

OFFICE OF SPECIAL MASTERS

No. 90-1427V

(Filed: December 2, 1999)

TAMMY ZIMMER, as mother of
KYLE ZIMMER, a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

TO BE PUBLISHED

William Dobreff, Esq., Warren, Michigan, for Petitioner.

R. Lynne Harris, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

ABELL, Special Master:

On 23 December 1997, Petitioner filed a claim for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)¹ for the alleged vaccine related injuries of her son, Kyle Zimmer, as a result of his 3 January 1995 Diphtheria-Pertussis-Tetanus (DPT) vaccination. On 8 February 1999, the Court conducted a full entitlement hearing but did not issue a bench ruling because Petitioner requested closing argument through the filing of posthearing briefs. The Court granted that request. After considering the posthearing submissions, the entire record, and the exhibits filed with the Court, the undersigned is compelled to deny Petitioner a favorable decision on entitlement and, therefore, compensation to young Kyle Zimmer.

¹ The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. §§ 300aa-1 *et seq.* (West 1991 & Supp. 1997). Reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

I. FACTS²

The facts are not in dispute. Eighteen month old Kyle Zimmer vomited three times on the morning of 6 January 1995. His face was swelling. A rash appeared on his face and groin. At 6:05 a.m., Tammy Zimmer and her husband carried their son, Kyle Zimmer, to the emergency room (ER) at St. Joseph's Hospital for the first time that morning. Upon arrival, medical personnel discovered that Kyle had a low-grade temperature of 100.1°.³ An examination by the ER doctor revealed that Kyle had a "mild" temperature, a swelling and erythema of his cheeks and below his eyes, and a rash to the groin. Ruling out an allergic reaction or viral infection, the ER doctor administered some antibiotics and Benadryl, an antihistamine. A short while later, Kyle was doing better and the ER staff subsequently discharged him at 6:40 a.m.

Fifteen minutes later, at 6:55 a.m., Kyle Zimmer's parents brought him "immediately" back to the emergency room (ER) at St. Joseph's Hospital because his facial swelling had increased. *See* P's Ex. 5 at 51 and Ex. 11 at 108. The ER doctor again evaluated Kyle, ordered lab work, and then decided to call a staff pediatrician to examine the child. P's Ex. 10 at 100 and Ex. 11 at 108. The ER discharged Kyle a second time at 8:25 a.m. P's Ex. 11 at 108. Later that day, Kyle's parents took him to his pediatrician's office for a follow-up visit. The pediatrician observed that Kyle had "some obvious swelling in his face and almost a bruised appearance to both cheeks." P's Ex. 11 at 104. His temperature had risen to 102.4°. *Id.* Kyle returned home.

During the night of 6 January 1995, Kyle was restless and lethargic. By the morning of 7 January 1995, Kyle's temperature peaked at 105° (P's Ex. 21 at 187-88 (Emergency Medical Systems records)) and appeared lethargic. At 6:45 a.m. Kyle had a seizure. P's Ex. 9 at 87. His parents again took him to St. Joseph's ER--this time by ambulance. Upon arrival at 8:40 a.m., St. Joseph's ER recorded Kyle's rectal temperature at 104.3°. P's Ex. 21 at 183-85. Kyle's mother and father told the ER staff that Kyle had "stiffened up and [his] eyes rolled back lasting one minute." *Id.*; *see also* P's Ex. 10 at 103. An ER consult, after discussing the matter with another physician, concluded that Kyle had a "febrile/allergic reaction" to a vaccination. P's Ex. 21 at 194.⁴ After drinking fluids and consuming alternating doses of Motrin and Tylenol, Kyle's rectal temperature finally dropped to 100.1° by 10:15 a.m. P's Ex. 21 at 186. Twenty-four hours later, the hospital discharged Kyle for the last time on 8 January 1995. He was eating and drinking, alert, playful--and afebrile all day. P's Ex. 21 at 191. No further seizure activity or neurological deficits were noted during Kyle's

² Hereinafter "P's Ex. ___."

³ All temperatures are in the Fahrenheit scale.

⁴ The attending ER physician at St. Joseph's noted that Kyle's parents had been told that he had suffered an "allergic reaction to something, [sic] was told to give him his Benadryl and they sent him home. He came back the next day because he had a rash on his face that turned into bruises and he developed a low grade temperature. Prior to this, a nurse practitioner at our Romeo office had thought he was developing a middle ear infection and prescribed some Biaxin." P's Ex. 4 at 55 (emphasis added.)

hospitalization.

The event that triggered Kyle's hospital emergency visits and hearing loss is attributed by Petitioner to 3 January 1995. On that day, Petitioner brought her son Kyle to his pediatrician for a routine evaluation and to receive his final and suspect series of vaccinations--specifically, his fourth DPT and third OPV vaccinations. *See* P's Ex. 6 at 66.

Before this last series of vaccinations, Kyle seemed to be developing normally. He was born on 21 June 1993, and appeared to be the product of a normal pregnancy though he "did have physiological jaundice . . . believe[d] secondary to breast milk." P's Ex. 4 at 38. By 27 December 1993, Kyle's baby visits continued to document that he was a "[v]ery pleasant young man who is smiling [sic] no distress at all." *Id.* at 40. At nine months of age, Kyle could use "2 syllable words ("ma ma" and "da da")." *Id.* at 42. At 12 months, his mother voiced "no problems." *Id.* at 45. Likewise, at his 15-month well baby visit, there were "[n]o problems per parent. No infections. Baby has been walking alone, playing with ball *and follows directions.*" *Id.* at 48 (emphasis added). Apart from his final DPT vaccination, Kyle received most of his vaccinations in due course and apparently without incident. *See* P's Ex. 4 at 47, Ex. 5 and 6.

