In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 10-323V

(Not to be Published)

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	*	Filed: May 8, 2015
LINDA S. PHILLIPS, *administratrix of the estate of* THOMAS ADEN PHILLIPS,	*	
Petitioner,	*	Respondent's Motion for a Ruling on the Record; Proof of Causation
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

James J. Gillespie, Jr., Pittsburgh, PA, for Petitioner.

Lara A. Englund, U.S. Dep't of Justice, Washington, DC, for Respondent.

ORDER DENYING RESPONDENT'S MOTION REQUESTING RULING ON THE RECORD IN LIEU OF HEARING[1]

On March 27, 2010, Linda Phillips (administratrix of the estate of her deceased husband, Thomas Phillips) filed a petition for compensation in the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that Mr. Phillips developed Guillain-Barré

[1] Because this order contains a reasoned explanation for my action in this case, it will be posted on the website of the United States Court of Federal Claims in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) provides that each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the order and its contents will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758 (codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2006)) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

syndrome ("GBS") and subsequently died as a result of his October 8, 2007, receipt of the trivalent influenza ("flu") vaccine.

After reviewing the petition and supporting documents, Respondent filed a motion for a ruling on the record, asserting that Petitioner had not met her burden of proof and thus requesting that I dismiss this case without a hearing (but otherwise indicating her intent to litigate the case should I find a hearing is necessary).[3] For the reasons outlined below, Respondent's motion is denied.

I. Summary Factual Background

Mr. Phillips was 61 years old and had a history of multiple health problems when he received the flu vaccine from Surayia Hasan, MD on October 8, 2007.[4] A week later, on October 15, 2007, Mr. Phillips presented to Dr. Hasan reporting itching all over his body. Although Dr. Hasan at the time (as reflected in the contemporaneous medical records) had no explanation for the itching, Mr. Phillips later informed Dr. Hasan that another doctor had attributed the itching to kidney impairment.[5] Mr. Phillips also reported experiencing numbness and weakness in his extremities, as well as muscle soreness, in the months immediately following receipt of vaccination.

Approximately one month post-vaccination, on November 11, 2007, Petitioner went back to Dr. Hasan and reported that he was experiencing a "feeling of numbness in both legs" that was initially attributed to diabetic peripheral neuropathy. Thereafter, Mr. Phillips' condition appeared to stabilize – although in early January of 2008, Mr. Phillips was seen at Appalachian Regional Healthcare in Beckley, West Virginia after complaining of leg pain and swelling, where he was diagnosed with cellulitis of the legs and treated with antibiotics.

Petitioner subsequently presented again to his doctor on January 9, 2008, reporting problems with walking and muscle soreness that were deemed "possibly due to peripheral neuropathy and anticholesterol medication." By January 12, 2008, Mr. Phillips symptoms were severe enough that he was admitted to Raleigh General Hospital in Beckley, West Virginia where he was diagnosed with GBS based on his clinical presentation and confirming test results.

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[3] Respondent made this representation during a status conference previously held in this case, and thus this motion presents circumstances unlike those where Respondent expresses the intent to abide by a ruling on the record regardless of outcome (such as by indicating that she does not intend to expend further resources in defense of the claim). Respondent has also submitted an expert report in support of her position in this case, which I take as further evidence of her desire to proceed if I decide a hearing is necessary.

[4] Petitioner filed medical records in this case on a compact disk that contained three volumes, none of which are paginated. *See* ECF No. 9 (Index of Medical Records on CD, dated Jan. 6, 2011). As a result, citations to specific pages in the record as it presently exists are not provided throughout this order.

[5] A prescription of Neurontin that Mr. Phillips received from his niece around this time appears to have helped relieve the itchiness (although there are conflicting notations in the medical records as to the drug's efficacy).

Thereafter, on January 13, 2008, Mr. Phillips was transferred to a different hospital to obtain treatment based on the presumed diagnosis of GBS.

After being hospitalized for a period of time, Mr. Phillips condition improved to the point where he was discharged and transferred for long-term skilled nursing facility care on February 6, 2008. On May 22, 2008, Mr. Phillips experienced a cardiac event that again resulted in his hospitalization. Not long thereafter, because his prognosis was very poor, Mr. Phillips was removed from life support and passed away on May 28, 2008.

II. Procedural History

As noted above, Mrs. Phillips filed this petition in March of 2010. ECF No. 1. Petitioner subsequently filed a number of medical records relevant to her claim, followed by the filing of a statement of completion on January 21, 2011. ECF No. 11.

