In the United States Court of Federal Claims OFFICE OF SPECIAL MASTERS No. 16-1140V Filed: March 9, 2018 UNPUBLISHED

Special Processing Unit (SPU);

Finding of Fact; Influenza (Flu)

Vaccine; Proof of Vaccination.

TRAMELLA HINTON, as mother and natural and proposed guardian of SHAWN'QUAVIOUS A'DREZ HINTON, an incapacitated and disabled person,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Bruce William Slane, Law Office, White Plains, NY, for petitioner. Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for respondent.

ORDER AND RULING ON FACTS – SPECIAL PROCESSING UNIT¹

Dorsey, Chief Special Master:

On September 14, 2016, petitioner, Tramella Hinton, as the mother, natural and proposed guardian of Shawn'Quavious A'drez Hinton ("Shawn") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,² (the "Vaccine Act").³ Petitioner alleges that her son suffered injuries, including the Acute Inflammatory Demyelinating Polyneuropathy ("AIDP") variant of Guillain-Barré syndrome ("GBS") that was caused-in-fact by the adverse effects of an influenza ("flu") vaccination he received on December 21, 2015 in Tarboro,

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

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).

³ An amended petition was filed on June 2, 2017. (ECF No. 35).

North Carolina. Amended Petition at 1. Petitioner has been unable to obtain documentary proof of vaccination and now moves (based on circumstantial evidence) for a fact-finding that Shawn'Quavious A'drez received a flu vaccination on December 21, 2015. After a review of the evidence submitted and the parties' briefs, the undersigned finds that petitioner has established adequate proof of vaccination.

I. Procedural History

In the petition, Ms. Hinton alleges that Shawn received a flu vaccine on December 21, 2015, at the office of his primary care physician, Dr. Gilbert Alligood in Tarboro, North Carolina. The petition states that Ms. Hinton's counsel "faced resistance from the office of Dr. Gilbert Alligood and Vidant Health in attempting to obtain the records of vaccination." Petition at 1, fn. 1. After obtaining authority to issue subpoenas for Shawn's medical records, petitioner filed the first set of medical records (petitioner's exhibits ("Pet. Ex.") 1-10) on January 11, 2017. No record of vaccination was included with these records.

On January 12, 2017, petitioner filed a motion (and was granted authority) to depose Dr. Gilbert Alligood regarding Shawn's December 21, 2015 flu vaccination. *Order* dated January 17, 2017. Dr. Alligood was deposed on March 17, 2017 and the transcript of the deposition has been filed into the record as petitioner's exhibit 12. On March 10, 2017, Ms. Hinton filed unofficial transcripts of recorded telephone conversations that she had with Dr. Alligood regarding Shawn's 2015 flu vaccination as well as a compact disc of the audio recording. During Dr. Alligood's deposition, portion of the recordings were played and transcribed into the official transcript of the deposition.

On June 2, 2017, petitioner filed an amended petition which included citations to the deposition transcript and medical records that were obtained after the filing of the original petition. A status conference was held on June 14, 2017, with counsel and the staff attorney managing this case. During that status conference, the parties stated that proof of vaccination remained an issue and requested that the undersigned conduct a fact hearing to determine whether and when Shawn received a flu vaccination in December 2015. The undersigned granted this request.

A fact hearing was held on September 8, 2017 in Raleigh, North Carolina, during which Ms. Hinton testified. Shawn and his stepfather were also present during the hearing, but did not testify. The transcript of this proceeding has been filed and the parties have filed the requested documentation from the hearing as well as their respective post-hearing briefs. This matter is now ripe for adjudication.

II. Relevant Factual History

In order to understand the unusual circumstances of this case, the undersigned will separately summarize the information contained in the medical records and witness affidavits, the testimony from Dr. Alligood's deposition, and Ms. Hinton's testimony from the fact hearing. Although not all of the evidence is summarized below, the undersigned has reviewed the record as a whole in reaching her decision.

a. Medical records and testimonial affidavits

Shawn'Quavious A'Drez Hinton ("Shawn") was born on September 24, 1988. Pet. Ex. 1 at 1. Shawn was born with Down Syndrome. Pet. Ex. 2 at 1, ¶2. He resides with his mother and three younger sisters. *Id.* Ms. Hinton reported to Shawn's treating physicians during the course of his treatment for GBS, that Shawn had never complained to her of any pain, weakness, tingling, decreased sensation, or decreased stability prior to December 21, 2015. Pet. Ex. 2 at 1, ¶3. Shawn was a healthy and active young man, attending school at Tarboro High school in the exceptional children's program. Pet. Ex. 2 at 1, ¶5.

