

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-0720V

Filed: 12 November 2008

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ROBERTO GARCIA,
Petitioner,
v.
SECRETARY OF HEALTH AND
HUMAN SERVICES,
Respondent.
* * * * *

PUBLISHED

Ronald Craig Homer, Esq., Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner;
Linda Sara Renzi, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING¹

ABELL, Special Master:

On 5 July 2005, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)² alleging that, as a result of the Td vaccination he received on 23 July 2003, he suffered a severe and debilitating bout of Guillain-Barré Syndrome (GBS).³ Amended Petition at 1.

¹ Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling within which to request redaction “of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, “the entire decision” may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

² The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

³ Guillain-Barré Syndrome is “acute idiopathic polyneuritis.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 803, 1819; see also the “About GBS” page of the GBS/CIDP Foundation International website, available at http://www.gbs-cidp.org/aboutgbs.htm (describing GBS more specifically as “an inflammatory disorder of the peripheral nerves ... characterized by the rapid onset of weakness and, often, paralysis of the legs, arms, breathing muscles and face”).

This petition was assigned to my chambers on 5 July 2005. Eventually, an evidentiary hearing on the ultimate issue of entitlement for compensation was held telephonically at the Court's Chambers in Washington D.C. on 1 August 2007. Hearing Transcript ("Tr.") at 1. Whereupon, the Court heard from medical expert witnesses for both parties: Dr. Derek Smith for the Petitioner, and Dr. Alfred Spiro for the Respondent. Tr. at 5. Subsequent to that hearing, the parties filed closing briefs with the Court, and the case is now ripe for a ruling.

As a preliminary matter, the Court notes that Petitioner has satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) he represents the real party at interest as the injured party; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 16 requirement that the Petition be timely filed have been met. On these matters, Respondent tenders no dispute.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I). In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine actually caused an injury not so specified. § 11(c)(1)(c).

I. FACTUAL RECORD

Despite their accord on certain factual predicates contained in Petitioner's medical records, there is, unsurprisingly, a pronounced conflict between the parties on certain factual issues of viewing understood scientific mechanisms of vaccine injury within the context of these medical records. Considering these disputes and the Court's commission to resolve them, it behooves the Court to explain the legal standard by which factual findings are made.

It is axiomatic to say that the Petitioner bears the burden of proving, by a preponderance of the evidence – which this Court has likened to fifty percent and a feather – that a particular fact occurred or obtains. Put another way, it is required that a special master, "believe that the existence of a fact is more probable than its nonexistence before [he] 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, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl. Ct. 476, 486 (1984).

This Court may not rule in favor of a petitioner based on his asseverations alone. This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

Medical records are afforded substantial weight, as has been elucidated by this Court and by the Federal Circuit:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary of HHS, 993 F.2d 1525, 1528 (Fed. Cir.1993).

Medical records are more useful to the Court's analysis when considered in reference to what they include, rather than what they omit:

[I]t must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 113 S. Ct. 263 (1992) (citations omitted), citing *Clark v. Secretary of HHS*, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

A. MEDICAL RECORDS *ET AL.*

The Court turns first to the recorded facts drawn from the medical records engendered and maintained by those responding to, and treating, Petitioner's condition. Both parties agree to the following circumstantial facts from the medical records:

On 23 July 2003, Petitioner was administered the Td and pneumococcal vaccinations in the right and left arms, respectively. Two days later, on 25 July 2003, Petitioner was admitted to the Emergency Room with complaints of bilateral weakness that began on 24 July 2003 and worsened progressively. The weakness began in the upper extremities, manifesting more severely in the right arm, before pervading his lower extremities, and culminating in shortness of breath and paralysis of the right upper extremity. Petitioner had suffered from a 48 hour bout of diarrhea approximately one week prior to admission. Once hospitalized, Petitioner's condition progressed to paralysis of both upper and lower extremities, and eventually required five days of intubation. After IVIG treatment, Petitioner slowly recovered, although some sequelae remained.

B. TESTIMONY AT THE ENTITLEMENT HEARING

1. Derek Smith, MD

Dr. Smith's medical expert opinion report (found at Petitioner's Exhibit 6) stated, inter alia, that:

[Regarding] the probable causes of his [GBS], it is likely that both his diarrheal illness and vaccinations contributed to the immunopathogenesis. Initially, immune responses tend to be compartmentalized to the locus of injury or infection. This is likewise the case for vaccines. In this regard, it is interesting that his most weak limb initially was his right arm, the arm into which the tetanus vaccine was administered.

...

[T]he diarrheal illness pre-primed the immune response, so that when the tetanus vaccine was administered the immune response was acute. [Because the gastrointestinal immune system functions to prevent food antigen reactions, w]hen infectious diarrhea occurs, it is likely that the entire immune system is in a greater state of activation, as the tolerogenic function of the gastrointestinal immune system is abrogated, so that an immune response against the gastrointestinal infection can be mounted. In this case, even if the infection may have been *Campylobacter jejuni*, the anatomical localization of the weakness initially is an indication that the DT vaccination precipitated [i.e., was the most proximate cause of] the AIDP.