Respondent filed her Rule 4(c) report on March 21, 2011, indicating that, based upon her analysis of the record, the claim did not merit compensation. ECF No. 14. Among other things, Respondent asserted that even if the flu vaccine is capable of causing GBS, Petitioner (who had not yet offered an expert report) had failed to establish an appropriate temporal relationship between receipt of vaccination and the onset of Mr. Phillips' alleged injury – because the treatment history revealed that Mr. Phillips showed no symptoms of GBS until three months after he received the flu vaccine. Rule 4(c) Report at 12. Respondent proposed instead that Mr. Phillips' cellulitis was a much more likely cause of his GBS. *Id.* at 13.

Following submission of Respondent's Rule 4(c) report, Petitioner filed additional medical records in support of her claim. On August 2, 2013, Petitioner also submitted notes from two of Mr. Phillips' treating physicians (including Dr. Hasan) linking the flu vaccine to his development of GBS and ultimately to his death. ECF No. 47. Thereafter, on April 24, 2014, after being granted a number of extensions of time to do so, Petitioner filed an expert report from Donald H. Marks, MD, PhD, which included abstracts from three articles he relied upon when formulating an opinion in this case. ECF No. 55-1. In his report, Dr. Marks opined that the flu vaccine was the cause of Mr. Phillips' GBS, via the mechanism of molecular mimicry. *Id.* at 5.

During a June 4, 2014, status conference in this case, Respondent indicated that even after reviewing Petitioner's expert report, she vigorously contested Petitioner's ability (based on the existing treatment record) to establish a reasonable temporal relationship between Mr. Phillips' receipt of the flu vaccine and onset of his GBS. ECF No. 57. Petitioner in response requested an opportunity to supplement her existing expert report, and I agreed to allow her to do so. *Id.*

Accordingly, on June 30, 2014, Petitioner submitted a supplemental expert report from Dr. Marks. ECF No. 58. Dr. Marks opined that any delay in Mr. Phillips' development of GBS was "short but entirely reasonable and not unexpected," and he provided various explanations for

his opinion. *Id.* at 2. Dr. Marks emphasized the fact that there is variable timing of onset of GBS following vaccination in the literature, and he also opined that some of the early symptoms of GBS that Mr. Phillips experienced may have been incorrectly attributed to other causes. *Id.* at 2-3. For example, Dr. Marks suggested that the bilateral numbness that Mr. Phillips reported on November 7, 2007 (which was at the time attributed to peripheral neuropathy) could have actually represented an early, if atypical, presentation of a GBS symptom. *Id.* at 2.

On October 31, 2014, Respondent filed a motion for a ruling on the record in this case in lieu of a hearing. Resp't's Mot. for a Ruling on the Record at 9 (ECF No. 64) ("Motion"). Respondent reiterated her previously-expressed view that Petitioner would be unable after hearing to establish a "proximate temporal relationship" between Mr. Phillips' vaccination and his GBS (as required under the third prong of the test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Motion at 7-10. In support, Respondent filed an expert report from Daniel M. Feinberg, MD, FAAN, a neurologist, dated October 22, 2014, as well as his curriculum vitae and six pieces of medical or scientific literature that he relied upon in formulating an opinion in this case. ECF No. 62-1 (Exhibit D to Motion). According to Dr. Feinberg's interpretation of the medical records, Mr. Phillips first developed signs and symptoms of GBS on January 9, 2008 – three months from the date of vaccination, and thus too far outside of what is thought to be reasonable for onset of GBS under the circumstances. *Id.* at 2.

Petitioner filed a brief opposing Respondent's motion on December 18, 2014. Pet'r's Response to Mot. for Ruling on the Record (ECF No. 66) ("Response"). Mrs. Phillips argued therein that she will in fact be able to establish preponderant evidence at hearing on the third *Althen* prong. *Id.* at 9. Contrary to Respondent's assertions, Mrs. Phillips maintained that Mr. Phillips began to experience GBS-related symptoms within thirty days of his vaccination (rather than three months, as Respondent suggested), citing the itchiness he was experiencing in October 2007, and the leg numbness he later complained of in November 2007. *Id.* Petitioner also cited Dr. Marks' expert report where he opined that the flu vaccine caused Mr. Phillips' GBS, and that the first symptom of the diseases was the numbness in his legs in November 2007. *Id.* at 6. And Petitioner observed that the medical record contained no evidence of other likely causes of Mr. Phillips' GBS (such as an infection). *Id.* at 9-10.

