In the United States Court of Federal Claims

No. 02-223 V

(Filed: August 31, 2005)

RYAN KELLEY, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	Vaccine Act; Non-Table Injury; Causation-in-fact; Not in Accordance with Law

Ronald C. Homer, Boston, MA, for petitioner.

Heather L. Pearlman, with whom were, Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Mark W. Rogers, Deputy Director, Gabrielle M. Fielding, Assistant Director, and Catharine E. Reeves, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

HEWITT, Judge

Petitioner Ryan Kelley seeks review in this court of the chief special master's dismissal of his Amended Petition for Vaccine Compensation (Petition or Pet.), filed under the National Vaccine Injury Compensation Program (Vaccine Act or Act), 42 U.S.C. §§ 300aa-1 to -34 (2000). On March 22, 1999, Mr. Kelley received a tetanus toxoid (TT) vaccination alleged to have caused him neurological injury first diagnosed as Guillain-Barré Syndrome (GBS),[1] Pet. at 1, but later categorized as Chronic Inflammatory

[1]GBS is an "acute, autoimmune inflammatory destruction of the myelin sheath covering peripheral nerves, causing rapid progressive symmetrical loss of motor function." Pet. at 1 n.2 (quoting Taber's Cyclopedic Medical Dictionary, 18th Ed., (1997)) (internal quotations omitted).

Demyelinating Polyneuropathy (CIDP),[2] id. at 6, ¶ 10. Petitioner filed for compensation on March 21, 2002 and amended his petition on November 5, 2002. See Kelley v. Sec'y of Health & Human Servs., No. 02-223V, 2005 WL 1125671, at *1 (Fed. Cl. Spec. Mstr. March 17, 2005). In a decision published March 17, 2005, the chief special master dismissed the Petition for failure to prove by preponderant evidence that the vaccination had in-fact caused petitioner's injury. Id. at *15.

Petitioner timely filed a motion for review under section 300aa-12(e) of the Act, claiming that the chief special master's decision imposed an improper standard of causation and should be reversed. See generally, Petitioner's Motion for Review (Pet'r's Mot.). Respondent argues that the chief special master applied the correct standard of causation and properly exercised his role as "gate-keeper" in rejecting the causation theory of petitioner's expert witness. See generally Response to Petitioner's Motion for Review (Resp.). For the reasons set forth below, the court GRANTS petitioner's motion for review, REVERSES and VACATES the chief special master's decision and REMANDS the case for an award of compensation to petitioner.

I. Standard of Review

This court reviews the decisions of the special master under the following standard:

> [T]he United States Court of Federal Claims shall have jurisdiction to . . . review . . . the record . . . and may thereafter . . . set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law . . . .

42 U.S.C. § 300aa-12(e)(2)(B); see also Rules of the Court of Federal Claims, App. B, Rule 27(b) ("The [court] . . . may . . . [s]et aside any finding of fact or conclusion of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and issue [its] own decision . . . ."); Saunders v. Sec'y of Health & Human Servs., 25 F.3d 1031, 1033 (Fed. Cir. 1994).

II. Background

A. Standard of Proof for Causation-in-Fact of an Off-Table Vaccine Injury

[2]CIDP is "[a] gradually progressing autoimmune muscle weakness in arms and legs caused by inflammation of the myelin sheath covering peripheral nerve axons." Pet. at 6 n.7 (quoting Taber's Cyclopedic Medical Dictionary, 18th Ed., (1997)) (internal quotations omitted).

The Act requires petitioners seeking compensation for vaccine-related injuries to prove causation in one of two ways. An injury shown to fall under the Vaccine Injury Table, see 42 U.S.C. § 300aa-14(a)–a so-called Table injury–is afforded a presumption of causation by operation of law, see § 300aa-11(c)(1). Any injury not listed in the Vaccine Injury Table (an off-Table or non-Table injury) must be proven by causation in fact, § 300aa-11(c)(1)(C)(ii)(I). Petitioners' theories of causation must be substantiated "by medical records or by medical opinion." § 300aa-13(a)(1). The Act further provides that

> [c]ompensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole . . . that the petitioner has demonstrated [causation for a Table or non-Table injury] by a preponderance of the evidence . . . and . . . that there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine . . . .

Id. The Act presumptively favors vaccine-related evidence of causation over allegations that the cause of a petitioner's injury is uncertain. See § 300aa-13(a)(2)(A) ("[T]he term 'factors unrelated to the administration of the vaccine' . . . does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.") (emphasis added); cf. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) ("[T]o require identification and proof of specific biological mechanisms [of causation] would be inconsistent with the purpose and nature of the vaccine compensation program."). In light of the legislative history of the Vaccine Act, the Federal Circuit has adopted a "substantial factor" standard of proof for actual causation. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351-53 (Fed. Cir. 1999) (rejecting the government's argument that petitioners in non-Table cases must show that a vaccine was the "predominant cause" of injury). Legal causation of a non-Table injury may be proven by a preponderance of evidence showing "that the vaccine was not only a but for cause of the injury but also a substantial factor in bringing about the injury." Id. at 1352.

More recently, in Althen v. Sec'y of Health & Human Servs., No. 04-5146, 2005 WL 1793399 (Fed. Cir. July 29, 2005), the Federal Circuit refined the standard of proof for causation-in-fact. See id. at *5 (finding the chief special master acted contrary to law by denying compensation for lack of medical literature supporting causation by tetanus toxoid (TT) vaccination of a non-Table injury).[3] The "requisite showings," Althen holds,

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[3]The petitioner in Althen suffered a "loss of vision" in her right eye following a TT vaccination. Althen v. Sec'y of Health & Human Servs., No. 04-5146, 2005 WL 1793399, at *1 (Fed. Cir. July 29, 2005). Her initial diagnosis, "inflammation of the optic nerve," was eventually converted to one of a more general "central nervous system demyelinating disorder,"

(continued...)

for establishing by preponderant evidence causation-in-fact for a non-Table vaccine injury are:

> [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 proximate temporal relationship between the . . . vaccination and [petitioner's] injury.

Id. These requirements track the plain language of the Act, which requires no "objective confirmation" in the form of "medical documentation." Id. at **3-4 ("To require [petitioner] to provide medical documentation would contravene the plain language of the statute."). As the Federal Circuit explained,

> The statute's language is clear; section 300aa-13(a)(1) instructs that a petitioner must prove causation in fact by a "preponderance of the evidence," substantiated by medical records or medical opinion, as to each factor contained in section 300aa-11(c)(1). . . . This court has interpreted

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[3](...continued)
id. at *1 & n.4, a condition not among those listed in the Vaccine Injury Table, see 42 U.S.C. § 300aa-14(a). The chief special master denied petitioner's claim for compensation for failure to show actual causation:

> Despite the testimony of Dr. Derek R. Smith, a board-certified neurologist with a subspecialty in neuroimmunology, that the TT shot caused her injury and that the onset of her optic neuritis occurred within a medically-accepted time period for causal connection, the special master found that because Althen did not provide peer-reviewed literature that demonstrated "'a suspected or potential association' between the tetanus toxoid vaccine and the alleged injuries" as required by Stevens v. Sec'y of Health & Human Servs., No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 20, 2001), she did not prove causation-in-fact.

Althen, 2005 WL 1793399, at *1 (quoting Althen v. Sec'y of Health & Human Servs., No. 00-170V, 2003 WL 21439669, at *14 (Fed. Cl. Spec. Mstr. June 3, 2003)). Petitioner moved for review, and the Court of Federal Claims determined that the application of "the Stevens test was not in accordance with law." Id. at *2; Althen, 58 Fed. Cl. 270, 284 (2003) ("As a threshold matter, the Vaccine Act does not preclude causation in fact from being established by a petitioner in the absence of peer reviewed literature. . . . [S]cientific literature is only one of several factors to be considered . . . in determining the reliability of an expert's opinion."). The Court of Federal Claims reversed the finding on causation and "remanded the case to the special master for an award of compensation to Althen." Althen, 2005 WL 1793399, at *2. The government appealed, and the Federal Circuit determined de novo that the chief special master had acted contrary to law in denying petitioner compensation for her non-Table injury. See id. at *5 ("[T]he special master's decision was not in accordance with law.").

