In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

BRYAN QUINONES and DONNA QUINONES, as parents and legal representatives of their minor daughter, Y.Q.,	*	No. 11-154V
	*	Special Master Christian J. Moran
Petitioners,	*	
v.	*	Filed: September 4, 2019
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; measles, mumps, rubella ("MMR") vaccine; febrile seizures; sequela
Respondent.	*	

Ramon Rodriguez, III, Sands Anderson PC, Richmond, VA, for Petitioners; Christine M. Becer, United States Dep't of Justice, Washington, DC, for Respondent.

PUBLISHED RULING ON ENTITLEMENT[1]

Bryan and Donna Quinones filed a petition on behalf of their minor child, Y.Q., under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10 through 34 (2012). The Quinoneses allege that Y.Q. suffered from a seizure disorder, sensory integration disorder, and behavioral changes after receiving a measles, mumps, and rubella ("MMR") vaccine on March 28, 2008. Pet., filed Mar. 11, 2011, at 1, 7. Following an entitlement hearing split between January 26, 2017, and November 29, 2017, the undersigned finds that the Quinoneses are entitled to compensation on their claim.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this ruling on its website (https://www.uscfc.uscourts.gov/aggregator/sources/7). Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Procedural History, including Expert Qualifications

This case's progression in litigation followed a relatively routine path, although the process took longer than usual. The Quinoneses filed their petition on March 11, 2011. Within approximately six weeks, they filed medical records and a statement of completion.

The Secretary assessed those records in her report, filed pursuant to Vaccine Rule 4, on June 24, 2011. The Secretary asserted that Y.Q. was not entitled to compensation. The Secretary challenged the reliability of the opinions of two people who treated Y.Q. and linked her problems to the MMR vaccination, Dr. Palevsky and Mr. Sherr, a chiropractor.[2] Instead, the Secretary urged that greater weight be given to the opinions of other treating doctors, such as Dr. Bello-Espinosa (a neurologist), who refrained from connecting the MMR vaccination to Y.Q.'s problems. Resp't's Rep. at 17-19.

After a status conference was held to discuss the Secretary's report, the petitioners were ordered to obtain a report from an expert by September 26, 2011. This deadline was extended several times.

The petitioners filed a report from Yuval Shafrir, a pediatric neurologist, on September 12, 2012. Dr. Shafrir graduated from medical school in Israel. After this graduation, he participated in various residencies and fellowships devoted to either pediatrics or neurology. Exhibit 22 (curriculum vitae) at 1. He has received board-certification in three disciplines: pediatrics, neurology and psychiatry with special qualification in child neurology, and clinical neurophysiology. Id. at 2.

He taught neurology and pediatrics at various institutions since 1988. He currently teaches residents and medical students at Sinai Hospital Department of Pediatrics and acts as an assistant professor of neurology and pediatrics at the University of Maryland. Exhibit 22 at 3. His other employment is working in private practice in Baltimore, Maryland. Id. at 3. Dr. Shafrir is a member of the American Epilepsy Society.

Dr. Shafrir's curriculum vitae lists 10 articles that Dr. Shafrir has written. The most recent of these articles was published in 1998. More recently, Dr. Shafrir has made presentations at conferences and on invited grand rounds. Exhibit 22 at 6-7.

[2] To distinguish chiropractors from medical doctors, this decision refers to Alan Sherr as "Mr."

In his report, Dr. Shafrir reviewed Y.Q.'s extensive medical history. Exhibit 21 at 1-18. He recognized that by August 2012, when he was writing his report, Y.Q.'s seizures were controlled but those seizures left her with "significant residual problems," notably neurobehavioral issues. Id. at 23.

Dr. Shafrir opined that the MMR vaccination, which Y.Q. received four days before her first seizure, caused the seizure.[3] He stated that various pieces of medical literature show that the MMR vaccine can cause adverse reactions within five days. He further opined that Y.Q. suffered an immune-related disorder, like acute disseminated encephalomyelitis (ADEM). Exhibit 21 at 21-24.

Following the filing of Dr. Shafrir's report, the parties attempted to resolve the case based upon the costs and risks of continued litigation. These efforts, however, did not succeed.

The Secretary answered Dr. Shafrir's report by filing a report from Gregory Holmes, also a pediatric neurologist. Dr. Holmes graduated from medical school in Virginia. He had an internship and residency in pediatrics at Yale University. He also had a residency in neurology at the University of Virginia. Exhibit B (curriculum vitae) at 1. He has received board certification in the same three disciplines as Dr. Shafrir: pediatrics, neurology and psychiatry with special qualification in child neurology, and clinical neurophysiology. Id. at 2.

Like Dr. Shafrir, Dr. Holmes has held various teaching positions at various institutions. Since 2002, he has been a professor of neurology and pediatrics at Dartmouth Medical School. He has been serving, since 2009, as the inaugural chair of the Department of Neurology at Dartmouth-Hitchcock Medical Center. Exhibit B at 2.

For more than 30 years, various institutions, including the National Institutes of Health, has funded Dr. Holmes's research. Much of Dr. Holmes's research has focused on seizures and epilepsy. Exhibit B at 4-5. He has served on editorial boards of academic journals devoted to neurology, generally, and epilepsy, specifically. Exhibit B at 6.

[3] Dr. Shafrir acknowledged that because the onset of Y.Q.'s encephalopathy was four days after the MMR vaccination, she did not satisfy the criteria for a Table case because the Table associates the measles vaccine with an encephalopathy that develops 5-15 days after vaccination. Exhibit 21 at 20; see also 42 C.F.R. § 100.3(a) ¶ (III)(B).

He belongs to several professional organizations, including the American Epilepsy Society. Exhibit B at 11. In 2005, 2006, and 2007, he served as the president elect, president, and past president of that group. Id. at 12.

The list of "named lectureships," and "invited lectures" runs more than a dozen single-spaced pages. The titles relate to epilepsy and seizures. Exhibit B at 14-30. He has also made presentations at conferences of leading professional organizations, including the American Academy of Clinical Neurophysiology, American Academy of Neurology, American Academy of Pediatrics, American EEG Society, American Epilepsy Society, Child Neurology Society, and the Epilepsy Foundation of America. Id. at 30-36.

His curriculum vitae lists more than 250 articles on which Dr. Holmes was an author or co-author. He is author or co-author on another 100 review articles. There are also more than 350 abstracts.

For his work in this case, Dr. Holmes's report also begins with a review of Y.Q.'s medical history. Exhibit A at 1-5. Dr. Holmes, then, challenged various aspects of Dr. Shafrir's opinion. Dr. Holmes stated that "there is no clinical or laboratory evidence to support the diagnosis of ADEM." Id. at 6. He asserted that "Dr. Shafrir does not specify the immune mechanisms that is the basis of [Y.Q.'s] vaccine-related injury. While Dr. Shafrir 'suspects that an immune mechanism is at the basis of [Y.Q.'s] vaccine related injury' a plausible mechanism of such process is not provided." Id. Finally, he asserted that the interval between vaccination and onset of seizures was too quick for the vaccination to have caused the seizures. Id.

The petitioners obtained a supplemental report from Dr. Shafrir. Dr. Shafrir agreed with Dr. Holmes that Y.Q. "did not have a typical presentation of acute severe ADEM at any point in her course." Exhibit 40 at 1. Dr. Shafrir also agreed with Dr. Holmes that he (Dr. Shafrir) had "not provided the exact immune mechanism which is the basis of [Y.Q.'s] vaccine related injury . . . . The reason for this omission is simply because an exact immune mechanism is not known. [H]owever there are plausible theories which are widely accepted by the court." Id. at 2. Dr. Shafrir's February 2, 2014 report created gaps in his opinion that the petitioners were directed to fill. Order, filed Apr. 2, 2014.

Dr. Shafrir's May 23, 2014 report disclosed opinions that advanced the petitioners' claim. With respect to diagnosis, Dr. Shafrir opined that Y.Q. "has chronic autoimmune encephalopathy." Exhibit 44 at 1. For the mechanism by which the MMR vaccine can cause chronic autoimmune encephalopathy, Dr.

