OFFICE OF SPECIAL MASTERS

No. 95-215V

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MELISSA TROJANOWICZ, by her parents and next friends, LORI TROJANOWICZ and JOHN TROJANOWICZ,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer, Boston, Massachusetts, for petitioners.

Mark Rogers, Department of Justice, Washington, D.C., for respondent.

DECISION

Petitioners filed for compensation under the National Childhood Vaccine Injury Act of 1986, alleging that their daughter, Melissa, suffered injuries resulting from the administration of a DPT and OPV given on March 2, 1994. While claiming in their Petition a variety of injuries as a result of the two administered vaccines, petitioners' claim crystallized through their medical expert, alleging that the DPT caused in fact Melissa's chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). See P Ex. 20.[(2)] Respondent vigorously contested petitioners claim. An evidentiary hearing was conducted at which factual and medical testimony was adduced. The parties thereafter filed closing arguments. The court has digested the totality of the record. Based upon its review, the court finds that petitioners failed to establish by a preponderance of the evidence that Melissa's CIDP was caused in fact by the DPT administered on March 2, 1994. The court's reasoning follows.

Background Facts

While the primary focus of this dispute was on the medical issues, key factual issues involving the

timing of onset of Melissa's CIDP remain. However, given the court's resolution of the medical issues, the court will not resolve the factual matters. It is noted that the court has serious doubts regarding the reliability of the mother's testimony at the evidentiary hearing. Ms. Trojanowicz's efforts to explain the contradictions between the medical records and her memory of the events was to say the least unpersuasive. Even though the medical records are not entirely consistent (which respondent argues supports their medical argument in this case), if resolution of the factual questions becomes critical the court would determine the facts based primarily upon the information contained in the medical records.

Since the court does not rely on the factual issues in resolving this case, the court will recite petitioners' factual allegations contained in the Amended Petition. Melissa was born on March 30, 1989, in Carbondale, Pennsylvania. There is no indication of any birthing problems and Melissa presented healthy with APGAR scores of 8 and 9 at 1 and 5 minutes respectively. By all indications, Melissa was developing normally with all pediatric exams being normal. On March 2, 1994, Melissa, who was now just shy of five years of age, was seen by her pediatrician, Dr. Davis, and noted to have "no problems." P Ex. 6 at 1. About one week[(3)] following the vaccination, Melissa collapsed while walking across the living room floor. This event was followed by a period of lethargy. During the next several weeks, Melissa required more assistance ambulating up stairs and rising from a sitting position. Her motor problems became more noticeable culminating on May 21, 1994, where she could barely walk. Melissa was seen by her pediatrician that day and his notes state as follows:

Mother concerned about increasing gait disturbance and difficulty getting up from the sitting position.

PE: Pt. has ataxic gait - otherwise pleasant and alert. Certainly non-toxic.

Pt. exhibits classic Gower maneuver upon arising-

I/P 1. ? Muscular Dystrophy of Gillian Barre

pt. emergency, referred to Dupont Institute.

P Ex. 6 at 2. Melissa was seen at the Alfred I. duPont Institute on May 25, 1994. Dr. Marks, the chief neurologist examined Melissa. Dr. Mark's impression was that Melissa was most likely suffering from Guillain-Barre syndrome. P Ex. 9 at 2. It is agreed at this point that the correct diagnosis is CIDP. See P Ex. 20 at 2.

Medical Experts

To support their case, petitioners presented the report and testimony of Dr. Charles Bean. Dr. Bean examined Melissa in July of 1996 on a referral basis. Tr. at 9. This was prior to his becoming involved in this litigation. Id. Dr. Bean is of the opinion that Melissa's CIPD was caused by her DPT. In coming to this opinion, Dr. Bean recognizes that there is no medical literature or epidemiological studies that support a relationship between DPT and CIPD. In fact, there are no case reports supporting such an association. Tr. at 61. Thus, to support his opinion, Dr. Bean draws upon a "related" condition, acute inflammatory demyelinating polyradiculoneuropathy (AIDP) or Guillain-Barre syndrome (GBS),[(4)] which has a known association to DPT. Dr. Bean states that GBS and CIDP have clinically similar symptoms, that their pathogenesis is similar, they are both inflammatory neuropathies and thus concludes that they can be analogized for purposes of causation. P Ex. 20 at 2. With this premise in mind, Dr. Bean then discussed the literature support for the association between DPT (most notably the tetanus component) and GBS. Lastly, relying upon the appropriate temporal relationship between Melissa's vaccination and the onset of her disease and the absence of any other apparent cause, Dr. Bean

opined as to the causative role of the vaccination.