> the "preponderance of the evidence" standard referred to in the Vaccine Act as one of proof by a simple preponderance, or "more probable than not" causation. . . . [T]he legal and practical effect of . . . requiring medical literature[] . . . contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof. [Such a requirement] prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.

Id. at *3 (footnotes and citations omitted).

Althen makes clear that previous decisions of the Federal Circuit were not intended "to raise the preponderance standard in vaccine cases to that of direct proof." Id. at *4 ("The government's postulate that the 'heavy lifting' referred to in Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)), signifies this court's desire to raise the preponderance standard . . . similarly fails."). "Heavy lifting," the Federal Circuit stated, was a phrase employed merely to distinguish between causation standards required by Table and non-Table injuries:

> While it may be true that proof of causation by preponderant evidence is not as "easy" as proof of causation by operation of law, neither Hodges nor Lampe instructs that the preponderance standard itself is to be made more onerous in vaccine cases. Nor is it to be made more difficult merely because our cases have referred to it as "heavy lifting."

Id.

The Federal Circuit found that the Althen petitioner had "provided the requisite showings of a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect . . ., and a proximate temporal relationship between the TT vaccination and her injury." Id. at *5. The Circuit rejected the government's argument that the Court of Federal Claims had "improper[ly] reweigh[ed] . . . the evidence" by "accept[ing] . . . [petitioner's expert's] theory of causation over that of the government's witness whose testimony the special master found more credible." Id. at *3; see also id. at **5-6 (affirming acceptance by the Court of Federal Claims of petitioner's proffered

evidence as "more convincing").[4] The Court of Federal Claims had looked to petitioner's expert testimony in finding causation:

> Dr. Smith testified that he is "highly confident that, in the right individuals, a tetanus toxoid vaccination can cause central nervous system demyelination. . . . [and] that the vaccine administered to petitioner . . . "probably" played a role in [her] illness[, as] . . . ["t]here was no other explanation for why she could have had a sudden onset of profound immune responses in the central nervous system."
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> . . . .
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> Dr. Smith also testified that the onset of petitioner's initial inflammatory condition . . . occurred within a medically accepted time period. In addition, in his judgment, whether petitioner's condition is diagnosed as relapsing . . . or [acute] "is not a big issue" as "the underlying inflammatory process is undoubtedly the same in each instance." Finally, Dr. Smith testified that he could ascertain no alternative causes to the tetanus toxoid vaccine in petitioner's medical history that would explain the onset of her demyelinating illness or its chronic nature.

Althen v. Sec'y of Health & Human Servs., 58 Fed. Cl. 279, 276-77 (2003) (citations omitted). Petitioner's expert testimony met the standard of causation-in-fact, see Althen, 2005 WL 1793399, at **5-6, despite medical literature on the record that "concluded that there was insufficient evidence . . . to accept or reject a causal relationship between

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[4] Althen reiterates that the "special master's role is . . . not to craft a new legal standard to be used in causation-in-fact cases," but "to assist the courts by judging the merits of individual claims on a case-by-case basis," and points out that, "because the special master's decision was not in accordance with law, the [Court of Federal Claims] was permitted to review the evidence anew and come to its own conclusion." 2005 WL 1793399, at *5 (citing 42 U.S.C. § 300aa-12(e)(2)(B) and Saunders, 25 F.3d at 1033); see also 42 U.S.C. § 300aa-12(e)(2)(B) ("[T]he United States Court of Federal Claims may set aside any findings of fact or conclusion of law of the special master found to be . . . not in accordance with law and issue its own findings of fact and conclusions of law.") (emphasis added). Upon determining that the special master did not properly apply the law, this court is not required to remand the case to the special master for "re-evaluation of the evidence under the proper legal" standard, Althen holds, "[s]o long as the record contain[s] sufficient evidence upon which to base predicate findings of fact and the ultimate conclusion of causation." Althen, 2005 WL 1793399, at *5; see Althen, 58 Fed. Cl. at 285-86 (finding by the Court of Federal Claims that record evidence of petitioner's good health before vaccination, a "medically appropriate time period" and "logical sequence of cause and effect" for manifestation of symptoms after vaccination, and reliable expert testimony on a theory of causation satisfied statutory requirement of causation by preponderant evidence).

tetanus toxoid vaccine and demyelinating disease." Althen, 58 Fed. Cl. at 276. Indeed, in light of the purpose of the Vaccine Act and the Althen petitioner's circumstances, the Federal Circuit stated:

> While this case involves the possible link between TT vaccination and central nervous system injury, a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.

Althen, 2005 WL 1793399, at *3 (emphases added). Thus, "the Vaccine Act does not require [petitioners] to provide medical documentation of plausibility, [and, a fortiori,] cannot require [them] to demonstrate that [their] specific injury is recognized by said medical documentation of plausibility." Id. at *5.

B. Factual Background[5] and Procedural History

On March 22, 1999, petitioner Ryan Kelley underwent a routine physical examination required for participation on his high school tennis team. Pet. at 2, ¶ 3. The notes of his pediatrician, Dr. Judith Hochstadt, indicate that petitioner "was a healthy [fourteen year-old] young man with no health problems." Id. at 2, ¶ 4; see also id. at 2, ¶ 2 ("[E]xcept for usual childhood ailments, [petitioner] was a healthy child, as indicated in his pediatric medical records."). After passing his tennis physical, petitioner received a tetanus booster at the recommendation of Dr. Hochstadt. See id. at 2-3, ¶ 4. Approximately two weeks later, he began to manifest symptoms of progressive numbness and tingling in his hands and feet, dizziness, headaches, a low grade fever, joint and neck pain, and fatigue. Kelley, 2005 WL 1125671, at *3. After his deteriorating physical condition led to more pediatric visits and a brief hospitalization, Mr. Kelley was diagnosed by Dr. Nallainathan, a pediatric neurologist, with "an atypical form of GBS." Id. In a letter to Dr. Hochstadt, Dr. Nallainathan states:

> [An] interesting feature [of Mr. Kelley's case] is that he had a tetanus toxoid booster recently. There is a report in Neurology, May 12th, Volume 52, 1999, page 1549, [titled "Assessment of Neurological Risk of Immunization"] (copy of which I would annex),[6] one adult and one child had a Guillain-Barr[é] type of picture following tetanus toxoid immunization.

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[5]The parties appear to be in agreement regarding the underlying facts of this case.

[6]Petitioner submitted this article as exhibit 17. See Petitioner's Exhibit (PX) 17 (Gerald M. Fenichel, "Assessment: Neurologic Risk of Immunization," 52 Neurology 1546 (1999)) (Fenichel Article).

> I discussed this case with Professor Gerald Fenichel, Professor of Pediatric Neurology, who had written the [above-mentioned] article. . . . He too agreed that this is probably a[n atypical form of] Guillain-Barr[é] which may be secondary to tetanus toxoid. . . . He also advised avoiding tetanus toxoid in the future years.

Petitioner's Exhibit (PX) 3 (Nallainathan Records), at 2 (5/17/99 Letter from Nallainathan to Hochstadt).

Petitioner subsequently responded well to a brief course of steroids, Kelley, 2005 WL 1125671, at *3 ("Ryan was walking much better and his headaches had disappeared."), but Dr. Nallainathan "no longer believed that Ryan had GBS," id. "On further evaluation, I feel that he probably now falls into the category of a chronic demyelinating polyneuropathy." PX 3 (Nallainathan Records) at 20 (8/9/99 Letter from Nallainathan to Hochstadt). Petitioner was eventually referred to Dr. David Cornblath, a neurologist at Johns Hopkins University, who noted: "This young boy presents with a difficult neuromuscular problem. After receiving a tetanus toxoid injection, he developed an acquired demyelinating neuropathy." PX 7 (Cornblath Clinical Notes) at 9 (11/5/99 Notes). Dr. Cornblath concluded that "[t]he differential diagnoses[7] for his syndrome considers GBS, CIDP, CIDP with a paraprotein, or CIDP following tetanus administration (if this exists)." Id. After two years of "largely unsuccessful" treatments to control his symptoms, Kelley, 2005 WL 1125671, at *4, Dr. Cornblath observed: "This is a challenging case. Mr. Kelley has a severe acquired demyelinating neuropathy. . . . He is, if anything, slightly worse than he was [when he was] seen 2 years ago . . . ." PX 7 (Cornblath Clinical Notes) at 2-3 (3/22/02 Notes).