At the hearing, Dr. Smith, a board-certified adult neurologist, noted that his predominant focus is on treating patients, but that still performs research tasks, even running clinical trials and some immunology research. Tr. at 8. In response to cross-examination, he stated that he treats “something like a dozen” patients with GBS per year, and that the most recent diagnosis of such was three months prior to the hearing. Tr. at 25.

On the issue of whether the tetanus vaccine in question can cause the neurologic damage of GBS alleged by Petitioner, Dr. Smith stated the following:

There was a case described by Pollard which was a man who was vaccinated twice with tetanus and in both cases developed Guillain-Barré Syndrome within two weeks of the vaccinations, and these vaccinations were seven years apart.

I think based on that and some other epidemiologic evidence the Institute of Medicine has accepted an association between tetanus and Guillain-Barré. I think with that kind of repeated exposure and tight timeframe that's fairly compelling evidence that it can occur.

Tr. at 9.

Dr. Smith articulated the mechanism of vaccine-related injury that he portrayed as current among the medical community:

[T]he current theory is that T cells are basically the executive command cells of the immune system and so I think with most autoimmune or immune mediated injury that it's likely that T cells are at the center.

It was once thought that T cells were highly specific for antigens and that a T cell, for example, that reacted against a foreign antigen basically would not react against any other antigen, but research that was done in the 1990s by various authors I think made it clear that the T cell response is much more degenerate and less specific than

we had previously thought, and so I think it's likely that in some rare cases that a vaccination can introduce an autoreactive T cell response against self antigen.

...in rare cases a T cell can be activated that also responds to a self antigen, in this case peripheral nervous system antigen, and that then leads to an acute immune mediated injury to the peripheral nervous system.

Tr. at 9-10.

Regarding whether the onset of Petitioner's injury "occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact" (*see de Bazan v. Secretary of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. August 28, 2008)), Dr. Smith stated his opinion that the onset of GBS two, or even three days post-vaccination was medically appropriate. Tr. at 11. He conceded that the Pollard article he had cited construed the timeframe to between one to two weeks, but noted that "cell mediated responses are generally thought to occur beginning about 24 hours out, but there have been cases described perhaps as short as 12 hours." *Id.*

Dr. Smith opined that the tetanus vaccine was a substantial factor in Petitioner's GBS, while also taking into consideration other potential causal factors: some that might have been at play instead of the tetanus vaccine, or which would have worked along with the vaccine to result in Petitioner's GBS:

[C]ampylobacter jejuni is a bacterial gastroenteritis that's known to be associated with GBS so it could well be that that was a contributing factor in his illness.

I think what I described in my opinion is that I think that all diarrheal illnesses probably predispose to immune activation and potentially autoimmune reaction, and that's because one-third of the immune system is in the gastrointestinal system, and it's believed that the main function of that portion of the immune system is to suppress immune reactions against food antigens.

So when there's inflammation within the gastrointestinal tract that is actually activating the gastrointestinal immune system in such a way that it may no longer be suppressing reactions, one, against food antigens as effectively, but possibly also against autoantigens as effectively.

Tr. at 13-14. Dr. Smith agreed with the Court's hypothetical question, that if "a week prior he had two days of diarrhea," that would mean "that he had no diarrhea in roughly the week prior to the administration of the vaccination." Tr. at 33.

What ultimately persuaded Dr. Smith that the vaccine was a substantial cause in causing Petitioner's GBS was the specific pattern that Petitioner's course followed in his increased weakness: the weakness spread from his right arm, where he had received the tetanus vaccine. Tr. at 15. This was centrally significant to Dr. Smith because "immune responses begin as local responses and then[,] generally speaking[,] the leukocytes in the immune system elements circulate throughout the body and ... become more generalized." Tr. at 15.

In Dr. Smith's opinion, Petitioner suffered from the more severe form of GBS, known as acute inflammatory demyelinating polyneuropathy (AIDP), which is significant because it may militate more strongly for vaccine causation than if Petitioner experienced the less severe form, known as acute motor axonal neuropathy (AMAN). Tr. at 12. Dr. Smith pointed out the existence of medical literature suggesting "that the diarrheal illness caused by *campylobacter jejuni* may be more associated with just the pure motor form," (i.e., AMAN) than with AIDP, which includes sensory involvement as well. Tr. at 12, 17.

On the whole, Petitioner's theory, supported by Dr. Smith's proffered expert opinion, is "that the diarrhea illness that is in the record that Mr. Garcia had, it primed the immune system so that when the tetanus vaccination was administered that it set out an acute reaction which eventually led to a diagnosis of Guillain-Barré syndrome." Tr. at 16. In fact, Dr. Smith saw the potential that gastrointestinal illness could have been "a contributing cause" in addition to the vaccine, and refused Respondent's urging to limit the reaction to one single, responsible cause of Petitioner's GBS. Tr. at 38. Dr. Smith explained his theory that the prompt immune response was the interplay of the two stimuli, as the infection would have "pre-primed" Petitioner's immune response, such that his T cell activation would have taken much less to then react (and overreact) to the tetanus toxin, leading to the onset of GBS. Tr. at 46. However, Dr. Smith admitted that there is no test that exists to provide direct evidence on whether an individual's immune system is pre-primed, only the circumstantial evidence of the sequence of Petitioner's course married with Dr. Smith's theory. Tr. at 48. He also agreed with Respondent's query on cross-examination that he can proffer no medical literature to support a timing sequence for onset as brief as that between the vaccinations at issue here and the onset of Petitioner's GBS. Tr. at 49.