The controversial point in this case surrounds Kyle's routine 18 month checkup on 20 December 1994--almost a month before his DPT immunization. His pediatrician noted that Kyle's language seemed to be "lagging" though Kyle could say "4-5 words" and make repetitive sounds. P's Ex. 5 at 50. On 9 January 1995, after Kyle's DPT vaccination, his doctor found him apparently normal and advised Kyle's parents to return to the office should any problems arise. Apparently, his parents found no cause to schedule further doctor visits until 30 January 1999. On that date, medical personnel record that Kyle was "*still having* difficulty with speech, . . ." without mentioning any association with Kyle's DPT immunization. P's Ex. 5 at 58 (emphasis added) Compare this statement, however, with a 7 February 1995 medical record:

[T]he family is concerned about speech delay. It seemed like [Kyle] was talking more, then *all of the sudden over the last month or so*, speech has decreased.⁵ He did have a febrile reaction to a DPT shot earlier in January where he spiked a fever as high as 105 and had febrile convulsions.

P's Ex. 8 at 71 (emphasis added.); *see also* P's Ex. 5 at 52.

Kyle's first hearing exam ever was performed *after his DPT shot* through various hearing tests. P's Ex. 8 at 71-74. Clinical observations recorded that Kyle's "head turns mainly to the left side to tonal and speech stimuli. [S]hows moderate to severe hearing loss in better ear." *Id.* at 72. Other

⁵ However, Kyle's grandfather "suspected a hearing loss in Kyle on Thanksgiving [in 1994 before the suspect vaccination]. He was concerned that Kyle's language had not developed appropriately and he was aware of this since he had a hearing loss himself." P's Ex. 9 at 87. This familial observation was not dispositive of genetic history since Kyle's mother was adopted. Tr. at 16-17. No familial history was available.

results suggested that Kyle had hearing loss in both of his ears. After these tests, a computer tomography (CT) scan of Kyle's ears revealed soft tissue disease within both of Kyle's middle ear chambers. P's Ex. 8 at 77. On 28 March 1995, Kyle visited the Michigan Ear Institute where Dr. Larry B. Lundy, M.D., an ear specialist, concluded that "[i]t is possible that the DPT vaccine could have contributed to Kyle's hearing loss." P's Ex. 9 at 86-89. As the basis of this conclusion, Dr. Lundy records on 31 March 1995 that

[Kyle] had a DPT vaccine in January. He had seizures and high fevers a few days later. Subsequently noted that his hearing was diminished and subsequent examination revealed him to have significant sensorineural hearing loss in the right ear. Since January, he has had several episodes of otitis media which have been refractory to antibiotics.

Id.

II. EXPERT WITNESSES

1. *Petitioner's Medical Expert - Dr. Gary Trock, M.D.*⁶

For Petitioner's expert opinion, Dr. Trock proffered a theory that Kyle suffered a sensorineural hearing loss, arising not from an immediate reaction to the DPT immunization, but from a delayed hypersensitivity reaction. Tr. at 10. In his words, Kyle's "immunization led to a[n] over-exaggerated immune response" that attacked a neural element, here Kyle's "auditory nerve and/or cochlea⁷" Tr. at 17-18. To clarify his explanation of a logical relationship, Dr. Trock explained the process by way of analogy: "*It is not a viral invasion of the nerve. It is a viral presence⁸ in the*

⁶ Dr. Trock graduated with class honors from Michigan Medical School on 6 June 1974. He interned at the University of Minnesota Hospitals and completed a pediatric residency at that same institution. Between 1977 and 1980, Dr. Trock also completed a fellowship at the University of Minnesota in the area of Pediatric Neurology and Clinical Neurophysiology. From 1980 to the present, he has been in private practice in the field of pediatric neurology and clinical neurophysiology. In addition to holding the title of Director of Pediatric Neurology at two Michigan hospitals, Dr. Trock is currently the Medical director of the Neurodiagnostic Lab at William Beaumont Hospital, as well as the attending pediatrician. He is board certified in the following several areas: Pediatrics, Neurology with Special Competence in Child Neurology, Electroencephalography and Evoked Potentials, and finally, Clinical Neurophysiology. The *curriculum vitae* filed with the Court referred to a separate form (not filed with the Court) listing Dr. Trock's lectures, conferences, publications, and courses that he directed. A perfunctory search on Lexis reveals that Dr. Trock has authored a number of articles in his field.

⁷ The cochlea is "a spiral tube forming part of the inner ear, which is the essential organ of hearing." DORLAND'S POCKET MEDICAL DICTIONARY, 24TH EDITION 133 (1989).