Petitioner's father filed for compensation on his behalf on March 21, 2002, alleging "neurologic injuries, including [GBS] and [CIDP]"[8] resulting from the TT vaccination received in the spring of 1999. Kelley, 2005 WL 1125671, at *1. The petition was amended on November 5, 2002 to allege that petitioner suffered GBS and "the residual effects of such injury for more than six months after the administration of the vaccine," see Pet. at 1 & 10, ¶ 16; on December 4, 2003, the case caption was amended to reflect that Mr. Kelley, having attained the age of majority, was the sole petitioner, Kelley, 2005 WL 1125671, at *1 n.3. The chief special master heard expert

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[7] "Differential diagnosis" is a standard scientific method of "identifying the cause of a medical problem by eliminating the likely causes until the most probable is isolated." Pet'r's Mot. at 21 n.22 (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999)) (internal quotations omitted). "The technique has widespread acceptance in the medical community, has been subject to peer review, and . . . has been accepted as reliable under the standards set forth in Daubert[v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593-94 (1993), and] by virtually every United States Court of Appeals to consider the issue." Id. (citations and internal quotations omitted).

[8] GBS and CIDP are both off-Table injuries. See 42 C.F.R. § 100.3 (2004).

testimony on March 30, 2004 from Dr. Carlo Tornatore[9] for petitioner and Dr. Vinay Chaudhry[10] for respondent and published a decision denying compensation on October 12, 2004. Id. at *1; see generally Transcript of Hearing on March 30, 2004 (Tr.).

Thereafter, petitioner supplemented the record with additional medical literature and moved for reconsideration. Id.; see PX 20 (Richard A.C. Hughes et al., "Immunization and Risk of Relapse of Gullain-Barré Syndrome or Chronic Inflammatory Demyelinating Polyradiculoneuropathy," Letters to the Editor, Muscle & Nerve 1230-31 (Sept. 1996)) (Hughes Letter); PX 21 (K. Mori et al., "Chronic Inflammatory Demyelinating Polyneuropathy Presenting with Features of GBS," 58 Neurology 979-82 (2002)) (Mori Article). Petitioner argued that this newly submitted evidence demonstrated that TT can cause CIDP and "that the only issue remaining for the Chief Special Master's reconsideration [was] whether TT in fact caused [Mr. Kelley's] CIDP." Kelley, 2005 WL 1125671, at *2. The chief special master granted the reconsideration motion, see id. at *2 (withdrawing the initial decision in the case and ordering a supplemental hearing); see generally Transcript of Supplemental Hearing on December 21, 2004 (Tr. II). However, "[a]fter reviewing the newly submitted evidence and evaluating the expert testimony" from the supplemental hearing, the chief special master concluded:

> [T]his new evidence does not support a finding that tetanus toxoid can cause CIDP, nor does it support a finding that the TT vaccine caused [Mr. Kelley's] CIDP in this case. Petitioner relies on the [supplemental evidence] to argue that . . . tetanus can cause CIDP. However, the undersigned concurs with Dr. Chaudry that . . . . [petitioner's supplemental evidence] is too speculative to rely upon for proof of causation. . . . [W]hile the articles may raise questions of blurring of the lines between GBS and CIDP, to which Dr. Chaudry agreed, the articles do not support Dr. Tornatore's argument that because GBS and CIDP share the same pathology they should also share causation. The sole support for the [Institute of Medicine (IOM)[11]] conclusion that tetanus can in-fact cause

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[9]Dr. Tornatore, "a board-certified neurologist and professor of medicine at Georgetown University Medical Center," directs the Multiple Sclerosis and Associated Autoimmune Disorders Clinic at Georgetown Hospital and sees an estimated ten to fifteen CIDP patients every couple of months. Kelley, 2005 WL 1125671, at *7 n.14 (citing PX 19 (Tornatore Curriculum Vitae) and Transcript of Hearing on March 30, 2004 (Tr.) at 6, 16).

[10]"[A] professor of neurology at the Johns Hopkins University School of Medicine," Dr. Chaudhry has numerous publications on CIDP and GBS. Kelley, 2005 WL 1125671, at *7 n.15 (citing Tr. at 100, 102).

[11] The Institute of Medicine (IOM), a branch of the National Academy of Sciences, was (continued...)

> GBS was based on the 1978 Pollard and Selby study involving rechallenge [(re-vaccination)].[12] No such support exists for CIDP.

Kelley, 2005 WL 1125671, at *15 (footnotes added). Thus, the chief special master found, "after considering the entire record in this case, that petitioner [was] not entitled to compensation under the Vaccine Act . . . because the medical records and the experts' testimony support petitioner's diagnosis of CIDP[,] . . . [and because] petitioner failed to provide sufficient evidence that the tetanus toxoid vaccination can cause CIDP . . . [or] that GBS and CIDP are so similar that, merely because the tetanus toxoid vaccine can cause GBS, it can also cause CIDP." Id.

The chief special master's second decision denying compensation in this case was published March 17, 2005, id. at *1, and petitioner timely moved for review in this court, see generally Pet'r's Mot. While petitioner's motion was pending, the Federal Circuit issued its decision in Althen, whereupon the parties supplemented their briefing to address the relevance of Althen to this case. See Order of Aug. 5, 2005 ("[The parties] may . . . file supplementary brief[s] addressing the relevance to this case of the decision of the Court of Appeals for the Federal Circuit in Althen[,] 2005 WL 1793399 (Fed. Cir.

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[11](...continued)
charged by the Vaccine Act with reviewing medical and scientific literature on risks associated with certain vaccines covered by the Act. See Watson v. Sec'y of Health & Human Servs., No. 96-639V, 2001 WL 1682537, at *5 n. 11 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). Special masters "frequently rely" on the IOM's 1994 report, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, (1994 IOM Report) "as a sound source for answering difficult issues of medical plausibility and causation." Althen, 2003 WL 21439669, at *11 n.28. "Due to the IOM's statutory charge, the scope of its review, and the cross-section of experts making up the committee reviewing the adverse events associated with vaccines, the court considers their determinations authoritative and subject to great deference." Id.

[12]The above-referenced article, submitted by petitioner, presents a case study of a patient who "suffered three episodes of a demyelinating neuropathy, each of which followed an injection of tetanus toxoid." PX 13 (Medical Literature), Tab E (J.D. Pollard & G. Selby, "Relapsing Neuropathy Due to Tetanus Toxoid," 37 J. Neurological Sci. 113-25 (1978)) (Pollard & Selby Study), at 113. The authors state that, "[i]n the majority of cases, [GBS] is a uniphasic disease, but in some patients the disease follows a chronic relapsing or progressive course. . . . Because the precise precipitating agent is usually not known, it is uncertain whether chronic relapsing cases may sometimes follow re-exposure." Id. at 113-14; see also id. at 120 ("Numerous precipitating events have been associated with both the acute and chronic idiopathic demyelinating neuropathy in man; these include viral [and] bacterial . . . infections[] [and] inoculations with foreign sera or proteins . . . ."). The 1994 IOM Report cites the Pollard & Selby Study as support for its conclusion that tetanus toxoid can cause GBS. See PX 13 (Medical Literature), Tab G (summary of the 1994 IOM Report appearing at 271 JAMA 1602 (May 25, 1994)) (1994 IOM Report Summary), at 1605 & n.8).

July 29, 2005)."); Petitioner's Response to Order of August [5], 2005 (Pet'r's Resp.); [Respondent's] Supplemental Memorandum (Resp't's Supp. Memo.).

C. The Chief Special Master's Decision

The Chief Special Master decided petitioner's case on three issues: "First, whether CIDP and GBS are distinct and separate diseases. Second, whether [Mr. Kelley] suffers from CIDP or GBS. And third, whether the TT vaccination can cause CIDP and, if so, did it do so in this case." Kelley, 2005 WL 1125671, at *6. He applied a "more likely than not" standard of causation, id. at *4 & n.9, and looked to decisions by the Court of Federal Claims for more specific guidance on evidentiary standards of proof by preponderance, id. at *5 (citing Hocraffer v. Sec'y of Health & Human Servs., 63 Fed. Cl. 765 (2005), and Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19 (2005)). Noting that Pafford established a preference for direct evidence of causation over indirect, or circumstantial, evidence,[13] the chief special master listed as examples of direct evidence epidemiologic studies or "'dispositive clinical or pathological markers'"–what the chief special master termed "vaccine footprints." Id. (quoting Pafford, 64 Fed. Cl. at 28 (citing Stevens v. Sec'y of Health & Human Servs., No. 99-594V, 2001 WL 387418, at *12 (Fed. Cl. Spec. Mstr. Mar. 30, 2001)). The chief special master explained that, absent epidemiologic studies or "vaccine footprints," indirect evidence of factual causation may take the form of:

> epidemiology (evidencing a relative risk greater than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles, institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive, but inferential clinical and laboratory studies.