On January 16, 2015, Respondent filed a reply in support of her motion. Reply in Support of Resp't's Mot. for a Ruling on the Record (ECF No. 67) ("Reply"). Respondent again focused on the third prong of *Althen*, asserting that "[i]t is undisputed that the appropriate temporal interval from flu vaccination to onset of GBS is no more than six weeks," but that "Mr. Phillips' GBS symptoms began on January 9, 2008, more than thirteen weeks after his flu vaccination." *Id.* at 2-4. Mrs. Phillips then requested the opportunity to file an additional expert report, and I permitted her to do so. Non-PDF Order, dated Feb. 6, 2015. Petitioner filed such a report on March 6, 2015, from a neurologist, Richard B. Kasdan, MD. ECF No. 69. In it, Dr. Kasdan

disagreed with Respondent's assertion that the symptoms Mr. Phillips experienced in October and November 2007 were appropriately attributed to diabetic peripheral neuropathy, rather than GBS.[6] *Id.* at 1-2. Dr. Kasdan opined that this suggestion (which was not itself a formal diagnosis) was not made until an office visit on November 7, 2007 (within a month of the vaccination), and was further based in part on subsequent electromyography/nerve conduction study results that could equally be understood as evincing GBS. *Id.* at 2. Dr. Kasdan also noted that the flu vaccine administration was the only event clearly linked to Mr. Phillips' GBS, as he did not have a gastrointestinal or pulmonary infection preceding the onset of these symptoms. *Id.*

III. Relevant Legal Standards

Respondent proposes that I resolve this case based on the written filings and medical record, instead of holding a hearing to permit live testimony of witnesses. The Vaccine Rules permit me the discretion to so act. Vaccine Rule 8(d); *Dickerson v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 593 (1996); *Plummer v. Sec'y of Health & Human Servs.*, 24 Cl. Ct. 304, 309 (1991) (special master's determination to make a damages decision without holding an evidentiary hearing was not an abuse of discretion under the circumstances in that case). As observed in *Dickerson*, in determining whether to hold a hearing, special masters should be mindful of Vaccine Rule 3(b), which indicates that "[t]he special master shall be responsible for conducting all proceedings, including requiring such evidence as may be appropriate, in order to prepare a decision, including findings of fact and conclusions of law ... [and] shall determine the nature of the proceedings, with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case . . . ." *Dickerson*, 35 Fed. Cl. at 598 (citations omitted).[7]

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[6] In reaching this conclusion, Dr. Kasdan disregarded notations in the treatment record suggesting that Mr. Phillips had diabetic peripheral neuropathy as solely attributable to the apparent success of Neurontin (which is commonly used in the treatment of diabetic peripheral neuropathy) in relieving Mr. Phillips' itchiness. ECF No. 69 at 2. In his view, Mr. Phillips presented with no other symptoms at the time that would have supported a diabetic neuropathy diagnosis. *Id.*

[7] Although Respondent has not formally moved for summary judgment in this matter, because she asks me herein to rule without a hearing (and therefore without allowing experts to testify and expand upon their opinions or theories), in exercising my discretion I give some consideration of the law governing motions for summary judgment under Rule 56 of the Rules of the United States Court of Federal Claims ("RCFC") (which is applied to Vaccine Program cases in accordance with Vaccine Rule 8). Summary judgment is appropriate where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. RCFC 56(c) ("[a] motion for summary judgment should be granted if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law."); *see also Jay v. Sec'y of Health & Human Servs.,* 998 F.2d 979, 982–83 (Fed. Cir. 1992) (a motion for summary judgment should be treated the same way in vaccine cases as it is in other cases). For purposes of summary judgment, there is no "genuine issue of material fact" when the evidence presented is insufficient to permit a reasonable finder of fact to find in favor of the non-moving party, and the moving party bears the burden of demonstrating absence of all genuine issues of material fact. *Jay*, 998 F.2d at 982–83. When ruling on a motion for

IV. Analysis

To receive compensation under the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, or (2) that her illness was actually caused by a vaccine (a category of claim often generically referred to as a "non-Table Injury"). *See* §§ 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8]

No Table Injury is alleged in this case, so Mrs. Phillips must prove causation-in-fact to ultimately prevail in this case. To do so, a petitioner must provide: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. To determine if a petitioner has carried her burden, I must assess "the record as a whole" and may not make an entitlement decision in her favor based solely on her own claims "unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1).