⁸ In his expert medical report, Dr. Trock explained that although Kyle's "illness, as described, could have been described by an unknown virus, the presence of such a virus would be speculative and we are certain that Kyle received the DPT immunization. The reaction, as described, within reasonable medical probability was the result of the immunization. It is well known, acute hearing loss may occur in association with various viral syndromes, with

body. The body's immune response attacks the virus, and in doing so, through a misguided immune response also attacks the neural elements." Tr. at 18. Because the body's immune cells attack the body's own healthy cells--an immune reaction and not an infectious reaction--various nerve impairments occur. According to Dr. Trock, the more common seventh nerve impairment (known as Bell's Palsy) and the involvements of multiple nerves that may lead to Guillain-Barre Syndrome, are similar illustrations of this process of impairment. Tr. at 17.

Dr. Trock was not suggesting that DPT was a viral insult. He testified that no virus was found, and, therefore, an unknown virus could not have caused the immune response.⁹ Petitioner's Expert Medical Report at 1. Rather, it was the body's reaction to a perceived infectious presence--here the introduction of the DPT vaccine and the attendant allergic reaction--that precipitated the immune response and subsequent attack on Kyle's auditory nerves.

However, critical points in the records indicate that family and medical personnel thought Kyle had a speech deficit before his DPT vaccination. The Court finds that this possibly suggests an existing undetermined state of hearing impairment before the suspect vaccination. And if true, this factor would make the DPT association appear merely temporal with the shot. To parry the concern that Kyle had a speech deficit before his DPT immunization because he could only speak "4-5 words," Dr. Trock opined the contrary:

[T]hat many words is in the normal range at that age. Also, he was repeating a number of sounds. That to me does not suggest a child who has profound hearing impairment. . . . I would expect [of a child with a profound hearing impairment] little or no words at that time, and not - the inability to repeat sounds.

Tr. at 13-14. On cross examination, Respondent queried Dr. Trock on the seeming inconsistency that arose between Trock's opinion and Kyle's pediatrician that before the vaccination in December of 1994, Kyle's "pediatrician not[ed] a possible early speech delay." Tr. at 24. Dr. Trock distinguished between what he termed "questionable speech delay" and "profound hearing loss," hinging the distinction on the hypothesis that,

if this child had profound hearing loss, he shouldn't have five single words, he should

the pathophysiology, an auto-immune attack on the cochlea and/or auditory nerve, *rather than direct viral invasion*. In the discipline of experimental neuroimmunology, it is well recognized immunizing an animal with components of various neurostructures may lead to a direct immune attack on those structures. Though there is no diagnostic test available to prove the relationship, it is in my opinion, with reasonable medical probability, based on the available history, and the available information concerning neuroimmunology, and causes of acute hearing loss, the DPT immunization was the cause of the hearing loss experienced by Kyle Zimmar [sic]." Dr. Trock's Expert Medical Report at 2.

⁹ Although Dr. Trock could not rule out a viral illness, he thought a virus was speculative. Tr. at 31. The reason he opined this--and the Court finds this more persuasive--is that a fever occurring "within a day or two after the symptoms is much more typical of a response, delayed hypersensitivity, than it is to a viral reaction." *Id.*

not be repeating various sounds. And the mother said the child abruptly stopped talking after the exam. . . . I don't think that he had a profound hearing loss prior to the immunization.

Tr. at 24. With this rationale, Dr. Trock discounted Respondent's theory that the hearing loss was a progressive deterioration. *Id.* For Dr. Trock, "Kyle suffered a sudden hearing loss in association with an acute illness." P's Expert Medical Report at 1.

Finally, Dr. Trock and Respondent's medical expert both agreed that fever could not cause hearing loss. Tr. at 30.

2. *Respondent's Medical Expert - Dr. Eavey*¹⁰

After setting forth his specialty as the "pediatric ear" and a current practice of approximately 50 pediatric patients per week (Tr. at 34), Dr. Eavey indicated all the copious sources he had researched, confidently stating that he did not find *anything* that linked fever and hearing loss, viral illness with hearing loss, or a DPT vaccination with hearing loss. Tr. at 41.¹¹ He did note, however, a possible link to hearing loss by way of an MMR vaccination but testified that he had not satisfactorily resolved that issue. Tr. at 42-43.

At the heart of his testimony, Dr. Eavey began with an introduction to hearing loss:

The most common cause of sensory-neural hearing loss is genetic or idiopathic. Genetic can be either that the patient has a positive family history or that they are actually the first person that will for the future pass on genes. So there can be, for

¹⁰ Dr. Eavey obtained his M.D. from the University of Pennsylvania in 1975. His postdoctoral training includes an internship and residence in Pediatrics and a residence in Surgery. Dr. Eavey was also a resident in the field of otolaryngology at Massachusetts Eye and Ear Infirmary in Boston, and a clinical fellow in otolaryngology at Harvard Medical School. His certification includes the National Board Examination, Part I of the American Board of Pediatrics, the American Board of Otolaryngology, and the American Board of Pediatrics. Of particular note, Dr. Eavey has taught, in various years, at the Harvard Medical School in the areas of Otolaryngology and Laryngology, and Emergency Procedures in Pediatrics. Among his numerous professional positions, Dr. Eavey has taught seminars, participated in many international events. To his credit, Dr. Eavey has either authored or co-authored over 41 articles, a number of book chapters, a book, and six videos, all in the area of otolaryngology.