Respondent's expert disagreed. Dr. Arnason contested the validity of analogizing GBS to CIDP. Dr. Arnason agreed that similarities in pathology do exist, but that the clinical course is different and the history of antecedent events is quite different. Tr. at 79. Dr. Arnason also took issue with any relationship between DPT and either GBS or CIDP. Except for one study of multiple tetanus injections and onset of GBS, Dr. Arnason stated that epidemiological studies of millions of people have "failed to find any meaningful association of AIDP with tetanus toxoid injections or other vaccinations." R Ex. A at 4. Regarding CIDP, he noted that the data is "scant," with a leading textbook author recanting an earlier suggestion of a relationship. Id. at 5. In conclusion, Dr. Arnason saw no support for a causal link between Melissa's vaccinations and her illness.

Statutory Requirements

Petitioners may establish causation in one of two ways.[(5)] First, petitioner may demonstrate what is commonly referred to as a Table case. The Vaccine Table lists vaccines covered by the Act and certain injuries and conditions that may result from the vaccines. § 14. If the special master finds that a person received a vaccine listed on the Table and suffered the onset or significant aggravation of an injury listed on the Table, within the time period prescribed by the Table, then the petitioner is entitled to a presumption that the vaccine caused the injury. § 13(a)(1)(A). The petitioner must then show that the injury for which they seek compensation is a sequela of that Table injury. § 14(a)(I)(E). Respondent may rebut the presumption of causation with a preponderance of the evidence that the injury or condition was due to factors unrelated to the administration of the vaccine. § 13(a)(1)(B).

Second, petitioner may establish causation by proving by a preponderance of the evidence that the vaccine actually caused the alleged injury. Actual causation requires proof of a "logical sequence of cause and effect showing that the vaccine was the reason for the injury." Strother v. Secretary of HHS, 21 Cl. Ct. 356, 370 (1990), aff'd without opinion, 950 F.2d 731 (Fed. Cir. 1991). The mere temporal relationship between a vaccination and the injury, and the absence of other apparent etiologies for the injury, are patently insufficient to prove actual causation. Wagner v. Secretary of HHS, No. 90-1109V, 1992 WL 144668, at *3 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, petitioner must show a medical or scientific theory causally connecting the vaccination and the injury. Strother, 21 Cl. Ct. at 370 (citing Hasler v. United States, 718 F.2d 202, 205-06 (6th Cir. 1983)).

"[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for a petitioner seeking to prove causation in fact. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), reprinted in 1986 U.S. Code Cong. and Admin. News 8344, 6356. In this regard, the recent Supreme Court 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 in this case the court is assessing the scientific validity of evidence already presented, Daubert is helpful in providing an analytical framework for evaluating the reliability of scientific evidence.[(6)] 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 goes on to suggest that 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 in not the sine qua non of admissibility, the Court found that the submission of a novel scientific theory to the scrutiny of publication is a component of "good science" and the fact of publication is a relevant, though not dispositive, consideration. Id. at 2797. Finally, the Court noted that, while not a precondition, the general acceptance of a theory within the scientific community of a scientific theory 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.

Since Melissa Trojanowicz's CIDP is not a condition listed on the Vaccine Injury Table, petitioners' claim that the DTP vaccination caused her condition must be analyzed under the causation in-fact rubric. This analysis in turn devolves to a two part inquiry: can the DPT vaccine cause CIDP and if the answer is affirmative, did the DPT vaccine cause the CIDP in this case. See Guy v. Secretary of HHS, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995) (two-step causation-in-fact analysis used); Alberding v. Secretary of HHS, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. March 18, 1994) (two-step causation-in-fact analysis used). The court finds that petitioner failed to prove by a preponderance of the evidence that the DPT can cause CIDP.

