In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-372V

(Filed: November 18, 2009)

NOT TO BE PUBLISHED

STEPHEN TORDAY, M.D.,	*	
Petitioner,	*	Influenza vaccine; Vaccine versus URI as cause; Guillain Barré Syndrome
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

MEMORANDUM RULING ON ENTITLEMENT AND ORDER[1]

GOLKIEWICZ, Chief Special Master.

Petitioner filed a Petition for compensation under the National Childhood Vaccine Injury Act of 1986, as amended ("Act" or "Program"), on June 12, 2007. Petitioner alleges that he developed Guillain-Barré Syndrome (GBS) and then chronic inflammatory demyelinating polyneuropathy (CIDP) as a result of an influenza vaccination administered on October 16, 2003. Petition at 11. Respondent contested petitioner's right to compensation, arguing that "petitioner has failed to meet his burden of proof of a vaccine-related injury, given his antecedent upper respiratory infection as a more likely cause." Respondent's Post-Hearing Submission ("R PH at _") at 1.

To address the factual and medical issues, a Hearing was conducted on September 4 and 5, 2008, in Santa Ana, California. Petitioner was the lone fact witness. Dr. Lawrence Steinman

[1] The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days 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 will be available to the public. Id.

testified to the medical issues on petitioner's behalf. Dr. Gerald Winkler testified for respondent. Following the Hearing, the undersigned discussed tentative findings with the parties and strongly encouraged settlement. Respondent indicated that settlement was not an option. The parties requested post-Hearing briefing, which was granted. Extensive, cogent briefing was completed and the case is poised for resolution. After considering the entirety of the record, the undersigned finds by the slimmest of margins that petitioner is entitled to compensation. The undersigned sees no compelling reason for an extensive discussion of this case, thus an abbreviated explanation follows.

The essential facts are not in dispute. While some differences arose between petitioner's testimony and the medical records, those differences did not prove critical to the ultimate determination. Thus, the undersigned will not include a detailed comparison of the testimony to the medical records. However, to the extent that these differences become meaningful during the damages phase of this case, the undersigned will rely upon the medical records. The undersigned was not impressed with Dr. Torday's testimony on several occasions when he was asked to explain discrepancies between his testimony and the medical records. Interestingly, petitioner's expert also questioned Dr. Torday's memory of his past medical history based upon the contemporaneous medical records. Tr. at 133-35; see also Stephen I. Torday's Post Trial Brief Re: Entitlement ("P PTB at _") at 9 ("Dr. Steinman . . . 'questioned' Dr. Torday's recollection that he had two separate episodes instead of a continuous respiratory infection . . . due to the medical records. . . .").

Dr. Torday was born on February 10, 1947. Pet at 2. He received an influenza vaccine on October 16, 2003. On November 11, 2003, Dr. Torday saw Dr. Paul Maestro, a neurologist for tingling and numbness in his hands and legs. P Ex 1 at 53. For purposes of this decision, the facts contained in this first consultation following immunizations will suffice. Dr. Maestro reported the following history:

> Symptoms started about four days ago, when he was taking the 13th capsule of 500 mg. Levaquin, for what seems to be respiratory infection. He developed symptoms of bronchitis about a month ago, and he initially tried azithromycin, Keflex, doxycycline, without any response, and eventually started Levaquin about two weeks ago. . . .

Id. It is noted under "Medical History" that Mr. Torday "has a history of bronchitis." Id. The "Clinical Impression" was:

> Mild sensory-motor neuropathy. This appears to be of the acute variety, and taken in the context of the respiratory infection, I have suggested that this could be a Guillain-Barré Syndrome, mild form.

Id. at 54. With treatment, petitioner's condition improved. Although it is recognized that the extent of the improvement will be the subject of further discussion during the damages phase of this case, Dr. Maestro noted on April 27, 2004, that petitioner indicated that "he has returned full-time back

to work" and was playing tennis two times per week. Id. at 41. Dr. Maestro' clinical impression was that:

> The patient has done remarkably well on IV IG. He is presently in complete remission. Will continue with exercise and a normal life.

Id. at 42. Petitioner's medical records are seemingly in accord with Dr. Maestro' statement; there are no documented doctor visits or medical treatment between April 27, 2004, and September 28, 2006.