Dr. Smith discussed medical literature supporting the conclusion that "the form of GBS in which *C. jejuni* [is implicated] is a different form than the GBS that Mr. Garcia had." Tr. at 17, discussing Pet. Ex. 6, Tab B. That is, Dr. Smith concludes that Petitioner was afflicted by the AIDP form of GBS, based on the history reflected in the medical records, and not the AMAN type, which is more strongly associated with the *campylobacter jejuni* bacteria. Tr. at 17-18. However, on cross-examination, Dr. Smith conceded that no test was performed to verify which of the two forms afflicted Petitioner, even if "the clinical course [was] much more consistent with AIDP than one of these other variants." Tr. at 35-36.

In rebuttal to a point raised by Respondent's expert report, that Petitioner had preexistent "walking" pneumonia leading up to, and during, his onset of GBS symptoms, Dr. Smith pointed out that a chest x-ray performed on Petitioner at his initial presentation to the hospital did not indicate pneumonia, but was normal. Tr. at 18. Dr. Smith reasoned that the pneumonia which developed three days following Petitioner's intubation in the hospital was "nosocomial" or "hospital-acquired." Tr. at 20.

In fact, Dr. Smith did not believe that any microbial infection plagued Petitioner's central nervous system, based on the absence of white blood cells found in spinal taps performed on Petitioner. Tr. at 20. Those only indicated elevated protein levels, which, Dr. Smith stated, are a normal sign of Guillain-Barré Syndrome. Tr. at 20-21.

All of these aspects of the medical history led Dr. Smith to conclude that Petitioner's GBS was caused by the tetanus toxoid vaccination at issue. Tr. at 23.

On cross-examination, Respondent questioned Dr. Smith's correlation of right-arm paralysis with the injection of the tetanus toxoid-containing vaccine in the same arm (whereas the left arm received the pneumococcal vaccine, and was merely weakened). Tr. at 26-27. Dr. Smith found this correlation probative for determining vaccine-related involvement, because it demonstrated asymmetrical onset of weakness tied to GBS; he certainly found it more supportive of vaccine-related causation than if the converse had been true, or if the onset was symmetrical. Tr. at 27-28. Incidentally, Dr. Smith did not seek to involve the Pneumovax vaccination into his discussion or theory of causation. Tr. at 28. This asymmetrical onset, more severely affecting the arm injected with the putative vaccinal culprit, was unusual, which Dr. Smith finds supportive of vaccine causation, inasmuch as "usually Guillain-Barré does start in the lower extremities, so having it start in the upper extremities is somewhat unusual." Tr. at 29.

When pressed by Respondent, Dr. Smith admitted that this correlation between injection site and locus point of onset was not reflected in medical literature tying tetanus toxoid vaccine to GBS, and specifically that the oft-cited "Pollard article" did not serve as a basis for using asymmetrical onset as proof of vaccine causation. Tr. at 29-30. Dr. Smith clarified that he employed his "common sense" to reach that conclusion, through a process of deductive reasoning derived from his experience and expertise in this area of medicine. Tr. at 30, 50. In response to further questioning by Respondent, Dr. Smith agreed that "a large percentage of patients with Guillain-Barré syndrome present with a history of [various infections] within the [six weeks [prior to presentation]]." Tr. at 36. Dr. Smith concluded by reiterating that he found it "most likely" that "the tetanus vaccine substantially contributed to the onset of Mr. Garcia's GBS." Tr. at 50.

2. Alfred Spiro, MD

In his written report, Dr. Spiro, after reviewing Petitioner's clinical history and agreeing with the diagnosis of GBS (despite the lack of "electrodiagnostic studies"), summarized Petitioner's course as "developing weakness about a week after he experienced two days of diarrhea." Respondent's Exhibit A. It was the diarrhea that Dr. Spiro believed was "a cause of [Petitioner's] neurological problem," such that the vaccinations Petitioner received in the meantime "were only coincidental findings." *Id.* In supportive explanation of that conclusion, Dr. Spiro pointed out that diarrhea "is a rather common co-existing feature of Guillain-Barré syndrome[,] in which a nonspecific infection is present for about a week before the development of weakness, and, between the nonspecific infection and the development of weakness, there is usually a period in which the patient has no symptoms or signs whatsoever." *Id.*

Dr. Spiro "attends" in both neurology and pediatrics at the Montefiore Medical Center in New York, and serves as Professor of Neurology and Pediatrics at the Albert Einstein College of Medicine, where he has remained on the faculty since 1966, having risen to the rank of full professor some thirty years ago. Tr. at 53-54. He is board-certified in pediatrics and neurology, with a special competence in child neurology. Tr. at 54. Dr. Spiro still treats patients, both child and adult. *Id.*

He treats adults with neuromuscular disorders as well as some others through a clinic supported by the Muscular Dystrophy Association. Tr. at 55.