¹¹ In *Bobbitt v. Secretary of HHS*, discussed *infra*, Special Master French identified a 1977 study on *Sudden Deafness and Vaccination*, XCI JOURNAL OF LARYNOLOGY AND OTOTOLOGY, No. 4 (April 1977). The authors of that article listed eight other reports in medical literature of hearing loss following tetanus vaccination along the same theory as the instant Petitioner. Dr. Eavey was aware of this fact, as he was Respondent's expert in the *Bobbitt* case and subsequently mentioned that case and attendant sources in his testimony. However, of note here is that this source merely "postulated" the existence of an association and could not find causal proof to a *medical certainty* in contradistinction to the preponderance standard. So when Dr. Eavey asserts that he does not know of any cases where children have hearing loss associated with DPT, the Court notes that the cases that may have suggested hearing loss were under a higher burden of medical proof.

example, a spontaneous mutation that occurs, . . .

Tr. at 43. Since Kyle's mother was adopted, she could not provide any family history in this area and Dr. Eavey--as with Dr. Trock--could only speculate as to a genetic disorder.

Looking to the facts of the case *sub judice*, Dr. Eavey felt that there were some "red flags" in Kyle's medical records. First, Kyle's pediatrician noted the "possibility of a hearing loss." Tr. at 47. Second, Kyle's mother also raised the possibility of a hearing loss with the pediatrician, as it was apparent the parents had done some "home testing." Tr. at 47-48. Respondent queried Dr. Eavey, asking whether the parents' concern that they sometimes thought that Kyle was "not hearing" and that "other times he respond[ed] to a very soft spoken voice," was a fairly common report indicating some degree of hearing loss. Dr. Eavey felt it was, noting that according to Kyle's parents, "it seemed . . . that apparently sometimes he could hear, [and] sometimes he didn't seem to hear as well as they thought he should be hearing." Tr. at 48. For Dr. Eavey, "[s]peech and language go together. . . . So if it seems to be a normal child, and they are not speaking, the primary thing you have to rule out is hearing." Tr. at 47. As a result, Dr. Eavey concluded that DPT did not play any role in Kyle's hearing loss. The other causes he felt more likely were idiopathic ("that basically means we don't know") Tr. at 50-51. These causes included inner ear malformations, bacterial meningitis, and various other causes. *Id.*

On cross examination, Dr. Eavey agreed that Kyle's hearing loss was sensorineural.¹² *Id.* He also agreed that this condition was only diagnosed after the shot. Tr. at 51-52. When asked for a diagnosis of an alternate cause for Kyle's condition, Dr. Eavey replied that he could not give a definitive cause. Tr. at 52. When asked for his opinion on whether Kyle's hearing was progressively worse after the DPT shot than it was before, Dr. Eavey stated, "Well, I am not sure if it got--well, let's say the DPT shot wasn't there. I am presuming that he has had some hearing along the way, and that he has a degree of hearing now." Tr. at 52. After being pressed again, Dr. Eavey admitted that it was possible that Kyle had no hearing impairment prior to the suspect vaccination. However, he added the caveat that one doesn't "have to have normal hearing to be developing some degree of language." Although Kyle's hearing might seem worse after the DPT shot, Dr. Eavey would not state a "cause and effect" for the impairment where the status of Kyle's hearing before the DPT shot was unknown. Tr. at 52-53. He did admit, however, that the medical records revealed "a history, a contemporaneous history on February 7, that the child seemed like he was talking more, *then all of a sudden*, over the last month or so, speech has decreased." Tr. at 54 (emphasis added.)¹³

Petitioner next sought to establish her theory that DPT was the stimulus that led to an

¹² Sensorineural refers to "a sensory nerve; pertaining to or affecting a sensory mechanism and/or a sensory nerve." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 27TH EDITION 1507 (1988). In Kyle's case, this term refers to his auditory nerve.

¹³ Critical to Petitioner's case was the fact that Dr. Eavey also agreed that Kyle did not have bacterial meningitis, a known cause of hearing loss. Tr. at 75.

autoimmune reaction. In response to Petitioner's query, "Are you aware that viruses can cause autoimmune reactions in humans?" Dr. Eavey responded, "Not in the ear, I don't believe. That is one of the things I do research on." Subsequently, Dr. Eavey appeared to contradict his testimony with "there are indeed autoimmune reactions that can occur within the ear. . . . The autoimmune reaction can occur in the inner ear area, yes." Tr. at 62-63, lines 18-19, and 24. However, he qualified these statements with his practice and clinical experience: "But I can say that in the cases that I have had, there is no connection that I have been able to put together, . . . I have seen no relationship whatsoever between autoimmune sensory-neural hearing loss and vaccinations." Tr. at 63. In addition, given the number of other factors in Kyle's medical record, such as Kyle's bilirubin level at birth, Dr. Eavey could not find any possible association between DPT and Kyle's hearing loss.