Petitioner's period of relative medical calm changed on September 28, 2006, when he presented to Dr. Maestro with "four or five days [of] worsening of the residual symptoms that he had over the last three years after he was treated for Guillain-Barré syndrome." Id. at 34. It was noted that petitioner developed an upper respiratory syndrome about two weeks prior to his symptoms, somewhere around September 12. Id. It is also noted that petitioner continued to work and that "he feels that the rate of deterioration is about a 10% decrement from his original functional level." Id. Dr. Maestro's clinical impression was that petitioner's symptoms represented "a recurrent Guillain-Barré Syndrome, taking into consideration the recent upper respiratory, possible viral syndrome." Id. Following further testing, Dr. Maestro's clinical impression was that petitioner's condition "may represent a transition into an established CIDP pattern." Id. at 18.

On October 25, 2006, petitioner saw Dr. Nudleman for a second opinion. In Dr. Nudleman's history, he notes the initial symptoms occurring following the 2003 immunization and states that petitioner "recovered about 80%" from that initial injury. Id. at 19. Dr. Nudleman indicates that petitioner "seemed to stabilize" but subsequently "developed a severe upper respiratory tract infection and had a relapse of similar symptoms." Id. Dr. Nudleman's "Overall Assessment" was:

> Dr. Torday likely sustained initially a Guillain-Barré syndrome in 2003. He made an incomplete recovery. He had a new onset of symptoms in September of 2006 following a respiratory infection. He continues to have complaints consistent with an autonomic neuropathy, a sensory painful paresthetic neuropathy, and mild motor findings. This constellation of symptoms would suggest that he has developed CIDP.

Id. at 20-21.

Against these facts, the parties staked out their respective positions.

LEGAL STANDARD

Causation in Vaccine Act cases can be established in one of two ways: either through a statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must

prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence.[2]

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions that, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Petitioner is not claiming a Table case Thus, petitioner must prove the vaccination was the in-fact cause of petitioner's injuries, a so-called "off-Table" case.

In Althen v. Sec'y of Dept. of Health & Human Servs., 418 F.3d 1274,1278 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit reiterated that petitioners' burden is to produce "preponderant evidence" demonstrating: "(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 the vaccination and injury." Id.; see also Andreu ex rel. Andreu v. Sec'y of Dept. of Health & Human Servs., 569 F.3d 1367, 2009 WL 1688231 (Fed. Cir. 2009).[3] The Federal Circuit in Althen further stated that "requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court's well established precedent." Althen at 1281. The Federal Circuit concluded that to support petitioners' theory of causation, there is no requirement in the Vaccine Act's preponderant evidence standard that petitioners submit "objective confirmation," such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature "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 the injured claimants." Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)); see also Capizzano v. Sec'y of Dept. of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) [hereinafter "Capizzano III"]. Moreover, the Federal Circuit stated, "[t]he 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." Id. Petitioner's case is measured against these standards.

DISCUSSION

Despite the extensive efforts in this case, the issue to be decided is actually quite narrow. This is because the experts are in agreement with most of the medical issues that must be analyzed to meet the Althen standard. Thus, both experts agree that the flu vaccine can cause GBS. Tr. at

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

114, 236, 248, 262; see also Tr. at 142- 148, 265 (discussing the medical theory). The undersigned would make that finding even in the absence of this testimony as many flu causing GBS cases have been compensated under the Program. See, e.g., Smith v. Sec'y of Dept. of Health & Human Servs., No. 05-1231V, slip op. (Fed. Cl. Sp. Mstr. May 16, 2007). Therefore, there is clearly a medical theory connecting the flu vaccine to GBS. In addition, both experts agreed that there was a proximate temporal relationship in satisfaction of prong three of Althen. Tr. at 213, 265. The complicating factor in this case, and the reason it was litigated, was the petitioner's antecedent upper respiratory infection ("URI"). Similar to the vaccine, both experts testified that the respiratory infection is a potential cause of GBS and it occurred in an appropriate temporal relationship to the immunization. Thus, the experts, while agreeing that either the vaccine or the respiratory illness is a potential cause of GBS, took opposite positions as to which was the actual cause in this case. Dr. Steinman stated that he agreed with most of Dr. Winkler's report except for his ultimate conclusion. Tr. at 149. And that is the issue for decision.

