In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 29, 2017

NOEMI FRETTE *on behalf of her minor child* N.F.,	*	PUBLISHED
Petitioner,	*	No. 14-1105V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Decision on Entitlement; Parties' Choice of Decision without a Hearing; Diphtheria-Tetanus-Acellular Pertussis ("DTaP") Vaccine; Epilepsy; Onset.
Respondent.	*	

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner.
Darryl R. Wishard, United States Department of Justice, Washington, DC, for respondent.

DECISION ON ENTITLEMENT[1]

On November 13, 2014, Noemi Frette ("petitioner") filed a petition on behalf of her minor child, N.F., under the National Vaccine Injury Compensation Program (the "Vaccine Act" or the "Vaccine Program").[2] Petitioner alleged that as a result of receiving a diphtheria-tetanus-acellular pertussis ("DTaP") vaccine on April 2, 2013, N.F. suffered injuries that were subsequently diagnosed as epilepsy, with onset occurring within approximately one week. Respondent filed a Rule 4(c) report recommending against compensation, in part because he disputed the alleged onset. After the parties filed reports from their respective experts in pediatric neurology and they were offered a hearing date, the parties agreed and requested that entitlement should be determined without a hearing.

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), **because this decision contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the decision is posted on the court's website, each party has 14 days to file a motion requesting 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). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

After a full review of the entire record, I hereby **DENY** petitioner's motion for a ruling resolving entitlement in her favor. Under the well-known *Althen* test, petitioner must establish the following three factors by preponderant evidence: (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) that the alleged injury occurred within a medically acceptable time frame after the vaccination. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In this case, the principal challenge for petitioner is to establish *Althen* prong three, that the onset of N.F.'s injury occurred within a medically acceptable time frame. Because petitioner has failed to do so, she is not entitled to compensation and her claim must be dismissed.[3]

I. Procedural History

On November 13, 2014, petitioner filed her claim and her signed statement of events. She alleged that within one week after receiving a DTaP vaccine on April 2, 2013, her minor son N.F. began experiencing episodes while he was breastfed. N.F. would pull away, exhibit a weird look on his face, stiffness throughout his body, and a failure to appropriately respond to stimuli. Petitioner alleged that beginning in June 2013, N.F.'s staring episodes turned into more pronounced epileptic episodes. She notes that in March 2014, N.F. was formally diagnosed with epilepsy. Petitioner alleged that these symptoms were caused in fact by the DTaP vaccine.[4] Petitioner filed medical records on November 21, 2014, and on March 18, 2015. Petitioner's ("Pet.") Exhibits ("Exs.") 1-8 (ECF No. 6); Pet. Ex. 9 (ECF No. 11).

On April 13, 2015, respondent filed a Rule 4(c) report recommending against compensation. Respondent's ("Resp.") Report ("Rep't.") (ECF No. 14). In the report, respondent agreed that N.F. has complex absence seizures that have been diagnosed as epilepsy, but disagreed to the alleged onset at one week after the DTaP vaccine. *Id.* at 6. Respondent contended that petitioner first reported an onset of nine months after vaccination to N.F.'s primary care provider, a Dr. Webb; petitioner later reported an onset of two months after vaccination to a neurologist; and either time period is too long for a causal association with the DTaP vaccine. *Id.* at 7. On April 14, 2015, I ordered petitioner to file an expert report and then for respondent to file a responsive expert report. Order (ECF No. 15).

On July 27, 2015, petitioner filed a motion to amend the schedule. She acknowledged that petitioner's statement of events (i.e., first symptoms occurring shortly after the vaccination) was not consistent with Dr. Webb's contemporaneous records. Petitioner stated that she made several complaints to Dr. Webb. Petitioner requested additional time to get additional information from Dr. Webb and then indicate how she wished to proceed. Pet. Motion ("Mot.") for Extension of Time

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[3] Pursuant to Section 300aa–13(a)(1), in order to reach my decision, I have considered the entire record including all of the medical records, statements, expert reports, and medical literature submitted by the parties. This decision discusses the elements of the record I found most relevant to the outcome.

[4] The petition alleged: "[B]y experiencing the initial signs of an encephalopathic event less than 72 hours after receipt of the DTaP vaccination, N.F.'s claim qualifies as a 'Table' claim qualified to a presumption of causation." Petition at 5. However, petitioner later abandoned the Table injury claim. See e.g., Petitioner's Motion for a Decision on the Record ("Petitioner does not allege that N.F. suffered a Table injury, and only makes a causation-in-fact claim").

(ECF No. 19.) On August 17, 2015, petitioner filed a letter from Dr. Webb, which states that his medical records were incomplete and did not reflect the mother's reports of an adverse reaction closer to the date of the vaccine. Pet. Ex. 10 (ECF No. 20). On September 28, 2015, petitioner filed a status report indicating: "Given the fact that Dr. Webb confirms the contemporaneous recordation of a vaccine adverse effect, as well as his recommendation of no further vaccinations, petitioner has contacted an expert for an opinion." Petitioner requested additional time to file this expert report. Status Report (ECF No. 21). I granted petitioner's request. Order (Non-PDF) entered September 28, 2015.

On November 30, 2015, petitioner filed pediatric neurologist Dr. Anthony Rodrigues's initial expert report and his curriculum vitae. Pet. Exs. 11-12 (ECF No. 22). Respondent filed pediatric neurologist Dr. Elaine Wirrell's initial expert report, medical literature cited therein, and curriculum vitae on January 22, 2016. Resp. Exs. A-V (ECF No. 23-25). After a Rule 5 status conference on March 24, 2016, petitioner filed Dr. Rodrigues's supplemental expert report on June 23, 2016. Pet. Ex. 13 (ECF No. 28). Petitioner filed a signed statement from Mr. Ryan Frette (N.F.'s father) on September 19, 2016. Pet. Ex. 14 (ECF No. 33).

Following a status conference on October 4, 2016, the parties agreed that petitioner would submit a demand to respondent. Order (ECF No. 34). Petitioner did so on October 7, 2016. Status Report (ECF No. 35). On November 4, 2016, respondent indicated he had considered petitioner's demand and elected to proceed to an entitlement hearing. Status Report (ECF No. 36). On November 22, 2016, I ordered the parties to propose dates for an entitlement hearing in January 2018. Order (ECF No. 37). After discussing with one another, the parties requested a status conference which was held on January 10, 2017. During the status conference, the parties indicated their agreement that entitlement could be resolved without a hearing. Order (ECF No. 38).