On July 10, 2015, approximately five months prior to the vaccination at issue in this case, Shawn was seen by his primary care physician, Dr. Gilbert Alligood, for what his mother described as behavioral and sleeping problems. Pet. Ex. 3 at 178-181. After a consultation and physical examination, Dr. Alligood prescribed Clonidine and Trazadone and instructed Ms. Hinton to return with Shawn in 30 days. *Id.* at 181. Shawn was seen again on August 3, 2015, for this follow-up visit. *Id.* at 184-188. Ms. Hinton reported that Shawn was sleeping better although he was still experiencing behavioral issues. *Id.* at 186. Dr. Alligood prescribed a refill for the Trazodone during this visit. *Id.* at 187. Upon leaving Dr. Alligood's office, Ms. Hinton made another appointment for Shawn to be seen on December 21, 2015 at 2:30 p.m., for a follow-up visit. Pet. Ex. 2 at 2, ¶15.

In her affidavit, Ms. Hinton states that she took Shawn for his four-month follow up appointment on December 21, 2015. Pet. Ex. 2 at 2. It was during this appointment that she alleges that Shawn received the flu vaccine at issue in this case. Pet. Ex. 2 at 1, 3. Ms. Hinton states that she was present in the exam room on December 21, 2015 and watched as Shawn received his annual seasonal flu vaccination, which was administered in his left upper arm by Dr. Alligood's nurse. *Id.* Ms. Hinton states that two days later, based on this December 21, 2015 visit with Dr. Alligood, a refill for the prescription for Trazodone was sent to Rite-Aid pharmacy. *Id.*

Dr. Alligood's records do show that Shawn was scheduled for an appointment on December 21, 2015; however, Shawn is marked as a "no show" for the appointment. See Pet. Ex. 9 at 1. The billing records associated with Dr. Alligood's office and Shawn's Medicaid and BlueCross BlueShield insurance records do not reflect a charge for a December 21, 2015 encounter or for any vaccination administered on that date. See Pet. Ex. 16, 17; Pet Ex. 3 at 30. Dr. Alligood's records indicate that Ms. Hinton contacted his office on December 23, 2015 by telephone to request a prescription refill of Shawn's Trazadone medication. See Pet. Ex. 3 at 190, 208-201. This record indicates that the prescription was ordered by another provider at Dr. Alligood's office and was filled at Rite Aid Pharmacy the same day. See Pet. Ex. 15 at 2; Pet. Ex. 12 at 144.

Ms. Hinton states in her affidavit that in the "days and weeks following Shawn's December 21, 2015 vaccination," he began to experience pain and weakness in his legs. Pet. Ex. 2 at 2, \P 6. She stated that on January 11, 2016, Shawn injured his left ankle as he was attempting to stand. *Id.* Ms. Hinton states that over the next three

days, Shawn continued to complain about the pain and soreness in his left ankle. *Id.* at 2, ¶7.

On January 14, 2016, Ms. Hinton took Shawn to Vidant Edgecombe Urgent Care to be seen for his left ankle pain. Pet. Ex. 3 at 195. The records from this visit note that Shawn presented for complaints of "joint pain, left ankle." *Id.* The history provided indicates that Shawn's ankle pain started over the past seven days and that his pain occurred constantly. *Id.* Shawn's symptoms were aggravated by walking and standing. It was noted that Shawn fell on his left ankle three days prior. *Id.* After an x-ray showed no fractures, Shawn was discharged with a prescription for Ibuprofen. *Id.* at 196. Ms. Hinton states in her affidavit that in the days and weeks following the January 14, 2016 visit to urgent care, Shawn's leg weakness and ankle pain progressed to the point where he had to use a walker to get around. Pet. Ex. 2 at 2, ¶8. Shawn lost the ability to maintain his balance and walk. *Id.*

On January 20, 2016, Shawn was taken to the emergency room at Vidant for complaints of left knee pain. Pet. Ex. 5 at 61. Shawn's stepfather provided the history stating that Shawn had difficulty walking and a significant gait change. *Id.* His stepfather explained that Shawn's abnormal gait was noticed a week prior after he sustained a fall. *Id.* At that time, Shawn was seen in the emergency department. *Id.* A CT scan of his head was normal but he was found to be significantly hyperthyroid. *Id.* Upon examination, Shawn was found to have decreased strength to dorsiflexion and plantar flexion. *Id.* at 62. He was noted to have a fine tremor and walked with a shuffled gait. *Id.* at 61-62. He was unable to ambulate without support. *Id.* Shawn was discharged with diagnosis of myalgias, pain, and hyperthyroidism and concerns for Guillain-Barre syndrome, myasthenia gravis versus transverse myelitis. *Id.* at 61-62. He was provided with a prescription for a beta-blocker and instructed to follow up with his primary care physician. *Id.*