As the undersigned summarized the dispute, "I have two possible agents. I have the timing is correct for both. I have no epidemiology for either one. I have no clinical distinctions that I can point out." Tr. at 208. When asked whether there is any hard evidence to determine on a probability scale whether it is the vaccine or infection that caused the GBS, Dr. Steinman replied "I don't think there is the kind of hard-weighted evidence that would make everybody's life easier." Tr. at 209.

So what did the experts rely upon for their respective differing opinions? Dr. Steinman in essence chose the known, the vaccine, over the unknown, the unknown cause of the URI. Tr. at 119. Dr. Steinman stated that not all viruses and infections are shown to cause GBS. Id. at 120. Dr. Winkler agreed. Id. at 264 ("That hasn't been examined."); see also id. at 240-41 (discussing P Exs 11-A and 7, which identified four infections associated with GBS.) Dr. Winkler agreed with Dr. Steinman that there is no indication in the medical records of what organism caused Dr. Torday's upper respiratory infection. Id. at 263. Thus, Dr. Steinman reasoned that faced with two potential causes of petitioner's GBS, the vaccine and an URI, he gave the edge to the immunization since without knowing what was causing the URI, there was no way of knowing whether it could cause GBS. He stated:

> So the reason being I don't know what microbe was in his lungs that would be a trigger, so again do I vote and give higher weight to something I do know that can cause it versus the great unknown? I gave much more weight to what I do know causes it.

Tr. at 129.

Dr. Winkler's approach to assigning causative blame relied primarily upon a statistical comparison, "which was the more probable provocative agent." Tr. at 247. As he stated:

> There were two factors that one had to look at in the case of Dr. Torday. One was the influenza vaccination, the other was the issue of antecedent infection. Based

> upon Dr. Torday's testimony, both factors fell within the window of opportunity for precipitating Guillain-Barré. Based upon the risk of developing it, determined statistically, the respiratory illness had the greater likelihood of precipitating that.

Id. at 248-49.

After considering the entire record, including the very good arguments put forth in the parties' post-Hearing Briefs, the undersigned finds for petitioner by the slimmest of margins. The preponderance of evidence standard is often described as 50 percent plus a feather. In this case, the undersigned interprets the experts' testimony to be that the vaccine and URI are potentially of equal culpability. However, when forced to choose, the experts disagree for the reasons stated as to which potential cause gets the feather. In resolving this case, the undersigned accepts and credits Dr. Steinman's logic that the known causative agent, the vaccine, should be weighted more heavily than the unknown agent causing the URI, which may or may not be a potential cause of GBS. Thus, the undersigned finds that the 50 percent and the feather goes to the vaccine as the cause of Mr. Torday's GBS.

In making this ruling, the undersigned has considered fully the strong arguments put forth by respondent in his post-Hearing brief. Several of those arguments will be addressed briefly.

Respondent argues that petitioner failed to showed that the vaccine was a substantial factor since petitioner did not show that the vaccine was more likely than the respiratory illness to have caused the GBS. R PH at 11. This argument ventures into the murky waters of the Federal Circuit precedent regarding the respective burdens of proof. See Petitioner's Reply Post-Hearing Brief at 4-6 (discussing the meaning of Pafford v. Sec'y of Dept. of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006); Walther v. Sec'y of Dept. of Health & Human Servs., 485 F.3d 1146 (Fed. Cir. 2007); and de Bazan v. Sec'y of Dept. of Health & Human Servs., 539 F.3d 1347 (Fed. Cir. 2008)); see also Heinzelman v. Sec'y of Dept. of Health & Human Servs., No. 07-01V, 2008 WL 5479123 (Fed. Cl. Sp. Mstr. Dec. 11, 2008). However, it is unnecessary for the undersigned to tackle that tricky legal issue that appears to the undersigned to require further Federal Circuit explication. In this case, Dr. Steinman, by the slimmest of margins, convinced the undersigned that it is logical and appropriate to assign causation to the influenza immunization. Therefore, even if petitioner bears the burden, as respondent contends, of addressing other potential causative agents, the undersigned has found that petitioner met that burden. Thus, this is not an issue of whether Pafford controls over Walther and de Bazan. Whether this case is analyzed under Walther and de Bazan as a factor unrelated or under Pafford as petitioner's burden to eliminate other potential causes, the undersigned finds that petitioner has established his right to recovery under the Vaccine Act.

