 1991 WL 169397, *4 (Cl. Ct. Spec. Mstr. Aug. 14, 1991)); *Bunting v. Secretary of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991) (a petitioner’s burden is “to show causation in the particular case,” not just a “generalized ‘cause and effect relationship’”).

DISCUSSION

Sensorineural hearing loss is not listed on the Table as an injury associated with MMR vaccine. Thus, Ms. Malloy pursues necessarily her claim under an actual causation theory. The special master has reviewed thoroughly the record as a whole, considering carefully the expert testimony. The special master determines that Ms. Malloy has failed to demonstrate by the preponderance of the evidence that Laura’s August 23, 1996 MMR immunization is the legal cause of Laura’s unilateral sensorineural hearing loss.

At its most basic, the actual causation standard requires Ms. Malloy (1) to adduce a theory of causation and (2) to apply the theory of causation. *See, e.g., Gall v. Secretary of HHS*, No. 91-1642V, 1999 WL 1179611 (Fed. Cl. Spec. Mstr. Oct. 21, 1999). According to the United States Court of Appeals for the Federal Circuit, “no hard and fast *per se* scientific or medical rules” govern the actual causation standard. *Knudsen*, 35 F.3d at 548. Indeed, Ms. Malloy’s theory of causation need not be “medically or scientifically certain.” *Id.* at 549. However, Ms. Malloy’s theory of causation--and the application of Ms. Malloy’s theory of causation--must be “logical” and “probable,” given “the circumstances of the particular case.” *Id.* at 548-49.

Through Dr. O'Rourke, Ms. Malloy proposes an elementary theory of causation. Dr. O'Rourke asserted that the medical community recognizes that natural viruses are capable of infecting the inner ear leading to sensorineural hearing loss. *See* Tr. at 7-9, 14, 16-17, 21, 25, 54-55. Therefore, Dr. O'Rourke postulated that, mimicking natural viruses, the attenuated viruses in MMR vaccine are capable of infecting the inner ear leading to sensorineural hearing loss. *See* Tr. at 8, 14, 21-22, 25, 53-55. Dr. O'Rourke testified that the interval between administration of MMR vaccine and the onset of symptoms of an MMR vaccine-related infection ranges from one week to three weeks. Tr. at 25.

In addition, through Dr. O'Rourke, Ms. Malloy proposes an application of the elementary theory of causation. Urging that Laura's "sudden onset of" hearing loss represented "major" confirmation of an MMR vaccine-related infection of Laura's inner ear, Pet. ex. 15 at 1; *see also* Tr. at 26, 42, 55, Dr. O'Rourke stated that Laura's sensorineural hearing loss following Laura's August 23, 1996 MMR immunization occurred almost "exactly" within the accepted interval between administration of MMR vaccine and the onset of symptoms of an MMR vaccine-related infection. Tr. at 19-20; *see also* Tr. at 9, 12, 22.⁸ Dr. O'Rourke offered that an investigation of potential etiologies for Laura's sensorineural hearing loss failed to yield another, plausible explanation for Laura's condition. Tr. at 15-16, 20-22. Therefore, Dr. O'Rourke opined that Laura's August 23,

⁸ Dr. O'Rourke was equivocal about the significance of other symptoms that Laura exhibited between August 23, 1996, and September 7, 1996. Dr. O'Rourke indicated that the symptoms may, or may not, have been related to Laura's August 23, 1996 MMR immunization. Pet. ex. 15; Tr. at 44-45, 51.

1996 MMR immunization is the “most likely cause of” Laura’s sensorineural hearing loss. Tr. at 6-7; *see also* Tr. at 10, 20-22, 25-26.

Despite Dr. Eavey’s seemingly solitary view that natural viruses do not cause sensorineural hearing loss, *see* Tr. at 60, 72, 82, 85, 90, 104, 108, 131, and despite Dr. Wientzen’s protestation that an association between MMR vaccine and sensorineural hearing loss has “never been proven,” Tr. at 160; *see also* Tr. at 148, 150, 159, the Institute of Medicine (IOM) of the National Academy of Sciences (NAS)--the august body that Congress designated to canvass scientific and medical evidence regarding adverse consequences of routine childhood vaccines, *see* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, §§ 312-13, 100 Stat. 3779-82 (1986)--endorses certainly to some degree Dr. O’Rourke’s theory of causation. The IOM acknowledges the “demonstrated biological plausibility that mumps vaccine,” and, to a lesser extent, measles vaccine, “could cause sensorineural deafness” like their natural counterparts. INSTITUTE OF MEDICINE, ADVERSE EFFECTS ASSOCIATED WITH CHILDHOOD VACCINES--EVIDENCE BEARING ON CAUSALITY 147 (1994). However, as Dr. O’Rourke conceded, all of the case reports that he relied upon to propound a theory of causation are the same case reports that the IOM reviewed. *See* Tr. at 35-36. And, as Dr. O’Rourke conceded, each case report involves a first MMR immunization rather than a second MMR immunization. Tr. at 35-36. The distinction is pivotal.