Discussion

The court finds that Dr. Bean failed in his effort to analogize CIDP to GBS and thus his opinion must fail. For purposes of his opinion, Dr. Bean viewed CIDP and GBS as essentially similar processes. See Tr. at 10. However, Dr. Bean provides little persuasive support for this proposition. As cogently presented by respondent in its closing argument, not one medical article submitted or cited makes this analogy. In fact, Dr. Bean was either highly selective in pulling support from the submitted articles or ignored clearly contradictory portions of the same articles. Dr. Bean testified that the Dick and Thomas paper at P Ex. 20, Tab A, "supports the close association between the acute and chronic cases and points out the immunogenic triggers that are supposed in both. . . . " Tr. at 27. However, Dr. Bean did not submit the prior page to that chapter which states that:

CIDP, like AIDP, is an inflammatory demyelinating polyradiculoneuropathy with cytoalbuminologic dissociation. As the mechanisms underlying AIDP and CIDP are unknown, it is possible that both syndromes are variants of the same disorder, as their shared pathologic features might suggest. **On the other hand, cogent reasons for separating CIDP from AIDP, whether this separation ultimately proves to have fundamental validity or not, can be advanced.**

R Ex. F at 1500 (emphasis added). When asked about the above-quoted section of the paper, Dr. Bean's response was a very unacceptable and highly unpersuasive "there's a lot that's unknown, but there is some evidence that there are similar causes for both conditions at times, possibly." Tr. at 43.

Similarly, Dr. Bean testified that the Schaumberg chapter, P Ex. 20 at C, and the Asbury and Thomas chapter, P Ex. 20 at G, "relate immunogenic triggers and close association between the chronic and acute from a pathologic clinical [standpoint]." Tr. at 27. Dr. Bean made no effort to detail the significance of these two chapters. The court's review reveals that while similarities of CIDP and AIDP are recognized and discussed, significant causation differences are noted. Thus, in Schaumberg, it is stated that while one-third of the CIDP patients experienced "antecedent, non-specific illness[es]", the association is not as strong with AIDP. P Ex. 20 at Tab C. In addition, the course and prognosis for the two disorders differ. Id. Likewise, Asbury and Thomas state that "Symptomatic infections immediately preceding the onset of CIDP are reported in a relatively small proportion of cases compared with GBS." P Ex. 20, Tab G at 193. While recognizing the "possibility" that infective agents may cause an immune response giving rise to either CIDP or AIDP, the authors state that "[t]here have been relatively few attempts to identify immune responses to myelin antigens in CIDP compared with AIDP and those that have been made have not been very rewarding." Id. (citation omitted). Thus, upon closer scrutiny and

without benefit of expert illumination, the articles relied upon by Dr. Bean do very little to support his working premise, that CIDP and AIDP are sufficiently analogous disease processes that they are subject to the same causative agents. In fact, if anything, the articles appear to undercut substantially Dr. Bean's working premise.[(7)]

Dr. Bean posits that there are sufficient similarities between CIDP and AIDP that one can surmise that what causes AIDP can also cause CIDP. However, the medical literature not only fails to support Dr. Bean's theory, the literature refutes it by showing differences in the causative agents. See R Ex. F at 1501 (high frequency of antecedent viral infections noted for AIDP, while antecedent infections for CIDP possibly not exceeding background); P Ex. 20, Tab C at 61 ("About one-third of patients with CIDP experience an antecedent, nonspecific illness but the association is not as strong as with AIDP."); P Ex. 20, Tab G at 193 ("Symptomatic infections immediately preceding the onset of CIDP are reported in a relatively small proportion of cases compared with GBS."). Further, the literature gives specific examples of causative agents for AIDP, see R Ex. E (association between AIDP and cytomegalovirus, Epstein-Barr Virus, Campylobacter infections mycoplasma pneumonia and swine flu documented). However, with regard to CIDP, the literature states that although:

[antecedent illnesses are reported in conjunction with CIDP] [o]n later analysis it was less clear whether any of the occurrences of preceding infection or receipt of biologic material was higher than in the control populations.

It is uncertain that the frequency of preceding infection exceeds that of a control population.

R Ex. F at 1501-02. Thus, while medical literature supports causal links between various viral agents and AIDP, medical literature does not support the same linkage with CIDP. Dr. Arnason in well-reasoned, persuasive testimony reached the same conclusion. Dr. Bean could only respond, on numerous occasions, that the issue needs study. See Tr. at 15 ("One of the problems in CIDP is that this has never been studied well."); Tr. at 20 ("The thing that . . . really needs to be done with this condition is a careful epidemiological study in order to really see if we can really pick up some of the issues" may have been missed due to the short period of study). Despite Dr. Bean's good faith efforts to support this case, it is logically and legally impermissible to extrapolate from similarities in pathogenesis to a conclusion of shared causative agents in light of the lack of support from the available medical literature, or some type of objective support from the relevant medical community, and in the face of medical literature indicating strong differences in antecedent events. Dr. Arnason persuasively made this point throughout his testimony. The court agrees.