On February 1, 2016, Shawn was taken to Vidant Multi-Specialty Clinic ("Vidant") for continued complaints of difficulty walking. Pet. Ex. 3 at 203. He presented in a wheelchair due to his inability to walk. *Id.* Shawn's parents again reported to the medical providers that Shawn had sustained a fall two weeks prior and had been previously evaluated at the emergency room on two separate occasions. Pet. Ex. 3 at 203. The results of a CT scan of his cervical and lumbar spine showed some disc bulging and narrowing of the neural exit foramina at L5-S1 bilaterally. *Id.* at 210. The CT scan of his head was normal. *Id.* at 207. In the assessment, it was noted that Shawn walked with a shuffling gait and demonstrated some "obvious tremors" in both upper extremities. *Id.* at 210. An MRI of his brain and cervical spine were ordered. *Id.* If the results were normal, an EMG and neurology referral would be considered. *Id.*

Shawn was next seen on February 15, 2016, when he was admitted to Vidant Medical Center for weakness of his lower extremities and inability to walk over the "past 1-2 months." Pet. Ex. 4 at 57-63. He was hospitalized for three days during which a nerve conduction study and lumbar puncture were obtained. *Id.* at 54. The results of the lumbar puncture showed an elevated protein level at 194 and his nerve conduction study showed blocks of absent H reflexes consistent with demyelinating peripheral neuropathy. *Id.* A diagnosis of Guillain-Barre syndrome was considered. *Id.* Shawn was given two doses of IVIG over 48 hours. *Id.* He continued to have difficulty ambulating and required assistance. *Id.* Shawn was to be discharged to inpatient

rehabilitation. *Id.* Regarding his immunization history, the medical records note that Shawn was "up to date, did not receive flu vaccine." Pet. Ex. 4 at 58. On the same date at 20:36 (8:36 p.m.), an "influenza risk assessment" flow sheet was completed with the notation "No" in the column marked "Influenza Vaccine received since Sept 1." Pet. Ex. 4 at 166.

Shawn attended inpatient rehabilitation at Vidant Medical Center from February 19, 2016 through March 18, 2016. Pet. Ex. 4 at 224. It was noted that Shawn's final diagnoses was Guillain-Barre syndrome. *Id.* The plan was for Shawn to attend a minimum of three hours per day, five days a week, of physical and occupational therapy to improve his functional outcome of impaired mobility, activities of daily living, transfers and self-care. Pet. Ex. 4 at 235. Upon discharge on March 18, 2016, Shawn had shown improvement in his bilateral and lower extremity strength. Pet Ex. 4 at 342. He was instructed to follow up with his new primary care physician, Dr. Kalind Parashar, in one to two weeks after his discharge. *Id.* at 344.

On April 11, 2016, Shawn presented for a follow-up appointment with Dr. Parashar after his discharge from Vidant Medical Center. Pet. Ex. 3 at 217-18. Shawn was now being seen in outpatient rehab and his mother reported that he had been making significant progress. *Id.* Shawn was noted to have the ability to ambulate but with support. *Id.* He was scheduled for another follow up with Dr. Parashar in two months. *Id.* at 220.

Shawn attended outpatient rehabilitation at Vidant Edgecombe Hospital from April 12, 2016 through July 19, 2016. Pet. Ex. 6 at 311. During an evaluation dated April 12, 2016, it is noted that Shawn was being treated after having been hospitalized for Guillian-Barré syndrome after receiving a flu shot on December 21, 2015. Pet. Ex. 6 at 21. In another physical therapy note dated April 15, 2016, under "Subjective/History of Illness/Injury" it states "December 2015 p[atien]t received a flu shot. P[atien]t began to become not ambulatory... An MRI revealed current diagnosis in February 2016..." Pet. Ex. 6 at 42. Shawn was discharged from outpatient therapy on July 19, 2016. It was noted that it had been more than 30 days since his last visit and he was being discharged due to poor patient attendance. Pet. Ex. 6 at 312.

On October 3, 2016, Shawn was seen by Dr. Parashar for another follow-up appointment. Pet. Ex. 3 at 223-28. There were no concerns noted. Shawn was reported to be sleeping well and that his appetite and behavior were unchanged. *Id.* Shawn continued to work with his physical therapist and it had been recommended that he attend psychotherapy three times a week to work on proprioception. *Id.* at 224. He was instructed to follow up in six months. *Id.* at 225

b. Documentation regarding the December 21, 2015 vaccination

On April 5, 2016, Ms. Hinton filed a formal request with Vidant Multi-Specialty Clinic for an amendment of the medical records that Dr. Alligood maintained for Shawn. Pet. Ex. 3 at 236. Ms. Hinton requested that Shawn's record be amended to contain a notation that read "12-21-15 Follow up visit: flu vaccination administered left upper arm. (Please check with clinic to see the flu vaccine manufacturer in use for that day, and include the vaccine manufacturer and lot number if possible)." *Id*.

