In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-1013V
Filed: July 24, 2019
(to be published)

LYNSIE KAMPPI,	*	PUBLISHED
Petitioner,	*	Dismissal; Onset; Guillain-Barré syndrome ("GBS").
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Braden A. Blumenstiel, Blumenstiel Falvo, LLP, Dublin, OH, for Petitioner.
Heather Lynn Pearlman, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT [1]

Oler, Special Master:

On September 14, 2015, Lynsie R. Kamppi ("Ms. Kamppi" or "Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that the influenza ("flu") vaccination Ms. Kamppi received on September 28, 2013 caused her to suffer from Guillain-Barré syndrome ("GBS"). Petition at 1.

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[1] This decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, 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, this decision will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I held a fact hearing on March 23, 2018 in Washington, DC to determine the date of onset of Petitioner's GBS. I found that Petitioner did not begin to experience symptoms associated with GBS until January 15, 2014. *See* Ruling on Onset at 2, ECF No. 59.

Upon review of the evidence submitted in this case, I find that Petitioner has failed to carry her burden showing that she is entitled to compensation under the Vaccine Act. In particular, Petitioner has failed to show that her injury was caused by the vaccination she received. The petition is accordingly dismissed.

I. Factual Background

Petitioner was born on April 25, 1981. She was 32 years old on September 28, 2013, when she received the allegedly causal flu vaccination in her right deltoid at Grant Hospital in Columbus, Ohio. Ex. 7.

A. Petitioner's Medical History Prior to the Flu Vaccination

Petitioner had a history of irritable bowel syndrome and gastroparesis prior to receiving her flu vaccination. Ex. 2 at 35.

B. The Flu Vaccination and Petitioner's Subsequent Medical History

After receiving her flu vaccination on September 28, 2013, Petitioner did not seek medical care until November 19, 2013. Ex. 2 at 29. On that date, she visited Dr. Robert Sears, her primary care physician, for a routine follow-up appointment to address hypoglycemia, anxiety, and depression. The physician's notes from that visit indicate that Petitioner had recently begun taking a new medication for depression, and that she was responding well to that medication. *Id.* at 29-30. The notes further indicate that Petitioner was "getting some hypoglycemic episodes [which occur] around 10:30am." *Id.* at 29. The notes from this visit do not reflect that Petitioner mentioned numbness, tingling, or pain in her legs. *Id.*

Petitioner did not seek medical care again until January 17, 2014, when she presented to OhioHealth Urgent Care complaining of "decreased mobility, joint tenderness, numbness, tingling in the legs and weakness." Ex. 15 at 1. The patient notes signed by Dr. Ebunoluwa Wion further indicate that onset began "2 days ago" and that Petitioner experienced "sudden onset of leg pain with pins/needles sensation and heaviness x2 days now." *Id.* The notes indicate that Petitioner did not mention experiencing previous symptoms of pain, numbness, and tingling back in October and November 2013 to Dr. Wion at this urgent care visit. *Id.*

After her urgent care visit, Petitioner was referred to the emergency room on that same day, where she was evaluated by Dr. Mark Renz. Ex. 3 at 15. The patient history indicates as follows: "On 1/15/2013[3] patietn [sic] developed left calf pain and numbness/tingling in her LLE[4].

[3] Although the medical history indicates Petitioner's condition began in 2013, this appears to be a typographical error, and should instead state "2014".

[4] Left lower extremities.