Dr. O’Rourke admitted that he grounds his opinion upon the assumption that Laura suffered an “acute viral infection” of her inner ear from her August 23, 1996 MMR immunization. Tr. at 26; *see also* Tr. at 42, 55. Noting that Laura’s August 23, 1996 MMR immunization was Laura’s second

MMR immunization, Dr. Wientzen and Dr. Zweiman challenged emphatically Dr. O'Rourke's assumption. *See* Tr. at 148-49, 151-53, 161, 169, 173-75, 180-81, 185-86. According to Dr. Wientzen and Dr. Zweiman, a second MMR immunization in an immunologically sound person does not produce viremia that is responsible for infection. Tr. at 151-53, 169, 172-75, 180-81, 185-86. Dr. Wientzen and Dr. Zweiman explained based upon principles of immunology that even in the absence of significant antibodies developed from an initial MMR vaccine, T-cells generated from an initial MMR immunization will provoke a rapid immune response that inhibits the propagation of viremia from attenuated virus in a second MMR immunization. Tr. at 151, 169-70, 172-75, 185-86. Thus, Dr. Wientzen and Dr. Zweiman asserted that a second MMR immunization in an immunologically sound person cannot cause an acute viral infection. *See* Tr. at 151-53, 185-86.

Dr. O'Rourke did not address substantively Dr. Wientzen's testimony or Dr. Zweiman's testimony about the immunological effect of a second MMR immunization. Dr. O'Rourke offered weakly that people can "be infected" by "measles or mumps after apparently successful vaccination." Tr. at 27-28. In addition, Dr. O'Rourke speculated that as "a host" ages, the "host" may be "more susceptible to certain types of complications" from reexposure to a vaccine. Tr. at 29.

Based upon medical literature and upon the medical testimony, the special master determines confidently that Dr. O'Rourke's theory of causation is medically probable as it relates to an initial MMR immunization. The special master understands that attenuated viruses in an initial MMR immunization may produce rarely an acute viral infection similar to natural viruses. However, because Laura's August 23, 1996 MMR immunization was Laura's second MMR immunization, the

special master rules that Dr. O'Rourke's theory of causation does not apply logically to the facts in this case. Based upon medical literature and the medical testimony, the special master determines equally confidently that Dr. O'Rourke's theory of causation is *not* medically probable to the extent that it relates to a second MMR immunization. The special master understands that attenuated viruses in a second MMR immunization are extremely unlikely, if ever, to produce an acute viral infection similar to natural viruses. However, the special master is willing to accept that tangible evidence that the initial MMR immunization more likely than not failed--such as proof that an initial MMR immunization was part of a defective lot of vaccine; proof reflecting the lack of seroconversion or proof of an underlying immunological deficiency--supports a proposition that attenuated viruses in a second MMR immunization may produce rarely an acute viral infection similar to natural viruses. Indeed, at hearing, Ms. Malloy attempted apparently to suggest that Laura may have been among the very small percentage of children who do not develop immunity after receiving an initial MMR immunization at age 16 months. *See* Tr. at 170. But, after an exhaustive search of the record, the special master cannot identify any evidence that persuades the special master that Laura's initial MMR immunization failed, allowing Laura's second MMR immunization to produce the acute viral infection of Laura's inner ear that Dr. O'Rourke hypothesizes.

The special master decides this case upon a critical, intellectual analysis of the medical evidence, the medical testimony and the specific fact that Laura's August 23, 1996 MMR immunization was Laura's second MMR immunization under the actual causation standard.⁹

⁹ Ms. Malloy presses the special master to use a five-pronged test that the Chief Special Master promulgated in *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387419 (Fed. Cl. Spec.