Shafrir reviewed several medical articles. Dr. Shafrir's summary included three "non-mutually exclusive mechanisms:" "molecular mimicry," "bystander activation," and "epitope spreading." Id. at 2-3. Dr. Shafrir also presented his opinion regarding timing. He proposed that reactions to MMR vaccination can occur in less than five days. He also stated that any irritability that Y.Q. may have developed in the one or two days immediately following vaccination was not relevant to the question of causality. Id. at 5-6.

Dr. Holmes's next report responded to Dr. Shafrir's previous two reports. On the question of diagnosis, Dr. Holmes asserted "There is no supporting evidence to indicate that [Y.Q.] had a chronic autoimmune encephalopathy." Exhibit O at 4. For the theory, Dr. Holmes maintained that "molecular mimicry, bystander activation, and epitope . . . spread as a pathological phenomenon following vaccination remain unproven." Id. He also argued that even if these processes could cause an adverse reaction, the amount of time required for them would exceed four days. Id. at 4-5.

The question of a four-day latency appeared again in Dr. Shafrir's September 2, 2014 report. Exhibit 64. He also reasserted that Y.Q. "had chronic autoimmune encephalopathy" and much of this report was devoted to a discussion of autoimmune encephalopathy / autoimmune encephalitis. Id. at 4-10.

When the petitioners filed Dr. Shafrir's September 2, 2014 report, the existing schedule called for a series of submissions leading to a hearing on January 14, 2015. Order, filed June 24, 2014. One step was for the petitioners to submit updated medical records. Order, filed Sept. 24, 2014, at 1-2. However, petitioners inadvertently overlooked this obligation. Due to the lack of updated information, the petitioners proposed to reschedule the hearing. See Pet'rs' Mot. to Continue, filed Nov. 14, 2014.

Petitioners began to obtain updated medical records. Because some providers failed to cooperate, the petitioners were forced to resort to a subpoena to obtain the necessary information. This process of updating medical records concluded in June 2015.

With additional information about Y.Q. in hand, the parties returned to their respective experts. Dr. Shafrir summarized the newly obtained records. Exhibits 90 at 1-11. To Dr. Shafrir, "The additional medical records do not relate to the question of causality in this relationship between MMR vaccination and [Y.Q.'s] encephalopathy. However, they establish the severity and extent of her chronic encephalopathy." Id. at 12. Dr. Holmes agreed. Exhibit P at 1.

Dr. Shafrir offered an opinion that an appearance of severe behavioral changes after seizures is "highly suggestive of autoimmune encephalopathy" in Y.Q. Exhibit 90 at 11. However, the nature of Y.Q.'s illness remained a point of disagreement between the experts. Dr. Holmes commented: "there is no radiological (MRI and CT scans), cerebral spinal fluid assessment, EEG or clinical findings supporting the diagnosis of autoimmune encephalopathy." Exhibit P at 1.

In February 2016, the parties anticipated that a mutually convenient time for a hearing would be in August 2016. The petitioners requested that the hearing be held in Long Island, New York, near their residence. See Order, filed Feb. 26, 2016.

On May 16, 2016, the petitioners filed the final pre-trial expert report. Dr. Shafrir maintained his position that autoimmune encephalopathy, which he described as a "new and exciting development in child neurology," fit Y.Q.'s clinical presentation. Exhibit 98 at 1. He also defended his assertion that MMR can cause autoimmune encephalopathy and that it did so in this rare case.

In anticipation of the scheduled August 4, 2016 hearing, the parties submitted briefs. The petitioners filed theirs on June 6, 2016, and the Secretary responded on June 27, 2016.

The August 4, 2016 hearing did not proceed as scheduled due to an unforeseen circumstance with the petitioners' attorney. Order, filed July 15, 2016. Thus, the hearing was rescheduled for January 26, 2017. Order, filed Aug. 9, 2016. Due to budgetary restrictions, the hearing could not be held on Long Island, New York. Instead, it was conducted in Washington, DC.

During the January 26, 2017 hearing, the Quinoneses' testimony revealed that other sources of information about Y.Q. had not been submitted into evidence. Following the first session of the hearing, the Quinoneses were ordered to submit the additional information, and the Secretary was ordered to file a response to the questions in the January 24, 2017 order regarding the amount of time for which an inference of causation was appropriate after a MMR vaccine and before the onset of febrile seizures. Order, issued Feb. 2, 2017.

The Secretary filed a response from Dr. Holmes (exhibit CCC) and a status conference was held on February 28, 2017 to discuss the response. Whether Dr. Holmes was setting forth his position or the Secretary's position was unclear. The Secretary was ordered to determine who would establish HHS's position on timing to discuss at a forthcoming status conference. Order, issued Feb. 28, 2017.

At a status conference on March 28, 2017, the Secretary confirmed that Dr. Holmes represented the Secretary's position on timing in this case. The Quinoneses continued their efforts to gather and to submit additional information about Y.Q. Order, issued Mar. 29, 2017.

After a status conference on May 9, 2017, the undersigned provided detailed instructions for the experts to address the sequencing of Y.Q.'s seizures and epidemiology. A supplemental expert report schedule was set and planning for a continuation of the entitlement hearing was begun. Order, issued May 10, 2017. The Quinoneses filed a supplemental report from Dr. Shafrir (exhibit 123), and the Secretary filed a supplemental report from Dr. Holmes (exhibit DDD).

The entitlement hearing continued and concluded on November 29, 2017. After the hearing, the parties were given the option of pursuing settlement or filing post-hearing briefs. Order, issued Jan. 19, 2018. The parties considered settlement but ultimately decided to proceed with filing post-hearing briefs. Pet'rs' Stat. Rep., filed Feb. 15, 2018.

While the due dates for the post-hearing briefs were pending, the case was referred to another special master for alternative dispute resolution. Order, issued, May 16, 2018. During the ADR process, the Quinoneses filed their post-hearing brief on July 23, 2018, and the Secretary filed his brief on September 10, 2018. The case was eventually removed from the ADR process. Order, issued, Nov. 28, 2018. The Quinoneses filed their reply brief on January 11, 2019.

On June 28, 2019, a status conference was held to discuss next steps. The undersigned advised the parties that he was preliminarily ruling in favor of the Quinoneses on entitlement. The parties were ordered to begin their preparations for the damages phase of the case. Order, issued July 1, 2019. Further to that order, the undersigned now issues this final ruling in favor of the Quinoneses on entitlement.

Facts

Y.Q. was born in December 2006. Exhibit 2 at 1. Ms. Quinones described her pregnancy and Y.Q.'s delivery as normal. Tr. 24-25. In her first year of life, Y.Q. was brought to her pediatrician at Kids Care Pediatrics for relatively routine illnesses. See Tr. 25-26. She periodically received vaccinations. See exhibit 8 at 55. According to Dr. Shafrir, she did not produce the expected levels of antibodies in response to the polio and diphtheria-tetanus-pertussis vaccine. Tr. 128-29, 291.

On March 28, 2008, Y.Q. went to Kids Care Pediatrics for a well-baby visit. She was healthy. Tr. 27, 96. During this appointment, she received the MMR vaccine. Exhibit 6 at 10.

According to affidavits from Y.Q.'s parents, in the first two days after vaccination, Y.Q. started to run a fever. In addition, her parents noted that her eyes were glassy. Exhibit 1 at 2; exhibit 2 at 1; Tr. 27-28, 108. Dr. Shafrir stated that behavioral changes, such as irritability, the day after a vaccination are "very common" and are not necessarily related to an immune reaction. Tr. 353, 362.

A. First Seizure and Follow-up: April 1, 2008 through May 3, 2008

In the early evening of April 1, 2008, Y.Q. was brought to the Emergency Department of Stony Brook University Medical Center. Her parents informed medical personnel that Y.Q. "had vaccinations on Friday, started crankiness Sunday, fever today Tmax 103.9, gave Tylenol and repeat Temp 102 at 3:40 PM." Exhibit 9 at 6. "At ~ 7 pm, baby fell over and shaking[,] turned blue in face[,] lasted reportedly ~ 4-5 min, called 911." Id.; accord at 30-31. The report also indicates no vomiting, no diarrhea, and no symptoms of an upper respiratory infection. Exhibit 9 at 6.