Respondent's motion focuses the most on the third *Althen* prong, which requires establishing a "proximate temporal relationship"[9] between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. In Respondent's view, too much time (approximately 12 weeks) passed between Mr. Phillips' October 2007 vaccination and the onset of his GBS in January 2008 (as reflected in the records detailing his hospitalization). Respondent offers her own expert to support this contention, and denies that the symptoms Mr. Phillips experienced in October and November of 2007 were GBS-related. Petitioner, by contrast, has offered two experts who disagree, based on their readings in the relevant literature and interpretation of the medical

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summary judgment, evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in favor of the non-moving party. *Id.*

[8] Decisions of special masters (some of which I reference in this decision) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit decisions are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

[9] This term has been equated to the phrase "medically-acceptable temporal relationship." *Althen*, 418 F.3d at 1281. The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

record. *See* ECF No. 69 at 1-2; ECF No. 58 at 2-3. These experts opine that Mr. Phillips' symptoms in the month immediately after receipt of the flu vaccine were in fact GBS-related.

Flu-GBS cases are not uncommon in the Vaccine Program, and therefore there are numerous well-reasoned special master decisions discussing a reasonable onset timeframe for GBS to develop after vaccination. *See, e.g.*, *Corder v. Sec'y of Health & Human Servs*., No. 08–228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011) (proposed four month onset period from vaccination to GBS too long; two months is longest reasonable timeframe). As noted in *Tompkins v. Sec'y of Health & Human Servs.*, No. 10-261V, 2013 WL 3498652, at *33 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd*, 117 Fed. Cl. 713 (2014), there are good scientific grounds for expecting onset to occur within approximately six weeks:

> the expected latency between an antecedent event (when infection or administration of antigen occurs) and the first symptoms of GBS is mainly between 7 and 21 days. Occasional cases appear to have latencies of between 22 and 42 days. All evidence indicates that GBS is immune mediated via a delayed-type hypersensitivity mechanism. Taken together, these two observations allow a range of latencies to be stated for GBS, that is, 5 days to 6 weeks.

(citations omitted). *See also Stitt v. Sec'y of Health & Human Servs*., No. 09-653V, 2013 WL 3356791, at *15 (Fed. Cl. May 31, 2013) (because petitioner's hospitalization occurred within 5–1/2 weeks of the vaccination, the period was acceptable for purposes of meeting *Althen* prong three).

There is plainly a fact dispute between both parties' expert as to the onset question. If Petitioner's experts are believed, onset of Mr. Phillips' GBS occured in a medically-acceptable timeframe. Resolving this factual dispute will require testimony from these experts to assess their credibility, and to determine how much weight to give their readings of the medical record. Thus, in the exercise of my discretion, I am not prepared to rule on disputed facts in this case without holding a hearing.[10]

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[10] Beyond onset, it is evident that (based solely on the written record) there are also fact disputes, the resolution of which is dependent on credibility determinations, with respect to the other two *Althen* prongs. Under *Althen* prong one, for example, Mrs. Phillips must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citations omitted). Mrs. Phillips offers two experts, both of whom opine that there is "more likely than not" a causal relationship between receipt of the flu vaccine and the development of GBS. Dr. Marks' expert report specifically provided a biological theory regarding vaccine causation and cited certain pieces of medical or scientific literature in support of this theory. Respondent offers her own expert in rebuttal. I will require testimony from all such experts to resolve this disputed issue.

The second *Althen* prong specifically requires proof of a logical sequence of cause and effect between a petitioner's vaccination and subsequent injury, usually supported by facts derived from the relevant medical records. *Althen*, 418 F.3d at 1278; *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1375-77 (Fed. Cir. 2009); *Capizzano*, 440 F.3d at 1326. Mrs. Phillips has produced documentation from two of Mr. Phillips' treating

Of course, my ruling should not be understood to mean that I believe or predict that Petitioner will ultimately prevail. Respondent has highlighted significant weaknesses in Petitioner's case. These matters must be addressed if Petitioner is to be successful in establishing entitlement to a Vaccine Program award of compensation.

CONCLUSION

For the reasons stated above, I DENY Respondent's motion. The parties shall contact chambers to schedule a status conference in this matter, at which time a deadline for any supplemental expert reports from Respondent will be established.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master

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physicians identifying the vaccination as the cause of Mr. Phillips' injuries (and ultimately his death). Such evidence can be strongly persuasive, especially to the extent it bulwarks a petitioner's medical theory. *See Moberly*, 592 F.3d at 1324–25. She also offers her experts, both of whom are prepared to opine that, to a reasonable degree of medical certainty, the flu vaccine caused Mr. Phillips' alleged injuries (and ultimately lead to his death). *See* ECF No. 69 at 2; ECF No. 55-1 at 5; ECF No. 58 at 2. Respondent for her part denies all of the above, and will call upon her expert to offer a competing understanding of the treatment history. This is yet another reason to hold a hearing rather than rule solely on the written record.