By the next morning this had resolved. Starting 1/17 patient developed recurrent LLE numbness/tingling, left calf pain, and weakness to the LLE. By the afternoon patient developed numbness/tingling to the RLE, pain to the right calf, and weakness of the RLE." *Id.* The ER patient notes do not reference any numbness, pain, or tingling that began prior to January 15, 2014. *Id.*

On January 18, 2014, Dr. Steven Simensky (a neurologist) evaluated Petitioner. The "Assessment and Plan/Recommendations" from this visit state that Petitioner "presents with 3 days h/o rapidly progressive, ascending paresthesias and weakness.…MRI and L-spine normal, LP with normal protein probably d/t early course of disease. The disease nadir is approximately 7-14 days." Ex. 3 at 19. The notes under "History [o]f Present Illness" state, "32 yo healthy GMC nurse with h/o IBS, gastroparesis, chronic diarrhea presents to GMC with a 3 d y/o progressive LE weakness. Pt states that she received the influenza shot approximately 7 weeks ago[5] without complications, later travelled to Bakersfield, CA for a family emergency and was surrounded by a pandemic of H1N1 flu.…She also developed sinus sx x 4 days last week. She was in this state when on 3 days prior to admission, she developed transient left calf numbness/tingling/pain which resolved until yesterday. At that point, her left leg sx recurred along with leg weakness and quickly thereafter, affected her right leg." *Id.* at 19-20. The assessment and plan portion of the record specifically mention "flu shot 7 weeks ago, probable recent exposure to H1N1 flu, [and] recent sinusitis sx." *Id.* at 19. There is no indication in the notes from this visit that Petitioner mentioned experiencing previous symptoms of pain, numbness, and tingling back in October and November 2013 when speaking with Dr. Simensky on January 18, 2014. *See Id.*

On January 18, 2014, Dr. Paul Willette examined Petitioner and took her medical history. Ex. 3 at 40. He wrote, "[t]his is a very pleasant 32-year-old female who is an L and D nurse here at Grant. She became sick in the past couple of days…. Her symptoms began Wednesday[6][,] Thursday she states she was not that bad, and today at 4:00 her symptoms progressed." *Id.* The notes do not reflect that Petitioner mentioned experiencing previous symptoms of pain, numbness, and tingling in October and November 2013 to Dr. Willette on January 18, 2014. *Id.*

On January 19, 2014, Petitioner was treated by Dr. George Connell. Ex. 3 at 22. In recording Petitioner's history, Dr. Connell documented "[s]ymptoms started several days ago now with sensory and motor loss to both lower extremities, left upper extremity weakness." *Id.* There is no indication that Petitioner mentioned experiencing previous symptoms of pain, numbness, and tingling back in October and November 2013 to Dr. Connell on January 19, 2014. *Id.*

On January 19, Petitioner was also seen by Dr. LeRoy Essig. Ex. 3 at 24. The notes from this visit indicate that Petitioner "presented to ED with several days worth of increasing LE paresthesias." *Id.* Dr. Essig noted in Petitioner's records that her clinical picture was very

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[5] Ex. 7 clearly indicates that Petitioner received her flu vaccination on September 28, 2013, which was 113 days or 16 weeks and one day before the date she was admitted to the ER, and not seven weeks, as it appears Petitioner relayed to Dr. Simensky.

[6] January 15, 2014 was a Wednesday.

consistent with GBS "secondary to influenza vaccine - 7 weeks ago."[7] *Id.*

On January 21, 2014, Dr. Julian Goodman (an infectious disease physician) treated Petitioner and documented that "last Wednesday started getting some numbness in her calf which fairly quickly progressed into LE weakness and progressive ascending paresis and diagnosed with GBS." Ex. 3 at 30. The notes do not reflect that Petitioner mentioned experiencing previous symptoms of pain, numbness, and tingling back in October and November 2013 to Dr. Goodman on January 21, 2014. *Id.*

On January 27, 2014, Dr. Nicole Burns treated Petitioner. When drafting the history of Petitioner's present illness, she wrote, "[o]n 1/15 she developed LLL numbness and tingling that resolved by the next morning. Then on 1/17 she again developed recurrent left sided numbness and tingling. She presented when she noticed symptoms on her right side as well with difficulty walking and writing." Ex. 3 at 34-35. The notes do not reflect that Petitioner related previous symptoms of pain, numbness, and tingling back in October and November 2013 to Dr. Burns on January 27, 2014. *Id.*