Dr. Spiro summarized his medical opinion in this case in stating that, although “the tetanus vaccination was temporally related,” nevertheless “it had nothing to do with the disease.” Tr. at 57. He believed such a close temporal relationship between the vaccination and the onset of GBS made it “much less likely” that the vaccine played any causative or triggering role in the disease. Tr. at 58. Dr. Spiro did not find the asymmetrical development of the GBS indicative of vaccine causation because “asymmetrical presentation in GBS is not an uncommon feature,” and did not know of any medical literature supporting association between vaccination location and GBS onset pattern. Tr. at 59. Dr. Spiro was also unaware of any support finding multiple immunologic stimuli responsible for the onset of GBS. Tr. at 62. It is therefore unsurprising that Dr. Spiro believed that, “absent the receipt of the tetanus vaccination,” Petitioner “would have developed GBS,” inasmuch as he thinks that vaccination had no cause and effect relationship with the GBS. Tr. at 64. Additionally, Dr. Spiro did not seem to indicate that Petitioner’s GBS symptoms were tied to a preexisting pneumonia. Tr. at 69.

In Dr. Spiro’s experience, “a high double digit percentage” of patients complaining of GBS “present with a history of infection in the weeks prior to onset,” and, more specifically, he believes that Petitioner’s diarrhea “was an antecedent to his GBS,” having developed “within the timeframe for an immune mediated response.” Tr. at 60-61. Dr. Spiro did not find it significant that Petitioner’s diarrhea symptoms “had resolved [] about one week prior to the vaccination.” Tr. at 63. Dr. Spiro found it mere speculation to suppose that Petitioner’s diarrhea was caused by *C. jejuni* or campylovirus, and that it was likewise speculation to type Petitioner’s GBS as AIDP (vis-a-vis AMAN). Tr. at 71. Dr. Spiro explained that any number of antecedent infections can lead to GBS, and he stated, “That’s why GBS is called a syndrome. It’s not one single disorder.” Tr. at 63-64.

Regarding the appropriate medical temporal association between immunologic trigger and the onset of GBS, Dr. Spiro stated that the latency period for an adaptive immune response (such as GBS) is “generally about three, four, [or] five days,” but, to his knowledge, cannot be as short as 24 hours. Tr. at 65. However, Dr. Spiro then noted that AIDP is included within the subset of GBS cases for which clinical response is rapid (also known as “Landry Guillain-Barre syndrome”)—as rapid as “within 12 to 24 hours.” Tr. at 65-66. Dr. Spiro then distinguished clinical response from immune response as different, but did not explain how they were distinct. Tr. at 67. He added that in the case of AIDP, “the [clinical] course...can be extremely acute,” but noted that much the same could be said of some cases of the AMAN type. Tr. at 67-68.

On cross-examination it was discovered that, although Dr. Spiro acknowledges that the IOM group found that tetanus can cause GBS, based on a documented “re-challenge” reaction, he nevertheless disagrees, concluding that, for him, such linkage was unpersuasive to demonstrate a causative relationship. Tr. at 72. He did agree with Petitioner’s statement, however, that the most prevalent form of GBS in America is the AIDP form, based upon his own professional experience, and that *C. jejuni* is more commonly associated in sources of medical literature with the AMAN form, affecting the nerve axons. Tr. at 73.

Also, whereas on direct examination, Dr. Spiro stated his disagreement with a theory contemplating more than one causative factor for GBS (Tr. at 62), on cross-examination, he stated that two separate immunologic exposures “both can be factors in the presentation with GBS.” Tr. at 77. However, he soon distinguished that statement, noting that he was considering two causes that were each “well-known antecedents of GBS, and in the case of tetanus we’re talking about something which most probably has never happened.” *Id.* When Petitioner reminded Dr. Spiro of the Pollard article, which the IOM found persuasive, Dr. Spiro countered by stating “I have to disagree with that reasoning because it’s extremely slim evidence.” Tr. at 78. In fact, on redirect examination, Dr. Spiro expressed that, when determining potential *causata* of GBS from a patient’s medical history, he does not take equally into account possible triggers of GBS that are not “statistically significant.” Tr. at 83.

C. POST-HEARING SUBMISSIONS

At the conclusion of the hearing, the Court ordered briefing by the parties, whose arguments are summarized here.

Petitioner “concedes that the vaccination must be a ‘substantial cause’ of the injury,” but argues, on the weight of cases from the Federal Circuit that “it need not be the sole factor or even the predominant factor.” Petitioner’s Closing Brief at 13, quoting *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1357 (Fed. Cir. 2006) and citing *Shyface v. Secretary of HHS*, 165 F. 3d. 1344 at 1352-1353). Petitioner also raises the Federal Circuit’s recent guidance in *Walther v. Secretary of HHS* that “the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.” 485 F.3d 1146, 1150 (Fed. Cir. 2007).

Moreover, Petitioner argues that he has met his burden through proving that the vaccine both *can* and *did* cause Petitioner’s GBS: (a) that the testimony of Dr. Smith, premised upon the Pollard article “has provided ‘a medical theory casually connecting the vaccination and the injury’ [by demonstrating that] a tetanus vaccine *can* cause GBS.” Petitioner’s Closing Brief at 13 (emphasis added), quoting *Althen v. Secretary of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005); and (b) that “Dr. Smith’s testimony describe[d] a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” by theorizing “that the diarrheal illness Roberto had prior to being admitted to the emergency room primed Roberto’s immune system for the acute immune mediated reaction he had to the TD vaccine.” *Id.* at 14, quoting *Althen, supra*.