On May 23, 2016, Vidant denied Ms. Hinton's request to amend Shawn's medical records noting that "the record you requested be amended is accurate and complete." Your requested amended would make the record inaccurate or incomplete." Pet. Ex. 3 at 233-35. On June 10, 2016, Ms. Hinton filed a complaint with the U.S. Department of Health and Human Services, Office of Civil Rights ("OCR") regarding the alleged failure of Vidant to amend Shawn's medical record. Pet. Ex. 3 at 10-18. On September 23, 2016, OCR notified Ms. Hinton and Vidant that it was "closing this case without further action, effective the date of this letter." Pet. Ex. 3 at 11-18. On October 26, 2016, Vidant provided correspondence to OCR stating, in part, the following:

Vidant has carefully reviewed the information provided by OCR. Vidant has found no basis for amendment of the medical records as requested by the complainant. While Vidant understands OCR has closed this case effective September 23, 2016, Vidant is writing this letter to assure OCR that Vidant is aware of its obligations...

Vidant Risk Management staff has invested considerable time and effort in investigating complainant's request for amendment by, among other things, repeatedly speaking with the complainant, conferring with the facility's clinic medical director, reviewing the patient's medical records, reviewing medical records of all patients seen by Dr. Gilbert Alligood on the day of the alleged visit, reviewing the medical records of all patients receiving a flu vaccination at the facility on the day of the alleged visit, interviewing pertinent staff, auditing access to the patient's records, reviewing payment and billing records, reviewing a record of complainant's telephonic request for a prescription refill from two days after the alleged visit, requesting technical assistance from Vidant's electronic health record vendor to confirm the audit of the patient's medical record, and requesting any documentation available from complainant. Dr. Gilbert Alligood, who alleged ordered the flu vaccination, has also independently review the patient's medical record. Vidant is unable to find any indication that the patient was seen at the Vidant Multi-Specialty Clinic - Tarboro on the date the complainant believes the patient presented...

c. <u>Recorded Telephone Conversations</u>

Petitioner filed as exhibit 8, a transcript⁴ of her July 27, 2016 telephone conversation with Dr. Alligood. The portions of the transcript that are relevant to this fact ruling are set forth below:

Ms. Hinton: But umm let me ask you this Ms Manning ain't umm Ms Manning wanna talk about when she had called me she talking about you know everything still remain the same.

⁴ The "transcript" was transcribed by petitioner's counsel's office staff and not by a formal court reporting service. The undersigned has reviewed the recorded telephone call and compared the transcribed exhibit 8 with the telephone call and finds the transcription to be accurate.

Dr. Alligood: Well, the only thing I can tell you that's different, I talked to their attorney and I talked to Ms. Manning today and there gonna try and get somebody from outside to come in and look to see if they can figure out what happened with that record so I'm hoping that, that will help us you know.

Ms. Hinton: Ok but listen though, when she marked Shawn down as a no show.

Dr. Alligood: Uh huh.

Ms. Hinton: I'm trying to see how did that effect it.

Dr. Alligood: Yeah and that's what I want to find out cause I don't that it, it's not supposed to, so I don't know what happened.

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Ms. Hinton: Ok well I'm saying Dr. Alligood did you ever tell them that Shawn got seen? Did you, did you let them know that?

Dr. Alligood: I told them exactly what I told you that Shawn was seen sometime I remember seeing him but I don't remember when and I do not remember if he got a flu shot.

Ms. Hinton: Oh ok so you don't remember your nurse coming in and giving him the flu shot?

Dr. Alligood: No.

Ms. Hinton: In the left upper arm.

Dr. Alligood: No.

Ms. Hinton: You was standing right there by the door.

Dr. Alligood: Yep.

Ms. Hinton: You was like you gonna get a flu shot today and you were like let me get my nurse back in to get on that flu shot.

Dr. Alligood: Yep.

Ms. Hinton: Right on December 21st.

Dr. Alligood: Now see I wish I could say I was right there looking at it but I wasn't I don't know if he, what happened.

. . .

Ms. Hinton: Ok so I'm saying as far as like ok if you get subpoenaed for court I mean so basically you you just. You don't remember that.

Dr. Alligood: No I remember seeing Shawn a lot of times and I...

Hinton: I'm talking about for the month of December when he got the flu shot

Dr. Alligood: Yeah right, and I want so bad, you don't know how much I want so bad to say Oh I remember exactly but I don't. I just don't.

Ms. Hinton: Wow but you know that he got seen? Right before you left.

Dr. Alligood: I remember, I remember that.