Thereafter, on March 10, 2017, petitioner filed the medical literature cited in Dr. Rodrigues's two reports. Pet. Exs. 15-26 (ECF Nos. 39-40). On the same day, petitioner filed a motion for judgment on the record as it stood. Pet. Motion (ECF No. 41). Respondent filed a response to petitioner's motion on March 20, 2017. Resp. Response (ECF No. 42). Petitioner filed a reply on March 27, 2017. Pet. Reply (ECF No. 43). This matter is now ripe for adjudication.

II. Applicable Legal Standards

A. Petitioner's Overall Burden of Causation in Vaccine Program Claim[5]

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and

[5] Decisions of special masters (some of which I cite in this decision) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). Decisions from the Court of Federal Claims are only binding in the same case on remand. *Id.* Federal Circuit decisions concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 Fed. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504278, at *7 n. 12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

generosity.'" *Rooks v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation in the Program, a petitioner must prove either: (1) that he suffered an injury listed on the Vaccine Injury Table, within a corresponding period of time after receiving a corresponding vaccine (a "Table Injury") or, in the alternative, (2) that he suffered an injury that was actually caused by a listed vaccine (an "off-Table Injury"). *See* §§ 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).

A petitioner bringing either a Table injury or an off-Table injury must prove entitlement by a preponderance of the evidence. § 13(1)(a). This has been interpreted to mean "more likely than not." *Moberly*, 931 F.2d at 873. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not be found entitled to compensation based solely on his or her own assertions; petitioner must derive support from either medical records or by the opinion of a competent physician. § 13(a)(1).

In the present case, petitioner does not allege a Table injury. Thus, she has the burden of proving causation in fact, by establishing each of the three *Althen* factors: "(1) a medical theory causally connective the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 132 (2011), *aff. per curiam*, 463 Fed. Appx. 932 (Fed. Cir. 2012) (specifying that each *Althen* factor must be established by preponderant evidence).

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received *can* cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). The 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. To establish *Althen* prong one, petitioner is not required to provide 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; *Althen*, 418 F.3d at 1274). "Where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury . . . Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380.

Under *Althen* prong two, petitioner must prove a logical sequence of cause and effect, indicating that the vaccine "did cause" the injury in this particular case. This prong is usually supported by facts derived from the petitioner or other vaccinee's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; Capizzano, 440 F.3d at 1326; *Grant v. Sec'y of Health*

& Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Some weight is given to the opinions and views of treating physicians, who are believed to be in the best position to evaluate whether there is a logical sequence of cause and effect. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326. Particular weight is given to medical records that are created contemporaneously to treatment. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

While the special master must consider and carefully evaluate treating physicians' medical records or opinions, the special master is not bound to adopt the same. *See* § 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 the 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 or rebutted"). As with expert testimony offered to establish a theory of causation, treating physicians' opinions 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); *Caves*, 100 Fed. Cl. at 356.

Under the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. This has been equated to mean a "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 of what is a medically acceptable timeframe must correlate with the theory of how the vaccine can cause the injury (*Althen* prong one). Id.; *see also Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011); *Koehn v. Sec'y of Health & Human Servs.*, 773 F.3d 1239 (Fed. Cir. 2014).

Additionally, "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." *Pafford*, 451 F.3d at 1358 (citing *Capizzano*, 440 F.3d at 1326). In *Pafford*, the Federal Circuit further explained:

> If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor.

Id. at 1358. Thus, the *Althen* prongs are closely linked and they inform one another.

B. Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Medical records that are created

contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked propositions that (1) sick people visit medical professionals; (2) sick people honestly report their health problems to those professionals; and (3) 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*, 993 F.2d at 1525. 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).

When contemporaneous medical records conflict with later accounts (i.e., affidavits or oral testimony), special masters generally give greater weight to the medical records. *Murphy v. Sec'y of Health & Human Servs.*, No. 90-88V, 1991 WL 74931, at *4 (Fed. Cl. Spec. Mstr. April 25, 1991). In *Murphy* and many other cases, the tension is between contemporaneous medical records and testimony from the petitioner seeking compensation. *See, e.g., Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("written 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").

However, in *Murphy*, the special master proposed alternative scenarios, for example: "If a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Murphy*, 1991 WL 74931, at *4.

The Court of Federal Claims later cited *Murphy* for the proposition that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (*citing Murphy*, 1991 WL 74931, at *4). The Court did not address the scenario in which a disinterested person later indicates that the entry was incorrect, but did provide that later testimony "must be consistent, clear, cogent, and compelling to outweigh medical records prepared for the purpose of diagnosis and treatment." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998).

More recently, the Court of Federal Claims has recognized 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. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014). In *La Londe*, the Court provided that the special master should consider all of these possibilities, as part of his or her responsibility to "consider all relevant and reliable evidence contained in the record." *Id.* at 204 (citing § 12(d)(3); Vaccine Rule 8). *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that 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 rational).

C. Consideration of Expert Testimony and Medical Literature

In addition to establishing the facts at issue, a petitioner often presents expert opinions and medical literature in support of his or her claim, particularly in order to present a theory of causation. Respondent frequently offers his own experts' opinions and medical literature in order to rebut a petitioner's case. Where both sides offer expert opinions, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 80-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F3.d at 1339). Weighing the relative persuasiveness of competing expert opinions, based on the particular experts' credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act"). In this case, I have fully reviewed the experts' reports and the medical literature submitted, in addition to the other evidence submitted, to reach my conclusion.

III. Factual Evidence

A. N.F.'s Condition Before the DTaP Vaccination

The medical records establish that N.F. was born on February 2, 2013. On February 7, 2013, his parents brought N.F. to a "post-hospital evaluation" with pediatrician Dr. Sergio Sotelo. Pet. Ex. 3 at 3-5. Dr. Sotelo's detailed records note that the hepatitis B vaccine was refused at birth. *Id.* at 3. Dr. Sotelo examined N.F. and talked with the parents about various matters, including:

> "Long discussion regarding vaccines. Father ok with vaccines, mother hesitant. Pros and cons discussed. Parents understand they would have to find another practice if they choose not to vaccinate. They will discuss it."

Id. The following day, February 8, 2013, Dr. Sotelo saw N.F. to check for jaundice. *Id.* at 6.