The doctors ordered various laboratory tests. Exhibit 9 at 13-16. A note written at 1:30 AM early in the morning of April 2, 2008 reads, Y.Q. "remains alert, playful [with] parents." Exhibit 9 at 7. At approximately 4:00 AM, Y.Q. was discharged home with a diagnosis of "febrile seizures." Id. at 7, 12; accord Tr. 31.[4] In agreement with this diagnosis, Dr. Holmes testified that the evidence did not show Y.Q. had any "encephalopathic process" at that point. Tr. 379.

Consistent with the instructions given upon discharge from the emergency room, Y.Q. was brought to Kids Care Pediatrics on April 2, 2008. There are two records from this date. On one record, the chief complaint is "seen at VASB ER for febrile [seizure]." The line for "neuro" on this form is blank. The doctor's assessment was "1st febrile sz." The plan was to give Tylenol and Motrin. Exhibit 6 at 10; see also Tr. 32.

For April 2, 2008, there is a second record in the files from Kids Care Pediatrics. In this record, the chief complaint is "cranky, different behavior, afebrile." For "neuro," the doctor stated "cranky, [normal] exam." The assessment was "s/p febrile sz." The plan was "observation" with follow-up as

[4] Mr. Quinones testified that the ER doctor associated the MMR vaccine with the fever. Tr. 100, 109, 120. However, this association does not appear in the written records.

needed. Exhibit 6 at 11. Dr. Holmes concurred that Y.Q. was neurologically normal. Tr. 379-80.

Although the pediatrician did not provide any details about how Y.Q.'s behavior was different, Ms. Quinones attempted to present a more complete picture. She testified:

> [Y.Q.] was 15 months at the time, so that's when the aggression had started, and indecisiveness, she couldn't make up her mind, she was tactile defensive, the sensory integration disorder, the look in her eyes, everything about her was different. She lost her vocabulary. She lost her eye contact, how to communicate with me. She would grunt and point and drool like she was severely disabled.

Tr. 53. Based on Ms. Quinones's descriptions and the medical records, Dr. Shafrir opined that Y.Q.'s behavioral changes after the vaccination and the changes after the seizure are separate behavioral changes based on different biological mechanisms. Tr. 354-55.

The next appointment occurred the following day, April 3, 2008. The chief complaint was "seen again, alert cooperative [no acute distress]." For "neuro," the doctor has written: "alert, gait standing tone & strength [normal]." He has noted a "[deep tendon reflex] 1+ [illegible] [extraocular movements] [illegible] [pupils equal and reactive to light and accommodation] for [illegible]."[5] The diagnosis was "status post simple febrile seizure. Neuro intact." The plan for follow-up remained "observation." Exhibit 6 at 12. Dr. Shafrir recognized that because Y.Q.'s gait was normal, she was not suffering from cerebral ataxia. Tr. 238.

The final record on this page from Kids Care Pediatrics is the note of a phone call that is undated.[6] The note states "at Father's request, spoke to Dr. Carlos Cuello in St. Petersburg Florida & gave him the above written information." Exhibit 6 at 11; accord Tr. 101-02.

[5] The experts provided some assistance with the poor handwriting in these records, but they could not decipher everything that was written. Tr. 60, 65, 229-30, 495-99.

[6] Given the context of other records, it appears that this phone call took place between April 3, 2008, and May 3, 2008.

In addition to bringing Y.Q. to see her pediatrician, it appears that Ms. Quinones also consulted a telephone service. The history of present illness portion of the form states "febrile seizure last night, seen in SBUH ER, all [negative], now T 103.5, gave [Tylenol]. Mom very concerned. S/P MMR." Under "special advice," someone has written "fevers could be [secondary to] MMR, cont. [Tylenol / Motrin] alt 3h." Exhibit 8 at 87. Ms. Quinones remembered very little about this telephone call. Tr. 55.

On April 6, 2008, Ms. Quinones completed a VAERS form, reporting that her daughter had an adverse event after the vaccination. The information on the VAERS form is more or less consistent with the history given above. Exhibit 8 at 88-90.

On May 3, 2008, Y.Q. was seen at Kids Care Pediatrics again. The chief complaint was "fever x 1d, vomiting x 1." The diagnosis was "viral illness." There is also a notation saying "h/o febrile seizure." Exhibit 6 at 12. With reference to this appointment, Ms. Quinones testified that Y.Q. was inconsolable and was having severe diarrhea "all day long." Tr. 58. More succinctly, Ms. Quinones described the situation was "horrible." Tr. 57. It appears that Y.Q. did not go to a subsequently scheduled appointment on June 17, 2008, and a note indicates that Y.Q. switched to "holistic healer." Exhibit 6 at 12.

B. Initial Appointments at Northport Wellness Center: May-July 2008

Ms. Quinones brought Y.Q. to the Northport Wellness Center for the first time on May 5, 2008. Exhibit 7 at 19. Ms. Quinones wrote that the purpose of the appointment was "MMR shot reaction." Id. at 19; Tr. 60. For the "present history," Ms. Quinones stated: "[On] April 1st Y.Q. had a seizure (four days after receiving her MMR). Since she has had good days & bad. Bad days consist of inconsolable crying, tantrums, fevers, aggression less interaction, restlessness, [and] does not cuddle." Id. at 20.

Cuddling (or Y.Q.'s lack of cuddling) carries a significant importance to Dr. Shafrir's opinion that the MMR vaccine harmed Y.Q. permanently. Dr. Shafrir testified that the "most important record" is the questionnaire that Ms. Quinones submitted five weeks after the seizure. Tr. 311. On this form, as just recited, Ms. Quinones has checked boxes for "constipation," "diarrhea," "anemia," and "behavioral changes." Exhibit 7 at 20. In handwritten notes, Ms. Quinones has elaborated that Y.Q. has, among other problems, "inconsolable crying, tantrums,

less interaction, and not cuddling." Id. In Dr. Shafrir's opinion, not cuddling is an extreme behavioral change for Y.Q. at this age. Tr. 350, 504.

At this initial appointment, Alan Sherr saw Y.Q. Mr. Sherr is a chiropractor. Mr. Sherr determined that Y.Q. suffered from "encephalitis." Exhibit 7 at 17; accord Tr. 230-31. Dr. Holmes said that it is unclear what criteria Mr. Sherr was using to diagnose Y.Q. with encephalitis and that chiropractors, such as Mr. Sherr, are not qualified to diagnose encephalitis. Tr. 381. Regardless of Mr. Sherr's (lack of) qualifications to diagnose encephalitis, to treat Y.Q.'s pain and inflammation, Mr. Sherr also performed craniosacral treatments. Exhibit 7 at 28; Tr. 61-62. Mr. Sherr recommended various supplements, including glutathione. Exhibit 7 at 11; Tr. 44. Dr. Shafrir stated that he does not use glutathione for an autoimmune problem. Tr. 233-36. Dr. Holmes agreed that supplements would not help an MMR-related encephalopathy. Tr. 381. For any patient suspected of suffering post-MMR encephalitis, Dr. Holmes would recommend admitting that patient for continuous EEG monitoring, MRI imaging, a spinal tap, and other testing. Tr. 382

Y.Q.'s next significant appointment at Northport Wellness Center occurred eight days later.[7] On May 13, 2008, she was seen by Lawrence Palevsky. Dr. Palevsky is a pediatrician. Exhibit 118 (curriculum vitae). Ms. Quinones stated that she found this group of doctors from the "ARI website." Exhibit 7 at 27.[8] In addition to recording a history from around the time of Y.Q.'s vaccination, Dr. Palevsky updated her current status. He recorded that "since [Y.Q.] started these supplements last week," Y.Q. has had "more regular bowel movements not [with] constipation or diarrhea so much, more playful, more consolable, less destructive, more willing to cuddle, less restless." However, her "vocabulary [was] still not back." Id.; accord Tr. 65. Y.Q. also "still has tantrums." Exhibit 7 at 11; see also Tr. 63-64 (describing tantrums). Dr. Palevsky examined her. For her neurologic system, Dr. Palevsky stated that Y.Q. was "alert [moves all extremities], [normal]

[7] Mr. Sherr's handwritten notes from visits from May 5, 2008 to April 10, 2010 appear as pages 17-18 in exhibit 7. They are very difficult to read, and the experts have not based their opinions on any of these notations. See Tr. 19-20.

