In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-801V
Filed: February 27, 2017

Nicole Muller on behalf of A.M., a minor child,	*	
Petitioner,	*	Special Processing Unit;
v.	*	Finding of Fact; Date of Vaccination;
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

FINDING OF FACT[1]

Dorsey, Chief Special Master:

On September 2, 2014, 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"). Petitioner initially alleged that her minor daughter, A.M., suffered Guillain-Barre Syndrome ("GBS") following receipt of two half doses of influenza vaccine on November 1, 2011, and December 28, 2011(Petition at 1) before later contending in testimony that A.M. was vaccinated only on December 28, 2011.

The exact date of the vaccination is the principle issue to be resolved in this case at this time. For the reasons described below, the undersigned finds that A.M. was administered an influenza vaccination on November 1, 2011, and that there is not preponderant evidence that any influenza vaccination was administered on December 28, 2011, or any other date in December 2011.

[1] Because this 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).

I. Procedural History

This claim was initiated on September 2, 2014. (ECF No. 1.) Based on the allegations in the petition, the case was assigned to Chief Special Master Vowell as part of the Special Processing Unit ("SPU"). (ECF Nos 4-5.) It was later transferred to the undersigned on September 3, 2015, in anticipation of Chief Special Master Vowell's retirement. (ECF Nos. 27-28.)

The petition alleged that A.M. received a first dose of FluMist vaccine on November 1, 2011, at the Mount Laurel, New Jersey, office of her pediatrician, Barbara Bernstein, and a second dose on December 28, 2011.[3] Petition at 1. Dr. Bernstein's office is part of a "Care Network" affiliated with the Children's Hospital of Philadelphia ("CHOP"). Initial medical records marked as Exhibits 1-5 were filed on September 12, 2014, including records from CHOP and the CHOP Care Network's Mount Laurel, New Jersey, office. (ECF No. 6.)

Subsequent to filing the petition, petitioner moved on September 9, 2014, for authority to issue a subpoena for records from CHOP. (ECF No. 7.) Petitioner contended that, although records had already been produced by CHOP, they were incomplete. (*Id*.) Petitioner's motion was granted (ECF No. 8) and petitioner subsequently filed proof of service for subpoenas to both CHOP and the CHOP Care Network, Mount Laurel (ECF No. 13).

In subsequent updates, petitioner continued to maintain that the records produced by CHOP were incomplete. (ECF Nos. 14-17.) During the course of petitioner's investigation, additional records were filed including: an affidavit of Ms. Muller dated September 25, 2014 (Ex. 6), additional CHOP records (Ex. 7), records from CHOP's division of neurology (Ex. 8), records from CHOP otolaryngology (Ex. 9), and A.M.'s billing records for both CHOP and the CHOP Care Network (Exs. 10-12).

In a status conference conducted with the staff attorney managing this case on April 6, 2015, petitioner's counsel explained that petitioner's investigation of missing records related to petitioner's alleged visit of December 28, 2011, wherein petitioner contended that A.M. received her second, injury-causing, dose of influenza vaccine. (ECF No. 18.) Petitioner cited height and weight measurements within A.M.'s medical records dated December 28, 2011, as evidence that the visit had occurred, but there were no additional records related to that date. (*Id*., citing Ex. 1, p. 205.) Petitioner was granted authority to conduct a deposition of CHOP's records custodian. (ECF No. 19.)

A deposition of Stephen Young was taken on December 18, 2015. (ECF No. 36.) At the time of deposition, Mr. Young was the Interim Director of Health Information Management and the Manager of Release of Information for CHOP, where had had worked for two-and-a-half years. (Ex. 16, p. 8.) During the deposition, Mr. Young

[3] Petitioner's allegation of a two dose series administered on November 1 and December 28 of 2011 was further sworn to in petitioner's affidavit of September 24, 2014. (Ex. 6.)

produced on behalf of CHOP an audiogram record (Ex. 13), as well as records generated using "ChartMaxxx" on December 17, 2015 (Ex. 14) and generated using "Epic" on December 16, 2015 (Ex. 15). The deposition was marked as Exhibit 16.[4]

Mr. Young effectively confirmed that the records produced at the deposition were complete. He testified that CHOP has access to all electronic records produced by the Care Network offices and that he confirmed that no additional paper records for A.M. were available to be produced from Mount Laurel. (Ex. 16, pp. 10, 17-18.) No additional records of the alleged December 28, 2011 visit were uncovered in connection with the deposition.