However, the special master recognizes that some statements in Laura's medical records may be construed as evidence supporting causation. Therefore, the special master discusses briefly the statements in Laura's medical records. In addition, while the special master does not resolve this case upon simple credibility issues, he comments briefly upon his assessment of aspects of Dr. O'Rourke's testimony that would prompt the special master to accord less weight to Dr. O'Rourke's testimony as opposed to Dr. Wientzen's testimony.

Ms. Malloy stresses that Dr. Dossett, a pediatric infectious diseases specialist whom Dr. Childs consulted, would attribute Laura's sensorineural hearing loss to Laura's August 23, 1996 MMR immunization "if [Laura's] hearing loss had started 8-10 days or more after [Laura] received the MMR." See P. Brief at 5, 13, citing Pet. ex. 3 at 80. Indeed, Ms. Malloy implies that Dr. Childs concluded that Laura's August 23, 1996 MMR immunization caused Laura's sensorineural hearing loss when, after reviewing Dr. Dossett's letter, Dr. Childs appended a memo exclaiming that Laura's hearing loss "did occur" within the period that Dr. Dossett cited. See P. Brief at 5, citing Pet. ex. 3 at 80 (emphasis in original). The statements are consonant surely with Dr. O'Rourke's testimony. However, a close examination of the record reveals that the evidence is in equipoise really. Dr. Childs consulted also Dr. Long, an infectious diseases specialist. Pet. ex. 3 at 31. Dr. Childs

Mstr. Mar. 30, 2001). See Petitioner's Closing Argument (P. Brief), filed June 28, 2002. The special master declines to adopt the *Stevens* test in this case. Regardless, the special master rules that Ms. Malloy's claim does not meet certain prongs of the *Stevens* test. Ms. Malloy has not presented case reports or other medical literature suggesting that sensorineural hearing loss is associated with a second MMR immunization, as opposed to an initial MMR immunization. See, e.g., Tr. at 35-36 (All case reports involve a first MMR immunization rather than a second MMR immunization).

indicated that Dr. Long was not aware of the “phenomenon” of hearing loss following a “booster” immunization. *Id.* (emphasis in original). Dr. Long’s statement is consonant surely with Dr. Wientzen’s testimony and with Dr. Zweiman’s testimony.

Dr. O’Rourke was a solid witness with sterling professional credentials. Yet, the special master finds that Dr. O’Rourke’s interpretation of several of Laura’s medical records was not persuasive. For instance, the special master discredits as ineffective Dr. O’Rourke’s attempt to distinguish between Laura’s May 1996 episodes of dizziness and Laura’s September 1996 dizziness. *See, e.g.*, Tr. at 29-35, 47, 49-50. Rather, the special master agrees with Dr. Wientzen that the record from May 22, 1996, and the record from September 7, 1996, are strikingly “internally consistent.” Tr. at 158; *see also* Tr. at 161. In addition, the special master rejects wholly Dr. O’Rourke’s criticism of Dr. Trella’s diagnosis of acute otitis media on September 7, 1996. *See* Tr. at 10-13, 40. Dr. O’Rourke stated that Dr. Childs described Laura’s right ear as “totally normal” on September 13, 1996, just six days later. Tr. at 11; *see also* Tr. at 13, 40. And, Dr. O’Rourke asserted that even with appropriate antibiotic treatment, “it’s quite unlikely” that an acute otitis media would resolve completely in “seven days.” Tr. at 11; *see also* Tr. at 13, 40. However, the record refutes Dr. O’Rourke’s interpretation. While Dr. Childs indicated in an October 24, 1996 letter to Dr. Deutsch that Laura’s right “[ear]drum looked very much better” on September 13, 1996, Pet. ex. 7 at 70, Dr. Childs wrote in his September 13, 1996 examination notes that Laura’s right ear was still “abn[orma]l.” Pet. ex. 3 at 29. Thus, Dr. Childs must have observed some remarkable residua of the “erythematous, bulging [and] immobile” tympanic membrane that Laura exhibited on September 7, 1996. Pet. ex. 3 at 28.

CONCLUSION

The special master is exceedingly sympathetic about Laura's circumstances. However, the special master is constrained to hold that Ms. Malloy is not entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

The clerk of court shall send Ms. Malloy's copy of this decision by overnight express delivery.

John F. Edwards

Special Master