. . . .

d. <u>Deposition Testimony</u>

On March 17, 2017, Dr. Alligood was deposed in connection with this case. The transcript from the deposition has been filed as petitioner's exhibit 12, and the exhibits used during the deposition have been marked as petitioner's exhibit 13. Dr. Alligood confirmed that he formally left Vidant Medical Group on December 31, 2015, and accepted a position with UNC Physicians Network in Middlesex, North Carolina. Pet. Ex. 12 at 7-8; Deposition Transcript ("Dep. Tr.") at 7-8. Dr. Alligood testified that the last day that he saw patients was December 21, 2015, although he did return to the office after December 21, 2015 to clean out his office and attend to any last pending matters. Dep. Tr. at 143; 152-53. During his deposition, Dr. Alligood repeatedly testified that he recalled seeing Shawn several times in 2015 but he did not recall whether he saw Shawn on December 21, 2015 and he also did not recall whether Shawn received a flu vaccine. Dep. Tr. at 44-45; 50-51; 59. The only other relevant information obtained during the deposition for purposes of this fact ruling is that Dr. Alligood described the check-in process for his office which is relevant to the hearing testimony provided by Ms. Hinton. Dr. Alligood testified that if an established patient presented to his office for a follow-up visit, it was typical for there to be no formal check-in process. One of his nurses would verbally acknowledge that a patient had arrived and the patient would be called back to an examining room. Dep. Tr. at 146-47. At the end of the visit, a patient would typically receive an "After-Visit Summary." Id. at 148. The majority of the deposition testimony merely established that Dr. Alligood does not specifically recall seeing Shawn on December 21, 2015 and he does not know whether Shawn received a flu vaccine from his office in 2015.

e. Fact Hearing Testimony

A fact hearing was held on September 8, 2017. Ms. Hinton was the sole witness. During her testimony, Ms. Hinton explained that in early 2015, Shawn was experiencing a number of sleeping and behavioral issues. Hearing Transcript ("Tr.") at 9. As a result, she scheduled an appointment for Shawn to be seen by his primary care physician, Dr. Alligood in July 2015. Tr. at 10. Ms. Hinton recalls that during that visit, after examining Shawn and discussing Shawn's behavioral issues, Dr. Alligood prescribed Clonidine

and Trazadone and instructed Ms. Hinton to bring Shawn in for a follow-up appointment in 30 days. Tr. at 10.

Shawn was seen again by Dr. Alligood in August 2015. Tr. at 10. Ms. Hinton reported that Shawn's sleeping issues had improved but that he was still experiencing behavioral issues. Tr. at 11. According to Ms. Hinton, Dr. Alligood told her to keep Shawn on his medications and to return for another follow-up visit in four months. Tr. at 11.

Ms. Hinton states that Shawn's four-month follow up visit with Dr. Alligood was scheduled for December 21, 2015 at 2:30 p.m. Tr. at 11. In November 2015, during an appointment her daughter had scheduled with Dr. Alligood, she learned that Dr. Alligood would be leaving Vidant at the end of the year. Tr. at 14. Ms. Hinton testified that Dr. Alligood's nurse told her that it would be a good idea to make sure all her children were seen before Dr. Alligood left. Tr. at 13-14. Ms. Hinton stated that she knew Shawn already had an appointment scheduled for December 21, 2015, so she did not need to make an additional appointment for him. Tr. at 15. Ms. Hinton stated that she recalls the December 21, 2015 date specifically because Shawn was out of school for his Christmas break. Tr. at 15.

Ms. Hinton testified that on December 21, 2015, she and Shawn arrived at Dr. Alligood's office for the scheduled appointment. Tr. at 11-12. Ms. Hinton testified that she stopped at the receptionist's desk to check in with Rosella, the receptionist, who acknowledged their arrival and stated that someone would be out to see them. Tr. at 11-12. Ms. Hinton testified that one of Dr. Alligood's nurses called them into an examining room and proceeded to take Shawn's vital signs. Tr. at 13. When Dr. Alligood arrived, he asked about Shawn's sleeping habits and how Shawn was doing with the medication that was prescribed at his prior visits. Tr. at 13. Ms. Hinton testified that she told Dr. Alligood that the medication seemed to be helping Shawn sleep. She recalls telling Dr. Alligood that she did not give Shawn his sleeping medication every night, especially if he had fallen asleep without it, because she did not "want his body to get immune to the medicine". Tr. at 13. According to Ms. Hinton, Dr. Alligood conducted a physical examination of Shawn. Tr. at 13. Ms. Hinton also recalls having a conversation with Dr. Alligood where she asked him why he was leaving Vidant. Tr. at 96. She stated that Dr. Alligood told her that he finally got a chance to be out on his own and he was taking the opportunity. Tr. at 96. Ms. Hinton specifically recalls that at the end of the examination, Dr. Alligood asked her if Shawn would be receiving a flu vaccination, to which she replied yes. Tr. at 12. Ms. Hinton testified that Dr. Alligood called his nurse in to administer the vaccine. Tr. at 12. Ms. Hinton states that the nurse administered the vaccine to Shawn's left upper arm. Tr. at 12. When asked whether she recalled the name of the nurse who administered the vaccine. Ms. Hinton stated that the nurse's name was Lisa. Tr. at 12. Ms. Hinton stated that when she and Shawn left the exam room, she stopped by Rosella's desk who informed her that information about Shawn's new primary care physician would be mailed to her. Tr. at 100.