[8] ARI probably refers to "Autism Research Institute." Ms. Quinones stated Mr. Sherr is a DAN! (Defeat Autism Now!) doctor. Tr. 43. His partner, Dr. Palevsky, is also a DAN! doctor. Tr. 62-63. Ms. Quinones testified that she found Mr. Sherr and Dr. Palevsky after researching Y.Q.'s symptoms for a long time on the internet and after reading the book Evidence of Harm. Tr. 43.

tone, tantrums, irritable but consolable, fussy, no words, some pointing." Id. at 11-12.

Dr. Palevsky's impression was that Y.Q. suffered from "post MMR encephalitis" and "post MMR enteritis." Exhibit 7 at 12; accord Tr. 104. Dr. Palevsky ordered various tests. See exhibit 7 at 25; exhibit 8 at 45.

A return appointment with Dr. Palevsky occurred on June 10, 2008. For the recent history, Dr. Palevsky stated:

> Cont'd ther-biotic probiotics, omega-cure, glutathione, homeopathic spray. Added vit A + vit C after one week, developed fever, diarrhea inconsolable crying, decreased eating. Seen by Dr. Sherr, who stopped vit A. Stayed off vit A for another week, once fever resolved, put back on vit A a few days ago, no fever yet. Received one B12 injection 4 days ago + will continue [every] 3 days.

Exhibit 7 at 12. For Y.Q.'s current status, Dr. Palevsky noted some improvements. He wrote:

> no further seizures. Inconsolable crying resolving since fevers resolved last week. Diarrhea + constipation resolving – [normal] stools. More interested in cuddling. Pointing consistently, words coming back slowly. Rare throwing self back [with] head banging -- some biting, hair pulling.

Id.; accord Tr. 65-66. Dr. Palevsky also recorded his observations:

> babbling in office, imitations of words and word sounds as if speaking in a sentence. Good eye contact, interactive, playing, climbing, pointing, laughing, still [with] slight temper. Color improving.

Exhibit 7 at 12. Dr. Shafrir interpreted Dr. Palevsky's notation as documenting "continued neurologic improvements." Tr. 240. Dr. Palevsky also stated he reviewed the results of the laboratory's testing with Ms. Quinones. Dr. Palevsky noticed the high titer for hepatitis B. Exhibit 7 at 12.

At the conclusion of this appointment, Dr. Palevsky recommended that the parents continue a dairy-free diet, probiotics, omega-care, glutathione,

homeopathic spray, vitamin A + C, and vitamin B12 injections. Dr. Palevsky also encouraged an early intervention evaluation and proposed returning in one month. Exhibit 7 at 29. Ms. Quinones did not have a clear recollection of requesting services. Tr. 62-69; see also Tr. 115 (Mr. Quinones's testimony).

The next appointment occurred on July 7, 2008. In the intervening month, Y.Q. had had no further seizures. Three weeks before the appointment, Y.Q. had a "short-lived" fever that apparently resolved with one Motrin. Ms. Quinones also reported "pointing continues, vocabulary increasing, picking up new words, some pretend play, some repetitive behavior. Head banging, throwing self back continues, cont[inued] to pull hair, hit, some spaciness, still aloof." Exhibit 7 at 13.

As to vocabulary, an aspect that Dr. Palevsky described as "increasing," Ms. Quinones did not recall whether her daughter could say "mommy." Tr. 70. With the notation of expanded vocabulary, Dr. Shafrir stated that this record showed improvement. Tr. 240.[9]

With respect to Y.Q.'s health while Dr. Palevsky was treating her from June to July 2008, Dr. Holmes opined that she was sick, but not with psychiatric problems. Tr. 463-64, 500. Dr. Holmes attributed Y.Q.'s crankiness and not wanting to be cuddled to her illness that was causing her to have diarrhea for months. Tr. 398-99. Similarly, Dr. Holmes stated that any problems with language, which appear to have resolved by July 7, 2008, could be due to a sickness. Tr. 427.

C. Second Seizure and Follow-up: July 28, 2008 through October 18, 2008

On July 28, 2008, Y.Q. suffered another seizure. See exhibit 10 at 185 (ambulance record). The emergency medical services initiated CPR because they could not obtain a heart rate or pulse. Id.; see also exhibit 9 at 78; Tr. 38.

In the Emergency Department, Ms. Quinones said that Y.Q. had a seizure "a few weeks ago S/P MMR vaccination. [Patient] had MMR vaccination today. Pt has had temps of 105 @ at home [with] Tylenol given." Exhibit 10 at 173.[10] The

[9] Dr. Shafrir also stated in his experience of treating autistic children, physicians who practice alternative medicine "always say the patient improves." Tr. 241.

[10] The report that Y.Q. received an MMR vaccination "today" appears to be mistaken. See Tr. 71.

physical exam in the Emergency Department revealed that Y.Q. was "lethargic" with "eyes deviated to [the] left." She was also on Ativan. At this time, she was not responding to pain. Id.

Late in the evening on July 28, 2008, a neurologist consulted on Y.Q.'s case. In brief, the history is consistent with the facts as presented above. In detail, the history of present illness from the resident stated:

> 19m old F girl [with] [history of] post-measles encephalitis developed after MMR vaccination in March 2008 [presents with] tonic-clonic seizure that started about 10:00 PM today (with urinary incontinence, foaming at mouth) lasting about 30-40 min until EMS came in. In ambulance found to be pulseless (~ 2 min) and was resuscitated. In ED given 1 mg Ativan + 200 mg phosphenytoin X1 [illegible] on EEG. As per Mom, today had temp of 101 running temp since Sat, but [no] cough, running nose, abdominal pain, ear pain. Has been having diarrhea/intermittent fevers up to 105 + more ever since MMR vaccination. No sick contacts. No family [history of] seizures. No vomiting. At the time of onset of seizure, pt was laying on bed with mom falling asleep.
>
> [History of] one seizure episode on April 1st. Was seen in ED, told that it was [secondary to] dehydration/fever . . . . That seizure lasted 5 min and was similar to the one today.

Exhibit 9 at 27-32.

The attending neurologist's comment was succinct: "19 mo old with 2nd febrile seizure --- this one prolonged [with] partial onset." Exhibit 9 at 27.

On July 29, 2008, Y.Q. was admitted to the pediatric intensive care unit of Stony Brook University Hospital and Medical Center. This admission report indicated that a CT scan of Y.Q.'s head showed bilateral "white matter paucity in parietal lobe." Exhibit 9 at 78; but see exhibit 11 at pdf 35 / 220 (7/28/08 CT scan that, while having limited ability to evaluate the slices due to motion artifact, did not note any abnormalities or disease). The admitting doctor's problem list was:

> Active: R/O Encephalitis (day: 1)
> Active: S/P questionable cardiac arrest (day: 1)

Active: S/P status epilepticus (day: 1)
Chronic: H/o questionable MMR Encephalitis (day: 1)

Exhibit 9 at 79. His review of the neurologic system was "Pt with developmental delay / PDD with [history of] seizure in past. Now presenting in status epilepticus; was loaded with phosphenytoin and had no new clinical seizures overnight. Peds Neuro following and to evaluate continuous EEG." Id. Dr. Holmes offered that Y.Q. suffering a cardiac arrest was "unlikely." Tr. 384.

Ms. Quinones discussed this report of developmental delay and her comments were not consistent. Initially, when asked about whether Y.Q. had a history of developmental delay, Ms. Quinones said "No," and "All her milestones were met." Tr. 74. But, after Ms. Quinones was informed that the July 28, 2008 report was shortly after the vaccination, Ms. Quinones said Y.Q. "was regressing. She was going backwards." Id. Ms. Quinones identified language as a primary skill in which Y.Q. was not developing normally. Id. On the topic of developmental delay at Y.Q.'s second seizure, Dr. Holmes said Y.Q. was talking less than she had been. Tr. 446-47 (referencing exhibit 9 at 79).