Petitioner was discharged from Grant Medical Center on January 28, 2014 and was admitted to the OhioHealth Institute for Rehabilitation on that same day. The OhioHealth Institute for Rehabilitation took Petitioner's medical history upon her admission and documented this history in her medical records. According to these records, "[s]he experienced an episode of numbness, tingling in her left leg on January 15, 2014, and did not pay much attention to it and thought maybe it was some type of musculoskeletal issue and it resolved the next morning but then it returned again in a much worse fashion on January 17, 2014, where the patient had difficulty walking and riding, and she was sent to the hospital from urgent care evaluation." Ex. 4 at 1. During intake at the rehabilitation facility on January 28, 2014, there is no indication that Petitioner mentioned experiencing symptoms of pain, numbness, and tingling in October and November 2013. *Id.*

As of the date of the fact hearing, Petitioner was still experiencing symptoms from GBS, to include numbness in her fingertips, falling due to weakness in her legs, and change in heart rate. Tr. at 115.

II. Procedural History

On September 14, 2015, Petitioner filed a petition alleging that she suffered from GBS as a result of a flu vaccination administered on September 28, 2013. Petition, ECF No. 1. Petitioner filed medical records on October 2, 2015 and February 26, 2016. ECF Nos. 8, 12.

On April 12, 2016, Respondent filed a Rule 4(c) Report stating that "[P]etitioner has failed to demonstrate entitlement to compensation and her petition for compensation should be dismissed." ECF No. 17.

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[7] Again, it is important to note that Petitioner's flu vaccination was 16 weeks prior to this visit with Dr. Essig, and not seven weeks, as reported in the record.

Petitioner filed affidavits on September 20, October 12, 2016 and November 11. 2016. Exhibits ("Exs.") 10, 11, 12, 13, 14. She then filed additional medical records on February 15, 2017. ECF No. 40 (Exs. 15-20).

I held a fact hearing on March 23, 2018 in Washington, DC to determine the date of onset of Petitioner's GBS. I issued my ruling on onset on April 26, 2018. In that ruling, I found that Petitioner did not begin to experience symptoms associated with GBS until January 15, 2014. *See* Ruling on Onset at 2, ECF No. 59. I directed Petitioner to either file an expert report supporting onset of GBS symptoms 15 weeks and five days after flu vaccination or a status report indicating how she intended to proceed. *Id.*

On June 11, 2018, Petitioner filed her first request for a continuance, requesting a 30-day extension of time to "obtain an expert report linking [P]etitioner's vaccine to her injury with a date of onset beginning January 15, 2014." *See* ECF No. 61 at 1.[8] I granted that Motion on June 13, 2018 and ordered Petitioner to file her expert report by July 11, 2018. *See* Non-PDF Order of 06/13/2018. In that Order, I also directed Petitioner to request a status conference if she was unable to timely file her expert report. *Id.*

On July 11, 2018, in lieu of filing her expert report, Petitioner filed a status report requesting a status conference. *See* ECF No. 62. In that status report, Petitioner represented that an expert had been provided with the necessary materials, and that a report would be produced within the next three to six weeks.[9] *Id.*

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[8] In that Motion, Petitioner represented the following regarding her counsel's efforts to procure an expert opinion in this case:

> Counsel for [P]etitioner is in the process of seeking an expert opinion explaining the connection between the vaccine and [P]etitioner's injury with a date of onset of symptoms being January 15, 2014. To date, he has been unable to obtain the expert report.

ECF No. 61 at 1.

[9] Specifically, Petitioner represented the following regarding her counsel's progress in procuring an expert report:

> Petitioner has submitted materials to an expert and notified the expert of Special Master Oler's Ruling on Onset determination that [P]etitioner first experienced symptoms on January 15, 2014. Counsel for [P]etitioner has notified the expert that any opinions must be based on the Ruling that the symptoms first began on January 15, 2014. Counsel for [P]etitioner has been informed a report will likely be available within 3 to 6 weeks.