Finally, Dr. Eavey referred to Kyle's CT scan and the fact that the films were not present for him to review the possibility of any inner ear malformation. For Dr. Eavey, this "is where the money is in this particular case." Tr. at 76. He believed that the CT reports did not analyze the inner ear very well and that recent findings in which he was involved suggested that an inexperienced radiologist probably could not recognize whether a patient had a stable or progressive hearing loss.¹⁴

III. DISCUSSION

Articulating an objective analysis for causation in fact is akin to locating an elusive wraith. As Dean Prosser and the editors of a Tort hornbook have put it,

There is perhaps nothing in the entire field of law which has called forth more disagreement, or which the opinions are in such a welter of confusion. Nor, despite the manifold attempts which have been made to clarify the subject, is there yet any general agreement as to the best approach.¹⁵

The question of causation in fact "is one upon which all the learning, literature and lore of the law are largely lost." *Id.* Indeed, "[i]t is a matter upon which lay opinion is quite as competent as that of the most experienced court." *Id.*

This general difficulty cuts across traditional tort law and unfortunately, appears in causation cases arising under the Vaccine Act. So too, other factors bear upon this Court's analysis. To wit, empirical studies, novel medical theories, scientific advances, and the rise of case law must go hand in hand with statutory interpretation. This means, for instance, that advances in either of these areas force the Court to address causation in a fashion not contemplated by the Congress who enacted the

¹⁴ See Tr. at 76-77 (discussing recognition of an enlarged vestibular aqueduct, "a very subtle" inner ear malformation.)

¹⁵ PROSSER AND KEETON ON TORTS, 5TH EDITION 263 (1984).

Vaccine Act. For the special master as fact-finder and as one who draws conclusions of law,¹⁶ the Act itself provides little guidance in its express language as to the standard *governing* causation in an off-table case. Section 300aa-11 (c) (1) (c) (ii) (1999) imparts merely that “a petition for compensation shall contain,” *inter alia*,

(1) . . . an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died--

(c)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table [or (ii), listed in the Table but not within the requisite time periods] but which *was caused* by a vaccine

(Emphasis added.) The context of whether an injury “was caused” by a vaccine has been explained in numerous decisions. Most notably, the circuit court in *Grant v. Secretary of HHS* illuminated the Act’s legislative history, specifically pointing to a remark of the House Committee on Energy and Commerce:

If the petitioner sustained or had significantly aggravated an injury not listed in the Table [or listed in the Table but not within the requisite time periods] *the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine.*

956 F.2d 1144, 1148 (1992) *quoting* H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986) *reprinted in* 1988 U.S.C.C.A.N. 6344, 6356 (emphasis by the *Grant* court). *Grant* held that the Act “relaxes proof of causation” for on-Table injuries, “but does not relax proof of *causation in fact* for non-Table injuries.” *Id.* at 1148 (emphasis added). This conclusion presumably flows from the “affirmatively demonstrate” language in the legislative history.

And while *Grant* never explained whether its use of “causation in fact” gave the signal to superimpose *governance* of traditional tort standards, it is significant that Judge Rader concurred in *Grant*’s holding. Though now a circuit judge, he previously discussed the causation matter as a claims court judge, noting that the “traditional causation in fact standard *governs vaccine tort cases outside the Act.*” *Strother v. Secretary of HHS*, 18 Cl. Ct. 816, 819-20 (1991) (emphasis added.)¹⁷ His rationale for this *governance* in traditional tort actions is that “these other state and federal vaccine tort cases are not subject to the compensation limits of the Act.” *Id.* at 820 (emphasis added.) To the contrary, for cases arising under the Act, the special master awards only *reasonable* compensation. Another rationale for not superimposing the governance of traditional tort standards can be found in the fact that full discovery is not available to petitioners.

¹⁶ “The decision of the special master shall-- include findings of fact and conclusions of law, . . .” See 42 U.S.C. § 300aa-12 (d) (3) (A) (I) (1999).

¹⁷ Judge Rader cited as an example, *Alvarez v. United States*, 495 F. Supp. 1188, 1206 (D. Col. 1980).

Indeed, like worker's compensation programs, the Vaccine Act is a balanced compromise between full blown tort litigation and concern for the bankruptcy of an important general welfare concern. Among its important purposes are to free vaccine manufacturers from the "specter of large, uncertain tort liability," to keep vaccine manufacturers in the market, and to keep vaccine prices fairly low. *Schafer v. American Cyanamid Co.*, 20 F.3d 1. (Mass C.A. 1994). If this Court were *absolutely governed* by traditional tort standards in causation in fact cases, the extreme litigation burden imposed might eventually make for a wide scale abandonment of the Program in cause-in-fact cases. This is not what the Program is designed for. And although causation in fact is a difficult burden, it is not as onerous as traditional litigation.

Causation in fact

Because Petitioner has alleged that Kyle's hearing loss was in fact caused by his 3 January 1995 DPT vaccination, the Court need not delve into an entitlement analysis based on a Table injury.¹⁸ Rather, the analysis turns completely on the burdens imposed as a result of proceeding under a theory of causation in fact. To state the obvious, hearing loss as a sequela to a DPT immunization is not a Table injury.

In order to demonstrate entitlement to compensation in a non-Table case, *to wit*, by causation-in-fact, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question *more likely than not* caused the injury alleged. §§ 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit, which summarized the legal criteria required to prove causation-in-fact under the Vaccine Act, requires that every petitioner:

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

This Court has organized the legal criteria in *Grant* by means of a two-part test. *First*, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. In short, can DPT cause the type of injury alleged? *Second*, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case.