In contradistinction, Respondent argues that “despite the proposed relationship between tetanus and GBS (as outlined in the IOM report), the medical community does not accept ‘that there is a higher risk for GBS following tetanus vaccination.’” Respondent’s Closing Brief at 12. Respondent contends that “Petitioner’s gastrointestinal illness, which occurred prior to his Td vaccination and within the timeframe accepted for causing GBS, was a much more likely cause for his overall condition,” such that “[any] effect of his vaccination within twenty-four hours is rendered insignificant, and is not a ‘substantial factor’ in bringing about his GBS.” *Id.* at 16.

After quoting from *Shyface* and the Restatement (2d) of Torts to explain the significance of “substantial factor” in the doctrine of proximate cause, within the greater context of legal causation, Respondent then curiously argues:

In an actual causation case, the question of whether a factor other than the vaccination was responsible for the alleged injury is necessarily subsumed in petitioner’s basic burden: *proving that the vaccine was the most likely cause* of the alleged injury. For petitioner in this case to successfully demonstrate that the vaccine was the most likely cause of his alleged injury, *he must concomitantly demonstrate other causes less likely.*

Respondent’s Closing Brief at 16-17 (emphasis added).

Also, Respondent spends an entire section of his brief arguing that “*Daubert* [*v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)] applies to Vaccine Act Proceedings,” in order to then argue that Dr. Smith’s testimony should be excluded because it was not reputable under a *Daubert* analysis.

II. ULTIMATE FINDINGS OF FACT

Both experts were personally and professionally credible; that premise is beyond a cavil of doubt in the Court’s mind. However, the Court must analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect that is biologically plausible to tie together the factual sequence and explain Petitioner’s injury. *See Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007); *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Of principal importance, the Court notes its conclusion that tetanus toxoid-containing vaccines *can* cause Guillain-Barré Syndrome, based on the Pollard article. If the article persuaded a panel of the IOM of the medical plausibility of such a relationship, the Court can hardly remain skeptical. The Court presumes until shown otherwise that members of an IOM panel represent the mainstream of medical thought. Dr. Spiro is entitled to his professional skepticism, but, given the lack of any stated basis for his stance, he did not persuade the Court to similarly embrace Pyrrho’s *akatalepsia* on the issue. Therefore, the Court accepts the basic plausibility of the proposition that a vaccine containing the tetanus toxoid *can* cause GBS.

Regarding the second question, regarding whether tetanus *did* cause Petitioner’s GBS, certainly the biggest stumbling block of Petitioner’s burden of persuasion is the shortened temporal sequence between the vaccination and the onset of GBS.

Although much was made of the distinction between the AIDP and AMAN types of GBS, each of the parties’ own experts downplayed the significance and ascertainability of identifying the exact form of GBS that affected Petitioner. The Court does not find it necessary to decide from which of those two Petitioner suffered. Likewise unnecessary is deciding whether the diarrheal illness that preceded both the vaccination and the onset of GBS was caused by *C. jejuni* or some

other microbial organism. The Court was left to conclude, based on the testimony of the experts, that more than one microbial influence could have caused the diarrhea, which could have been causally related with the onset of GBS, the symptomatological course of which could implicate more than one expression of the syndrome. As Dr. Spiro himself pointed out, “That’s why GBS is called a syndrome.” Tr. at 64.

Especially where, as here, a petitioner’s injury is a syndrome, semantic boundaries are less important. What remains important, as it is in all actual causation cases, is etiology. What biologic process can be concluded to have been operating, based upon the facts presented to the Court? The term “Guillain-Barré Syndrome” refers simply to a syndrome⁴ identified by Messrs. Guillain and Barré (*inter alia*); it does not necessarily communicate a particular etiological explanation. It certainly does not establish the organism, compound, or biologic process that acted as the impetus for the symptoms that did develop. Furthermore, all of the subcategories thereof more or less describe the expression of the symptoms, such as what tissues or bodies are affected, how quickly, and for how long a duration. These terms do not communicate whether the categories they represent are etiologically distinct. However, this is the central inquiry of determining actual causation.

The experts distinguished themselves in their expert reports and at the hearing by how thoroughly they aided the Court’s understanding of etiology. On the one hand, Dr. Smith explained T cell activation and the process whereby a person’s immune system could be pre-primed to respond to a succession of immune stimuli. On the other hand, Dr. Spiro concluded that he does not think the tetanus vaccination has anything to do with the GBS Petitioner experienced. Dr. Smith’s testimony revealed to the Court Petitioner’s theory of causation; Dr. Spiro’s testimony required the Court to accept his conclusions based solely upon the credibility of his personal conviction.

The Court’s task is not primarily to weigh the comparative professional merit of the two experts before it; its principal task is to determine which of two competing etiological explanations is more persuasive.