During the next visit on February 11, 2013, Dr. Sotelo checked N.F. again for jaundice, administered a Vitamin K injection, and noted "need for prophylactic vaccination and inoculation." *Id.* at 7. At the 10-14 day wellness appointment on February 13, 2013, N.F.'s circumcision was completed and the parents were given a consent for the Hepatitis B vaccine. *Id.* at 9-10. At the one-month wellness visit on March 7, 2013, the mother was instructed to review information sheets for N.F.'s two-month vaccines and to bring infant Tylenol to the two-month wellness visit. *Id.* at 11-12.

On April 2, 2013, the mother brought N .F. to his two-month wellness appointment with Dr. Sotelo. *Id.* at 13-14. N .F.'s development was normal. *Id.* at 13. Vaccines were again discussed "at length." *Id.* at 14. The decision was made to "proceed with DTaP, Hib, PCV one at a time. Defer IPV, Rotavirus." The DTaP vaccine was administered. The mother was told to bring N.F. back for Hib and PCV prior to the four-month well child visit. The chart further noted: "Discussed need for vaccines, reviewed side effects of any vaccines given." *Id.* The records reflect that Dr. Sotelo and his practice performed thorough examinations, took significantly detailed histories, and gave the parents advice and counseling. However, this was N.F.'s last visit to Dr. Sotelo's practice.

B. N.F.'s Condition Between the DTaP Vaccination on April 2, 2013 - February 2014

The evidence submitted is less consistent regarding N.F.'s condition following the DTaP vaccination. In an effort to organize and fully consider this evidence, I have separated it by source.

i. Parents' Statements

The petitioner in this case is N.F.'s mother, Ms. Naomi Frette. During the time in question, she was N.F.'s primary caregiver. She also indicates that she had more communication with and attended more appointments with N.F.'s medical providers. In a statement signed on October 20, 2014, the mother states that on April 2, 2013, after N.F. received the DTaP vaccination, he began to run a fever and he was fussy. Pet. Ex. 1, ¶ 3. On April 3, 2013, N.F. continued running a fever, was very fussy, and could not be consoled; she gave N.F. Tylenol as directed by Dr. Sotelo. *Id.* at ¶ 4. She states that N.F. remained feverish and fussy for several days. *Id.* She then states:

> "One week after the vaccine, N.F. suddenly pulled away when he breastfed. Along with the pulling away, N.F. had a weird look on his face and stiffness throughout his body. N.F. exhibited a lack of response to his environment, specifically, by not responding when spoken to and looked upon. N.F. seemed not to recognize familiar people or things or sensations, and was in what I would describe as a semi-conscious daze. Within a minute of these incidents, N.F. would latch back on and continue to breastfeed. N.F. continued to do this every time he nursed and slept, over the next few weeks."

Id. Despite observing these symptoms, the parents did not call or schedule an appointment with Dr. Sotelo or any other medical provider. The mother states that "during this time, [she] began researching a new pediatrician." *Id.*, ¶ 5. She scheduled an appointment for N.F. with another pediatrician, Dr. Mark Webb, in May 2013. *Id.* The mother recounts:

> "During this period, beginning specifically in June of 2013, N.F.'s semi-conscious episodes turned into more pronounced episodes with eye widening and breathing without behavioral arrest. These episodes were lasting up to one minute, associated with a mechanical smile/ grimace and the same lack of response to his environment. N.F. has no prior history of episodes of staring or unresponsiveness or convulsions. These episodes were happening approximately 15 times a day. N.F. had them all throughout the night, as well. I spoke with Dr. Webb at our initial visit about the signs and symptoms I was seeing in N.F. Dr. Webb and I talked several times about the neurological symptoms I was seeing with N.F."

Id. The mother does not recount anything specific said by Dr. Webb during these visits.

The mother states that during an appointment on February 4, 2014, Dr. Webb "was unwilling (or perhaps unable given his qualifications as a pediatrician) to ultimately concludes that N.F. was experiencing seizures." *Id.* at ¶ 6. Therefore, Dr. Webb referred N.F. to a pediatric neurologist. Dr. Korwyn Williams.

In a signed statement dated September 9, 2016, the father recalls the mother telling him that N.F. was "a little fussy and slightly warm" on the night he received the vaccination and that she had given him Tylenol, as Dr. Sotelo had directed. Pet. Ex. 14, ¶ 2. The father states that "within the next few days," the mother asked him to observe N.F. while nursing. *Id.* at ¶ 3. The father states that N.F. would pull away from the mother's breast, stiffen, and open his eyes. *Id.* The father states that N.F. displayed this behavior during other nighttime feedings and when he observed him when he was at home on weekends. *Id.* at ¶¶ 3, 4. The father states that sometimes while falling asleep, N.F. would "jerk awake" and his body would be stiff. He also observed that N.F. would sometimes "wake up for no reason and have a weird look on his face." *Id.* at ¶¶ 5, 6.

The father recalls "[t]here was one incident that really frightened" him. In June 2013, the family was traveling. While the mother took a shower, the father held N.F. The father observed that N.F.'s entire body stiffened, his breath changed, and his eyes opened extremely wide. The father told the mother something was wrong with N.F. The mother said it looked like N.F. was having an episode. The father states that he works, he only sees N.F. in the evenings, and the mother spent more time with N.F. *Id.* at ¶ 7.

The father states that he asked whether the mother had discussed N.F.'s episodes to the new pediatrician, Dr. Webb (discussed below). The mother "said that she had discussed these episodes with [Dr. Webb], and she was told to just wait it out, that it could be N.F.'s nervous system was not fully developed." *Id.* at ¶ 8.

ii. Dr. Webb's Medical Records

The medical records indicate that after N.F. received the DTaP vaccine at Dr. Sotelo's practice on April 2, 2013, his primary care was transferred to Dr. Mark Webb. *Id.* Dr. Webb's practice with regard to charting of the visits could most charitably be called casual, particularly when compared with the detailed notes kept by Dr. Sotelo's office. Dr. Webb's records were frequently not dated. It also appears that on November 22, 2013 at 5:42 PM, Dr. Webb batch signed several different records, even though the records reference N.F. being four months, six months, and nine months of age. Pet. Ex. 2 at 14-17.

What appears to be the first record indicates "normal growth and development at four months of age" (which would have been in approximately May 2013). It also notes "mother wishes to defer vaccinations" and that N.F.'s next appointment should be in two months. The record provides that N.F. was at the 75th percentile for weight, 50th percentile for height, and 25th percentile for "OFC."[6] *Id.* at 17.

[6] Medical professionals often use "OFC" as an abbreviation for occipital frontal circumference. Davis, Medical Abbreviations (15th ed.) at 238.