The 24-hour video EEG was abnormal. It showed "diffuse background slowing" and "right hemispheric slowing which is higher in voltage with absence of sleep architecture." Exhibit 11 at pdf 36 / 221. The EEG did not show subclinical seizures. Tr. 290. The EEG also did not show that the status epilepticus caused lasting brain damage. Tr. 289. In Dr. Shafrir's view, the slowing on the EEG was consistent with an encephalopathy. Tr. 303. An MRI was also abnormal. Id. at pdf 34 / 219; see also Tr. 531.

The records from Kids Care Pediatrics include a note indicating that on July 28, 2008, Y.Q. suffered a febrile seizure lasting approximately 40 minutes for which she was given Ativan. Y.Q. is "now seeing holistic healer Dr. Palevsky, Sherr. Parents think that [after] MMR shot, seizure caused loss of milestones." Exhibit 6 at 12.[11]

The records from Northport Wellness Center similarly contain a record of a telephone call, informing Dr. Palevsky that Y.Q. had a fever for the past few days and developed a seizure that lasted 30 minutes. Dr. Palevsky "asked to have CSF [cerebrospinal fluid] sent for measles / mumps / rubella virus cultures." Exhibit 7

[11] The identity of the person who communicated with Kids Care Pediatrics is not readily apparent.

at 13; accord Tr. 80-81. Subsequently, a doctor added measles IgG onto the tests for previously drawn CSF. Exhibit 9 at 52. Although it appears this test was performed, the result is not readily apparent. Exhibit 11 at pdf 17 / 202; Tr. 18-19 (representation from the attorneys that they could not find results from this test).

Results from more routine studies on Y.Q.'s CSF were generally within normal limits. For example, her protein was 30.7 mg/dL when the range of expected value is 15.0-45.0 mg/dL. Exhibit 11 at pdf 14 / 199.

During this admission to Stony Brook, a consulting doctor created a report on August 1, 2008. The report indicates some questions about the consistency of the history the parents provided and sheds light on the role of Mr. Sherr, the chiropractor treating Y.Q.

> On arrival to [the hospital unit on July 29, 2008, a] more extensive history [was] taken from previously agitated parents which revealed first seizure on 4/1/08 was believed by parents to be secondary to MMR vaccine and her holistic physician. Dr. Sherr had labelled the patient as having post-MMR encephalitis. Parents believe [patient] had lost milestones over months since MMR. Speech had declined, [patient's] activity was 'erratic' and [patient] was 'constantly variable.' Parents also report [patient] has had cyclic episodes of fever for one week, [increasing] [illegible] and non-bloody, non-muscoid diarrhea described as usual color but more watery. Mother notes occasional constipation also, but progression of episodes and overall course since vaccine are often described poorly with no documentation and explanations and details change with retelling. Originally parents report patient had been getting worse, later explain she has been regaining milestones on holistic therapy – including gluten-free, lactose-free, casein-free diet (not followed strictly as per parents), vitamin supplements and unspecified chelation therapy.
>
> Parents have been told by Dr. Sherr that measles is alive in her gut and reactivating monthly causing fever and diarrhea and encephalitic symptoms. Apparently no tests were done to support or confirm this belief because 'I've

> seen this so often I can diagnose this with clinical exam'
> (Dr. Sherr on phone on 7/29/08 with Resident).

Exhibit 10 at pdf 36-37 / 131-32. On cross-examination, the Secretary asked Dr. Shafrir whether he agreed with the statement, attributed to Mr. Sherr, that the measles virus was "alive in her gut." Dr. Shafrir disagreed. Tr. 242.

Y.Q.'s discharge from Stony Brook came on August 1, 2008, five days after she was admitted. The discharge report presents an excellent summary of her stay in the hospital. The discharge report indicates that the consulting neurologists opined that Y.Q. was "neurologically" "intact." Exhibit 9 at pdf 24-26; see also Tr. 241. Other specialists consulted included doctors from infectious diseases, gastroenterology, and genetics. Follow-up appointments were scheduled. Exhibit 9 at pdf 24-26.

The final diagnoses were "status epilepticus due to febrile seizure." Pending the results of outstanding studies, the doctors had not reached any conclusion about the cause of the underlying febrile seizure. Exhibit 9 at pdf 24-26. From his review of this hospital stay, Dr. Holmes stated that there was no indication that Y.Q.'s treating physicians were concerned about autoimmune encephalopathy, and that the only connection between the first two seizures was that they both occurred in the context of a febrile illness. Tr. 386.

Three days after this discharge, Dr. Palevsky saw Y.Q., and reviewed the records that her parents brought to him. Dr. Palevsky noted that "multiple requests [were] made for measles testing to be done, [but] chart doesn't indicate test is pending."[12] Exhibit 7 at 14. With respect to the care the family received during the hospitalization, Dr. Palevsky stated: "Parents bullied, talked down to on pediatric unit for dietary changes, use of vitamin A, vitamin B12, use of alternative approaches, parenting styles. Parents felt treated poorly." Id.; accord Tr. 77. Dr. Palevsky's notes also indicated: "Since being in [hospital], broke out in rash under neck which spread down her back, trunk, thighs – spotted -- mid way last week, -- patches blotches on [right] + [left] arm. [Ms. Quinones] suggested it could be a measles rash, denied by medical staff." Exhibit 7 at 14.

For Y.Q.'s current status, her "parents feel she's interacting more, talking more, 'smarter,' alert more, sleeping well since [discharge] from hospital, showing more babbling, words, more affectionate, [illegible] [with] some eye deviation."

[12] Actually, the discharge report stated that after the lumbar puncture was performed, "specific tests ordered [included] . . . CSF for measles IgG." Exhibit 9 at pdf 26 / 25.

Exhibit 7 at 14. Dr. Palevsky's record is consistent with Ms. Quinones's memory. She testified "I definitely saw changes and she regained what she had lost, so by August, probably she was a little better. I don't remember when she regained full speech." Tr. 78. With a caveat about expectations of holistic doctors, Dr. Shafrir acknowledged that this report showed improvements. Tr. 243.

Dr. Palevsky added that the parents "restarted supplements this week." Exhibit 7 at 14. Dr. Palevsky's note concludes: "tried DMSA challenge, couldn't catch urine pre-provocation, pills not given. Met [with] EI [probably early intervention] for evaluation – felt motor skills were [within normal limits], recommended speech and psychology." Exhibit 7 at 14.

Dr. Palevsky recommended 13 actions. Some of these were suggestions for supplements. The 11th item reads:

> For fever, make sure she's well hydrated.
> Lavender essential oil to tops of ear lobe, back of neck and down spine 2-3x/ day. German chamomile essential oil to tops of ear lobes, back of neck + down spine 1-2 times a day.
> Warm bath, bundle to bed.
> Yarrow flower in bath tub when having fever.
> Catnip tea with chamomile tea + honey for fever.
> Motrin as needed.

Dr. Palevsky also requested that Y.Q. "return in one month" (item 12) and maintain her follow-up appointments with infectious disease, neurology, genetics, and gastrointestinal (item 13). He also suggested that the MRI should be repeated (also item 13). Exhibit 7 at 31. Ms. Quinones did not obtain the repeat MRI that Dr. Palevsky suggested. Tr. 80. A later record indicates that Y.Q. "was not followed by neurology as choice of parents." Exhibit 11 at pdf 95 / 280 (record dated April 3, 2009).

On October 18, 2008, Y.Q. was "picked up by arms [and] may have pulled out shoulder." Thus, her parents brought her to the Emergency Department at St. Catherine of Siena Medical Center. The past medical history on the triage form states: "post measles encephalitis from vaccine." Exhibit 60 at 3; see also Tr. 82. It appears that after a doctor examined her, Y.Q. was discharged to follow up with her primary medical doctor. Id. at 6. Ms. Quinones recalled that Y.Q. was not meeting her developmental milestones as she was in the midst of "years of diarrhea and screaming and fever." Tr. 82.