ECF No. 62 at 1.

Thus, I note that, as of the date of Petitioner's status report of July 11, 2018, Petitioner and her counsel represented to the Court that Petitioner will file her expert report by August 22, 2018, i.e., six weeks after her status report.

I held a status conference on August 13, 2018, primarily to discuss Petitioner's efforts to obtain an expert report in this case. *See* Minute Entry for 8/13/2018; *See also* ECF No. 63. At that time, Petitioner's counsel represented that an expert report was now expected within three weeks.[10] Respondent questioned whether there was a reasonable basis for Petitioner's claim. ECF No. 63. I informed Petitioner's counsel that, in light of my Ruling, I also questioned whether there was a reasonable basis to proceed in this case. Additionally, I expressed my concerns to Petitioner's counsel that "Petitioner does not have a reasonable likelihood of proving a medically appropriate temporal relationship of 15 weeks and five days between [Petitioner's] vaccination and onset of [her] GBS." ECF No. 63 at 1.[11] Moreover, I relayed to Petitioner's counsel that there has not been a successful case in the Program to hold that such a lengthy time frame between vaccination and onset of GBS is medically reasonable to support causation. *Id.* Nonetheless, I granted Petitioner's second requested extension of time, ordering Petitioner to now file her expert report or status report by October 15, 2018. *Id.*

On October 15, 2018, Petitioner filed a status report requesting a third extension of time. *See* ECF No. 64. In that status report, Petitioner again represented that an expert has been contacted, and a report should be available in four weeks.[12] In response to Petitioner's status report (ECF No. 64), I issued an Order granting Petitioner's third request for an extension of time. ECF No. 65. In that Order, I detailed Petitioner's numerous attempts to produce an expert opinion that supports onset of GBS following flu vaccination at 15 weeks and five days. *Id.* I further clarified that no further extensions of time would be entertained and that, if Petitioner does not file her expert report, an order to show cause would issue. *Id.*

On November 15, 2018, Petitioner filed her fourth request for an extension of time.[13] *See* ECF No. 66. In that Motion, Petitioner represented that she was in possession of medical literature

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[10] Petitioner's counsel stated that the case materials were provided to a neurologist. I note that, as of the date of the status conference, Petitioner expected the receipt of an expert report from a neurologist by September 3, 2018.

[11] During that status conference, I also told Petitioner's counsel that if Petitioner is unable to obtain an expert report, Petitioner's counsel shall "show this Order to Petitioner and discuss dismissal of the petition." ECF No. 63 at 1.

[12] In her status report of October 15, 2018, Petitioner provided the following:

> Counsel for [P]etitioner] submitted this Court's Ruling on Date of Onset Hearing to Dr. James Lyons-Weiler. Dr. Lyons-Weiler is conducting a medical literature review to explore whether medical research is supportive of an onset of GBS symptoms 15 weeks and five days after flu vaccination. Counsel for [P]etitioner believes a report will be available within the next four weeks.

ECF No. 64. I note that Dr. Lyons-Weiler is not a neurologist and, therefore, not the expert discussed in our August 13, 2018 status conference. *See* ECF No. 63.

[13] Petitioner further added that "Petitioner has not been able to communicate with counsel for respondent with regard to this request, but will reach out to her as soon as possible." ECF No. 66. Respondent's counsel informed chambers, through informal communications that he had not been contacted by Petitioner or notified of the Motion (ECF No. 66).

and a medical literature review conducted by Dr. James Lyons-Weiler. *Id.* Petitioner claimed, however, that the expert report from Dr. Lyons-Weiler had not been signed and that Petitioner required until December 15, 2018, to obtain the signed report. *Id.* Petitioner further represented that she had not previously filed a motion for enlargement of time with regard to this matter. *Id.*

On November 16, 2018, following the informal communications conducted between chambers and the parties, Petitioner filed two documents labeled as "Expert Reports of Dr. James Lyons-Weiler." *See* ECF No. 67, 68. After reviewing the documents, I notified the parties that a status conference was necessary in order to determine Petitioner's next steps.