Another undated record from Dr. Webb notes "normal growth and development at 6 months of age" (which would have been in approximately July 2013). The record states "parents defer vaccinations at this time", and that they would follow up in two months. It provides that N.F. was at the 5th percentile for weight, 15th percentile for height, and 50th percentile for OFC. *Id.* at 16.

Another undated record from Dr. Webb indicates that N.F. had a three-day history of nasal congestion and a viral URI; the plan was to continue with symptomatic care. *Id.* at 15.

Another undated record provides "normal growth and development at nine months of age" (which would have been in approximately October 2013). It states that "strategies for weaning off of nursing are discussed", and "patient will return in one year of age for next well examination." This record provides that N.F. was in the 50th percentile for weight, 25th percentile for height, and 25th percentile for OFC. *Id.* at 14.

Despite the apparently gyrating growth milestones, Dr. Webb's records simply note normal growth and development at four months, six months, and nine months of age. These records do not mention any of the symptoms that are described in the parents' later statements and that the mother recounts discussing with Dr. Webb.

Dr. Webb's first contemporaneous medical record of these symptoms is signed on February 6, 2014. *Id.* at 13. This was the 12-month well child appointment. N.F.'s weight, height, and OFC are all recorded as being at the 50th percentile. Dr. Webb wrote:

> "History(+) Over last 2-3 months, patient has been having intermittent episodes of tensing of the body without clear loss of consciousness. The episodes have occurred when sleeping or awake. The episode does not last more than 15 seconds. There has never been witnessed apnea or cyanosis with any of the episodes."

Id. Dr. Webb's assessment was "1(+) repeated episodes of muscular rigidity – no clear evidence of seizure activity." He noted that the parents continued to defer vaccinations. He referred N.F. to pediatric neurology. *Id.*

iii. Dr. Webb's Statement

In an undated letter filed on August 17, 2015 (four months after respondent filed the Rule 4(c) report), Dr. Webb states that he first saw N.F. on May 30, 2013. Pet. Ex. 10. Dr. Webb recalls that at the first visit, the parents described that N.F. had "suffered an adverse reaction to his two month vaccinations… [N.F.] had run a fever and was very fussy for several days, followed by [N.F.] starting to experience a lack of response to stimuli and stiffness throughout his body that would last for less than a minute." *Id.* Dr. Webb states that it was because of this conversation at the May 30, 2013, visit that any further vaccinations were deferred. *Id.* Dr. Webb did chart the deferral. He states that he "distinctly remember[s the parents'] concern about continuing with the next series of vaccinations because of the severe reaction that [N.F.] had had to his initial vaccinations even though this was not documented in the chart." *Id.*

Dr. Webb states that he saw N.F. again on August 6, 2013, October 3, 2013, and November 8, 2013. He recalls that at each of these appointments, the parents were concerned about N.F.'s continuing abnormal movements and staring spells. He states that because of the parents' concerns, vaccines were not given. Dr. Webb states that he "did not see anything on exam or in the

developmental history to make a referral at that time. It was not clear to me at those visits that there was any neurological process that would warrant a referral." *Id.*

Dr. Webb states that he saw N.F. again on February 4, 2014:

> "At this time, I made the decision to refer [N.F.] to a pediatric neurologist, as the parents[']s concerns about the abnormal behaviors had continued and actually increased in frequency over the proceeding [sic] 2-3 months. I had originally discussed with [N.F.'s] parents that we would take a 'wait and see' approach with [N.F.'s] symptoms, but because they had gone on for so long, we made the neurology referral. The February 4th note documented that the episodes had been going on for 2-3 months, but in reality, the behaviors were first noted by parents soon after the first set of vaccinations which is why we continued to defer any further vaccinations. In reality, the note should have reflected that the episodes had ***increased in frequency*** in the proceeding [sic] 2-3 months which is why the decision was made to send [N.F.] to pediatric neurology."

Id. (emphasis in original).

C. N.F.'s Subsequent Medical History

The following facts are derived from the available medical records and are not disputed. On Dr. Webb's referral, Dr. Korwyn Williams, a pediatric neurologist at Barrow Neurological Institute at Phoenix Children's Hospital, saw N.F. for possible epilepsy on March 6, 2014. Pet. Ex. 6 at 70. Dr. Williams recorded the parents' account of onset as June 2013, with "episodes of eye widening and gagging/ breathing without behavioral arrest lasting up to 5 seconds associated with a mechanical smile/ grimace (the parents don't think that he is happy)." *Id.* Dr. Williams recorded that these episodes were occurring two to ten times per day with no known precipitants, and that N.F. reportedly "never had episodes of staring and unresponsiveness, myoclonus or generalized convulsions." *Id.* Dr. Williams's impression was epilepsy. *Id.* at 72.

A brain MRI on March 15, 2014, showed mildly low-lying cerebellar tonsils but was otherwise unremarkable. *Id.* at 63. An EEG on March 18, 2014, was abnormal, showing intermittent left temporal quadrant focal slowing, frequent epileptiform discharges in the left posterior quadrant, and probable left posterior onset focal seizure with motor semiology. *Id.* at 48. N.F. was started on oxycarbazepine. *Id.* at 39.

On May 11, 2014, N.F. returned to Dr. Webb, who recorded that N.F. had been diagnosed with partial absence seizure disorder and that N.F. was on oxycarbazepine with a noticeable decrease in the amount of seizures. Dr. Webb recorded that N.F. was using 5 to 10 words, but also wrote that N.F. was at "normal growth and development at 15 months of age." Pet. Ex. 2 at 9. At the next appointment on June 10, 2014, Dr. Williams' impression was partial-onset epilepsy. N.F. had new language delay and he was only using 1 word. N.F.'s oxycarbazepine was increased. Pet. Ex. 6 at 40-42.