Id.

However, the chief special master observed that the "speculative nature" of indirect evidence "requires that a petitioner do much more of the 'heavy lifting' than in an on-Table case or even in an off-Table case where there is direct evidence." Id. at *6

[13]The opinion in Pafford v. Sec'y of Health & Human Servs., 64 Fed. Cl. 19 (2005), draws on the analytical framework of Stevens that was disapproved in Althen. Compare Pafford, 64 Fed. Cl. at 28 n.11 ("The court finds Stevens' thorough review and discussion of the state of Vaccine Program causation-in-fact jurisprudence extremely useful as an analytic tool and a starting point for analysis.") with Althen, 2005 WL 1793399, at *5 (determining that the chief special master's application of the Stevens test was not in accordance with law).

(citing Pafford, 64 Fed. Cl. at 29 (citing Lampe, 219 F.3d at 1360)). "If a petitioner's proposed biologic mechanism is beyond the realm of plausibility," he reasoned, "th[e]n other circumstantial evidence, no matter how probative, cannot overcome the petitioner's failure to establish biologic plausibility." Id. (citing Pafford, 64 Fed. Cl. at 29); cf. Pafford, 64 Fed. Cl. at 29 ("If the petitioner's proffered mechanism is beyond the realm of plausibility, then any other circumstantial evidence that remains, no matter how persuasive, cannot overcome the petitioner's initial fallacy."). But see Kelley, 2005 WL 1125671 at *6 n.11 (acknowledging that "requir[ing] identification and proof of specific biologic mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."). Once a petitioner establishes "biologic plausibility," the "nexus" between the proposed biologic mechanism and the injury must be demonstrated:

> [P]roof that a vaccine can cause a particular injury is not per se proof that it caused the injury in petitioner's case. To be sure, a petitioner should present more proof than just biologic plausibility combined with a strong temporal relationship to buttress his argument that the vaccine in-fact caused his injury. The elimination of other causes as well as the establishment of a scientifically appropriate temporal relationship weigh significantly in a special master's evaluation of the evidence.

Id. at *6.

As to the first two of the "primarily three issues" presented by petitioner's case, id. at *6, the chief special master determined that "CIDP and GBS are two distinct and separate diseases," id. at *11; see also id. at *12 ("[Dr. Tornatore] could not provide solid evidence that CIDP and GBS are a single disease process."), and that petitioner "suffered from CIDP," id. See id. ("[B]ased on Dr. Chaudry's testimony coupled with medical records and medical literature, the court concludes that [Mr. Kelley] suffered from CIDP."). The decision next considered the "biologic plausibility" of a causal relationship between TT and CIDP–that is, "whether the tetanus toxoid vaccination can cause CIDP and, if so, whether it caused [Mr. Kelley]'s CIDP." Id. The chief special master summarized petitioner's argument:

> Based on the temporal relationship between the vaccine and Ryan's illness, the biologic plausibility demonstrated in the Pollard and Selby article, and the antecedent event of the tetanus toxoid vaccination, Dr. Tornatore concluded that the TT vaccination caused Ryan's illness . . . [and] testified that GBS and CIDP share the same underlying pathogenesis and the same causation mechanism. Thus, petitioner takes the position that because the

> tetanus toxoid vaccine is known to cause GBS, it can also cause CIDP, which is merely a chronic variant to the same disorder.

Id. (citations and footnote omitted). However, the chief special master rejected petitioner's "biologic plausibility" argument: "[P]etitioner cannot link the tetanus vaccination to CIDP based solely on the vaccination's possible causal relationship with GBS." Id.

The chief special master "canvassed the medical literature submitted in this case," id. at *10, and considered the testimony of Dr. Tornatore, which he found "failed to offer sufficient, objective support demonstrating that CIDP and GBS have the same pathogenesis," id. at *11.[14] The chief special master criticized Dr. Tornatore's reasoning:

> "[I]t is logically and legally impermissible to extrapolate from similarities in pathogenesis to a conclusion of shared causative agents in light of the lack of . . . some type of objective support from the relevant medical community, and in the face of medical literature indicating strong differences in antecedent events."

Id. (quoting Trojanowicz v. Sec'y of Health & Human Servs., No. 95-215V, 1998 WL 774338, at *5 (Fed. Cl. Spec. Mstr. July 1, 1998), aff'd, 43 Fed. Cl. 469 (1999)). The chief special master rejected Dr. Tornatore's testimony because "the little medical

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[14]The chief special master discredited petitioner's expert testimony from the initial hearing:

> [T]he court found Dr. Tornatore to be a marginal witness. While he is clearly well qualified, his testimony strayed from accepted medical princip[le]s into speculative, argumentative, and unsupported statements. The undersigned suspects that Dr. Tornatore misunderstood his role. As stated by the American Medical Association ("AMA"): "The medical witness must not become an advocate or a partisan in the legal proceeding." Dr. Tornatore, however, appeared to make every effort, no matter how thinly supported, to advocate petitioner's position. It was unhelpful testimony for the court and ultimately unhelpful to petitioner.

Kelley, 2005 WL 1125671, at *7; see also id. at *7, n.13 ("In order to make 'his' case, Dr. Tornatore ignores the medical records and creates facts which support his assertions which, in themselves, are not based on his clinical practice or knowledge. He has done this before [in other vaccine cases]."). "In contradistinction," the chief special master noted, testimony from respondent's expert "was marked by experience, cogent explanations, and literature and textbook support. His testimony was highly persuasive and its contrast to Dr. Tornatore's testimony highlighted even further the dubious quality of Dr. Tornatore's assertions." Id. at *7.

literature presented by petitioner was lacking in any evidence establishing . . . a causal relationship" between TT and CIDP. Id. at *13; see also id. ("Dr. Tornatore . . . conceded that there are no epidemiologic studies to support [his testimony on causation]."). Although a medical article based on an animal study concluded that "[t]his [animal study] lends support to the view that GBS and its chronic variant, . . . CIDP[], are part of a single disease process," PX 18 (J.D. Pollard, "Immunopathology of Guillain-Barré Syndrome," in Guillain Barré Syndrome 146 (Thieme Med. Pub., 1993)) (Pollard Animal Study), at 147, the chief special master observed that "this statement alone is not strong enough for the court to conclude that GBS and CIDP are the same disease process. As discussed at [the] hearing [on March 30, 2004], and acknowledged by Dr. Tornatore, animal studies do not translate exactly into humans." Kelley, 2005 WL 1125671, at *9 (citing Tr. at 67). But see id. at *5 (observing that animal studies are among the types of indirect evidence that may establish "biologic plausibility"). Similarly, the chief special master rejected the Fenichel Article referenced in the notes of petitioner's treating physician, which states that the subject of the well-known Pollard & Selby Study "subsequently experienced additional relapses [of illness] without prior immunization and was diagnosed as having [CIDP]." PX 17 (Fenichel Article), at 1548:

> [D]espite Dr. Fenichel's statement that the patient in the Selby and Pollard case report suffered CIDP, the Selby and Pollard case report itself provides only that the patient suffered from . . . GBS, and does not indicate that he suffered from CIDP. Further, . . . the complete excerpt [of the article, stating, "It is not possible to know whether tetanus toxoid caused or triggered CIDP in the susceptible individual,"] demonstrates that [it] is inconclusive about the relationship between TT and CIDP.

Kelley, 2005 WL 1125671, at *13 (citation and footnote omitted) (alteration quoting PX 17 (Fenichel Article) at 1548). The chief special master also noted that, "[w]hile the IOM did conclude that there is sufficient evidence favoring the acceptance of a causal relationship between the tetanus vaccination and GBS, it did not find a causal relationship between tetanus and CIDP." Id.