I held a status conference that same day, on November 16, 2018. *See* Minute Entry for 11/16/2018. During that status conference, I allowed Respondent's counsel to comment on the documents filed by Petitioner that day. ECF No. 70. As articulated thoroughly in my Order filed on November 16, 2018, Respondent did not view the documents to be at the substantive level of expert reports or to address a plausible causation theory. *Id.* When given an opportunity to respond, Petitioner's counsel agreed that these were not expert reports and did not address the issue of onset. *Id.* Counsel added that he was aware the documents would "not have a huge impact" on the prosecution of the claim but filed them since they were the only evidence Petitioner was able to produce. *Id.*

I informed Petitioner's counsel that I did not view the documents to be adequate medical literature reviews and noted that no literature had been filed in support of the claim. *Id.* I further impressed upon Petitioner's counsel that, given the insurmountable issue of onset in this case, Petitioner should move to dismiss her claim. *Id.* I directed Petitioner's counsel to speak with Petitioner regarding the dismissal of the claim and file a status report by November 26, 2018, indicating how she wished to proceed. *Id.*

Petitioner did not file her status report on November 26, 2018, as directed, but on November 27, 2018, filed a request for an extension of time to file her status report. *See* ECF No. 71. Petitioner represented that she had spoken with her counsel, and that she directed her counsel to conduct further research regarding the issue of GBS onset. *Id.* Petitioner stated that she would consider dismissal of the claim only after her counsel had presented her with this research. *Id.* I granted Petitioner's request for an extension. ECF No. 72. In that Order, I included references to cases decided by this Court in which several Special Masters found varying lengths of time in excess of 42 days to be medically infeasible onset time frames for GBS following flu vaccination. *Id.* Petitioner's status report was due November 30, 2018. *Id.*

Petitioner did not filed her status report on November 30, 2018; instead on December 4, 2018, Petitioner filed a second request for an extension of time to file her status report. ECF No. 73. In that Motion, Petitioner stated that her counsel had provided her with the relevant case law regarding the issue of onset and that they were scheduled "to speak yesterday about how [P]etitioner would like to proceed."[14] *Id.* Because Petitioner had several opportunities to consider her position since my Ruling on Onset in April of 2018 and had been unable to produce evidence supporting GBS onset 15 weeks and five days post-vaccination, I did not grant this request for an

[14] Petitioner represents that she was scheduled to speak with counsel regarding the status report on December 3, 2018, which is three days after her most recent deadline. ECF No. 73.

extension of time and instead issued an order to show cause as to why her petition should not be dismissed. ECF No. 74.

Petitioner responded to the Order to Show Cause on January 3, 2019. ECF No. 75. Respondent replied on February 13, 2019. ECF No. 76.

I held a status conference with the parties on February 15, 2019. During that status conference, I informed Respondent that I believed he needed to file an expert report addressing the feasibility of onset of GBS 15 weeks and five past after flu vaccine. Respondent submitted a report by Dr. J. Lindsay Whitton entitled "Review of the causes of GBS, with particular attention to influenza vaccines." Ex. A. Respondent filed Dr. Whitton's CV as Ex B.

On April 26, 2019, the parties each filed a status report indicating their agreement that I decide this case on the record. ECF Nos. 80, 81. Through informal communications on June 17, 2019, the parties were asked if they required an additional briefing schedule. Respondent replied that they did not intend to submit a brief. On June 30, 2019, Petitioner filed a status report, stating that she did not require a briefing schedule. ECF No. 82. The matter is now ripe for adjudication.