Respondent also contends that Dr. Steinman's logic in ruling out the URI is legally deficient. R PH at 11. Relying on the Federal Circuit's decision in Knudsen v. Sec'y of Dept. of Health & Human Servs., 35 F.3d 543 (Fed. Cir. 1994), respondent contends that specific identification of the viral infection is not required for purposes of alternative causation. Id. Respondent's contention is accurate as the Circuit determined that the Act does not contain "a *per se* rule that alternative

causation cannot be proved when the specific virus is not identified." Knudsen, 35 F.3d at 549. However, it is also true that the Circuit rejected the Government's contention that proof of the mere existence of the virus was sufficient to defeat petitioner's claim. Id. The Circuit made clear that it was necessary to establish that "the particular infection present in the child actually *caused* the table injury complained of." Id. (emphasis in original.) As applied to this case, the experts agreed that not all causes of an URI have been shown to cause GBS. Thus, to show a medical theory of how the cause of Dr. Torday's URI actually caused his GBS, necessitates the identification of the virus or microbe. Stated another way, it is illogical and thus unpersuasive to say that an unknown agent can and did cause a particular injury. To put the shoe on the other foot, respondent would not accept an argument from petitioner, and neither would the undersigned, that an unidentified vaccine caused a known injury. An expert simply could not construct a plausible and reliable opinion without identifying the alleged causal agent. Similar to Dr. Steinman's testimony regarding viruses and GBS, not all vaccines are accepted or are shown to cause the same injuries. Thus, simply arguing that you received a vaccine and suffered an identified injury would be insufficient proof since no reliable medical theory could be presented as to how the unknown vaccine caused the injury. That is the essence of Dr. Steinman's analysis regarding the unknown cause of Dr. Torday's URI; analysis the undersigned accepts as convincing.

In finding for petitioner, the undersigned implicitly rejects Dr. Winkler's reasoning for implicating the URI as the more likely cause. In short, Dr. Winkler's use of a statistical comparison between the vaccine as a cause and the URI as a cause was explicitly rejected by the Federal Circuit in Knudsen. Tr. at 249 (Dr. Winkler stated that "[b]ased upon the risk of developing it, determined statistically, the respiratory illness had the greater likelihood of precipitating that.") The Federal Circuit soundly rejected such analysis. Knudsen 35 F.3d at 550 ("The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and not caused by the DTP vaccine.") Thus, Dr. Winkler's reasoning is legally deficient.

Lastly, this case contained an extensive, and at times confusing, discussion of whether Dr. Torday's relapse or new onset in 2006 was properly diagnosed as GBS, CIDP or relapsing GBS. The treating doctors described the 2006 event as CIDP, and Dr. Steinman agreed. Tr. at 138. Dr. Winkler described it as relapsing GBS. Id. at 245. As the undersigned made known to the parties at multiple times, the undersigned saw this issue as irrelevant to the real issue, which was what caused the initial bout of GBS. While not universally accepted, both doctors testified that GBS and CIDP are closely related, with CIDP representing the chronic form of GBS. Tr. at 140, 271. As Dr. Winkler stated "[i]t's an issue of the lumpers versus the splitters." Id. at 271; see also Kelley v. Sec'y of Dept. of Health & Human Servs., 68 Fed. Cl. 84, 100 (2005) (holding that "[t]he 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.") Again, the undersigned mentions the issue because of the amount of attention it garnered throughout the entitlement portion of this case, but does not find the resolution of the issue meaningful to the entitlement question presented.

In summary, the undersigned saw this case from the beginning as a very close case, and communicated the same to the parties throughout. In the final analysis, Dr. Steinman's testimony persuaded the undersigned that the vaccine is the more likely cause of Dr. Torday's GBS. Accordingly, petitioner is entitled to compensation. It is reiterated that the medical records will be relied upon heavily in evaluating the course of Dr. Torday's condition and thus the level of compensation.

ORDER

- Petitioner shall file within thirty (30) days, by no later than December 18, 2009, a status report detailing his plan for determining and presenting his claim for damages.

IT IS SO ORDERED.

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master

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