IV. Expert Testimony

A. Expert Qualifications

Petitioner's expert Dr. Anthony Rodrigues received a Ph.D. in Neuroscience at the University of Florida, in Gainesville, Florida, in 2005, and received an M.D. from the Tufts University School of Medicine, in Boston, Massachusetts, in 2009. Pet. Ex. 12 at 1. He did a pediatric residency followed by a pediatric neurology fellowship at the Tufts Floating Hospital for Children. *Id.* Since 2014, Dr. Rodrigues has been an Assistant Professor of Child Neurology at Tufts University School of Medicine, as well as the Director of the Pain Clinic and the Program Director of the Child Neurology Fellowship at Tufts Floating Hospital for Children in Boston, Massachusetts. *Id.* Dr. Rodrigues has authored a number of articles, generally relating to neuropathy and fibromyalgia. *Id.*

Respondent's expert Dr. Elaine Wirrell received an M.D. from the University of British Columbia, in Vancouver, B.C., in 1989. Resp. Ex. B at 1. She did a pediatric residency and internship, followed by a fellowship in pediatric neurology, at the IWK Hospital for Children, in Halifax, Nova Scotia. *Id.* She is currently a professor and consultant in child and adolescent neurology at the Mayo Clinic, in Rochester, Minnesota. Since 2008, she has also served as the Fellowship Director for Pediatric Epilepsy at that institution. *Id.* at 15. Dr. Wirrell has also authored numerous book chapters and many articles on pediatric epilepsy and seizure disorders, including one cited by petitioner's expert. *Id.* at 39; *see* S.F. Berkovic, E.C. Wirrell et al., *De Novo Mutations of the Sodium Channel Gene SCN1A in Alleged Vaccine Encephalopathy: A Retrospective Study,* 5 Lancet Neurol. 488 (2006) [Pet. Ex. 20, also filed as Resp. Ex. C]. Dr. Wirrell states that she has treated over 4,000 children with epilepsy and seizure disorders, and those conditions are the focus of her clinical practice. Resp. Ex. A at 1.

In my estimation, both experts have strong credentials and are well-qualified to offer opinions regarding causation in this case. The next step is to evaluate those opinions, including their accounts of the underlying facts and the medical literature they have provided.

B. Expert Opinions

Dr. Rodrigues theorizes that N.F. suffered "an adverse vaccination reaction including fever, encephalopathy, and seizures (between 1 to 7 days post-vaccination)" and that a biologically plausible mechanism of injury exists. Pet. Ex. 11 at 4; *see also* Pet. Ex. 13 at 1. Dr. Rodrigues states that vaccinations can increase levels of IL-1B, IL-6, TNF-a, and G-CSF. Pet. Ex. 11 at 3. TNF-a and IL-6 result in the disruption of the blood-brain barrier, allowing cytokines to enter the brain and stimulate proliferation of microglia, which then produce even more cytokines that further affect cells within the central nervous system. *Id.* at 3-4. Dr. Rodrigues concludes that the immune response to vaccination can induce a process that can cause disruptions in the central nervous system and possible brain injury. *Id.* at 4.

Dr. Rodrigues states that the connection between the pertussis vaccination and neurologic injury has been discussed in a number of publications. Pet. Ex. 11 at 3. He states that it was realized that the whole cell pertussis vaccine contained an endotoxin that caused a severe immune reaction leading to fevers and febrile seizures in many subjects, and caused encephalopathy in a

small number of subjects. *Id.* He further states that the Institute of Medicine has concluded that there is likely a causal, but rare, relationship between the DTaP vaccine and encephalopathic reactions, although the association may have decreased since the introduction of acellular pertussis vaccines. *Id.*

Dr. Rodrigues maintains that while genetic abnormalities such as SCN1A are believed to cause some cases of encephalopathy/seizures, these do not account for all of the cases. *Id.* He writes: "The medical communit[y's] stance on the link between the pertussis and neurological sequela has swung like a pendulum over the years," but the community currently leans toward the two not being related except in rare cases. *Id.*

Dr. Rodrigues states that the literature reviewing whether the acellular DTaP vaccination causes adverse events has been debated for many years. "Previously, there were case series and epidemiologic studies that revealed an increase in adverse events related to the vaccination, while some recent studies show minimal differences between vaccinated and unvaccinated kids developing encephalopathy and seizures." Pet. Ex. 13 at 1. However, Dr. Rodrigues states that these inconsistent findings reflect the fact that this is a rare outcome not easily identified in epidemiology. *Id.* He notes that the adverse reaction table for the pertussis vaccination still states encephalopathy, leaving the biologically plausible possibility of the vaccination causing central nervous system dysfunction. *Id.*

In response, Dr. Wirrell opines that the whole-cell pertussis vaccine (typically combined with diphtheria and tetanus) contained an endotoxin that led to an immediate febrile reaction in some children. Resp. Ex. A at 4. There were also concerns that more serious neurological effects could be seen in a very small number of children. *Id.* at 4-5. Several large epidemiologic studies and an Institute of Medicine panel review have studied the risk of encephalopathy following DPT (the combination including the whole-cell pertussis vaccine), with inconclusive results. *Id.* at 5.

Dr. Wirrell states that the current vaccines, which N.F. received, utilize an acellular pertussis vaccine (typically combined with diphtheria and tetanus, and abbreviated as DTaP), which has a significantly lower risk of adverse effects than the whole-cell vaccine. Resp. Ex. A at 6. The Red Book indicates that systemic reactions may occur within several hours of vaccination and subside spontaneously within 48 hours. A post-licensing study did not show an increased risk of seizures, and that seizures, if associated with DTaP, are usually simple febrile seizures. *Id.* Several large epidemiological studies have evaluated the risk of seizure after DTaP. *Id.*

Dr. Wirrell adds that infancy is a high-risk time for the development of epilepsy. *Id.* at 6. Fever may unmask several epilepsy syndromes in infancy. Thus, it is imperative to assess the underlying etiology of seizures with onset shortly after vaccination. *Id.* at 7. In most cases, genetic or structural defects are the underlying cause and the vaccines just unmask this predisposition. *Id.*

Each expert reviewed the contemporaneous medical records, the mother's statement, and Dr. Webb's statement. Dr. Rodrigues notes the "discordance" between the medical records and the later statements from N.F.'s mother and Dr. Webb. Pet. Ex. 11 at 1-2. Dr. Rodrigues opines medical records "do not always reflect the complete history." For purposes of preparing his report,

Dr. Rodrigues accepts the later statements as true. Additionally, "there is evidence of deference of vaccinations… which indirectly supports that N.F. had a prior reaction." *Id.* at 2.

Dr. Rodrigues opines that the statements indicate that the onset of N.F.'s condition began within one week of the DTaP vaccine. *Id.* at 2. He states that N.F. had "fever then seizures," and at a different point in his report, "fever, encephalopathy, and seizures." *Id.* at 4. Dr. Rodrigues does not address why the symptoms he accepts that N.F. experienced represent either encephalopathy or seizures. He only states that respondent "appears to acknowledge that [N.F.] does suffer from a seizure disorder (injury)… [t]herefore, the following opinion will not address the question of injury (seizures)." *Id.* at 2.