III. Expert Opinions

A. Dr. James Lyons-Weiler

Petitioner submitted two separate one to two-page documents authored by Dr. James Lyons-Weiler. *See* Exs. 21, 22. Petitioner did not submit Dr. Lyons-Weiler's CV and did not submit the two articles referenced in exhibit 21. In the first document, Dr. Lyons-Weiler states that studies of GBS use a six-week risk period, which he describes as an arbitrary exclusion of cases with later onset. *See* Ex. 21. The document concludes by stating,

> I can firmly state given that arbitrary cut-offs were used in the studies, and that now some studies use cut-offs influenced by rulings and employ circular logic, that there is no scientific or medical justification for a "< 15 plus 5 days cutoff" for your, or anyone else's client – nor do I know of any reasonable cut-off not based on an arbitrary assumption.

Ex. 21 at 2.

The second document makes similar assertions, stating that there are "no scientific or medical criterion [sic] based on any data from any study or studies that supports the notion that any cut-off, be it five, fifteen, or 52 weeks exists in the etiology of GBS following influenza vaccination." Ex. 22.

B. Dr. J. Lindsay Whitton

On April 1, 2019, Respondent filed an expert report authored by Dr. J. Lindsay Whitton, titled Review of the causes of GBS, with particular attention to influenza vaccines. *See* Ex. A. In

his report, Dr. Whitton addressed three main topics: 1) the probability of developing GBS following influenza vaccination, 2) the likelihood of an onset of GBS occurring at 15 weeks and 5 days following vaccination, and 3) the incidence of GBS following various etiologies.

As an initial matter, Dr. Whitton outlined the clinical features of GBS, before discussing the possible infectious and vaccination-related causes of GBS that have been observed in practice and well documented in literature. Ex. A at 2-4. In his report, Dr. Whitton estimated that approximately two-thirds of GBS patients report a preceding illness, usually a gastrointestinal or upper respiratory tract infection, that occurred within 21 days prior to onset. *Id*. at 4. Dr. Whitton explained that both bacterial and viral infections can trigger GBS, to include bacteria such as *Campylobacter jejuni*, Haemophilus influenza, and Mycoplasma pneumoniae and viruses such as human cytomegalovirus ("CMV") and Epstein-Barr virus. *Id*. at 4-6. He stated, however, that GBS following vaccination was rare and only two types of vaccinations had been causally associated with GBS, nervous-tissue derived rabies vaccines and the 1976 Swine influenza vaccine. *Id*. at 7. According to Dr. Whitton, the medical literature does not support a causal relationship between GBS and any other vaccine. *Id*. at 14.

Dr. Whitton addressed the increased risk periods and onset time frames for GBS following certain causal events. Following CMV infection, Dr. Whitton stated that GBS usually occurred several weeks later. *Id*. at 6. GBS associated with influenza infection usually arose within thirty days following infection. *Id*. Dr. Whitton reiterated the rarity of a causal association between vaccines and GBS, before addressing onset of GBS following the 1976 swine influenza vaccine. *Id*. at 8. Specifically, Dr. Whitton discussed in great detail the results of the Langmuir et al. study. In his opinion, the study addressed, amongst others, the following questions: 1) the extent of the causal relationship between GBS and the 1976 swine influenza vaccine and 2) the periods of time following vaccination when the risk of developing GBS is increased. *Id*. Dr. Whitton summarized that the study results indicated while there was indeed an increased risk of GBS following vaccination, any detectable risk diminished after four weeks and returned to the baseline incidence of GBS at six to eight weeks. *Id*. at 9-10. No increased risk of GBS, therefore, was observed after eight weeks. *Id*. Dr. Whitton claimed that as a measure of care, the CDC recognized a time frame of ten weeks as an acceptable window for developing GBS following the 1976 swine flu vaccination, but any GBS event arising past ten weeks was considered as unrelated to the vaccine. *Id*. at 10.