Given that Dr. Spiro primarily spent his testimony at the hearing describing symptomatology, and the substance of his conclusions (without much more) on several questions posed, the Court is unable to weigh his etiological explanation against Petitioner’s. It was of little help to the Court’s decision-making process to learn which tests Dr. Spiro would have performed for various potential *causata* when none of them were performed in this case. To contend against Petitioner’s theory of causation on the basic argument of “never heard of it” does not explain why such theory is more or less probable. Coupled with his belief that the IOM was wrong to associate tetanus with GBS, the Court is left to conclude that Dr. Spiro is just more skeptical than most. (*See, e.g.*, the following exchange: “Q: So in the case of a rechallenge[,] you don’t believe that that actually proves that the agent caused the injury? A: In my opinion, I can’t say that there’s a causal relationship there, no.” Tr. at 72.)

⁴ A syndrome is “a set of symptoms that occur together; ... a symptom complex.... See also disease.” DORLAND’S, *supra*, at 1808.

The problem arises when a third party such as the Court attempts to weigh Dr. Spiro's conclusion against the theory of another: then Dr. Spiro's argument rises and falls with how universal one assumes his experience to be. Even if one assumes that every GBS case during Dr. Spiro's history of practice arose from diarrheal illness or post-surgical infection, how does that negate that a vaccine caused GBS in another case? Moreover, that assumption alone may be undermined by the fact that Dr. Spiro does not take into account potential *causata* that are not "statistically significant." Tr. at 83. The Court notes that assessing differential diagnoses based upon their statistical prevalence may be good practice for a doctor trying to diagnose a patient for purposes of treatment; however, excluding potential explanations because of weak statistical representation is not the rule followed here in the Vaccine Program.

Turning to Dr. Smith's theory, the Court found it generally helpful for making sense of Petitioner's clinical progression. The theory of pre-primed immune response to the vaccine, made possible because the diarrheal illness had already run riot with the gastrointestinal immune system, is persuasive to explain why the reaction time was abbreviated below what is typical for GBS. Due to its basic *prima facie* plausibility, and because Respondent did not offer evidence that would tend to undermine that theory as an etiological explanation, the Court can do no better than to accept it as persuasive.

Therefore, the Court finds that the diarrheal illness pre-primed Petitioner's immune response, such that when Petitioner received the tetanus vaccine, his immune system was highly reactive and his T cell population was numerous and combative. The Court finds further that the tetanus vaccine, once administered, then triggered an over-reactive autoimmune response that led Petitioner's immune system to attack his own nervous system, resulting in symptomatology best described as the syndrome known as Guillain-Barré Syndrome.

III. CONCLUSIONS OF LAW

As aforementioned, the Court is authorized to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a cognizable Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). If Petitioner had claimed to have suffered a "Table" injury, to him would § 13(a)(1)(A) have assigned the burden of proving such by a preponderance of the evidence. In this case, however, Petitioner does not claim a presumption of causation afforded by the Vaccine Injury Table, and thus the Petition may prevail only if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury alleged. *See* § 11(c)(1)(C)(ii)(I) & (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 has indicated that, to prevail, every petitioner must:

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.

Furthermore, the Federal Circuit has articulated an alternative three-part causation-in-fact analysis as follows:

[Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

As part of that analysis, the Federal Circuit recently explained:

[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.

de Bazan v. Secretary of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury, they must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been viewed with approval by the Federal Circuit,⁵ and which guides the Court's practical approach to analyzing the *Althen* elements:

The Undersigned has often bifurcated the issue of actual causation into the "can it" prong and the "did it" prong: (1) whether there is a scientifically plausible theory

⁵ *See Pafford v. Secretary of HHS*, No. 01-0165V, 2004 WL 1717359, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd* 451 F.3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*"), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

which explains that such injury could follow directly from vaccination; and (2) whether that theory's process was at work in the instant case, based on the factual evidentiary record extant.

Weeks v. Secretary of HHS, No. 05-0295V, 2007 WL 1263957, 2007 U.S. Claims LEXIS 127, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

Here, the Court has found, as a matter of fact, that Petitioner's diarrheal illness and tetanus vaccine were each and together instrumental in precipitating an autoimmune reaction that culminated in Petitioner's condition (GBS). The Court found that tetanus could cause GBS, and that, acting in tandem with a previous diarrheal illness, that it did cause GBS. In so doing, the Court accepted Petitioner's theory that causally connected the tetanus vaccine to Petitioner's GBS. The Court thereby also accepted the logical sequence advocated by Petitioner that the diarrheal illness led to a pre-primed response to the vaccine, which led to an autoimmune reaction, which led to nervous system damage, which led to the weakness, pain and numbness medically categorized as GBS.

Based on the Court's finding, the GBS would not have resulted as it did but for the occurrence of both together. Likewise, both were substantial causes leading to the result of Petitioner's GBS. The legal doctrines of legal causation do not require that a substantial cause be a predominant cause, as Respondent has argued. If the diarrheal illness and the vaccine were competing causes in the Court's findings, the Court might need to proceed with a "superseding cause" analysis, but that is not obvious from the facts, and Respondent has not argued for such.