The first prong of the test is established in numerous decisions of the Special Masters. Under this prong, a petitioner must demonstrate the biologic plausibility of their theory. This may be

¹⁸ See 42 U.S.C. § 300aa-14 (a) (II).

accomplished in a number of ways. First, a petitioner must proffer a scientific pathogenesis underlying the alleged causal relationship. Reliability and plausibility are found by providing evidence that a sufficient minority of physicians have accepted the theory. In addition, epidemiological studies, while not dispositive,¹⁹ lend significant credence to the claim of plausibility. Articles published in respected medical journals, which have been subjected to peer review, are also persuasive.²⁰ Of course, where

¹⁹ This first prong of the Court's test meets easily with cases where epidemiological or case study reports are already available. Beginning with this prong is practical when there is epidemiological evidence, for it avoids the circular reasoning that would result when one attempts to answer *Can It?* without having reports and studies that previously would have answered *Did It?* The Institute of Medicine (IOM) has recognized this point,

Although Can It? causality is usually addressed from epidemiologic studies, an affirmative answer can occasionally be obtained from individual case reports. Thus, if one or more cases have clearly been shown to be caused by a vaccine (i.e., Did it? can be answered strongly in the affirmative), then Can It? is also answered, even in the absence of epidemiologic data. In several circumstances, for example, the committee based its judgment favoring acceptance of a causal relation solely on the basis of one or more convincing case reports.

But, the IOM also noted that the absence of convincing case reports cannot be relied upon to answer *Can It?* in the negative where a given vaccine has an extremely long history of use. And yet, because of the fallibility of a passive surveillance system and the extremely rare occurrence of an adverse vaccine related event generally, the IOM acknowledges that "that which has not been reported might indeed have occurred." See KATHLEEN R. STRATTON, ET AL., ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES, EVIDENCE BEARING ON CAUSALITY 21-23 (1994) (emphasis added).

In other words, before one can answer *Can It?*, the *Did It?* query had to have been answered first in the tautological analysis. Clearly, in cases where there is no research data or other reports, *Can It?* and *Did It?* are one and the same query. Not only has the IOM acknowledged this point when referring to individual cases, they credit discovery of known adverse vaccine related events to the suggestions of DPT associations from one or more cases. *Id.* at 22. Therefore, for a few petitions under consideration before this Court, individual cases provide the only available report of the occurrence of an adverse event associated with a vaccine and therefore, the only means to answer *Can It?*

²⁰ As stated by the Supreme Court of the United States, "evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for petitioners seeking to prove causation-in-fact. H.R. Rep. No. 99-908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6356. In this regard, the Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786 (1993), is instructive. While that case dealt with the admissibility of scientific evidence and here we are assessing the scientific validity of evidence already presented, *Daubert* is helpful in providing a framework for evaluating the reliability of scientific evidence. The Court in *Daubert* wrote:

[I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation -- i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Id. at 2795. The Court also suggested a key criterion of scientific reliability is whether a theory has been tested and subjected to peer review and publication. *Id.* at 2796-97. While acknowledging that publication is not the *sine qua non* of admissibility, the Court found the submission of a novel scientific theory to the scrutiny of publication is a

the injury claimed is rare,²¹ as in the case before the Court, there may not be any studies or data available to support the claim. In such a case, the analysis automatically merges into the second prong, *Did It?*

The second prong of the causation-in-fact test is difficult but not impossible. Petitioner must show, by a preponderance of the evidence--a test based on 50% and a feather--that the vaccine caused the symptoms that manifested in this case. A petitioner does not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. Rather, a petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1993), cert. denied, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it). As shall be seen, in order to hurdle the factual causation barrier, a petitioner must methodically set forth her case.

Applicability of the Two Part test in Kyle Zimmer's Case

In Kyle's case, the Court follows the two pronged causation in fact analysis tailored as: (1) Can DPT cause a sensorineural hearing loss?; and, (2) Did Kyle's DPT vaccination result in his sensorineural hearing loss?²²

component of "good science" and the fact of publication is a relevant, though not dispositive, consideration. *Id.* at 2797. So too, the general acceptance of a scientific theory within the scientific community--while not a precondition--can have a bearing on the question of assessing reliability while a theory that has attracted only "minimal support" may be viewed with skepticism. *Id.* Of course, this Court does not take *Daubert's* suggestions as mandatory. As the Supreme Court recently noted in *Kumho Tire Co. v. Carmichael*, 119 S.Ct 1167, 1999 U.S. Lexis 2189 *23-24 (1999),

Daubert makes clear that the factors it mentions do not constitute a definitive checklist or test. . . . Indeed, those factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged. It might not be surprising in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist.

Thus, application of *Daubert's* factors are entirely discretionary and dependant on the facts and circumstances.

²¹ Because the Court realizes that not every petitioner is always able to prove the *Can It?* where no epidemiological data exists, it does not penalize a petitioner for being the first *Did It?* To reiterate, the Court's decision is one reflecting public policy and never concludes to a medical certainty. Asking the special master to decide whether a vaccine can cause a certain adverse event requires him to assume the Herculean role of the IOM. If there is epidemiological evidence, Petitioner's task is easier. Without that evidence, Petitioner must do more than assert that: "Petitioner relies on its prior brief, however, as simplistically as possible when you inject foreign material into the body including vaccines into the blood stream an autoimmune reaction will occur." Petitioner's Reply Brief at 1.

²² Of course, before answering the second prong, the Court would have to make a factual determination of the status of Kyle's hearing prior to his 3 January 1995 DPT vaccination.