Following the deposition, the parties were advised on February 9, 2016, of the undersigned's conclusion that any further search for additional records would be unreasonable in light of Mr. Young's testimony that the records were complete. (ECF No. 38.) However, petitioner was afforded an opportunity to seek out further circumstantial evidence supporting her allegations. (*Id*.)

On April 25, 2016, petitioner filed a second affidavit by Ms. Muller.[5] (ECF No. 41.) In the second affidavit, Ms. Muller disavowed the statements of her prior affidavit, indicating that those statements were based on a review of A.M.'s prior medical billing records, and asserting instead that A.M. was given a single influenza vaccination on December 28, 2011, and no vaccination on November 1, 2011. (Ex. 19.) Ms. Muller averred that her other daughter, G.M., and not A.M., was vaccinated on November 1, 2011. (*Id*.)

During a status conference held on June 8, 2016, the undersigned informed the parties that a fact hearing would be necessary to resolve the factual issues surrounding the date of A.M.'s vaccination. (ECF No. 45.) That fact hearing was held before the undersigned in Camden, N.J. on November 16, 2016. (*See* ECF No. 59, Transcript of Proceedings (hereinafter "Tr.").) Four witnesses testified – Barbara Bernstein, M.D., A.M.'s pediatrician; Denise Fox-Sulitzer, R.N., a nurse in Dr. Bernstein's office; Nicole Anne Muller, A.M.'s mother; and Carol Anne Pellegrino, A.M.'s maternal grandmother.

During the hearing additional evidence was presented which was subsequently filed into the record. Specifically, petitioner filed medical records for A.M.'s sister G.M.'s November 1, 2011 medical visit at Mount Laurel (Ex. 21) and a Vaccine Adverse Events Reporting System ("VAERS") form completed by Ms. Muller in October of 2012 (Ex. 22). (ECF No. 56.) Respondent filed a VAERS event accessed online that matched the details of A.M.'s condition (Ex. A). (ECF No. 55.)

In a follow-up status conference, the undersigned encouraged the parties to explore a litigative risk settlement. (ECF No. 60.) Petitioner was also ordered to file updated medical records for A.M. and more complete records and billing records for

[4] A certification page signed by the witness was subsequently filed as Exhibit 17.

[5] The affidavit marked as Exhibit 18 is unsigned. A signed copy was subsequently filed as Exhibit 19.

G.M. (*Id*.) Petitioner filed additional records on January 17, 2017, including updated pediatric and neurology records for A.M (Ex. 24 and 26 respectively), and additional billing and treatment records for 2011 for G.M (Ex. 25). (ECF No. 61.) Following these filings, the undersigned advised the parties that the record appeared ripe for a fact ruling. (ECF No. 64.) Petitioner subsequently filed additional updated medical records and a statement of completion on February 16, 2017. (ECF No. 65-66.)

This case is now ripe for a fact ruling regarding the date of A.M.'s vaccination.

II. Relevant Factual History

A. Medical Records and VAERS

A.M. was born on October 26, 2005. (*See, e.g.* Ex. 4, p. 3 (noting DOB).) Pertinent to this case, she began seeing Dr. Bernstein at the CHOP Care Network, Mount Laurel, on April 25, 2011, for her routine pediatric care when she first established care at a well visit at age five. At that time her prior history was noted to be unremarkable, although it was later reported that she previously had bilateral myringotomy and tubes placed in February of 2010. (Ex. 15, pp 1-9, 52.) At that visit, there was a complaint of congestion in the context of a family history of seasonal allergies. (Ex. 15, p. 3.) She was diagnosed with allergic rhinitis and Mometasone nasal spray was prescribed. (Ex. 15, pp. 5-6.) An immunization history taken as of that date indicates that A.M. had received a number of prior vaccinations, including influenza vaccinations on November 16, 2006, December 18, 2006, and October 30, 2009. (Ex. 15, p. 1.)

A.M. was next seen at the Mount Laurel Office on November 1, 2011.[6] (Ex. 15, pp. 29-38.) The time of the visit was 1:45 PM. (Ex. 15, p. 29.) She was accompanied by her mother, grandmother, and sibling.[7] (*Id.*, p. 31.) A.M.'s temperature, taken at 1:50 PM, was 97.6 ºF. (Ex. 15, p. 30.) The reason for the visit is listed as both "earache" and "flu vaccine." (*Id*., p. 30.) It is specifically noted under the Reason for Visit section of the record that petitioner was "requesting flu mist." (Ex. 15, p. 30.) Additionally, A.M.'s diagnoses for the visit indicates a primary diagnosis of "need for prophylactic vaccination and inoculation against influenza." (*Id*.)