Finally, Dr. Whitton clarified that the causal association between the 1976 swine influenza vaccine and GBS cannot be extrapolated to other types of influenza vaccines. Ex. A at 10-14. The increased risk of GBS occurrence that is associated with 1976 Swine influenza vaccination has not been observed with other influenza vaccines or even with other swine influenza vaccines. *Id*. Though studies conducted on the association between GBS and subsequent influenza vaccines have revealed higher incidences of GBS, Dr. Whitton clarified that this does not indicate an increased risk of GBS following vaccination. *Id*. at 11. Greater populations and wider spread administration of influenza vaccinations can lead to greater incidences of GBS temporally associated with vaccination. *Id*. at 11. However, when compared to the occurrence of GBS in a baseline population, no statistically significant increase in risk of GBS is observed. *Id*. at 11. In support of his position, Dr. Whitton cited to numerous studies, which investigate the risk of GBS following several influenza vaccines, to show that the medical literature does not indicate an

increased risk of GBS. *Id*. at 12. Dr. Whitton pointed out that, most recently, the 2009 mass administration of the H1N1 vaccine did not introduce a substantially increased number of GBS cases. *Id*. at 13. A slightly higher incidence of GBS (0.8 per million vaccines) was noted; Dr. Whitton emphasized, however, that the editors of this analysis concluded "the association described above cannot prove a causal relationship between vaccination and GBS." *Id*. at 14.

In summary, Dr. Whitton opined that "there is no compelling scientific evidence that any flu vaccine since 1976 has conferred an increased risk of developing GBS." Ex. A at 14.

IV. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that he suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one,

petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." Id. at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second Althen prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., No. 06-522V 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third Althen prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also 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. den'd 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 den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

V. Analysis

I will address each *Althen* prong in the order that it is relevant to this case.

A. *Althen* Prong 3

Petitioner cannot demonstrate that 15 weeks and five days from vaccination to onset of her symptoms of GBS is a medically-appropriate temporal gap.

1. *Petitioner's GBS had an Onset of January 15, 2014*

Petitioner's medical records surrounding her GBS diagnosis are clear, internally consistent, and complete. She received her vaccine on September 28, 2013 and presented to her primary care provider in November of 2013 with unrelated medical issues. There is no mention of numbness or tingling at that visit. Ex. 2 at 29. She spoke with nine different medical providers between November 2013 and January 2014. There is no reference in those records to onset of pain, numbness, or tingling that began in October or November of 2013 (as is articulated in the affidavits and the testimony at the onset hearing). Instead, each of those medical providers consistently documents that Petitioner began experiencing symptoms of GBS on January 15, 2014.[15] Based on these medical records, I found that Petitioner began to experience onset of GBS on January 15, 2014, 15 weeks and five days after she received her flu vaccination. *See* Ruling on Onset at 2, ECF No. 59.

2. *Onset of GBS 15 Weeks and 5 Days after Vaccination is too Long to be Medically Feasible*

Under 42 C.F.R. § 100.3(a)(XIV)(D), in order to satisfy the Table requirement for GBS, vaccination to onset of symptoms must occur within three to 42 days. Petitioner's symptoms began more than 15 weeks (110 days) after flu vaccine, and clearly fall outside of the Table. In non-Table GBS claims, petitioners must prove causation in fact. Dr. Whitton's report is persuasive. The Langmuir study demonstrates that GBS does not occur in a statistically significant manner longer than eight weeks after swine flu vaccine. I find this report to be persuasive and have relied on it in making my determination in this case.