Respondent has argued that Petitioner must prove not only that the vaccine was a substantial cause, but that it was "the most likely cause" of Petitioner's GBS. The Court is unsure as to what Respondent refers. The question of factual probability—i.e., which facts more *likely* than not occurred—has been addressed in the Court's factual findings. The Court determined what had more likely than not occurred in finding to a preponderance of the evidence the facts stated *supra*. Respondent's legal argument concerning probability would seem to infer that this case involves several mutually exclusive causes of the GBS, each of them more or less likely to have occurred in isolation, or, alternatively, that the Court should determine what occurred in Petitioner's case based upon statistical likelihood, the epidemiology argument. None of these analytical rubrics are apposite.

The legal tradition surrounding the proximate cause portion of legal causation doctrine contemplates that there are potentially infinite antecedent events that may have had some causative influence on a state of reality. Those antecedent events may have each actually occurred, and, even in some small way, contributed to the state of reality as it is (or was). In that fashion, they are all "likely" causes of the final result. However, the line drawn by the law is to differentiate remote causes from proximate ones. Some antecedent conditions or events may be logically causative, but so inconsequentially related such that the law will not abide a conclusion that they are "reasonably" connected. In the mind of the law, there may be multiple causes for any given event or circumstance. That is why proximate cause is determined by deciding how "substantial" a causative factor is. *See Pafford* at 1357-58; *see generally Shyface, supra*. That is the question before the Court.

On the facts as they were found by the Court, both the diarrheal illness and the tetanus vaccine were causes of the GBS. The question arises: was the vaccine a substantial cause of the

GBS? Or was its effect overborne by some superseding, alternative cause? No evidence has been proffered to persuade the Court that the diarrheal illness or the later-contracted pneumonia superseded the effect of the vaccine. Diarrheal illnesses may be known to cause GBS on their own, by triggering the body's autoimmune response. However, the Court found here that the diarrheal illness did not act in isolation, but rather that it was consistently plausible that the diarrheal illness and the vaccine worked in concert to bring about the autoimmune reaction. Considering the theory presented, in light of the medical records submitted and the medical expert testimony taken, the Court rules that the tetanus vaccine was a substantial cause of the GBS.

The Court is left to conclude that both aspects of legal causation have been met, and that therefore the tetanus vaccine actually caused Petitioner's GBS.

Lastly, the Court turns to address Respondent's arguments that "*Daubert* [*v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)] applies to Vaccine Act Proceedings," and that Dr. Smith's testimony was not reputable under a *Daubert* analysis and therefore should be excluded from the Court's consideration. As the Undersigned has already addressed this contention when previously argued by Respondent in another case, the Court does not wish to expend further judicial resources to answer again that contention here. *Banks v. Secretary of HHS*, No. 02-738, 2007 WL 2296047, *20-21 (Fed. Cl. Spec. Mstr. Jul. 20, 2007); *see also de Bazan v. Secretary of HHS*, 539 F. 3d 1347, n.4 (2008) (finding Respondent's argument to apply *Daubert* to be "inapposite" where expert evidence is not excluded,⁶ but is admitted and weighed on persuasive merit).

As the Court summarized in *Banks*:

[*Daubert v. Merrell Dow Pharms., Inc.*] addresses a trial court's "gatekeeper" function, to protect the fact-finder from unreliable testimony that will confuse, rather than inform, the fact-finding process. 509 U.S. at 595-597. The Supreme Court there connected the precondition that testimony comport as "scientific knowledge"⁷ to "a standard of evidentiary reliability." *Id.* at 590. The Court then linked evidentiary reliability to a supportive foundation of scientific validity. *Id.*, note 9. A proposition or theory is scientifically valid where it supports the conclusion that "it purports to show." *Id.*

The Court in *Daubert* readily distinguished, as a separate component, the issue of relevance. *Id.* at 591. Unsurprisingly, evidence is only admissible in the first place when it is relevant, but even potentially relevant testimony is excluded as inadmissible under the *Daubert* analysis of FRE 702 whenever it is not reliable. *Id.* at 592-93. Therefore, the two are distinct, and not to be conflated.

The *Daubert* opinion state[d] that, prior to determining the relevance of expert opinion evidence, a trial judge must first assess "whether the reasoning or

⁶ Respondent did at no point timely move for exclusion of Dr. Smith's testimony. Therefore, any objection tethered to *Daubert* was thereby waived. *See infra*.

⁷ In *Daubert*, the Court was interpreting Federal Rule of Evidence 702, which allows expert opinion testimony regarding "scientific, technical, or other specialized knowledge." 509 U.S. at 589.

methodology underlying the testimony is scientifically valid and [] whether the reasoning or methodology properly can be applied to the facts in issue.” *Id.* at 592-93. The Court gives guidance for this determination by way of some factorial examples, but [left] the determinative process to the logic and reason of the trial judge.... *Id.* at 593. The Court proceed[ed] to list [] four examples ... but reiterate[d] such an inquiry remains “a flexible one,” focused not on a mechanistic weighing of predetermined factors, but on the scientific validity of the opinion offered. *Id.* at 594-95.

Later in the decision, the *Daubert* Court assuaged the fear that such a result would allow materials to be considered which might technically comport to the reliability standard [*the standard on a motion to exclude*], but which are only minimally relevant (i.e., of slight probative value). *Id.* at 595-96. The Court’s assurance was that the assaying process of trial would sufficiently test, weigh, and prove the proper amount of weight to be afforded to such testimony. This reassuring concept makes clear that even if a proffered theory is not “generally accepted”, it may still be admissible, and will be left to the winnowing analytical process of the fact-finder to assign an ultimate probative value.