With regard to the earache, Dr. Bernstein's progress note on November 1, 2011, explains that A.M. was previously fit with ear tubes, but that an ENT specialist recently recommended removal due to fluid build-up and hearing issues. (*Id*., p. 31.) Ms. Muller was reportedly unsure of the recommendation. (*Id*.) Dr. Bernstein's record documents a physical examination, with specific and detailed findings of the location of A.M.'s ear

[6] In the intervening period the records show that calls were placed regarding A.M.'s allergy prescription on April 26, 2011, and a prescription for sodium fluoride July 29, 2011. (Ex. 15, pp. 21-28.)

[7] In fact, the record incorrectly states that she was accompanied by her grandfather. Ms. Muller testified, however, that A.M.'s grandmother accompanied her and that A.M.'s grandfather was deceased at that time. (Tr. 74.)

tubes ("tube on left is out of the TM but is pushed against the TM, tube on right is in the cerumen in the canal"). (Ex. 15, pp. 31-32.) Dr. Bernstein's plan was to have Ms. Muller consult an ENT with CHOP for a second opinion. (*Id*., p. 32.) Instruction was given for Ms. Muller to contact CHOP's ENT and a number was provided. [8] (Ex. 15, p. 34.)

Dr. Bernstein's assessment/plan for November 1, 2011, also confirms that A.M. was given an influenza vaccine ("Given flu vaccine. Immunizations were given today.") (Ex. 15, p. 32.) Dr. Bernstein's notes indicate that flu mist was requested ("requesting flu mist"). (Ex. 15, p. 31.) Nurse Fox-Sultizer's notes further reflect that a vaccine questionnaire was presented, that no contraindications were indicated, and that A.M. "presents today for influenza vaccine only" and that the "immunization given as per order." (*Id*.) Additionally, under the medical Orders and Results section, dated November 1, 2011, Nurse Fox-Sulitzer documented that "FluMist 0.2 mL intranasal (now)" was "completed" at "1434" (2:34 PM). (Ex. 15, p. 33.) Patient instructions regarding administration of the intranasal flu vaccine were also documented. (Ex. 15, p. 34.) Nurse Fox-Sulitzer also updated A.M.'s immunization list to include the influenza vaccine on November 1, 2011. (Ex. 15, p 29.)

In all, there are eight separate places in the record of A.M.'s November 1, 2011 office visit where either the need for or the administration of an influenza vaccination is noted. (Ex. 15, pp. 29-38.) Additionally, the influenza vaccine is also reflected on A.M.'s billing records for that date. (Ex. 10, p. 9.)

Significantly, A.M.'s younger sister, G.M., was also seen by Dr. Bernstein on November 1, 2011, for a 12 month well child visit. (Ex. 21.) G.M.'s November 1, 2011 record likewise indicates that her sister was also present. (Ex. 21, p. 3.) G.M. was noted to be due for pneumococcal, influenza, and varicella vaccinations, as well as hepatitis A and MMR, which had been previously deferred. (Ex. 21, p. 5.) According to her record, G.M. received influenza,[9] pneumococcal and varicella vaccinations at that visit (Ex. 21, p. 6).

CHOP has also maintained an additional encounter record within A.M.'s file, dated December 1, 2011, which indicates "PROVIDER MTL NURSE FLU." (Ex. 15, p. 43.) This encounter record is otherwise blank. (*Id*.)

As recommended by Dr. Bernstein on November 1, 2011, A.M. was seen by ENT physician Dr. Steven Handler on December 15, 2011. (Ex. 15, pp. 50-88.) A.M. was diagnosed with serous otitis media, chronic otitis media, and unilateral conductive hearing loss. (Ex. 15, pp. 62, 80.) Dr. Handler recommended surgery for bilateral myringotomy and tube placement as well as adenoidectomy. (Ex. 15, p. 62.)

[8] Records show that appointment was later scheduled for December 15, 2011, via telephone on November 7, 2011. (Ex. 15, p. 39.)