1. Can DPT cause hearing loss?

As Respondent has noted in her argument, hearing loss is not among the conditions and illnesses identified in the Vaccine Act as potentially or presumptively related to the administration of DPT, or any other covered vaccine. Respondent's Post Hearing Brief at 8.²³ While the absence of hearing loss as an express sequela to a vaccine injury is not itself dispositive, the Court finds that beyond any tergiversation, Petitioners did not meet their preponderance burden on the second prong--that is, did DPT cause Kyle's hearing loss.²⁴ Since the parties could not produce any epidemiological evidence other than medical testimony *sans* apropos literature, this Court is faced with a paucity of reliable medical evidence. The Court notes that this foundation militates adversely to a finding that the preponderance standard has been met as to *Can It?*. However, if the Court assumes, arguendo, that Petitioner is able to prove *Can It?*, then the Court must examine whether DPT actually caused the injury alleged?

2. Under the facts of the record as a whole, did DPT cause Kyle Zimmer's hearing loss?

To date, only one other case has come before this Court involving permanent hearing loss as a result of exposure to the DPT vaccine. *See Bobbitt v. Secretary of HHS*, 1992 WL 159524, No. 90-1156 (Fed. Cl. Spec. Mstr. June 10, 1992). In that case, the petitioners' medical expert based his opinion on a "differential diagnosis, eliminating all other known contributory possibilities." His theory was that the DPT induced a fever that caused the child's hearing loss. The special master did not conclude that the petitioner's theory was wrong or theoretically impossible, but failed because of the paucity of medical evidence--the Bobbitt's medical expert admitted that he could not prove his theory while the patient was still living--he could only prove his theory by an autopsy. However, assuming the truth of their expert's theory, the *Bobbitt* petitioners were still unable to prove that their child could hear before the DPT shot was administered. As a result, the Bobbitt's medical expert testimony rose only to the "level of conjecture."

The instant case is different in two respects. First, the parties here do not dispute that Kyle Zimmer had some degree of hearing prior to his DPT vaccination. What is unknown here is Kyle's state of hearing prior to the DPT vaccination and whether he was suffering from progressive hearing loss. *Bobbitt's* petitioner, on the other hand, had no evidence to prove that he could hear prior to the DPT shot. And this was fatal to a favorable entitlement decision. Second, Petitioner's theory is quite different from the *Bobbitt* theory, which claimed that pertussis caused a high fever, which in turn caused a swelling in the inner ear that precipitated hearing loss. *Bobbitt*, 1992 WL 159524 *2. Bobbitt's medical expert could only prove his theory by an autopsy because the structures affected

²³ Hereinafter "R's brief at ___."

²⁴ For instance, Petitioner raised *Tinnerholm v. Parke Davis* as a standard of her burden of proof. 411 F.2d 48, 53 (2d Cir. 1969). However, *Tinnerholm* squarely addressed the *Can It?* prong when it answered that "Quadri-gen is capable of causing exactly the symptoms that occurred. . . ." *See* Petitioner's Posthearing Brief at 9.

were encased in bone. Since Christopher Bobbitt was still living, that would have been obviously impossible.

Though the facts and theory in the case *sub judice* differ greatly, the reason for denial here is similarly based on a paucity of qualitative--not necessarily quantitative--evidence. The Court assumes for the purposes of its decision, that Petitioner's medical theory is plausible and does state a logical explanation of cause and effect. In reaching its conclusion, the Court used the traditional burdens of production and persuasion by a preponderance as a guide to its analysis. At the outset, it is important to note that the Court is open to alternative modalities to prove causation in fact. However, whatever the modality, the evidentiary burden is always the same.

A. Petitioners' Evidentiary Burden

Every petitioner bears two evidentiary responsibilities in persuading the Court that the injury complained of *was caused* by the vaccine: the burden of persuasion and the burden of production. Petitioners carry their burden of persuasion throughout. The latter burden of production, however, is one that shifts from petitioner to Respondent depending on the quality and perhaps quantity of evidence.²⁵ This requires a petitioner to plead specific facts relevant and supportive of her theory. Next, the petitioner must prove each of those facts. Then, Petitioner must persuade the Court that a specific reasonable inference should be drawn from any of those facts, and how that inference supports her theory. Whether a petitioner seeks an inference from a single fact or in combination is entirely up to her. If the Court draws the inference, the burden of production shifts to the Respondent who must raise a counter fact by a sufficiency.²⁶ It is important to note that when the Court does draw an inference, the mere fact that the inference is reasonable does not make it conclusive. Even if Respondent fails to raise a counter fact, the burden of persuasion is always on the petitioner to prove her case. All traditional tort theories of causation, including but not limited to proximate and intervening causes, are apropos and provide a coherent framework to address the analysis.

As noted earlier, the Court finds that the factual evidence in the record is not quantitatively deficient; rather, it is a qualitative paucity that compels this Court to deny compensation. If, arguendo, Petitioner's medical expert theory is plausible and provides a logical explanation of cause and effect, this Court finds that the facts do not contain the requisite inferences that could support Petitioner's theory. Ergo, the Court cannot arrive at a reasonable conclusion that Kyle Zimmer suffered hearing loss because of his DPT vaccine.