Similarly, the chief special master found the material submitted by petitioner on reconsideration "too speculative to rely upon for proof of causation." Id. at *15. One of the articles submitted in support of reconsideration refers to the subject of the Pollard & Selby Study as "a man whose first three relapses of CIDP were each triggered by tetanus toxoid" and cites a "personal communication" from Dr. Pollard as the source of information on treatment of the subject's "subsequent illness." PX 20 (Hughes Letter) at 1230. Dr. Tornatore testified that the Pollard "personal communication" clarified "that the patient studied [in the 1978 Pollard & Selby Study] . . . subsequently was felt to have

CIDP," Tr. II at 6, 8.[15] However, the chief special master concurred with respondent's expert that the reference to a personal communication with Dr. Pollard was inconclusive, see Kelley, 2005 WL 1125671, at *15 ("[Petitioner's theory of causation] may be proven correct someday, but as it stands now there is insufficient evidence that GBS and CIDP are cut from the same cloth so that proof of causation related to GBS can be applied to CIDP.").

"Based on the lack of support from the medical community and absence of medical literature," the chief special master found "that petitioner's assertion that the TT vaccine can cause CIDP must . . . fail." Id. at *14; see also id. at *14 n.25 (recalling that "the undersigned rejected a similar argument in Trojanowicz [because] [n]o other articles supported a known studied relationship between CIDP and the tetanus vaccination") (citing Trojanowicz, 1998 WL 774338, at *5). The chief special master reasoned: "As the court found above that Ryan suffered from CIDP and that there is insufficient evidence to support a finding that the tetanus vaccine can cause CIDP, it follows that the tetanus vaccination could not have caused Ryan's CIDP in this case." Id. at *14. Nonetheless, the decision reviewed the record for evidence supporting petitioner's assertion that treating physicians believed the vaccination caused his illness:

> While Dr. Nallainathan did note the possibility of a Guillain-Barré secondary to tetanus toxoid . . ., after he determined that Ryan suffered from CIDP instead, Dr. Nallainathan no longer noted any connection between Ryan's CIDP and the TT vaccination. Further, although Dr. Cornblath noted the temporal relationship between Ryan's CIDP and the vaccination, and provided as one of several possible differential diagnoses, "CIDP following the tetanus administration (if this exists)," the records do not indicate that Dr. Cornblath concluded that the TT vaccination caused Ryan's CIDP.

Id. at *13. The chief special master read the foregoing record as providing no support for the contention that petitioner's illness was caused by his vaccination: "[T]he medical records do not reflect th[e] assertion [that petitioner's treating physicians believed TT caused his illness]." Id.

D. Petitioner's Argument

[15]The chief special master noted that "Dr. Tornatore's testimony at the supplemental hearing was very helpful and did not suffer from the infirmities expressed" earlier. Kelley, 2005 WL 1125671, at *14 n.26.

Petitioner asserts that "the Chief Special Master imposed too rigorous a standard" of actual causation, thereby "abandon[ing] Congressional intent," Pet'r's Mot. at 4; see id. at 7 (arguing that "the Vaccine Program was a political solution rather than a quest for scientific truth" based on Congressional acknowledgment that the program "'may provide compensation to some children whose illness is not, in fact, vaccine-related'" (quoting H.R. Rep. No. 99-908 at 18)).

> [T]he Chief Special Master seeks proof approaching scientific certainty. Congress certainly never intended that such a burden be placed on petitioners in this supposedly friendly forum. It cannot be [petitioner's] burden to show epidemiology, pathological markers, rechallenge (i.e. Did the disorder reappear when the exposure was reintroduced?), or general acceptance [by the medical community] of his theory. It cannot be [petitioner's] burden to disprove that GBS and CIDP are different diseases. It was his burden to show, by a simple preponderance of the evidence, that the TT was the likely cause of his CIDP.

Id. at 19. Petitioner also argues that the decision requires scientific certainty provable only by re-challenge (re-vaccination) and is thus "not in accordance with law." Id. at 36.

> In the view of the Chief Special Master, a not-Table claim in the Vaccine Program can only be proved by re-challenge . . . . Since [petitioner] heeded the warning of [his doctor] and received no more TT boosters, he cannot prove–to the Chief Special Master's satisfaction–that the TT caused his CIDP.

Id. at 36 (citation omitted); see also Pet'r's Resp. at 14 (acknowledging that petitioner "has no epidemiology[,] . . . no 'biological markers[,]' . . . [and] no evidence of 'rechallenge'" but arguing that the "strong circumstantial evidence" valued by Althen "tip[s] the scales in his favor.").

Petitioner avers that "he has met his statutory obligations" by "show[ing], by a preponderance of the evidence, that his TT [vaccination, rather than an unrelated factor,] was the likely cause of his CIDP." Pet'r's Mot. at 17. Petitioner argues that "he is entitled to compensation based solely upon his medical records," id. at 23, which "demonstrate a strong temporal relationship between the TT and the injury . . . [and] a logical sequence of cause and effect[,] . . . cite scientific literature supporting the treating physicians' opinions . . . [and] rule out all other reasonably likely causal agents," id. at 20. Although his initial diagnosis of GBS was converted to one of CIDP, he claims that "[t]he chronic nature of [his] illness did not change the treating physicians' opinions with

respect to the cause" and that these opinions were ultimately "confirmed because there was no evidence of another likely cause." Id. at 22. In sum, petitioner believes that

> his medical records, the opinions of his treating doctors, his expert medical opinion, [and] the scientific literature . . . [amount to a preponderance of circumstantial evidence] in his favor. He has CIDP. The likely cause was the TT. There is no other likely cause.

Pet'r's Resp. at 14.

Petitioner objects to the analytical framework constructed by the chief special master in deciding the case. See Pet'r's Mot. at 17 (asserting that requiring proof that GBS and CIDP are similar diseases was "arbitrary, capricious, and an abuse of discretion"). Petitioner points out that "respondent's expert . . . did not dispute Dr. Tornatore's methodology" for analogizing the causation of GBS and CIDP. Id. at 26 (quoting Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 592-93 (1993)) ("The 'methodology underlying the testimony' . . . must be 'scientifically valid.'"). Nor, petitioner asserts, did respondent's expert "deny the scientific validity of the proposition that TT can cause CIDP" when confronted with supplemental evidence upon which Dr. Tornatore relied; Dr. Chaudry instead accorded this evidence less weight than peer-reviewed publications. Id. at 27. Petitioner claims that the scientific literature presented on his behalf establishes similarities between GBS and CIDP in support of Dr. Tornatore's opinion. See generally id. at 28-29. Petitioner also claims that respondent's scientific literature and testimony support Dr. Tornatore's conclusion of causation. See id. at 31-32, 34 (quoting Tr. at 125-26) (testimony of respondent's expert that the two conditions have a "common theme at some level" and that "maybe . . . 10 years from now we [will] all say these were all exactly the same") (second alteration in original); cf. Kelley, 2005 WL 1125671, at *15 (observation by the chief special master that petitioner's theory of causation "may be proven correct someday, but as it stands now there is insufficient evidence that GBS and CIDP are cut from the same cloth so that proof of causation related to GBS can be applied to CIDP").

Finally, petitioner argues that the Federal Circuit in Althen "clarified the evidentiary burden of a non-Table petitioner" by reversing the chief special master's "impermissibl[e] rais[ing] [of] the requisite standard of proof" in off-Table cases. Pet'r's Resp. at 9.

> Althen is relevant to the facts of this case. The decision promotes Congress' intent to discourage civil litigation. It does so by highlighting the words of the statute, words that allow Vaccine Program petitioners to prove

> their cases with circumstantial evidence, as long as they meet the preponderance standard of [the Act]. The Chief Special Master required more. To do so was legal error.

Id. at 15.

E. Respondent's Argument

Respondent argues that the chief special master's decision should be affirmed under the highly deferential "arbitrary and capricious" standard of review. Resp. at 5 ("Where, as in this case, the factual findings of the trier of fact are challenged, . . . [s]o long as the Special Master has considered the relevant evidence, drawn plausible inferences, and stated a rational basis for the decision, reversible error is extremely difficult to establish.") (citing Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Respondent acknowledges that Althen "rightly concluded that a formulaic requirement of medical literature support in all cases is contrary to law," Resp't's Supp. Memo. at 2, but believes "Althen does not affect the result in this case" because the chief special master did not apply "any per se rule that petitioner must supply objective confirmation in the medical literature to prevail," id. at 4 (noting that the chief special master did not apply the Stevens standard rejected by Althen to petitioner's case). However, respondent contends that Althen does not "forbid[] a special master from ever considering the extent to which a proposed scientific theory is, or is not, supported by medical literature in assessing the reliability of that theory," id. at 5, nor does it permit petitioners to propound "[un]scientific" causal theories, id.