At the hearing and in order to provide additional evidence of her whereabouts on December 21, 2015, Ms. Hinton produced her telephone records from December 21, 2015 to demonstrate that she was present at Dr. Alligood's office at 2:30 p.m. for Shawn's appointment. Tr. at 16. Ms. Hinton testified that she was on the phone for most of the day because she was trying to contact Social Services because she did not

receive her monthly benefit check which she was expecting on December 19, 2015. Tr. at 17. She also explained that she was speaking with a temp agency that had called her about an available job, and she also had several telephone conversations with her grandmother, and her friend, Felicia. Tr. at 17. Ms. Hinton testified that there are no records of telephone calls between 2:41 p.m. and 3:09 p.m. on December 21, 2015, because that was the time that Shawn was being seen by Dr. Alligood. Tr. at 18-19.

In the months following Shawn's hospitalization, Ms. Hinton attempted to obtain documentation of Shawn's December 2015 flu shot from Dr. Alligood's office. She testified that she first went to Vidant's billing office to obtain a printout of Shawn's medical encounters for 2015. Tr. at 31. It was then that she learned that Shawn had been marked as a "no show" for the December 21, 2015 appointment. Tr. at 31. Ms. Hinton was informed that Shawn had indeed had an appointment scheduled for December 21, 2015 at 2:30 p.m., but the printout Ms. Hinton received marked him as a "no show." Tr. at 31-32. When Ms. Hinton told the billing staff member that Shawn was present for that appointment, she was directed to Cynthia Manning, Vidant's risk management person. Tr. at 32. Ms. Hinton testified that she was directed by Ms. Manning to complete a form requesting an amendment to Shawn's medical records regarding the December 21, 2015 visit. Tr. at 34. Ms. Hinton completed the form and was informed that an investigation would be conducted into her request. Tr. at 34.

Ms. Hinton also testified that as soon as she learned that Shawn had been marked as a no show for his December 21, 2015 appointment, she went to Dr. Alligood's office to speak with him. Tr. at 33. She testified that Dr. Alligood stated that he did not understand how there was no documentation of the visit but that he would try "to make it right." Tr. at 33. Thereafter, Ms. Hinton stated that she contacted Dr. Alligood on numerous occasions to address the situation. Tr. at 35.

In May 2016, Ms. Hinton received a letter from Vidant stating that her request to amend Shawn's medical records for December 21, 2015 had been denied. Tr. at 36. After receiving this letter, Ms. Hinton testified that she tried contacting Dr. Alligood again to correct the situation. Tr. at 36. She stated that she contacted Dr. Alligood's office at least once a week for six weeks. Tr. at 37. On June 14, 2016, Ms. Hinton testified that she went to Dr. Alligood's office to try to speak to him in person. Tr. at 37. She was informed by Dr. Alligood that he could not do anything without speaking with Vidant first. Tr. at 38. Ms. Hinton continued to call Dr. Alligood in July 2016. She testified that she began recording her telephone conversations with him to document his responses since he seemed to be changing his account of the events. Tr. at 38-39.

Ms. Hinton filed a complaint with HIPAA against Vidant. Tr. at 46. She testified that she filed this complaint because she felt that her son's rights were violated. Tr. at 48. Ms. Hinton stated that Dr. Alligood told her he was not contacted or interviewed by Vidant regarding her request to amend Shawn's medical records. Tr. at 47. Even after speaking with Dr. Alligood in person, Ms. Hinton continued to contact him. She testified that because Dr. Alligood was the physician who saw Shawn on December 21, 2015, he was the only person who could correct the error that had been made, and that is why she continued calling his office. Tr. at 51. Ms. Hinton testified that she worked with her attorney to prepare an affidavit for Dr. Alligood's signature so that he could confirm that he saw Shawn on December 21, 2015 and that Shawn received a flu vaccination. Tr. at 56. Dr. Alligood refused to sign the affidavit and he instructed Ms. Hinton to stop calling

him because Vidant was not going to change their decision to deny her request to amend Shawn's medical records. Tr. at 56-57.