Dr. Wirrell agrees that N.F. has epilepsy, but raises questions about the initial onset. She states that it is "notable" that after observing N.F.'s episodes within one week of the DTaP vaccine, the mother did not contact N.F.'s pediatrician Dr. Sotelo, bring N.F. to the emergency room, or seek medical care from any other physician. *Id.* at 3. Dr. Wirrell notes that N.F.'s new pediatrician Dr. Webb's medical records do not contain any mention of these symptoms. *Id.* Dr. Webb's subsequent letter does indicate that the family reported an adverse reaction to the DTaP, consisting of fever and fussiness for several days, followed by what Dr. Wirrell describes as "spells." *Id.* at 4. But, as Dr. Wirrell opines: "The exact timing of the onset of spells, after the vaccine was given is not documented." *Id.* After reviewing the submitted evidence, Dr. Wirrell opines:

> "While [N.F.] may have had some fever and fussiness after the DTaP vaccination, there is no convincing evidence that he had encephalopathy or encephalitis within 72 hours of this vaccination.[7] Infants with encephalopathy or encephalitis have a profound and persistent, as opposed to episodic, alteration in their level of consciousness along with seizures. Given the severity of symptoms expected with these conditions, [N.F.] would have been extremely ill, to the point that his family would almost certainly have sought medical care in this acute period, particularly given their initial concerns regarding vaccination as documented in Dr. Sotelo's notes."

Id. at 8. Dr. Wirrell opines that the medical records better suggest that onset was at least two months after vaccination (based on the initial consult note from Dr. Williams). *Id.*

Dr. Wirrell states the literature would be supportive of DTaP causing an increased risk of febrile seizures the day of vaccination, but it does not support causality of afebrile seizures, particularly those with onset at least one week after, and possibly two to eight months after vaccination. *Id.* Dr. Wirrell suggests that cortical dysplasia could be an alternative cause. *Id.* at 8. Dr. Wirrell opines that the mechanism Dr. Rodrigues sets forth would not support a causal link between vaccination and seizures that likely had onset anywhere from two months to 7-8 months

[7] As noted above in the procedural history section, the petition alleged that N.F. suffered a Table encephalopathy within 72 hours of the DTaP vaccine. Petition at 5. However, petitioner's motion for a decision on the record provides that petitioner is not alleging a Table injury and that she is only making a causation-in-fact claim. Pet. Mot. at 5.

after the vaccine. She acknowledges that rarely febrile seizures may occur post-vaccination, but she contends that N.F. did not experience febrile seizures.

V. ANALYSIS

As stated above, the parties agree with N.F.'s eventual diagnosis of epilepsy following pediatric neurology evaluations, an EEG, and a brain MRI in March 2014. Rather, the parties disagree as to the onset of N.F.'s condition. This is a critical issue in the case, that goes to whether N.F.'s condition occurred within a medically acceptable time period for this alleged vaccine injury. Based on my consideration of the record as a whole, I conclude that petitioner has not carried her burden under the Federal Circuit's test for off-Table causation claims established in *Althen*. I address the relevant *Althen* prongs in order of their significance to my determination.

A. *Althen* Prong Three: Petitioner Has Not Shown a Temporal Relationship Between N.F.'s Vaccine and his Condition.

As stated above, to fulfill *Althen* prong three, petitioner must establish an acceptable temporal association between the vaccine and the injury alleged. This has been interpreted to mean a time frame that is consistent with the "medical understanding of the disorder's etiology." *de Bazan*, 539 F.3d at 1352. Establishing a temporal association can also help petitioner establish a logical sequence and cause and effect (*Althen* prong two) which fits with his or her theory (*Althen* prong one).

In this case, the timing informs the experts' opinions and my eventual determination of causation in this case. Petitioner contends that the onset of encephalopathy and/ or seizures occurred about a week after N.F. received the DTaP vaccine on April 2, 2013. This contention is based on her memories at least a year after these events, and her husband and Dr. Webb's memories at least three years after these events. Dr. Webb did not mention these events in any records prior to February 2014. There are no other medical records from any other providers during this period.

Respondent argues that the absence of any such notation and in fact the inconsistent history in the records is significantly probative in this case. He argues that the medical records in this case should be viewed as trustworthy and given substantial weight, under the presumption that they are accurate and complete. He argues that I can rationally determine to afford greater weight to the medical records than to the subsequent statements from the parents and Dr. Webb. Respondent's Response (*citing Burns*, 3 F.d at 417; *Cucuras*, 993 F.2d at 1528; *Camery*, 42 Fed. Cl. at 391). In her reply, petitioner contends that medical records should not receive as much weight when they are not complete, as clearly stated by Dr. Webb in this case. Pet. Reply at 2 (*citing Murphy*, 1991 WL 74931, *4) (reasoning that "[i]f a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the latter correction must be taken into account").

The legal arguments of both sides on this point have merit. Medical records are indeed very important sources of credible evidence in these cases, but my many years of experience reading medical records have demonstrated that they are not infallible. In this case, I have considered the entire record including the medical records, the affidavits, and Dr. Webb's letter to reach a

conclusion as to whether a reliable date of symptom onset in proximity to the vaccine can be established.

It appears that Dr. Williams, the pediatric neurologist at Barrow, took the most detailed history and performed the most careful evaluation – including a brain MRI, which was normal, and an EEG, which was not – at his initial appointment in March 2014. Pet. Ex. 6 at 70. Dr. Williams noted that N.F. was being seen based on Dr. Webb's referral, which referenced episodes of tensing. Dr. Williams recorded onset as being in June 2013. He recorded that there were episodes of eye widening and gagging/breathing without behavioral arrest lasting up to 5 seconds associated with a mechanical smile/grimace. He noted that the parents didn't think that N.F. was happy. He noted that these events occur 2-10 times a day with no precipitant and that they occur during wakefulness and sleep. Importantly, Dr. Williams noted that N.F. has never had episodes of staring and unresponsiveness, myoclonus, or generalized convulsions. Pet. Ex. 6 at 70. Dr. Williams did not make any record of the early symptoms described by N.F.'s mother (fever and fussiness immediately after the vaccine, followed by staring, stiffness, and lack of responsiveness to the environment).