D. Third Seizure: April 3, 2009

In the morning of April 3, 2009, Y.Q., who was then two years old, had decreased activity and had a fever of 101.5. At approximately 2:45 PM, her fever was increasing, and she looked flushed. Then, her eyes fluttered, her face, arms, and legs shook. The episode lasted approximately 3-4 minutes and she was given Diastat, which resolved the seizure. EMS was called and the ambulance brought her to Stony Brook. Exhibit 11 at pdf 95 / 220. The triage form from the Emergency Department states as part of the past medical history "febrile seizures post measles encephalitis." Id. at pdf 94 / 219.

She was seen by a neurologist who also obtained a history. This report stated that Y.Q. had had "rhinorrhea x several days [and] rash." Id. at pdf 98 / 283. The neurologist's past medical history noted the first seizure four days after MMR vaccination and the second seizure was a prolonged febrile episode of status epilepticus. It also stated "post measles encephalopathy (as per parents)." Under developmental history, the neurologist has written: "norm" and "dev. delay(?)." Id. at pdf 99 / 284. Both Dr. Shafrir and Dr. Holmes recognized that the treating neurologist characterized her neurologic exam as normal. Tr. 245 (Dr. Shafrir); 447 (Dr. Holmes noting that Y.Q. had regained any losses in speech).

The neurologist ordered an EEG. The impression was "normal waking EEG." Exhibit 11 at pdf 109 / 294; accord Tr. 245. A comment was "This EEG does not exclude the clinical diagnosis of seizures or epilepsy." Exhibit 11 at pdf 109 / 294.

It appears that Y.Q. was discharged later on April 3, 2009. Her parents were given instructions about "Childhood Seizures" and directed to follow up with a neurologist in 5-7 days. Id. at pdf 104 / 289-91; see also Tr. 387 (Dr. Holmes's brief testimony about the third seizure). Ms. Quinones testified that she followed up with Dr. Horn, who was "very biased," and then Dr. Bello. Tr. 83.[13]

E. Fourth Seizure and Follow-up: September 3, 2009 through November 3, 2009

On September 3, 2009, Y.Q. was in her usual state of health, not sick. Tr. 84. Then she started "'twitching' to upper torso and extremities, 'spitting up'

[13] The first outpatient record from Dr. Bello appears to be from October 19, 2009, which is after the next seizure. The petitioners have not located any record from Dr. Bello from earlier than October 19, 2009. See Pet'rs' Status Rep., filed Feb. 23, 2017, at 2.

mucous," and her "'lips turned blue.'" Although Ms. Quinones gave her Diastat, the behavior continued for approximately 25 minutes. Exhibit 12 at pdf 32 / 347. It appears that an ambulance was called, although the record of transport is largely illegible. See id. at pdf 34 / 349.

When she was initially examined in the Emergency Department, Y.Q. was "awake, crying [and] inconsolable." She was not having any "seizure-like activity." She also felt warm to the touch. Id. at pdf 32 / 347.

A resident in neurology was consulted. The history of present illness begins: "Patient is known to our service for several previous seizures." The remainder repeats Y.Q.'s history of seizures. With respect to the seizure earlier that day, the resident stated that by the examination, Y.Q. was "now back to normal mental status." Exhibit 11 at pdf 122 / 307. The attending neurologist added: "treated by holistic doctors. Offered medication in the past, parents refused." Id.

The doctors kept Y.Q. overnight. During this time, she had a 24-hour video EEG. The impression was "abnormal . . . due to frequent left para – central sharp waves with phase reversals at CZ. This finding is indicative of focal cerebral dysfunction in the left para – central region." The doctor recommended correlation with neuro-imaging. Exhibit 14 at pdf 2 / 1. Dr. Shafrir interpreted this EEG as showing a worsening. Tr. 291.

After the video EEG, a neurologist again examined Y.Q. The doctor prescribed Keppra and recommended another MRI. The doctor approved a discharge home. Exhibit 12 at pdf 12 / 327.[14] In addition to including the prescription for Keppra, the discharge plan ordered an MRI on an outpatient basis and scheduled a follow-up appointment at a neurology clinic on October 19, 2009. Exhibit 11 at pdf 120 / 305.

The day following the discharge from Stony Brook, Y.Q.'s parents brought her to a different hospital for a second opinion. Exhibit 15 at 38. The chief complaint was "Mom wants to know why [Y.Q.] has seizures and behavioral problems." Id. at 13. The doctor at the Schneider Children's Hospital of the North Shore-Long Island Jewish Health System recorded a brief history of the seizures, including the fact that the MMR vaccination preceded the first seizure by four days. For medications, the note states probiotic and cellular defense. Another

[14] Although this note is dated September 3, 2009, the overall context suggests that the correct date was September 4, 2009.

medication listed is Keppra.[15] For development, the record states "Patient has been evaluated and has had [speech therapy]." In separate handwriting, the next line reads: "Mom feels child has had [developmental] regression after MMR, with return of speech." Id.

The assessment / plan reads:

> 2½ [year old] female with known seizure disorder, cyclic fevers, reports of developmental regression and chronic diarrhea. Mom has not followed with pediatrician since 15mo and has been assessed solely at DAN Center, which has supported her belief that MMR vaccine is the root of all her problems. She presents at the recommendation of pediatrician who would like all blood work done.

Id. at 15.

Again, Y.Q. stayed overnight in a hospital. Discharge from the hospital occurred the following afternoon. The plan was for Y.Q. to be seen, as an outpatient, by doctors with specialization in neurology, gastroenterology, asthma and allergy, and behavior and development. Exhibit 15 at 37; see also id. at 27.

On September 10, 2009, Y.Q.'s parents brought her to the Queen's Long Island Medical Group. She was a "well-child" but needed a referral to obtain an MRI. Exhibit 16 at 1-2. An MRI was performed at Stony Brook on September 14, 2009. It revealed a "T2 hyperintensity in the terminal zones of myelination in the parietal lobes which is less pronounced than on the previous study indicating normal progression of myelination. Again noted are prominent perivascular spaces in the bilateral frontal lobes especially." Exhibit 14 at 13.

Another visit with Queen's Long Island Medical Group took place on October 5, 2009. The reason for the visit was that Y.Q. was having a fever for four days. Ms. Quinones reported that she gets a fever up to 104 "every month."

[15] In the Schneider Children's record, the word "refused" is close to the word "Keppra." However, the word "refused" could refer to recent vaccinations. Tr. 86. In any event, another record indicates that on September 5, 2008, while at Stony Brook, Y.Q. was started on Keppra. Exhibit 15 at 39. Ms. Quinones testified that Y.Q. tried Keppra but "she started getting worse, way worse, overturning furniture, throwing tantrums. And I researched, the side effect was Keppra rage, so we had to discontinue." Tr. 85.

Exhibit 16 at 3. The doctor wanted Ms. Quinones to treat the symptoms of fever with "Tylenol / Motrin." Id. at 4.

On October 19, 2009, a pediatric neurologist, Lourdes Bello, saw Y.Q. in her office at the request of Dr. Palevsky. Dr. Bello's history of present illness mentions that Y.Q. has been taking a dose of Keppra without significant side effects. The past history includes the recitation of "post MMR vaccination encephalitis." Exhibit 14 at 4.[16] It also states that Y.Q. "has been followed by a holistic physician who relates her symptoms to her initial episode of encephalitis. Her parents had been reluctant, until this last episode, to the administration of anti-seizure medication. She also has returned episode of high fever every month with unexplained diarrhea with a temperature that goes up to 105." Exhibit 14 at 3-4. Under developmental history, Dr. Bello recorded "her milestones have been achieved on time. Her mother states that she [had] loss of speech after she had the episode of vaccination. She recovered after intervention." Id. at 4. Dr. Shafrir acknowledged that Dr. Bello's history did not note any behavioral problems. Tr. 247.

After obtaining this information, Dr. Bello conducted a neurologic exam. Based upon her examination, Dr. Bello reported: "She was awake, alert and interactive with appropriate orientation. She followed commands with good attention and concentration. She displayed an age appropriate language and articulate speech." Exhibit 14 at 5.

Dr. Bello's impression was that Y.Q.