On cross-examination, Ms. Hinton insisted that Dr. Alligood employed a nurse named Lisa. Dr. Alligood testified in his deposition that he did not have any nurses named Lisa. Tr. at 59. He stated that he employed two nurses, one named Kim and another named Angie. Pet. Ex. 12 at 91; Dep. Tr. at 91. Ms. Hinton also testified that she attempted to obtain a listing of all the other patients that were seen by Dr. Alligood on December 21, 2015, but her request was denied due to patient privacy. Tr. at 62-63. Ms. Hinton also testified that she attempted to reach out to Dr. Alligood's office staff including Rosella and Dr. Alligood's nurses, but that they had all been instructed not to speak to Ms. Hinton. Tr. at 72. When questioned about the notation in Dr. Alligood's records that Ms. Hinton called the office to request a refill of Shawn's Trazadone, Ms. Hinton stated that she did not recall calling Dr. Alligood's office on December 23, 2015 to request a refill. Tr. at 103.

Also on cross-examination, Ms. Hinton was asked about the documentation in the medical records, petitioner's exhibit 4 at 58, completed by Dr. Robin Collin that states that Shawn's vaccinations were "up to date. Did not receive flu vaccination." Tr. at 107. Ms. Hinton testified that she specifically told the physician that Shawn had received the flu vaccine and that the notation was an error. Tr. at 107-08.

III. Analysis

a. Standard of Proof to be Applied

A Vaccine Act petitioner must, as a threshold matter in advancing a claim for damages, establish by a preponderance of the evidence receipt of "a vaccine set forth in the Vaccine Injury Table." § 300aa-11(c)(1)(A). The preponderance of the evidence standard means that an allegation is established to be "more likely than not." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed.Cir.2010).

Although contemporaneous documentation of vaccination from a healthcare provider is the best evidence that a vaccination occurred, it is not absolutely required in all cases. *Centmehaiey v. Sec'y of Health & Human Servs.*, 32 Fed. Cl. 612, 621 (1995) ("[t]he lack of contemporaneous documentary proof of a vaccination ... does not necessarily bar recovery"). Indeed, as Vaccine Rule 2 states, "[i]f the required medical records are not submitted, the petitioner must include an affidavit detailing the efforts made to obtain such records and the reasons for their unavailability." Vaccine Rule 2(c)(2)(B)(i). Furthermore, if a petitioner's claim is "based in any part on the observations or testimony of any person, the petitioner should include the substance of each person's proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition." Vaccine Rule 2(c)(2)(B)(i).

Special masters have thus found that vaccine administration occurred even in the absence of direct documentation. In such cases, preponderant evidence was provided in the form of other medical records and/or witness testimony. For example, corroborative, though backward-looking, medical notations have been found to tip the

evidentiary scale in favor of vaccine receipt. *Lamberti v. Sec'y of Health & Human Servs,* No. 99–507V, 2007 WL 1772058, at *7 (Fed.CI.Spec.Mstr. May 31, 2007) (finding multiple medical record references to vaccine receipt constituted adequate evidence of administration); *Groht v. Sec'y of Health & Human Servs,* No. 00–287V, 2006 WL 3342222, at *2 (Fed.CI.Spec.Mstr. Oct. 30, 2006) (finding a treating physician's note—"4/30/97—Hep B. inj. # 1 (not given here) (pt. wanted this to be charted)"—to be sufficient proof of vaccination); *Wonish v. Sec'y of Health & Human Servs.,* No. 90–667V, 1991 WL 83959, at *4 (CI.Ct.Spec.Mstr. May 6, 1991) (finding parental testimony "corroborated strongly by medical records [referring] back to the [vaccination]" to be sufficient to establish vaccine administration).

In addition to corroborative medical records, witness testimony can also help establish a sufficient basis for a finding that a vaccine was administered as alleged. *Alger v. Sec'y of Health & Human Servs,* No. 89–31V, 1990 WL 293408, at *2, 7 (Fed.Cl.Spec.Mstr. Mar. 14, 1990) (oral testimony from a parent and the doctor who administered the vaccine was "more than adequate to support a finding that the vaccine was administered"). The Court of Federal Claims has recognized the existence of precedent supporting the proposition that a court may base a finding of vaccination on lay testimony. *Epstein v. Sec'y of Health & Human Servs.,* 35 Fed. Cl. 467, 478 (Fed.Cl.1996); *see also Brown v. Sec'y of Health & Human Servs.,* 18 Cl.Ct. 834, 839–40 (1989) (proof of vaccination in the absence of contemporaneous medical records established via testimony of petitioner's parent, her personal calendar, and evidence of a charge for the vaccine on the physician's billing statement), *rev'd on other grounds,* 920 F.2d 918 (Fed.Cir.1990); *Gambo v. Sec'y of Health & Human Servs.,* No. 13-691V, 2014 WL 7739572, at *3 (Fed. Cl. Dec. 18, 2014).