[9] G.M. did not receive FluMist intranasally, but instead received the injected form due to her age. (Ex. 21, p. 1; Tr. 28, 34.) G.M. was administered a "6-35 MO" dose. (Ex. 21, p. 7.)

A further notation within the record for the December 15 office visit indicates that on December 28, 2011, the record was edited to reflect that Rian Jenkins subsequently scheduled A.M.'s surgery with Dr. Handler for March 2, 2012. (Ex. 15, p. 65.) The notation does not indicate whether the surgery was scheduled in the office or by telephone.

Additionally, one CHOP record includes a notation listing a height and weight measurement dated December 28, 2011, among a list of height and weight measurements taken on several different dates. (Ex. 1, p. 201; Ex. 14, p. 77.) No other record exists to confirm that an office visit occurred on December 28, 2011. There is no billing record reflective of a December 28, 2011 office visit or any other care provided on December 28, 2011. (Ex. 10-12.) However, upon admission to neurology on February 28, 2012, A.M. was later reported via parental history to have had a FluMist influenza vaccination given "12/11" or December 2011. (Ex. 1, p. 16.)

Later that year, on October 28, 2012, Ms. Muller completed a Vaccine Adverse Event Reporting System (VAERS) form and submitted it to the CDC. (Ex. 22; Ex. A.) At that time, Ms. Muller placed the date of A.M.'s influenza vaccination at December 28, 2012, and the onset of her GBS symptoms, including pain in all extremities, at January 15, 2012. (Ex. 22.) The CDC subsequently contacted Dr. Bernstein's office to confirm the details of A.M.'s vaccination, before ultimately recording the date of vaccination as November 1, 2011. (Ex. 15, pp. 609, 625; Ex. A.)

B. Dr. Bernstein's Testimony

Dr. Bernstein testified that A.M. received her 2011 influenza vaccination intranasally on November 1, 2011, as reflected in her medical record. (Tr.33-34, 41-43.) Although she did not know the origin of the height and weight measurement dated December 28, 2011, she testified that such a record does not constitute a record of an office visit at her practice, noting that there is no chief complaint or appointment record for such a visit. (Tr.43-44) Based on her records, Dr. Bernstein denied that A.M. received an influenza vaccination in her office on December 28, 2011. (Tr. 46.) Dr. Bernstein also confirmed that she did not at any point during December of 2011 see A.M. without creating a medical record. (Tr. 51.) Dr. Bernstein also testified based on her own habit and practice, she would not have given A.M. a second dose of influenza vaccination following her November 1, 2011, immunization.[10] (Tr. 41-43, 51.)

C. Nurse Fox-Sulitzer's Testimony

Nurse Fox-Sulitzer also testified that A.M. received her influenza immunization intranasally on November 1, 2011, as reflected in her medical record. (Tr. 65) Nurse Fox-Sultizer further confirmed that she was the individual who administered that vaccination. (*Id.*) Like Dr. Bernstein, Nurse Fox-Sulitzer testified that A.M. did not

[10] Dr. Bernstein explained that the first time a child receives an influenza vaccination, they are typically given a second booster dose about a month later. (Tr. 13-14.) After that first immunization, a second booster is not considered necessary and is not recommended. (Tr. 13-14, 42.)

present to Dr. Bernstein's office in December of 2011 nor did she receive a second dose of influenza vaccine in December of 2011. (Tr. 65-66.) With regard to the encounter record dated December 1, 2011, nurse Fox-Sulitzer explained that the notation "PROVIDER MTL NURSE FLU" would suggest that the encounter was intended for nurse administration of an influenza vaccination, but that no administration is suggested by that record, because it lacks any notation of a vaccine lot number or any notation of who would have administered it. (Tr.63-65.)

D. Mr. Stephen Young's Testimony

In a prior deposition, Stephen Young testified on behalf of CHOP as a designated records custodian. As noted above, Mr. Young testified that all electronic records produced by the Care Network offices were produced in this case and further confirmed that no additional paper records for A.M. were available to be produced from Mount Laurel. (Ex. 16, pp. 10, 17-18.) Mr. Young also testified that the date and time stamp on the height and weight measurement does not necessarily indicate that the data was recorded on that date. (Ex. 16, pp. 19-20, 50-51.) Mr. Young indicated that it cannot be determined from the records whether an actual site visit occurred on December 28, 2011, or not. (Ex. 16, pp. 13-14, 16, 22.)