First, a little more than one month prior to the vaccination, Kyle's grandfather, who is not

²⁵ A presumption arises when basic facts are established and have at least the effect of shifting the burden of production to the other party. *See* F.R.E. 301. It is important to distinguish between mandatory legal presumptions crafted by statute and those that are merely inferences of fact.

²⁶ A sufficiency of evidence is measured under the standard of whether a reasonable jury could find that such evidence exists.

related by blood to Kyle, thought that Kyle exhibited some hearing difficulties during a 1994 Thanksgiving holiday. The grandfather concluded this because he, too, had a hearing impairment and recognized signs and symptoms. The Court draws the inference that Kyle had a hearing deficiency prior to his DPT vaccination. Of course, if drawn in isolation from the record, this inference is speculative at best. However, in combination with other facts raised by Petitioner, this Court finds that Kyle Zimmer had a hearing impairment that existed for an unknown time before his DPT vaccination--beginning in November 1994. One fact is that Kyle's parents raised the possibility of a hearing problem with Kyle's pediatrician (at his 18 month well baby visit, prior to the suspect vaccination). This was three weeks after the grandfather's Thanksgiving Day observation.

While temptation might lead the reasonable fact-finder to consider these two facts as nothing more than a case of overly concerned parents and grandparents, the Court is required to consider the record as a whole.²⁷ Kyle's parents were worried about Kyle's hearing before his vaccination. Their continuing anchor of fear with respect to Kyle's language and hearing ability is found in pediatric records dated 30 January 1995. Notably, Kyle was observed as "*still having* difficulty with speech, . . ." P's Ex. 5 at 58 (emphasis added). A reasonable inference to be drawn from this record is that Kyle's parents were *still* concerned that his earlier speech problem had not resolved. Kyle was *still* having problems. In addition, the Court also notes that Kyle's problems appear to indicate that he was *still having at least the same trouble* hearing. Though a subsequent 7 February 1995 record indicates a "sudden" cessation of talking, Petitioners have raised no facts that allow this Court to consider an inference that DPT changed Kyle's hearing sometime between the day of vaccination and 30 January 1995, let alone caused the sudden onset of hearing loss on 7 February 1995.

So, whether Kyle's hearing loss slowly deteriorated from the time prior to, or immediately after, Thanksgiving Day in 1994 until the period of 7 February of 1995; whether Kyle's hearing loss occurred between 30 January and 7 February 1995; or, whether his hearing loss occurred sometime between the time of his DPT vaccination on 3 January and his doctor visit on 7 February 1995, is incapable of being established by a preponderance. Petitioners bear the burden of producing facts to support their time frame of onset while likewise defeating other time frames that might hurt their theory.

Without speculating what factual evidence may have rendered a favorable conclusion, the Court finds that Petitioners' burden of production has simply not been met and that the quality of evidence leaves gaps in Petitioners' own theory. Of note here is that the Court is not discounting Petitioner's theory; rather, it is denying compensation because there is a paucity of sufficient qualitative evidence that can hurdle the preponderance standard. The Court finds it unreasonable to draw a speculative inference that a "sudden" hearing loss occurred between the day of vaccination and the "sudden" cessation of Kyle's speech officially documented on 7 February 1995.

B. Significant Aggravation

²⁷ See generally 42 U.S.C. § 300aa-11 (1999).

Finally, the Court raises *sua sponte*, the issue of significant aggravation. However, the analysis used above yields the same conclusion. Assuming Kyle's hearing loss was progressively deteriorating, how to decide whether it was significantly aggravated by a DPT vaccination? The Court cannot find for Kyle on significant aggravation because there is no factual record indicating how progressive Kyle's hearing loss might have been to begin with. If there were parental accounts in the medical records, additional ear evaluations, or facts that accounted for gaps of time before and after the shot, then perhaps this Court's conclusion might be different on both issues.

IV. CONCLUSION

If Respondent had not presented any medical expert to contradict Petitioner's expert, this Court would still be compelled to deny compensation. Petitioner's burden has not been met and it is unnecessary to discuss the onus of persuasion where there is not a sufficiency of facts in the record to meet Petitioner's theory. The song of the Sirens would have this Court compensate every young child that sought compensation for an alleged Table vaccine injury. However, to avoid the perils of Scylla and Charybdis, this Court is tied to an objective standard--the ever attendant mast of the Vaccine Act and the decisions of the judicial system.

More likely than not, the facts allow the Court to draw the reasonable inference that Kyle Zimmer had an unknown degree of hearing and hearing impairment beginning sometime in November of 1994 and culminating in a diagnosed loss on 7 February 1995. Kyle had a problem before the vaccination, and Kyle *still* had that problem after the vaccination. Without other facts to link the temporal association of DPT to Kyle's progressive or sudden hearing loss immediately after the day of vaccination, the Court finds it more likely than not that Kyle Zimmer did not have a hearing loss as a result of his vaccination. The Court finds, therefore, that a paucity of facts and medical evidence exists to support a causal association between the DPT shot and Kyle's hearing loss. Further, in the *petitio principii* that is Petitioner's theory of *Can It?*, this Court finds the demonstration of that theory unpersuasive and the evidentiary burden unmet.

For the reasons stated above, this Court finds that Petitioner was unable to establish that Kyle's hearing loss was associated or derived from a vaccine-related injury. In the absence of a motion for review filed pursuant to RCFC, Appendix J, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master