Banks v. Secretary of HHS, 2007 WL 2296047 at *21.

The Court pauses here only to add, that within cases in the Vaccine Program, direct application of *Daubert* is infrequent, largely because, in each case, the special master is statutorily authorized to act as finder of fact and to apply the law to those facts once found. §12(d)(3)(A)(I). Moreover, the Federal Rules of Evidence, which the Court in *Daubert* was interpreting, do not apply in Vaccine Act proceedings by the explicit words of the Vaccine Act. §12(d)(2)(B); Vaccine Rule 8(a). As such, the need to protect the fact finder from confusing, unreliable expert opinion through a separate examination performed by the legal arbiter, *when they are the same person in every case*, quickly becomes logically attenuated, especially where, as here, there is no rule of evidentiary admissibility that requires it. Since the medical theory of causation under scrutiny is often the linchpin to the entire issue of entitlement, conservation of judicial resources will most often militate against a separate sub-proceeding in the case where the Court must decide “whether the reasoning or methodology underlying the testimony is scientifically valid and [] whether the reasoning or methodology properly can be applied to the facts in issue.” *Daubert* at 592-93. As members of this bench hear these cases consistently, their mind is not a naïve *tabula rasa*, like “infants, tossed back and forth by the waves, and blown here and there by every wind of teaching and by the cunning and craftiness of men in their deceitful scheming.” Eph. 4:14. They bring a background of knowledge and experience in evaluating medical and scientific theories and do not require the same procedural protection afforded to lay juries. In fact, the option is always available to the Court, even when Respondent does not object to evidence on relevance grounds, for the Court to challenge the relevance of proffered testimony. In sum, it may be totally appropriate in individual cases to challenge the scientific reliability of a proffered theory through a motion to exclude; however, due to practical considerations, that situation is a rarity.

Moreover, evaluating a medical theory upon a motion to exclude would often prove redundant or unnecessary. This bifurcated question of “whether the reasoning or methodology

underlying the testimony is scientifically valid and [] whether the reasoning or methodology properly can be applied to the facts in issue” (*Daubert* at 592-93) closely resembles the “can it”—“did it” question of etiology and causation that is the heart of entitlement considerations in actual causation cases. In fact, this Court has, in times past, employed analytical factors such as those referenced in the *Daubert* case for the purpose of evaluating a proffered medical theory, not in the context to which *Daubert* refers (motions to exclude unreliable evidence as inadmissible), but on the central question of causation. See *Terran v. Secretary of HHS*, Case No. 95-0451V, 1998 WL 55290 *11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998) (finding petitioner’s theory of causation insufficient because it was “not generally accepted in the scientific community,” had “not been subjected to peer review publication because ... it is not generally accepted and would not get published in the United States,” and had “not been satisfactorily tested” as no tests had then been developed). However, since that time, the Federal Circuit has provided significantly more guidance on the analytical standards to be used in the Vaccine Program to evaluate evidence (including expert testimony) in determining the issue of causation, such that the Court no longer needs to lift factors from persuasive authority because there has been provided direct, mandatory authority to follow. See *Shyface, Althen, Pafford, Walther*, and *de Bazan*, *supra*. Thus, in this current context, the similarity between this preliminary “gateway” question and the ultimate issue of the Court’s determination of entitlement raises the substantial concerns of redundancy and inefficiency.

Those cases where exclusion of proffered testimony is appropriate are therefore not common. Most often, the central question of the case is how well the expert’s theory comports with the facts culled from the medical records and fact witness testimony (if any is offered). This question is one of persuasiveness and logical relevance, not admissibility. Nevertheless, there is certainly a component of scientific reliability and/or validity that will bear upon the Court’s determination of whether Petitioner’s expert was persuasive enough to surmount the preponderance standard, or if Respondent’s expert was more persuasive *per contra*. To be sure, the Federal Circuit’s guidance on this point is clear in cases like *Knudsen*, *supra* at 549 (each petitioner “must proffer a *plausible* medical theory”), *Althen*, *supra* at 1278 (“a medical theory causally connecting” coupled with “a *logical* sequence of cause and effect”), and *de Bazan*, *supra* at 1352 (“onset of symptoms [must occur] within a timeframe for which, given the medical understanding of the disorder’s etiology, it is *medically acceptable* to infer causation-in-fact”) (emphasis added). But in this context, the question of whether an expert’s theory possesses scientific *bona fides* goes to the persuasiveness of the evidence on the question of etiology and causation; the Court is not actually applying *Daubert* for the purpose of determining credibility, reliability, and therefore admissibility of the testimony.

On this latter concern, Respondent’s argument is a day late and a dollar short. The finder of fact already heard Dr. Smith’s testimony, rendering the objection waived and therefore moot: it is water under the bridge. To the extent Respondent’s position is really to argue that Dr. Smith’s testimony was unpersuasive, that issue is addressed at length *supra*.

IV. CONCLUSION

Therefore, in light of the foregoing, the Court rules in favor of entitlement in this matter. The parties are instructed to contact the Court for further proceedings, regarding the issue of damages.

IT IS SO ORDERED.

Richard B. Abell
Special Master