E. Ms. Muller's Affidavits and Testimony

1. Affidavits

Initially, Ms. Muller submitted an affidavit dated September 25, 2014, in which she averred that A.M. received a first dose of FluMist influenza vaccine on November 1, 2011, and a second dose of FluMist influenza vaccine on December 28, 2011. (Ex. 6.) Subsequently, she submitted a second, contradictory affidavit dated April 28, 2016, in which she averred that A.M. only received one influenza vaccine in 2011, and that it was administered on December 28, 2011, and not November 1, 2011. (Ex. 19, p. 1.)

In her second affidavit, Ms. Muller averred that it was her other daughter G.M., and not A.M., who received an influenza vaccine on November 1, 2011. (*Id*.) Ms. Muller denied that A.M. had any appointment on November 1, 2011. (*Id*., p. 2.) Ms. Muller noted that her normal habit would be to schedule A.M.'s well visits on A.M.'s days off from school. (Ex. 19, p. 1.) She reasoned that A.M. would have been in school on November 1, 2011, but would have been on Christmas break on December 28, 2011. (*Id*., pp. 1-2) G.M., on the other hand, was an infant and would not have been in school yet. (*Id*., p. 1.)

Ms. Muller described the alleged December 28, 2011, visit as being a follow-up for "ear infections and high blood sugar" as well as snoring and a potential surgery for adenoid removal. (Ex. 19, p. 2.) She indicated that the December 28, 2011, visit was a follow-up to A.M.'s December 15, 2011, visit where those issues were originally raised. (*Id*.)

Further, contrary to her first affidavit, Ms. Muller indicated that she distinctly recalled that A.M. was administered an injection and not a mist. (*Id*.) Ms. Muller further averred that A.M. would not have been present at the November 1, 2011, office visit where G.M. received her vaccination, reasoning that A.M. would have been in school. (*Id*.)

2. Fact Hearing Testimony

During the fact hearing, Ms. Muller testified that she had a clear recollection that her younger daughter, G.M., received her one year immunizations at the November 1, 2011, visit, but that she could not recall A.M.'s appointment on that date. (Tr. 73, 101.) Ms. Muller testified on direction examination that she would have scheduled G.M.'s one year well visit for a time when A.M. was in school. (Tr. 73.) She also felt that a December 28, 2011, well visit for A.M. would be consistent with her habit and practice of scheduling visits around A.M.'s school hours. (Tr. 71-72.) Ms. Muller testified that December 28, 2011, was the date of A.M.'s 2011 influenza vaccination and that she is very certain of that fact. (Tr. 71.) She noted that the date remains in her memory, because she had to repeat it several times when she was providing medical histories during the period when A.M. was becoming symptomatic and being seen repeatedly for what was later diagnosed as GBS. (Tr. 76.)

Ms. Muller confirmed on cross-examination, however, that during the 2011-2012 school year, A.M. was in half-day kindergarten and was released from school at noon.[11] (Tr. 98.) She subsequently reiterated on later questioning by the undersigned that she would not have taken A.M. out of school for a well-visit, but also acknowledged that she had not recalled the earache noted in the record of A.M.'s November 1, 2011 visit, suggesting A.M. could have been taken out of school for that reason.[12] (Tr. 111.) Furthermore, Ms. Muller testified that at the time she completed her first affidavit – which indicated that A.M. received an influenza vaccination on November 1, 2011 – she did believe at that time that A.M. was vaccinated on that date. (Tr. 102.) Contrary to the above-discussed testimony, she testified that this affidavit was based on her reasoning that she would have brought both her daughters for well visits at the same time. (*Id*.) Based on a review of A.M.'s medical records during the hearing, Ms. Muller also agreed that it appeared that she had called to schedule A.M.'s subsequent December 15, 2011 ENT appointment on November 7, 2011, following Dr. Bernstein's examination and recommendation on November 1, 2011. (Tr. 96.)

Ms. Muller was unable to provide any particulars regarding what happened at the December 28, 2011 visit. (Tr. 110-11.) She confirmed that she has no personal

[11] As noted above, A.M.'s medical records reflect that the November 1, 2011, appointment was at 1:45 PM. (Ex. 15, p. 29.)