In the present case, the undersigned finds that Ms. Hinton has presented barely enough circumstantial evidence to conclude that Shawn more likely than not received the flu vaccine on December 21, 2015. The circumstances of this case are troubling, and the undersigned acknowledges that the lack of documentation regarding the December 21, 2015. However, the undersigned finds that Ms. Hinton is a highly credible witness and that her actions and the circumstantial evidence she obtained have fulfilled her duty to produce preponderant proof of vaccination.

b. Finding of Fact Regarding Proof of Vaccination

The undersigned first acknowledges respondent's arguments that while Dr. Alligood's records show that Shawn was scheduled for an appointment on December 21, 2015, Shawn is marked as a "no show" for the appointment. See Pet. Ex. 9 at 1. There is no dispute that the billing records associated with Dr. Alligood's office and Shawn's Medicaid and BlueCross BlueShield insurance records do not reflect a charge for a December 21, 2015 encounter or for any vaccination administered on that date. See Pet. Ex. 16, 17; Pet Ex. 3 at 30. In addition, there are two reference in Shawn's hospitalization records that indicate he did not receive a flu vaccination. See Pet. Ex. 4 at 58 ("up to date, did not receive flu vaccine."); Pet. Ex. 4 at 166 (the "influenza risk assessment" flow sheet was completed with the notation "No" in the column marked "Influenza Vaccine received since Sept 1). However, Ms. Hinton has presented, in a very detailed and credible account, her recitation of the events which occurred on December 21, 2015, and the undersigned finds her testimony to be highly credible for the reasons set forth below.

First, the actions that Ms. Hinton took and the lengths that she went through to obtain evidence, any evidence that her son was seen on December 21, 2015, are simply not the actions that an individual would take if she did not believe the events occurred as she recalled. In her affidavit, Ms. Hinton details each of the people she contacted and the actions she took to establish that Shawn was seen by Dr. Alligood on December 21, 2015 and that he received a flu vaccination on that day, including: contacting and appearing in person at Vidant to obtain a copy of Shawn's vaccine record and any records of his visit on December 21, 2015; filing a formal request for an amendment of Shawn's records with Vidant and understanding that a formal investigation would take place into her request; calling and attempting to see Dr. Alligood on many, many instances (Dr. Alligood testified that Ms. Hinton called his office 10-15 times a day; see Pet. Ex. 12 at 42); filing a complaint with HIPAA to report a violation of Vidant's record-keeping practices; filing a formal complaint with the Office of Civil Rights; contacting her private insurance company and Medicaid to obtain any documentation regarding the December 21, 2015 visit, and even resorting to recording her telephone conversations with Dr. Alligood. See Pet. Ex. 10. These are actions of a dedicated mother demanding for what she believed was an accurate record for her child. While Ms. Hinton's telephone records from December 21, 2015, are certainly not definitive proof that she was at Dr. Alligood's office with Shawn on December 21, 2015, the records do provide some support for her claim. In addition, there are two medical record references indicating that Shawn did receive a flu vaccine prior to his onset of GBS. Pet. Ex. 6 at 21, 42.5

In reviewing Dr. Alligood's deposition transcript, it is clear that Dr. Alligood does not recall whether Shawn was seen on December 21, 2015, or whether Shawn received a flu shot on that date or any time in 2015. However, Dr. Alligood does seem to imply that he saw Shawn in late 2015 before he left Vidant in December 2015; Pet. Ex. 8. There is no dispute that Shawn had an appointment scheduled for December 21, 2015 at 2:30 p.m. Ms. Hinton testified that she was not working on that date and that Shawn was out of school on December 21, 2015 for his Christmas break. Ms. Hinton described, in detail, the events of the morning of December 21, 2015 leading up to Shawn's appointment, clear details of the appointment with Dr. Alligood, including specifics of her conversations with Dr. Alligood and specific information about the administration of the flu vaccine by Dr. Alligood's nurse to Shawn.

There are definitely some questionable occurrences in this case, such as Dr. Alligood's denial of having a nurse named Lisa, the lack of documentation from any source regarding the December 21, 2015 appointment, and the two notations in the medical records that indicate Shawn may have not received a flu vaccine. However, in reviewing the facts of this case, the testimony and actions of Ms. Hinton, and the circumstantial evidence, the undersigned finds, as a whole, that the evidence presented by Ms. Hinton satisfies the preponderance of the evidence standard. The undersigned therefore finds that Shawn received a flu vaccination on December 21, 2015.

⁵ The undersigned is aware, as respondent has noted, that these medical references occur after Ms. Hinton retained counsel.

IV. Conclusion

Based upon the undersigned's review of the record, including the affidavits, witness statements, deposition testimony, and testimony from the fact hearing, the undersigned findings that petitioner has established by preponderant evidence that Shawn'Quavious D'Adrez received an influenza vaccination on December 21, 2015. Petitioner has thus satisfied the burden as to receipt of a vaccine listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa11(C)(1)(A) and (B).

The parties are encouraged to consider an informal resolution of this claim. Petitioner shall file a joint status report by <u>Friday, April 13, 2018</u>, updating the Court on the status of the parties' settlement discussions.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey Chief Special Master