> has a very high risk for recurrent episode of status epilepticus and in the past she had [an] episode of cardiac arrest that has been necessary to admit her in the hospital. Explained to the parents upon admission and now during the visit that it is very important that Y.Q. gets medication in order to prevent these episodes that are becoming more frequent.

Exhibit 14 at 5-6. Dr. Bello also stated that after reviewing the results of the MRI, the "findings [that] were present during her admission for possible measles encephalitis are not present any more." Id.; accord Tr. 88. Dr. Bello closed her

[16] Dr. Bello added that she did "not have details from [the] admission" when Y.Q. presented with changes in her mental status after the MMR vaccination. Exhibit 14 at 5. Dr. Shafrir stated that this notation meant that Dr. Bello did not review the medical records from that hospitalization. Tr. 249.

letter by stating "I expect her to be under control." Exhibit 14 at 5-6. Dr. Holmes agreed with Dr. Bello's finding and added a diagnosis of epilepsy. Tr. 387-88.

On November 3, 2009, Y.Q. returned to see Dr. Palevsky for the first time in 15 months. His note begins by saying in those 15 months Y.Q. "has been seeing Dr. Sherr." See exhibit 7 at 34 (May 21, 2009 note from Alan Sherr stating that Y.Q. is "under [his] care").

Dr. Palevsky has a lengthy description of Y.Q.'s current behavior:

> [She] did summer camp – did well, no hitting, no biting. At home-bites, hits throws herself on the floor, hitting, spitting throws up, go after dog, makes herself throw up. [She] has order, compulsion about things, very repetitive, gets angry very easily. Parents have tried time-outs, discipline, nothing seems to work.

Exhibit 7 at 15. Additionally, Dr. Palevsky recorded that Y.Q. was restless, especially at bed time.

Dr. Palevsky made eight recommendations, mostly about supplements which Y.Q. had not been taking. He also asked that Y.Q. return in one month. Id. at 35.

F. Fifth Seizure: November 10, 2009

On the evening of November 9, 2009, Y.Q. had a fever and did not eat as much. The next day, at approximately 6:45 PM, she had a seizure. After approximately 15 minutes, her parents gave her Diastat, but it had no effect. Exhibit 13 at pdf 18 / 440. When an ambulance arrived, her pupils were dilated, and she was unconscious. Id. at 21 / 443. The ambulance brought her to Stony Brook. In the Emergency Department, she was given another dose of Diastat, which improved her condition slightly. The doctors then gave her 1 mg of Ativan intravenously and the Ativan broke her seizure. Id. at 440.

A neurologist came to evaluate Y.Q. at approximately 8:00 PM on November 10, 2009. The neurologist added that before she had her seizure, Y.Q. missed her morning dose of Keppra. During the seizure in the Emergency Department, she had desaturated and was placed on a face mask. When the neurologist was examining her, Y.Q. was "post ictal" and "responsive to verbal commands." Exhibit 12 at pdf 81 / 396. The neurologic resident's notes of past medical history include: "febrile seizures since 15 mo." "post measles encephalitis" "monthly fevers + diarrhea" "evaluated for autism due to [history of]

loss of speech and eye contact post immunization [with] MMR." The attending neurologist revised this note, stating "Disagree re 'measles encephalitis.' This is mother's report as febrile seizures occurred post MMR." Id. at pdf 82 / 397; accord Tr. 252.

After an examination, the neurology team admitted Y.Q. to the Pediatric Department. They ordered various tests, including a head CT, a lumbar puncture, an EEG, labs in the morning, and Keppra now. Id. at pdf 84 / 399.

The CT scan did not show any "acute intracranial pathology." Exhibit 13 at pdf 60/ 482. However, the 24-hour video EEG was abnormal. "Intermittent high voltage slowing [was] seen over the left hemisphere." Id. at pdf 62 / 484.

While in the hospital, a pediatrician created a comprehensive assessment. Dr. Stern also obtained a history that Y.Q. "missed Keppra doses x2." Exhibit 12 at pdf 93 / 408. He stated, "Mom attributes loss of milestones @ 15 months to MMR vaccine and has sought out 'vaccine reversal' therapy from her current [primary medical doctor]." For developmental and behavioral history, he recorded "no concerns until 15 mo, has had speech delay since. No current [occupational therapy] / speech therapy." Id. at pdf 95 / 410. The items in his plan included "Mom requests measles [immunoglobulin] of LP performed." Id. at pdf 100 / 415.

While still in the hospital, Dr. Bello consulted on Y.Q.'s case. Her impression was "epilepsy symptomatic with seizures associated with fever. Status [epilepticus] triggered by withdrawal / missed one dose [of Keppra]." Exhibit 13 at pdf 6 / 428. Under plan, Dr. Bello wrote "I believe seizures are multifactorial, not only febrile. [Y.Q.] has abnormal MRI in the past with focal spike over the [left] hemisphere. Keppra should be optimized." Id. at pdf 7 / 429. Dr. Shafrir interpreted Dr. Bello's use of the term "symptomatic" as indicating that Dr. Bello believed that the epilepsy was secondary to some problem in Y.Q.'s brain, even if the doctors could not identify the cause of the epilepsy. Tr. 189, 293. Dr. Holmes concluded that Y.Q. was predisposed to seizures but there was not a firm etiology for the seizures. Tr. 390.

Other events were summarized in the discharge report. The expected follow-up care was to see a neurologist in three weeks. Exhibit 12 at pdf 78-80 / 393-95.

G. Remainder of 2009, 2010, and 2011

Before this appointment with the neurologist occurred, Y.Q. saw Dr. Palevsky on December 8, 2009. Dr. Palevsky records many behavioral concerns.

Exhibit 7 at 15-16. For example, Y.Q. "can't make a decision — wants, doesn't want" and she "screams [with] radio in kitchen when turned on." Id. at 15. On physical exam, she was "alert, active, [moves all extremities]." She had "NL tone." She was "happy, playful [and] calm." Id. at 16. For assessment, Dr. Palevsky indicated "seizures, fever, [and] food allergies." Id. Dr. Palevsky continued his recommendations for supplements, a restricted diet, and to continue Keppra with Diastat for emergencies. Id. at 36.

Although Y.Q. saw Dr. Bello less frequently in 2010, one appointment occurred on In January 11, 2010. Her parents reported that Y.Q. has had "some episodes of monthly fever without seizures." Exhibit 14 at 14. Dr. Bello emphasized the need to prevent fevers. Dr. Bello's conclusion stated, in part:

> recommendations were given about the management of these recurrent episodes of fever that it [sic, presumably Y.Q.] has been experiencing in monthly basis for more than one year. Extensive workup had been done in the past and no apparent reason has been found for these episodes of fever. I explained the importance of controlling the fever despite the fact that she has been recommended not to give the medication for it by her primary pediatrician according to her mother. I chose . . . to keep the current dose of Keppra 3.5 mL twice a day that seems to be working for her.

Exhibit 14 at 15.[17]

Other portions of the history that Dr. Bello obtained indicated that Y.Q. "appears to be cranky and irritable and she is worried about the presence of new seizures. Other than that[,] no new symptoms from the neurological point of view at present." Exhibit 14 at 15. Dr. Shafrir interpreted crankiness and irritability as example of behavioral problems. Tr. 250.

Dr. Bello conducted a neurologic examination, recording the following information: "She was awake. She displayed an appropriate affect, and age-appropriate fund of knowledge and skill development was demonstrated. Speech

[17] Although Dr. Bello's report states that mom said that Y.Q.'s primary pediatrician (meaning Dr. Palevsky) had recommended not giving medication, Dr. Palevsky's December 8, 2009 recommendations included maintaining Keppra.

and language and participation in tests of neurologic examination were age appropriate." Exhibit 14 at 15.

Dr. Bello's strongest recommendation was to prevent fevers as mentioned above. Dr. Bello also ordered lab tests. "Other than that[,] no other intervention is needed at this point." Id. Dr. Bellow recommended a follow-up in four months.