[12] Ms. Muller initially testified that if A.M. had been seen for a sick visit on November 1, 2011, she would not have received an influenza vaccination, but subsequently agreed that A.M. was not found to have an infection and therefore would not have been precluded from having her vaccination. (Tr. 111-12.)

documentation supporting her recollection of the alleged December 28, 2011, visit.[13] (Tr. 109-10.) Contrary to her second affidavit, on the detail of whether A.M. received her influenza vaccination as a nasal mist or an injection, Ms. Muller testified that she could not be positive. (Tr. 76.)

Ms. Muller also recounted during the hearing that she had discussed A.M.'s influenza vaccine with the neurologist, including the fact that she reported A.M.'s vaccination date as December 28, 2011, and that he had told her that A.M.'s GBS was secondary to the vaccination.[14] (Tr. 113-15.)

Ms. Muller could not recall whether she took A.M. to Dr. Bernstein's office on December 1, 2011. (Tr. 73-74.)

F. Ms. Pellegrino's Testimony

Ms. Pellegrino, A.M.'s maternal grandmother, submitted an affidavit in which she averred that she routinely attends A.M.'s medical appointments and that A.M. had a medical appointment in December of 2011 sometime between Christmas and New Year's. (Ex. 20.) During the hearing, Ms. Pellegrino testified that she recalled G.M.'s November 1, 2011, office visit with Dr. Bernstein, but believed that A.M. would not have been there due to being in school. (Tr. 150-51, 153.) She acknowledged, however, that she had no independent recollection of the visit. (Tr. 151.)

III. Legal Standard To Be Applied

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring). Moreover, the Vaccine Act states that "[t]he special master or court may not make such a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Nonetheless, special masters are not bound by the reports, summaries, or conclusions contained in the medical records. § 300aa-13(b)(1). Rather, the special master must consider the entire record. *Id*.

However, medical records do ordinarily "warrant consideration as trustworthy evidence." *Cucuras v. HHS,* 993 F.2d 1525, 1528 (Fed.Cir.1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters

[13] Although she maintained an appointment calendar, she has been unable to locate it. (Tr. 109; *See also* Status Report, February 16, 2017 (ECF No. 67).)

[14] While there is a medical record indicating that Ms. Muller provided a history that A.M. received an influenza vaccine in December of 2011, there is no medical record of a history of vaccination specific to December 28, 2011. Further, there is no medical record corroborating Ms. Muller's testimony that a neurologist attributed the cause of A.M.'s GBS to her influenza vaccine.

frequently accord more weight to the medical records. *See, e.g., Reusser v. HHS.,* 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later."); *See also Vergara v. HHS*, 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded later in medical histories, affidavits, or trial testimony.").

Nonetheless, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd* 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992). "Medical records are only as accurate as the person providing the information." *Parcells v. HHS*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec Mstr. July 18, 2006).

IV. Finding of Fact Regarding the Date of Vaccination

Mindful of the above considerations, the undersigned finds in this case that, when the record is viewed as a whole, the evidence preponderates in favor of an influenza vaccination having occurred on November 1, 2011, and not on any date in December of 2011.

A. A.M. Did Receive an Influenza Vaccination on November 1, 2011

It is clear from A.M.'s medical records that she received an influenza vaccination on November 1, 2011. This fact is recorded in multiple places, including A.M.'s immunization history, Dr. Bernstein's progress note, and nurse Fox-Sulitzer's note and in the billing record. (Ex. 4, p. 3; Ex. 15, pp. 31-32; Ex. 10, p. 9.) Additionally, the encounter record for A.M.'s November 1, 2011 office visit indicates that receiving an influenza vaccine was one purpose of that visit. (Ex. 15, p. 30.) The record further reports that a FluMist vaccine was requested and confirms that nurse Fox-Sulitzer reviewed a vaccine questionnaire with Ms. Muller prior to administering the vaccine. (Ex. 15, pp. 30-31.) Moreover, A.M.'s billing records confirm that petitioner was billed for an influenza vaccination on November 1, 2011. (Ex. 10, p. 9.) Additionally, both Dr. Bernstein and nurse Fox-Sulitzer testified that A.M. received her influenza vaccination on November 1, 2011, as recorded in the medical records.

To the extent that petitioner contends that it was her other daughter G.M., and not A.M., who received an influenza vaccination on November 1, 2011 (Ex. 19, ¶ 1), G.M.'s own medical record for November 1, 2011, records a separate influenza vaccination administered to G.M. (Ex. 21, p. 5.) G.M.'s records show that G.M. was administered an injected influenza vaccination, which was specifically noted to be dosed for 6-35 month olds and which is distinct from the intranasal FluMist documented in

A.M.'s records. (*Id*.) This vaccination was also included within G.M.'s separate billing record. (Ex. 25, p. 19.)