Given his specialty and the fact that he was being consulted for possible seizures, it is not surprising that Dr. Williams would take a thorough history from the parents - with particular focus on their concerns about possible seizure symptoms - and conduct a complete physical examination. From this history, several things of importance to this case can be derived. First, the parents told Dr. Williams that the date of onset was June 2013. Second, there was no mention of the early episodes recalled by N.F.'s mother. In fact, it was noted that there had never been episodes of staring. Dr. Williams also noted that the episodes of eye widening and gagging last up to five seconds, not for nearly a minute. Finally, Dr. Williams's evaluation does not refer to a date of onset in close association with the DTaP vaccine.

Dr. Webb's records are considerably less detailed, but they also do not mention the symptoms and the time frame described by N.F.'s mother. Dr. Webb's first record of symptoms similar to what the mother described is in February 2014, when he wrote: "Over the last 2-3 months, [N.F.] has been having intermittent episodes of tensing of the body without clear loss of consciousness. The episodes have occurred when sleeping or awake. The episode does not last more than 15 seconds." Pet. Ex. 2 at 13. Neither this contemporaneous record nor Dr. Webb's later letter mentions the initial symptoms described by N.F.'s mother, of pulling away from the breast while feeding within one week of the vaccine.

Additionally, Dr. Webb's contemporaneous record suggests that the parents were saying N.F.'s episodes began in November or December of 2013. In his later letter, Dr. Webb indicates that he should have noted that the events increased in frequency, rather than began, during that 2-3 month time frame.

In his letter, Dr. Webb does say that it was not clear to him that there was any neurological process that would warrant a referral when he saw N.F. at appointments before February 2014. He writes that the increased frequency of the symptoms at that time caused him to make a neurological referral.

Although Dr. Webb did not chart any of the seizure-like symptoms contemporaneously at the appointments beginning in May 2013, Dr. Webb indicates a distinct memory of those symptoms in his letter filed two years later, after N.F.'s mother and her counsel explained that his records did not support N.F.'s mother's statement of events. In this letter filed two years after his first appointment with N.F., Dr. Webb states that he recalls that the parents wanted to defer further vaccinations because N.F. had suffered an adverse reaction to his two-month vaccinations: "At the first visit [on May 30, 2013,] the parents described that N.F.] had run a fever and was very fussy for several days, followed by [N.F.] starting to experience a lack of response to stimuli and stiffness throughout his body that would last for less than a minute." Pet. Ex. 10. Even in this letter, when he was asked to elaborate on the early symptoms and their timing, Dr. Webb is not particularly specific. He only states the fever and fussiness were "followed by" episodes of unresponsiveness and stiffness. He does not address the duration of time between the fever and the subsequent symptoms.

Dr. Webb then states: "The February 4, note documented that the episodes had been going on for 2-3 months, but in reality the behaviors were first noted by the parents soon after the ***first set of vaccinations***." *Id.* (emphasis in the original). Despite this apparent detailed recollection of uncharted events two years later, Dr. Webb apparently did not realize that N.F. had <u>not</u> received the set of two-month vaccinations, but had in fact only received the DTaP vaccine because of the mother's concern about vaccinating at all.

It is not difficult to believe that the parents were concerned simply based on N.F. exhibiting a fever and fussiness for several days after the one DTaP vaccination (not the vaccinations plural, stated by Dr. Webb). After receiving vaccines, some children develop fevers and fussiness, then usually recover without further issue. But as the mother had major reservations about vaccinating at all to the extent that she changed pediatricians over the issue, it seems more likely that the fever and fussiness after the DTaP furthered her resolve to not allow any further vaccinations. It is also easy to accept that the mother was concerned about this reaction and that she would have mentioned a general bad reaction to the DTaP vaccine to Dr. Webb when she first saw him with N.F. on May 30, 2013.

However, in her signed statement, the mother goes much farther, saying that one week after the vaccine, N.F. "suddenly pulled away when breastfed" and "had a weird look on his face and stiffness throughout his body." Pet. Ex. 1, ¶ 4; *see also* Pet. Ex. 14, ¶ 3 (father's recollection that mother reported these events shortly after the vaccine). The mother also recalls that N.F. exhibited a lack of response to his environment, not responding when spoken to or looked at and "seemed not to recognize familiar people or things or sensations, and was in . . . a semi-conscious daze." Pet. Ex. 1, ¶ 4. She states that within a minute of these incidents, N.F. would latch back on and continue to breastfeed. *Id.* The mother recalls that N.F. continued to do this every time he nursed or slept over the next few weeks. This degree of detail seems to stretch credulity, particularly when these events are not mentioned in Dr. Williams's records. Additionally, these symptoms – the pause in breastfeeding; lack of responsiveness to the environment; and recognition of familiar faces – are variously described as lasting 5 seconds, 15 seconds, or up to a minute. These differing accounts raise additional doubt about the accuracy of her recollection of events.

Furthermore, if the parents were actually observing not just an initial fever and fussiness, but additional, repeated episodes that they believed to be significantly abnormal, it seems surprising that they would not have sought medical attention. But there are no records of the parents contacting or bringing N.F. to their established pediatrician Dr. Sotelo, urgent care, or any other medical providers for the nearly two months between the vaccine and their first visit with Dr. Webb on May 30, 2013.

Moreover, Dr. Webb said in his letter he did not see anything on exam or in the developmental history to make a referral upon first seeing N.F. on May 30, 2013, or at subsequent appointments. He only made the referral in February 2014. It seems unlikely that if the mother of a young infant was detailing her concerns about these allegedly repetitive incidents that Dr. Webb would not have made some note. In any event, Dr. Webb did not suspect that N.F.'s mother was describing encephalopathy or seizures when she gave whatever history was given at the appointments prior to February 2014.

It must also be noted, as observed by respondent's expert Dr. Wirrell, that none of the treating physicians linked the onset of N.F.'s symptoms to the vaccination. Neither do the records indicate that any physician was told about the early events or considered that they were likely to be manifestations of encephalopathy or seizure activity. Although Dr. Webb says he remembers the mother describing abnormal symptoms, Dr. Webb did not think anything merited a neurological referral prior to February 2014. Finally, during pediatric neurologist Dr. Williams's initial evaluation in March 2014, the parents reported that the symptoms began in June 2013 and that there was no prior history of staring.