Respondent defers to the chief special master's "thorough review of petitioner's medical records" and the subsequent finding "that none of the doctors concluded that the tetanus toxoid vaccine caused his CIDP." Id. at 6. "In the end," respondent claims, "the Chief Special Master rejected the opinion of Dr. Tornatore not only because it lacked medical literature support, but because it lacked any convincing support." Id.

> The Chief Special Master's construct of the case and subsequent findings are manifestly supported by the record and should be affirmed. He reached his conclusions by using the evidentiary standard of causation mandated by the Vaccine Act and the case law of the Federal Circuit. In considering the totality of the evidence, the Chief Special Master found that petitioner's proposed theory of causation was unsupported in the medical literature and in the medical community.

Resp. at 6. Respondent states that, "[b]efore he could reach the issue of causation, the Chief Special Master was required to determine which condition Ryan had." Id. at 7. "In light of the overwhelming medical evidence that CIDP and GBS are distinct clinical entities, and [in light of] Dr. Tornatore's reliance on literature and studies pertaining to GBS to support his opinion on vaccine-causation of CIDP," it was petitioner's burden, the government asserts, "to disprove that GBS and CIDP are different diseases." Id. at 8 (citations, internal quotations and footnote omitted).

Respondent emphasizes petitioner's lack of "relevant medical literature": "[The chief special master] found that Dr. Tornatore's attempt to analogize CIDP to GBS was unsupported by any medical article submitted in this case . . . [and] further concluded that Dr. Tornatore failed to offer sufficient, objective support demonstrating that CIDP and GBS have the same pathogenesis." Id. at 8-9 (citations and internal quotations omitted). Respondent also contests petitioner's argument that the chief special master applied "too rigorous an evidentiary standard" in finding a lack of causation:

> In finding that petitioner failed to prove causation by a preponderance of the evidence, the Chief Special Master relied on petitioner's medical records, which concluded that his correct diagnosis was CIDP and not GBS; the lack of compelling evidence from the medical literature or elsewhere in support of the conclusion that tetanus toxoid can cause CIDP; and on the medical expert testimony, finding Dr. Chaudhry to be more persuasive than Dr. Tornatore.
>
> . . . His conclusions in this regard are due great deference. Given the relevant standard of review, petitioner's invitation to this Court to re-weigh the evidence must be rejected . . . [and petitioner's argument] that he is entitled to compensation as a matter of law . . . must be rejected.

Id. at 13-15 (citations and footnote omitted). Even under Althen, respondent argues, "petitioners remain obliged to prove not only that the vaccine could have caused the injury, but also that it did cause it in their particular case." Resp't's Supp. Memo. at 3 (citing Hines v. Sec'y of Health & Human Servs, 940 F.2d at 1527).

Finally, respondent argues that, under Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319 (9th Cir. 1995), on remand from 509 U.S. 579 (1993), the chief special master properly accorded petitioner's expert testimony "little weight." Resp. at 17; see also id. ("The Chief Special Master noted that Dr. Tornatore had been 'either highly selective in pulling support from the submitted articles or ignored completely

contradictory portions of the same articles.'") (quoting Kelley, 2005 WL 1125671, at *10).

> [I]t was completely proper, indeed obligatory, for the Chief Special Master to determine whether Dr. Tornatore's interpretation of the medical literature in this case was reliable. In fulfilling that obligation, moreover, it was within his discretion to juxtapose Dr. Tornatore's theories and testimony with the body of peer-reviewed medical literature and find that there was no evidence to support them.

Id. at 17-18; see also Resp't's Supp. Memo. at 4 ("[T]he standard of review for the special masters' findings regarding the credibility of expert witnesses remains highly deferential.") (citing Lampe, 219 F.3d at 1360).

III. Discussion

The court is struck by the similarities between this case and that of the Althen petitioner. The Althen petitioner, as did Mr. Kelley, received the tetanus toxoid vaccine and developed within two weeks symptoms ultimately attributed to a chronic autoimmune disorder. See Althen, 2003 WL 21439669, at *1; see also id. at *5 ("[Petitioner's expert] recognizes that identifying [her] condition is difficult, but believes calling her illness relapsing . . . or [chronic] 'is not a big issue[;] [t]hose are probably the same entity [because] the underlying inflammatory process is undoubtedly the same in each instance' and her condition evidently developed following her . . . [TT and Hepatitis A] vaccinations.") (citations omitted) (third alteration in original). The chief special master denied compensation in Althen on the same grounds. See id. at *14 n.45 ("[B]ecause the court's decision rests on petitioner's failure to . . . provid[e] the necessary objective support for Dr. Smith's theory [of causation], the court need not resolve the outstanding factual issue in this case[,] which is what is the true diagnosis of petitioner's illness."). The Althen decision also cites to Trojanowicz to criticize the causation theory of petitioner's expert: "The undersigned rejected a similar argument in Trojanowicz . . ., wherein petitioners relied on the causal relationship between tetanus and GBS to posit a theory that the vaccine caused their child's CIDP . . . ." Id. at *13 n.32. It is also notable that experts for both petitioners supported their theories of causation with the 1994 IOM Report, support which was rejected by the chief special master in both cases. Compare Althen, 2003 WL 21439669, at *13 ("[A]lthough the IOM found that . . . 'the evidence favors a causal relation between tetanus toxoid and GBS,' petitioner's expert failed to present persuasive medical or scientific evidence supporting that a causal association between [TT] and . . . GBS[] correlates to the . . . injuries suffered by petitioner.") (quoting 1994 IOM Report at 86-89) with Kelley, 2005 WL 1125671, at *12

("[P]etitioner [argues] that because the tetanus toxoid vaccine is known to cause GBS, it can also cause CIDP, . . . [but] petitioner cannot link the tetanus vaccination to CIDP based solely on the vaccination's possible causal relationship with GBS.") (citing 1994 IOM Report at 86-90) (footnote omitted) and id. at *13 & n.24 ("While the IOM did conclude that there is sufficient evidence favoring the acceptance of a causal relationship between the tetanus vaccination and GBS, it did not find a causal relationship between tetanus and CIDP.") (citing PX 13 (Medical Literature), Tab G (1994 IOM Report Summary), at 1605).

In light of the final disposition of Althen in the Federal Circuit, the differences between Althen and this case are perhaps even more striking than their similarities, and all of the differences appear to the court to support a finding of causation with even greater force than did the evidence in Althen. See Althen, 2003 WL 21439669 (Fed. Cl. Spec. Mstr. June 3, 2003), rev'd and vacated by 58 Fed. Cl. 270 (2003), aff'd by 2005 WL 1793399 (Fed. Cir. July 29, 2005), at *1 (noting that petitioner received a hepatitis A vaccination at the same time she received a TT vaccination). For example, the medical record evidence in Althen does not appear to be nearly as explicit regarding the TT vaccination as a causative agent as are Mr. Kelley's medical records. Compare Althen, 2003 WL 21439669, at *3 (noting as the lone reference to vaccination in the medical records that, a year and a half after petitioner's vaccinations, her treating physician "addressed petitioner's question of the hepatitis A's [causal] role in her illness" by replying "that he did not know, but it definitely could be a possibility since we do know that influenza vaccine can sometimes be a precipitating factor") (internal quotations omitted) (emphasis added) with PX 3 (5/17/99 Letter from Nallainathan to Hochstadt) at 2 ("[T]his is probably a Guillain-Barr[é] which may be secondary to tetanus toxoid. . . . I would be hesitant to give Ryan any more tetanus toxoid immunization because of this reaction.") (emphasis added) and PX 7 (Cornblath Clinical Notes) at 9 (11/5/99 Notes) ("The differential diagnoses for his syndrome considers GBS, CIDP, CIDP with a paraprotein, or CIDP following tetanus administration (if this exists).") (emphasis added).