As noted above, contemporaneous medical records typically "warrant consideration as trustworthy evidence." *Cucuras,* 993 F.2d at 1528. Moreover, given the extensiveness of the notations included in A.M.'s medical records regarding the influenza vaccination, it is unlikely that they would have been made in error. Where medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. HHS*, No. 03-1585V, 20015 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). In any event, the undersigned declines to credit Ms. Muller's testimony over the contemporaneous records and testimony of the health care providers for the reasons discussed below. Thus, upon consideration of the record as a whole, the undersigned concludes that there is preponderant evidence that A.M. received an influenza vaccination on November 1, 2011, as reflected in the contemporaneous medical record.

B. There is Not Preponderant Evidence that A.M. received an Influenza Vaccination on December 28, 2011 or any other date in December 2011

In contrast to the clear record of A.M.'s November 1, 2011 influenza vaccination, there is no contemporaneous medical record suggesting that A.M. received an influenza vaccination on December 28, 2011, as petitioner alleged. The only evidence even suggestive of any medical care occurring on December 28, 2011, is a height and weight measurement marked with that date. (Ex. 1, p. 201; Ex. 14, p. 77.) But Dr. Bernstein testified that the height and weight measurement is not evidence of a primary care office visit in her office (Tr. 43-44, 51), let alone constituting evidence that an influenza vaccine was administered. The notation "PROVIDER MTL NURSE FLU," dated December 1, 2011, likewise fails to establish that any vaccination occurred. As nurse Fox-Sulitzer testified, although it suggests a nurse visit was intended, it lacks any actual notation of the administration of a vaccination.[15] (Tr. 63-65)

The records suggest that the height and weight measurement associated with A.M.'s December 15, 2011, office visit with Dr. Handler could have been edited by Dr. Handler's office to reflect that A.M.'s myringotomy and tube placement had subsequently been scheduled on December 28, 2011. (Ex. 15, p. 65.) In that regard, CHOP's record custodian, Mr. Young, testified that the date and time stamp on the height and weight measurement does not necessarily indicate that the data was recorded on that date. (Ex. 16, pp. 19-20, 50-51.) Mr. Young testified that it cannot be determined from the records whether an actual site visit occurred on December 28, 2011, or not. (Ex. 16, pp. 13-14, 16, 22.)

[15] Of note, petitioner has never asserted that A.M. was vaccinated on December 1, 2011. Moreover, Ms. Muller did not have any recollection of an office visit occurring on that date. (Tr. 73-74.)

Significantly, A.M.'s billing records do not reflect any influenza vaccination on or around December 28, 2011, nor any office visit or any other type of care. (Exs. 10-12.) Nor, for that matter, did Ms. Muller provide any hearing testimony describing the nature of the visit she alleges to have occurred on that date.[16] Both Dr. Bernstein and nurse Fox-Sulitzer testified that A.M. was not seen in Dr. Bernstein's office at any point during December 2011. (Tr. 46, 51, 65-66.)

Further weighing against any December 2011 vaccination date is the fact that A.M.'s immunization history includes several prior influenza immunizations, including two half doses administered in November and December of 2006, and a further single dose administered in October of 2009.[17] (Ex. 4, p. 3.) Thus, in light of A.M.'s prior immunization history, it would not have been medically necessary or expected for A.M.'s 2011 influenza vaccination to have included a second dose following her clearly documented November 1, 2011, vaccination. (Tr. 13-14.) In that regard, Dr. Bernstein denied that A.M. received a second dose of influenza vaccine in 2011 in addition to her November 1, 2011 vaccination. (Tr. Tr. 41-43, 51.) Dr. Bernstein explained that a second dose for A.M. would not have been in keeping with her normal practice. (*Id*.)

A.M.'s neurology intake dated February 28, 2012, also includes a notation indicating that Ms. Muller gave a history in which she stated that A.M. was administered an influenza vaccine in "12/11" or December 2011. (Ex. 1, p. 16.) Additionally, Ms. Muller completed and submitted a VAERS form in October of 2012 that placed A.M.'s influenza vaccination on December 28, 2012. (Ex. 22.) However, because they reflect later parental histories and not the contemporaneous actions or observations of A.M.'s physicians or nurses, these records carry less weight. *See, e.g. Vergara v. HHS*, 08-882V, 2014 WL 2795491,*4 (Fed. Cl. Spec. Mstr July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); *see also R.K. v. HHS*, No. 03-632V, 2015 WL 10936124, at *76 (Fed. Cl. Spec. Mstr. May 23, 2016) (finding that later medical histories contained in the medical records were less reliable than earlier medical records).