While petitioners' primary argument relied upon establishing the pathogenic similarities between CIDP and AIDP and therefore the alleged causative similarities, petitioners strayed occasionally into arguing that medical literature supports the proposition that the tetanus vaccine has been linked to CIDP. Such a showing would obviate the need to establish the CIDP/AIDP analogy. To the extent that this argument was put forth, the court finds the argument highly unpersuasive. Dr. Bean was asked on direct "do any of the articles relate CIDP and the relationship [sic] with immunization?" Tr. at 21. Dr. Bean responded with a reference to and explanation of an article that discusses AIDP and tetanus. Id.[(8)] No other articles supported a known studied relationship between CIDP and the tetanus vaccination. In fact, Dr. Bean acknowledged that he was unaware of any case reports of CIDP following the tetanus vaccine. Tr. at 61. Thus, the court finds that there is insufficient evidence in this record to support a finding that the tetanus vaccine can cause CIDP.

The Supreme Court has counseled the lower courts to test the adequacy of an expert's testimony by requiring some showing that the opinions proffered are not mere speculative pronouncements of the

expert, but have been "derived by the scientific method." Daubert, 113 S.Ct. at 2795. This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand from 113 S.Ct. 2786 (1993). It is clear from reviewing the medical evidence submitted in this case and after reviewing the medical testimony, that Dr. Bean's proffered syllogism - that shared pathogenic characteristics necessarily mean shared causes - is devoid of objective support. This court was unimpressed with the quality of Dr. Bean's testimony on this issue, finding it nothing more than unsupported speculation.

Conclusion

Petitioners failed to prove by a preponderance of the evidence that the DPT caused in-fact their daughter's CIPD. Thus, the Clerk is ordered to dismiss this case.

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Gary J. Golkiewicz

Chief Special Master

1. This Decision was originally entered by the court on July 1, 1998, as an unpublished decision. This reissuance as published decision follows in response to respondent's written request for publication which is hereby granted.

2. Petitioners' Amended Petition alleges that Melissa suffered Guillain-Barre syndrome (GBS) as a result of her DPT vaccination. Petitioners presented no evidence that Melissa currently suffers GBS and no evidence supporting the other claims raised in their Petition, and thus the court deems those claims waived.

3. This time period is disputed by respondent. The medical records contain a range of different periods - from the day after vaccination to two and one-half months following vaccination. See Respondent's Post-Hearing Brief at 21-24 for summary of medical records. This factual issue is critical to petitioners' case as their expert recognized that the outside dates on the range were inconsistent with the expert's opinion. However, since the court decides this case on other bases, this factual issue will not be resolved.

4. Although technically speaking AIDP is a subform of GBS, for purposes of this case and thus for this decision, GBS and AIDP are used synonomously. See Tr. at 86.

5. Petitioner must prove her case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970)(Harlan, J., concurring), quoting F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (Cl. Ct. 1984).

6. In Daubert, the Supreme Court held that Federal Rule of Evidence 702 is binding on federal courts with respect to establishing the admissibility of scientific evidence. Daubert, 113 S.Ct. at 1795. The Federal Rules of Evidence are not binding on this tribunal.

7. The remaining articles submitted by petitioners either dealt with the causal relationship between AIDP and the tetanus vaccination or involved another vaccination altogether. P Ex. 20, Tabs D, E, and I. As such, the articles add no support for the proposition that CIDP and AIDP are analogous processes that share the same causal agents.

8. Dr. Bean suggested that this case report was actually a case of CIDP, not AIDP. This suggestion suffers from no foundation, either in literature or testimony. The most Dr. Bean could say was that there "is a very good possibility." Tr. at 13. Dr. Bean makes no effort to address the findings of the authors themselves, P Ex. 20, Tab D, or the review of the Institute of Medicine, R Ex. G. Dr. Bean provides no support for his suggestion other than this bare statement. While Dr. Bean's statement was undoubtedly well-intentioned, it was not well thought out. Such unsupported, speculative remarks damaged Dr. Bean's credibility before this court.