In fact, the record evidence in Althen led the special master to consider whether "factors unrelated to administration of the [TT] vaccine" caused petitioner's illness. Id. at *14 & n.44 (pondering "the actual effect of Mrs. Althen's hepatitis A vaccine on her health" while maintaining that "[w]hether the hepatitis A vaccine played a role in [her] onset of a demyelinating disorder remains an open question which the court need not address given petitioner's failure to satisfy [her burden of proof of causation under] Stevens") (internal citations omitted). Furthermore, the medical opinion evidence in Althen was less robust than that offered by petitioner in this case. Compare Althen, 2003 WL 21439669, at *14 ("Dr. Smith's . . . equivocal opinions[] . . . frequently included words such as 'possibility,' 'might very well,' 'could happen,' 'could have,' and 'my best guess.'") (citations omitted) and id. at *4 ("[Dr. Smith] further opines that the [TT] vaccine more probably than not substantially contributed to [petitioner]'s optic neuritis

and subsequent demyelinating disorder.") (emphasis added) with Kelley, 2005 WL 1125671, at *8 ("Dr. Tornatore opined that the TT vaccination caused Ryan's inflammatory neuropathy[,] . . . explained that an acute . . . inflammatory neuropathy, such as GBS, can become chronic[,] . . . [and] further opined that distinctions between relapsing, progressive and chronic inflammatory demyelinating polyneuropathies are artificial.") (citations omitted) and Tr. at 97-98 (testimony of Dr. Tornatore that the TT vaccination is "the smoking gun" in Mr. Kelley's case).

The court finds that the chief special master's decision in Kelley does not reflect the standard of proof for a non-table injury under the Vaccine Act as set forth by the Federal Circuit in Althen and is therefore contrary to law. Althen makes clear that "sequence[s] hitherto unproven in medicine" may be supported by indirect evidence to resolve "close calls regarding causation . . . in favor of injured claimants." 2005 WL 1793399, at *3. The legal standard in Kelley does not employ the Stevens test facially, see Resp't's Supp. Memo. at 4 ("[The chief special master did not apply] any per se rule that petitioner must supply objective confirmation in the medical literature to prevail."), but it nonetheless applies the requirement that conclusive medical literature support causation in off-Table cases–a requirement squarely rejected in Althen, see 2005 WL 1793399, at *5 ("[T]he Vaccine Act does not require [petitioners] to provide medical documentation of plausibility, . . . [and, a fortiori,] cannot require [them] to demonstrate that [their] specific injury is recognized by said medical documentation of plausibility.").

Respondent argues that it is the chief special master's "factual findings" regarding the credibility of petitioner's expert witness that are at issue, see Resp. at 5; Resp't's Supp. Memo. at 4, and that the arbitrary and capricious standard applies, see Althen, 2005 WL 1793399, at *3 (observing that the Court of Federal Claims and the Federal Circuit "review the special master's factual findings under the arbitrary and capricious standard"). The court disagrees. The decision in Kelley discredits the testimony of Dr. Tornatore for its causal analogy of GBS to CIDP "in the face of medical literature indicating strong differences in antecedent events," 2005 WL 1125671, at *11 (citation and internal quotation omitted) (emphasis added), not because of any defect in Dr. Tornatore's credentials, see, e.g., id. at *7 & n.14 (observing that petitioner's expert, a board-certified neurologist and Georgetown University Medical Center professor, "is clearly well qualified"); id. at 14 n.26 (noting that Dr. Tornatore's testimony at the supplemental hearing was "very helpful").[16] Indeed, Dr. Tornatore's assertions were

[16]The transcript of the initial hearing in this case displays a repeated insistence on conclusive medical documentation of petitioner's theory of causation:

> THE COURT: It's fair to say, though, that there's nothing that you can look at this child, this young man, and say that the vaccine–there's nothing on that child or

(continued...)

deemed "dubious" because they "strayed from accepted medical princip[le]s" set forth in the literature, id. at *7, or drew from animal studies, which "do not translate exactly into humans," id. at *9, or cited no articles that "supported a known studied relationship between CIDP and the tetanus vaccination," id. at *14 n.25 (citation and internal quotation omitted) (emphasis added). The chief special master similarly rejected direct references to vaccine causation in petitioner's medical records because they were not "conclu[sive]." See, e.g., id. at *13 (rejecting treating physician's differential diagnosis of "CIDP following the tetanus administration (if this exists)" for its lack of "conclu[siveness]"). However, Althen teaches that the Vaccine Act does not require "known," "studied," "exact," or "conclusive" evidence of causation. See 2005 WL 1793399, at *5 (describing "requisite showings of a medical theory . . . [founded on] a

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[16](...continued)
young man, there's nothing pathological or a piece of evidence that you can say yes, that points the finger at the vaccine.

THE WITNESS: You mean is there a fingerprint immunologically that we could–

THE COURT: Some sort of, yes.

THE WITNESS: . . . [O]ther than what I've already stated, the answer is no.

But [the TT vaccination is] the smoking gun. . . . [W]e have something that we know could potentially do it. I don't know if we're ever going to have that degree of specificity . . . . I'm not sure we'll ever be able to say that.

. . . .

THE COURT: Okay. And other than [the Pollard & Selby Study], you are not aware of any other articles that draw a relationship between CIDP and tetanus toxoid vaccine.

THE WITNESS: Not that I'm aware of. I mean, if we wanted to know if tetanus was the cause in this case, we could re[-vaccinate] him. But I don't think anybody would do that. And the reason nobody will do it is because we're afraid that we're right.

Tr. at 97-98. The following admonition to petitioner's expert also adumbrates the chief special master's ultimate requirement of medical documentation:

> THE COURT: The question is regarding the literature. Not speculation. The question had to do with literature. Is there any literature that you can cite that says the same inciting events, causation, whatever you want to call it, is apparent for CIDP and GBS? They share the same inciting events? The question to you is give us literature.

Tr. at 69:11-17 (statement of the court) (emphases added).

logical sequence of cause and effect . . . [and] a proximate temporal relationship" between vaccine and onset symptoms) (emphasis added).

The court also finds the chief special master's framework for deciding this case, see Kelley, 2005 WL 1125671, at *1 ("[W]hether CIDP and GBS are distinct and separate diseases . . . [and] whether Ryan suffers from CIDP or GBS [are two primary issues presented by this case.]"), to be contrary to law. The Vaccine Act does not require petitioners coming under the non-Table injury provision to categorize their injury; they are merely required to show that the vaccine in question caused them injury–regardless of the ultimate diagnosis. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (providing for compensation of "any illness, disability, injury, or condition not set forth in the Vaccine Injury Table . . . which was caused by a [designated] vaccine") (emphases added). If petitioner proves causation by preponderant evidence under the non-Table injury provision of the Act, whether he suffers from GBS or CIDP is immaterial. See supra n.8 (noting that neither GBS nor CIDP is recognized as a Table injury).

Because the court determines that the chief special master applied legal standards that are not in accordance with law, the court must review the record in this case to draw its own conclusions of fact and law. See supra n.4. Upon reviewing the record, the court determines that petitioner has established, by preponderant evidence, a medical theory of causation, a logical sequence of cause and effect, and a proximate temporal relationship between the tetanus toxoid vaccination and his subsequent illness. Although the Act only requires petitioners to provide one form of proof, see 42 U.S.C. § 300aa-13(a)(1) (petitioners' theories of causation may be substantiated "by medical records or by medical opinion"), Mr. Kelley has provided both medical records and reliable expert testimony that substantiate his claim of causation-in-fact.

First, Mr. Kelley's treating physicians specified TT as a possible cause at both the initial and later phases of his diagnosis. Compare PX 3 (Nallainathan Records), at 2 (5/17/99 Letter from Nallainathan to Hochstadt) ("[T]his is probably a Guillain-Barr[é] which may be secondary to tetanus toxoid. . . . I would be hesitant to give Ryan any more tetanus toxoid immunization because of this reaction.") (emphasis added) with PX 7 (Cornblath Clinical Notes) at 9 (11/5/99 Notes) ("The differential diagnoses for his syndrome considers GBS, CIDP, CIDP with a paraprotein, or CIDP following tetanus administration (if this exists).") (emphasis added). And, as petitioner argues, these opinions were ultimately "confirmed because there was no evidence of another likely cause." Pet'r's Mot. at 22; see also id. (arguing that "[t]he chronic nature of [petitioner's] illness did not change the treating physicians' opinions with respect to the cause").