In addition, I take note of the decisions of other special masters when considering reasonable onset timeframes. Special masters in the Program have not awarded compensation when onset occurs more than two months after vaccination because it is not medically plausible for the immune response that is a central component of the autoimmune process resulting in GBS to take this long. *See, e.g., Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (eight weeks is the longest reasonable timeframe for a flu/GBS injury); *De La Cruz v. Sec'y of Health & Human Servs.*, No. 17-783V, 2018 WL 945834, at *1 (Fed. Cl. Spec. Mstr. Jan. 23, 2013) (onset of GBS more than two months after flu vaccination is not compensable); *Corder v. Sec'y of Health & Human Servs.,* No. 08-

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[15] *See* Ex. 2 at 29 (medical visit on November 19, 2013 where Petitioner does not mention symptoms of GBS); Ex 15 at 1 (urgent care visit on January 17, 2014 where Petitioner describes numbness, tingling and weakness in the legs with onset "2 days ago"); Ex. 3 at 15 (ER visit on January 17, 2014 which indicates that Petitioner developed left calf pain and numbness and tingling on January 15, 2014); Ex. 3 at 19 (neurology evaluation on January 18, 2014 which notes three day history of rapidly progressive ascending paresthesias and weakness); Ex. 3 at 40 (medical examination noting that Petitioner became sick on Wednesday (which was January 15, 2014)); Ex. 3 at 22 (medical visit with an anesthesiologist on January 19, 2014 noting sensory and motor loss to both extremities which "started several days ago."); Ex. 3 at 30 (January 21, 2014 record from an infectious disease physician who noted that Petitioner's numbness and progression of symptoms began last Wednesday); Ex. 3 at 34-35 (doctor who notes numbness and tingling that began on January 15); Ex. 4 at 1 (rehabilitation records which describe an initial episode of numbness and tingling on January 15, 2014).

228V, 2011 WL 2469736 (Fed. Cl. Spec. Mstr. May 31, 2011) (dismissing suit involving four-month onset of GBS after flu vaccination).

3. *Dr. Lyons-Weilers' Documents do not Advance Petitioner's Case*

The two documents submitted by Dr. Lyons-Weiler (referred to by Petitioner as "medical literature reviews" as opposed to an expert report, *see* ECF No. 70) did not advance any theory as to how the flu vaccine Petitioner received on September 28, 2013 could have caused her to develop GBS 15 weeks and five days later. Further, nothing was filed into the record informing me as to Dr. Lyons-Weiler's background, his past research, or his area of expertise. While I considered the documents submitted by Dr. Lyons-Weiler, I gave them little weight in my analysis.

Ultimately, 15 weeks and five days is well outside a temporally-appropriate onset window. Such a temporal gap is medically infeasible and results in Petitioner's failure to establish the third *Althen* prong.

B. *Althen* Prong 2

There is no doubt that Petitioner developed GBS in mid-January of 2014. However, Petitioner has offered no evidence in the form of medical records or medical opinion linking her vaccination to her injury. While one of her treating physicians suggested such a link, this notation by Dr. Essig seemed to be based on an incorrect fact, namely that Petitioner had received her flu vaccination seven weeks before developing GBS. *See* Ex. 3 at 24 (stating that Petitioner's history was consistent with GBS "secondary to influenza vaccine - 7 weeks ago"). The documents filed by Dr. Lyons-Weiler do not discuss any specifics concerning Petitioner's case. Accordingly, Petitioner has failed to meet her burden of proof with respect to *Althen* prong 2.

C. *Althen* Prong 1

It is well established that the swine flu vaccination can cause GBS. *See eg.* Ex. A. Further, GBS that occurs between three and 42 days after flu vaccination is a Table injury. *See* 42 C.F.R. § 100.3 (2017). Because of the close relationship between the first and third *Althen* prongs, petitioners are obligated to establish that the timing of onset of symptoms is "medically appropriate" under their proposed causation theory. *See, de Bazan*, 539 F.3d at 1352. As discussed above, Petitioner has not met *Althen* prong 3. So while flu vaccination can cause GBS, the facts of this case make it clear that it did not do so here.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, I conclude that Petitioner has not shown by preponderant evidence that any of her injuries were caused by her flu vaccination. Accordingly, Petitioner's claim for compensation is dismissed.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the clerk shall enter judgment in accord with this decision.

IT IS SO ORDERED.

s/Katherine E. Oler
Katherine E. Oler
Special Master