Accordingly, though I have considered Dr. Webb's letter in support of the mother's statement, I believe the letter is unlikely to accurately reflect Dr. Webb's actual memory of events that he is saying were reported to have occurred two years before he wrote the undated letter and which he did not chart. To be sure, his notes leave a good deal to be desired, particularly when compared to Dr. Sotelo's or Dr. Williams's. His memory that the parents told him about an adverse reaction to the vaccine in the form of a fever and fussiness for several days is easy to accept, but his specific memory of the breastfeeding events seems improbable. It is difficult to imagine that even a casual record keeper like Dr. Webb would not chart symptoms that the parents of an infant were describing as abnormal and repetitive, particularly when they claim to have discussed this problem at several appointments. In any event, even in his later letter, he does not make a diagnosis of seizures shortly after the vaccination, but says that he did not see anything that merited a neurological referral before February 2014. In sum, I recognize that medical records may be incomplete and I have fully considered the letter from Dr. Webb stating that his records were indeed incomplete. However, I do not find that the letter is sufficiently "consistent, clear, cogent, and compelling" to outweigh the medical records from Dr. Webb and Dr. Williams. *Camery*, 42 Fed. Cl. at 391 (internal citations omitted); *see also Burns*, 3 F.3d at 417 (holding that the special master can make a rational determination to afford greater weight to contemporaneous medical records than to other evidence, such as testimony given later in time).

Further, there is no persuasive evidence that the early events described by the mother were actually encephalopathy or seizures. Dr. Webb saw nothing to warrant a neurological referral. Dr. Williams recorded the onset as approximately two months after the vaccination, in June 2013, and does not mention the activities while feeding described by N.F.'s mother. In fact, Dr. Williams records no prior history of staring. Petitioner's expert Dr. Rodrigues simply notes that respondent agreed that N.F. had epilepsy. Dr. Rodrigues does not analyze whether the symptoms described as occurring earlier were likely to be early manifestations of N.F.'s condition, although he did apparently conclude that they were based upon N.F.'s mother's statement.

Accordingly, I am not persuaded that petitioner has presented sufficiently reliable evidence to overcome the lack of medical documentation of early onset of seizures and in fact contradictory evidence on that point as found in the records of Dr. Williams. Petitioner has not submitted testimony from Dr. Williams or otherwise alleged that his records are not complete, although she has done so regarding Dr. Webb. While it is clear that N.F. had epilepsy when he was seen by Dr. Williams in March 2014, petitioner has not met her burden of establishing the onset of N.F.'s condition. For the reasons discussed above, I am inclined to believe that Dr. Williams's note made while taking a history directed at the possibility of an epilepsy diagnosis is most likely to accurately reflect the contemporaneous history given by the parents and would suggest a date of onset in June 2013, approximately two months after the vaccination.

I note that petitioner alleges injuries including an encephalopathy. On this issue, respondent's expert Dr. Wirrell opines, "infants with encephalopathy or encephalitis have a profound and persistent, as opposed to episodic, alteration in their level of consciousness along with seizures." Resp. Ex. A at 8. Petitioner argues that Dr. Wirrell's opinion "clearly mirrors" the Vaccine Injury Table definition of encephalopathy. Pet. Reply at 4. Petitioner notes that she is only alleging an off-Table claim and that several special masters have declined to apply the restrictive Table definition to off-Table claims. She requests that I apply the National Institute of Neurological Disorders and Stroke's broader definition of encephalopathy, as "any diffuse disease of the brain that alters brain function or structure." This definition, as cited in petitioner's brief, also provides:

> "The hallmark of an encephalopathy is an altered mental state. Depending on the type and severity of encephalopathy, common neurological symptoms are progressive loss of memory and cognitive ability, subtle personality changes, inability to concentrate, lethargy, and progressive loss of consciousness. Other neurological symptoms may include myoclonus (involuntary twitching of a muscle group or group of muscles), nystagmus (rapid, involuntary eye movement), tremor, muscle atrophy and weakness, dementia, seizures, and loss of ability to swallow or speak."

Pet. Reply at 4.[8] Many of the symptoms listed above would be difficult or impossible to discern in a two month old child. However, it is not clear that the alleged early episodes of pulling away,

[8] *Citing Encephalopathy Information Page*, National Institute of Neurological Disorders and Stroke, https://www.ninds.nih.gov/disorders/all-disorders/encephalopathy-information-page.

staring, and stiffness fit even this broader definition of encephalopathy. Neither the primary care provider Dr. Webb nor the neurologist Dr. Williams have addressed this issue. Moreover, petitioner's expert Dr. Rodrigues specifically states that because respondent has acknowledged that N.F. has a "seizure disorder", Dr. Rodrigues does not address "the question of injury (seizures)." Pet. Ex. 11 at 2. Thus, petitioner has not established that that N.F. suffered an encephalopathy.

Dr. Rodrigues's opinion is based upon acceptance of the facts of onset as described by the mother and subsequently supported by Dr. Webb. But as I have rejected the assertion that the child experienced encephalopathy and/ or seizures within a week of the vaccine as lacking reliable evidence, I must reject Dr. Rodrigues's opinion of a temporal association between the vaccine and the onset.

I also do not accept Dr. Wirrell's assertion that the seizures were likely caused by dysplasia that was not seen on MRI. Though her assertion may be correct, on the record before us it is entirely speculative. But I do accept her argument that it is unlikely that a vaccine could cause seizures that have their onset somewhere between two months and eight months after the vaccination based upon either a June or November date of onset. As these later dates of onset were not addressed by Dr. Rodrigues, I have no reliable or even likely evidence before me that there is a temporal association between the TDaP vaccine and symptoms that much later.

B. *Althen* Prongs One and Two

Although petitioner raises interesting arguments about the potential mechanisms of encephalopathy and seizure causation as related to the immune response to vaccination together with medical literature which I have reviewed and considered (and with which respondent disagrees), I have decided that the detailed analysis of those arguments should await a case with a firm foundation in the facts which this case lacks. As there is neither a reliable history of the onset in less than two months post-vaccination, nor a contemporaneous medical diagnosis that the symptoms now described by petitioner were actually an encephalopathy or seizures, it is essentially impossible to determine whether there is a logical sequence of cause and effect between the vaccine and N.F.'s condition which fits an acceptable theory. Also, petitioner has not presented expert testimony that the vaccines could cause afebrile seizures beginning about two months after the vaccination.

VI. CONCLUSION

For these reasons, petitioner has not established entitlement to compensation in the Vaccine Program. Therefore, the claim is **DISMISSED.** In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment forthwith.[9]

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master

[9] Pursuant to Vaccine Rule 11(a), the entry of judgment may be expedited by the parties separately or jointly filing notice renouncing their right to seek review.