C. Neither Ms. Muller's Nor Ms. Pellegrino's Testimony Can Be Credited over the Medical Records

As noted above, contemporaneous medical records typically "warrant consideration as trustworthy evidence." *Cucuras,* 993 F.2d at 1528. Thus, special masters in this Program have traditionally declined to credit later testimony over contemporaneous records unless it is "clear, cogent, and consistent." (*See, e.g. Stevens v. HHS*, 90-221V, 1990 WL 608693, *3 (Cl. Ct. Spec. Mstr. 1990); *see also*

[16] The description contained in Ms. Muller's second affidavit is consistent with A.M.'s December 15, 2011, appointment with Dr. Handler. (Ex. 19.)

[17] In her second affidavit, Ms. Muller called into question the details of A.M.'s prior vaccination history, but ultimately averred that she could not remember whether A.M. had previously received a prior two-dose series of influenza vaccine. (Ex. 19, pp. 1-2.)

Vergara, 2014 WL 2795491,*4 ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") Here, the testimony by Ms. Muller has been inconsistent.

Ms. Muller initially swore in her first affidavit that an influenza vaccination *was* administered to A.M. on November 1, 2011. (Ex. 6.) During the hearing, she explained that this affidavit was based on her belief at that time that she would have scheduled simultaneous appointments for A.M. and G.M. (Tr. 101-02.) In her second affidavit, she contradicted her first affidavit and asserted that A.M. did not receive a vaccination on that date and further reasoned that A.M. would not likely have been at the appointment due to being in school. (Ex. 19.) At the hearing, Ms. Muller acknowledged that she could not remember whether A.M. had a November 1, 2011, appointment. (Tr. 101.)

With regard to the alleged December 28, 2011 visit, Ms. Muller's testimony was supported in part by her assertions regarding her habit and practice of scheduling well-visit appointments around A.M.'s schooling. Ms. Muller was unable to provide any details during the hearing regarding the December 28, 2011 visit, but suggested that such a visit would have been more appropriate than a November 1, 2011 visit due to the Christmas break from school. (Tr. 71-72, 110-11.) However, Ms. Muller's testimony was inconsistent on whether it would have been consistent with her habit and practice to bring A.M. to the November 1, 2011 appointment with her sibling, G.M. (Tr. 73, 101-02.) Moreover, she acknowledged that A.M. was only in school for half-days during the 2011-2012 school year, and in any event ultimately testified that she may have taken A.M. out of school on November 1, 2011, due to her earache, which Ms. Muller had not initially recalled. (Tr. 98, 111.)

Ms. Muller was similarly inconsistent regarding the details of A.M.'s vaccination. In her initial affidavit, she indicated that A.M. had received two FluMist doses. (Ex. 6.) In her second affidavit, she averred that A.M. had received only one influenza dose and indicated that she distinctly remembered that it had been injected, because the nurse had to "sweet talk" A.M. into receiving the injection. (Ex. 19, p. 2.) At the hearing, Ms. Muller acknowledged that she could not be positive whether A.M. received a nasal mist or an injection. (Tr. 76.)

Ms. Pellegrino's affidavit provided only vague support for Ms. Muller's testimony, being unable to recall any specific details of the alleged encounter. (Ex. 20.) During the hearing, however, Ms. Pellegrino disclaimed any independent recollection. (Tr. 150-51.)

In this case, viewing the record as a whole, Ms. Muller's and Ms. Pellegrino's testimony appears far less reliable than the medical records. Although the undersigned found both witnesses credible in that they appeared to be truthful people desiring to provide honest testimony, their testimony suffered too many significant inconsistencies to be credited over the contemporaneous record. Contemporaneously recorded 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; *Murphy*, 23 Cl. Ct. at 733 (citing *United States v. United States 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 entitle to little evidentiary weight.")

VI. Conclusion

Based on all of the above, the undersigned finds that A.M. received an influenza vaccination on November 1, 2011, and not during December of 2011.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master