Second, the testimony of Dr. Tornatore provided credible medical opinion in support of factual causation: "It's my opinion that the vaccination did indeed cause the [chronic] inflammatory neuropathy." Tr. at 60:15-16 (testimony of Dr. Tornatore). At the first hearing, the chief special master elicited the following grounds for Dr. Tornatore's testimony:

> THE COURT: I just am curious, Doctor. . . . [Y]ou testified a number of times [that] you know that[] [causation is] a difficult issue for us. Just so we're clear, what are the factors that are apparent in this case[] that . . . allow you to say . . . to a degree of probability[] that the vaccine was the cause . . . in this case? What are you relying on specifically?
>
> THE WITNESS: There's really a couple things. . . . [T]he temporal relationship and the biological plausibility, are probably the strongest things. . . . [T]here clearly was an antecedent event with the tetanus toxoid. And that's clearly been identified as a cause of CIDP, via the Pollard and Selby article.
>
> So all things being equal, when we have something that we know can potentially cause an acute inflammatory demyelinating polyneuropathy, and it's . . . in the right time frame, it seems that that's a very reasonable assumption to make.
>
> . . . .
>
> . . . [The TT vaccination is] the smoking gun. . . . [W]e have something we know could potentially do it.

Tr. at 95-97. Petitioner summarizes the basis of Dr. Tornatore's expert opinion as follows:

> (1) [Petitioner] was healthy when he received the TT; (2) the strong, appropriate temporal relationship between the vaccine and the onset symptoms; (3) the several references [to the TT booster] in the medical records by treating physicians . . . ; (4) the recognized association in the medical community between the vaccine and acquired inflammatory demyelinating disorders; (5) the plausible biological mechanism (i.e. an autoimmune neuropathy triggered by a vaccination which activates the

> immune system) . . . ; (6) extensive scientific literature that TT can cause inflammatory demyelinating polyneuropathies.

Pet'r's Resp. at 3 (citations and footnote omitted); see also Kelley, 2005 WL 1125671, at *8 ("Dr. Tornatore's fundamental argument was that CIDP and GBS share the same pathogenesis. . . . [and] the real distinction between the two is the 'tempo,' or strength of the immune response. . . . [W]ith GBS, patients would experience 'greater symptoms within a very short period of time,' while with CIDP, patients would have a 'more prolonged course' due to a weaker immune response.") (citations omitted).

To support Dr. Tornatore's theory of causation, petitioner submitted eleven pieces of medical literature. See generally PX 13 (Medical Literature), Tabs A-G; PX 17 (Fenichel Article); PX 18 (Pollard Animal Study); PX 20 (Hughes Letter); PX 21 (Mori Article). Among them, a 1993 animal study by one of the authors of the Pollard & Selby Study "support[s] . . . the view that GBS and its chronic variant, . . . (CIDP)[,] are part of a single disease process." PX 18 (Pollard Animal Study) at 147; see also PX 13 (Medical Literature), Tab D (J.D. Pollard, "A Critical Review of Therapies in Acute and Chronic Inflammatory Demyelinating Polyneuropathies," 10 Muscle & Nerve 214-21 (Mar./Apr. 1987)) at 214 ("The classification of inflammatory demyelinating polyneuropathies into acute and chronic is based partly upon clinical course. Both conditions present [similar symptoms]. The pathological signs of demyelination and inflammation are common to acute and chronic varieties. . . . Some acute cases later relapse and become recurrent or progressive."); PX 20 (Hughes Letter) at 1230 (making no distinction between "recurrent" or "relapsing" GBS and CIDP); PX 21 (Mori Article) at 979 (Abstract), 982 (case study of five patients with a "GBS-like onset" of symptoms, but with "persistent symptoms" similar to CIDP, proposing theories of "chronic persistent transformation of GBS" or "CIDP pathophysiology in the initial phase, [despite] . . . a GBS-like onset").

Petitioner also points to one of respondent's submissions, a 1993 textbook chapter by P. J. Dyck, a well-known neurologist who first confirmed and named CIDP, see generally Tr. at 150-51 (colloquy between petitioner's counsel and Dr. Chaudry), for its analogizing of CIDP to the more acute GBS:

> CIDP, like [GBS], is an inflammatory demyelinating polyradiculoneuropathy with cytoalbuminologic dissociation. As the mechanisms underlying [GBS] 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 [GBS], whether this separation ultimately proves to have any fundamental validity or not, can be advanced.

RX Q (P.J. Dyck et al. "Chronic Inflammatory Demyelinating Polyradiculoneuropathy," Peripheral Neuropathy (3d ed. 1993) 1498-1517) (Dyck Chapter) at 1500 (emphases added). The chapter also describes the diagnosis and treatment of CIDP and states, under the section "Preceding Infection or Receipt of an Immunogen":

> Initial symptoms and recurrences in CIDP do not appear to follow an infection as frequently as in [GBS]. Considering the insidious onset of CIDP and the passage of time before our evaluation, this may in part reflect failure to recall a preceding infection. We reported a not infrequent history of preceding infection, immunization, or receipt of biologic material (sting, bite, or medical injection) within a few weeks or months of onset or exacerbation. On 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. . . . The control[] [populations] . . . are not totally satisfactory, and whether the incidence of antecedent infection in CIDP cases exceeds what would be expected by chance alone is not known.

Id. at 1501-02 (emphases added).

Furthermore, petitioner's medical literature links TT directly to the non-acute variety of inflammatory demyelinating neuropathies. See, e.g., PX 13 (Medical Literature), Tab E (Pollard & Selby Study) at 120 ("Numerous precipitating events have been associated with both the acute and chronic idiopathic demyelinating neuropathy in man; these include viral [and] bacterial . . . infections, [and] inoculations with foreign sera or proteins. . . ."). One case study submitted by petitioner details a "reported case of peripheral neuropathy following tetanus toxoid administration" suggestive of chronicity. PX 13 (Medical Literature), Tab F (Leon Reinstein et al., "Peripheral Neuropathy After Multiple Tetanus Toxoid Injections," 63 Arch. Phys. Med. Rehabil. 332-34 (July 1982)), at 332. Although the study does not distinguish between acute and chronic illness, the patient was assessed "at several month intervals for 2 years" and experienced only partial recovery. Id. The authors concluded from a summary of fourteen TT-induced polyneuropathies that "it appears that an interval of 14 or more days between tetanus toxoid injection and onset of neurological symptoms indicates poorer prognosis for complete recovery." Id.; cf. Kelley, 2005 WL 1125671, at **3-4 (noting that petitioner's neurological symptoms manifested approximately fourteen days after his receipt of the TT injection and were ongoing more than two years later).

Finally, the record evidences a proximate temporal relationship between the onset of petitioner's symptoms and administration of the vaccine. See, e.g., id. (noting that

petitioner's symptoms manifested approximately two weeks after vaccination). Mr. Kelley's treating physicians ruled out non-vaccine related causes for his illness. See, e.g., PX 3 (Nallainathan Records) at 2 (5/17/99 Letter from Nallainathan to Hochstadt) (ruling out Lyme disease based on negative results of blood and spinal fluid tests), 5 (5/5/99 MRI Results) (indicating negative brain MRI). And respondent advanced no evidence of non-vaccine related causation. See generally Resp't's Supp. Memo.; see Pet'r's Resp. at 16 ("The respondent has offered no alternative cause."). The court agrees with petitioner that, "[w]hile he has no literature conclusively showing TT causes CIDP, he submitted an abundance of literature showing TT causes GBS and [that] GBS and CIDP are conditions on a spectrum, and that distinctions between them are hopelessly blurred." Pet'r's Resp. at 11 (emphasis added).

Both the medical records and the medical opinion proffered by petitioner demonstrate by preponderant evidence that the vaccination he received was a "substantial cause" in fact of his injury. Because respondent did not demonstrate by preponderant evidence that a factor unrelated to the vaccine was the cause of injury, petitioner's evidence meets the statutory burden of causation for compensation of off-Table injuries. See 42 U.S.C. § 300aa-13(a)(1) (disallowing compensation where the special master or court finds "a preponderance of the evidence that the [injury] . . . is due to factors unrelated to the administration of the vaccine").

IV. Conclusion

For the foregoing reasons, petitioner's motion for review is GRANTED, the March 17, 2005 decision of the chief special master is REVERSED, and the case is REMANDED to the chief special master for a determination of compensation due to petitioner.

IT IS SO ORDERED.

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EMILY C. HEWITT

Judge