On May 3, 2010, Dr. Bello recorded that since the last admission in November 2009, Y.Q. "has not had any other episodes of seizures and she is doing very well." However, Ms. Quinones expressed "significant behavioral issues." Ms. Quinones also believed that Y.Q. "has sensory integration disorder." Exhibit 14 at 19. Dr. Bello referred them to a behavioral pediatrician and to occupational therapy. Id. at 20. Ms. Quinones reported that children protection services has been involved with Y.Q. due to allegations of paternal drug abuse. Id. at 19. Ms. Quinones stated that she was currently separated from her husband and feared for her safety. Id.

In a follow-up appointment nearly five months later, Dr. Bello reported that Y.Q. "was evaluated by a specialist in sensory integration disorder and they agreed that she meets the criteria." Id. at 22. Y.Q. had not had any seizures in the interim.

The specialist who concluded that Y.Q. suffered from sensory integration disorder is not readily apparent.[18] However, on December 1, 2010, a developmental psychologist, Janet E. Fischel, PhD, spent approximately 75 minutes with Y.Q. Dr. Fischel noted behavioral concerns and recommended that Ms. Quinones explore whether the local school system could provide some intervention. Exhibit 20 at 2-4.

Earlier in 2010, on September 16, 2010, Mr. Sherr, the chiropractor affiliated with Dr. Palevsky, completed a form to aid in determining whether Y.Q. was entitled to disability benefits pursuant to the Social Security Act. Mr. Sherr's treating diagnosis was "Post Encephalitis as a result of MMR inoculation." Y.Q.'s current symptoms included: "irate behavior, mood changes, toxicity changes, muscle spasms, intermittent fevers + seizures." Exhibit 8 at 117. In response to a question about the "etiology of impairment," Mr. Sherr wrote "MMR Inoculation

[18] During the hearing, the petitioners' attorney identified Dr. Fischel as a consultant relevant to the sensory integration disorder. Tr. 22. However, the record that the attorney identified, exhibit 20 at 1, indicates that the family cancelled an appointment with Dr. Fischel scheduled for July 21, 2010.

— May 2008." Id. at 118. Mr. Sherr also indicated that he could not provide a medical opinion about Y.Q.'s ability to work. Id. at 120.

In 2011, Dr. Bello saw Y.Q. three times. Dr. Bello continued to report that although Y.Q. was not having more seizures, she was having behavioral problems. See exhibit 61 at 3 (Mar. 22, 2011), exhibit 36 at 3 (Aug. 13, 2011), exhibit 39 at 2 (Dec. 7, 2011); accord Tr. 88-89. In 2011, Y.Q. began receiving some early intervention services through the local school system. See exhibit 120, passim.

H. 2012 through 2016

By June 2012, Dr. Bello was recommending a psychological evaluation for Y.Q. However, Ms. Quinones was resisting. Exhibit 39 at 5. However, on August 17, 2012, Y.Q. was involved in a violent episode resulting in a visit to the Emergency Department of Stony Brook. Exhibit 62 at 20. In Stony Brook, Y.Q. received a psychiatric consult. Id. at 46.

The behavioral issues for which Y.Q. received psychiatric and psychological treatment need not be detailed here. Dr. Holmes testified that the behavioral problems are linked to her epilepsy in that the seizures and the behavioral issues both flow from some disorganization or problem in Y.Q.'s brain. Tr. 409, 426, 430; c.f. Tr. 520 (Dr. Shafrir's assessment of Dr. Holmes's opinion that the same process causes seizures and psychiatric problems). Thus, if Ms. Quinones establishes that the March 28, 2008 MMR vaccine caused epilepsy, then she will receive compensation for Y.Q.'s psychological problems as a sequela to those seizures. For purposes of this decision, it is sufficient to note that Y.Q.'s psychological problems remain severe. See exhibit 39 at 6 (Dr. Bello's note from Sept. 26, 2012), exhibit 83 at 3-6 (service plan from Amanda Romano, dated May 7, 2013), exhibit 62 at 218 (admission to Stony Brook on May 24, 2013), exhibit 61 at 18-20 (Dr. Bello's note from Sept. 18, 2013), exhibit 62 at 400 (discharge from Stony Brook on Oct. 21, 2013), exhibit 62 at 762 (Emergency Department triage on Jan. 14, 2014), exhibit 85 at 171 (discharge from South Oaks Hospital on Jan. 25, 2014), exhibit 80 at pdf 478-82 (psychiatry evaluation at Stony Brook on Oct. 23, 2014), exhibit 83 at 107 (Peterson Krag service plan, dated Nov. 26, 2014), exhibit 113 at 3-9 (psychological evaluation performed by school system when Y.Q. was in second grade on June 1, 2015), exhibit 115 at 7 (abnormal video EEG, dated Aug. 24, 2015).

Records from Longwood School district indicate that Y.Q. scores within the average range on standardized tests. However, she continues to have significant psychological problems. See exhibits 113, 121.

Y.Q.'s parents testified during the January 26, 2017 hearing that her most recent seizure was September 4, 2015. Tr. 36-37, 46, 104. They also stated that she likes to express herself through art. Tr. 91.

Standards for Adjudication

Compensation under the Vaccine Act is available in two major forms. Table injuries, which presume causation, can be established if a prescribed injury occurs during a set period of time following a specific vaccination. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Alternatively, petitioners can receive compensation for injuries not provided for in the Vaccine Injury Table by bringing a successful petition for compensation under 42 U.S.C. § 300aa-11(c)(1)(C)(ii) of the Vaccine Act.

Petitioner's burden of proof as an off-Table injury is explicitly defined by Congress. The Act provides that a petitioner must show, by a preponderance of the evidence, that the vaccination caused or significantly aggravated his illness or injury. See 42 U.S.C. § 300aa–13(a)(1) and 42 U.S.C. § 300aa-11(c); see also Moberly, 592 F.3d at 1322 (noting that petitioners must prove causation by the traditional tort standard of preponderance). As for what is specifically required to meet this burden, the statute requires that the conclusion of the court or special master may not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). The statute does not speak to the strength or reputability of the medical opinion, just that a medical opinion or medical records are necessary for a claim to be meritorious. See id.

In drawing conclusions on causation, the Federal Circuit has noted that special masters must be careful not to raise petitioners' burden by establishing tests that create requirements not in the statute itself. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (rejecting a test that required "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities"); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279 (Fed. Cir. 2005) (rejecting a test requiring "confirmation of medical plausibility from the medical community and literature" to prove causation in fact); Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) ("to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

Instead, special masters must consider all the evidence and decide whether the causal link between the vaccination and the injury was logical and legally

probable. See Knudsen, 35 F.3d at 549 ("The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [] injury"); Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury"); Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991) ("causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury").

In determining whether preponderant evidence exists, the Federal Circuit has set forth a three-part framework for evaluating claims of vaccine injury causation. As explained in Althen, and subsequent opinions, petitioners must put forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

Analysis

I. Prong one - Theory

Although the theory connecting a vaccine to an injury is frequently a difficult point of evaluation, see Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed Cir. 2012), this case is exceptional. Here, at the start of the hearing, the Secretary admitted that the MMR vaccine can cause febrile seizures. Tr. 10, 12.

This admission, in turn, is well rooted. In 2012, the Institute of Medicine evaluated 19 epidemiological studies and 15 publications regarding mechanistic evidence for a causal relationship between the MMR vaccine and febrile seizures. The IOM found "The evidence convincingly supports a causal relationship between MMR vaccine and febrile seizures." Court Exhibit 1001 (Institute of Medicine, Adverse Effects of Vaccines Evidence and Causality, Stratton, Kathleen et al. (eds) (2012)) at 132.

The Secretary acknowledged the conclusions of the IOM when the Secretary proposed changes to the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, 45139 (proposed July 29, 2015). However, the Secretary independently concluded that he did not need to revise the Table because the "injury is transient in nature." Id. at 45135. Based upon two epidemiologic studies, the Secretary

determined that "the overwhelming majority of children who have febrile seizures recover quickly and have no lasting effects. Only very rarely can febrile seizures lead to serious injury or disability . . . . [T]he Program will consider causation-in-fact claims for febrile seizures leading to serious injury or death on a case-by-case basis." Id. at 45139-40.

Thus, on the most basic level, the evidence supports a finding that the MMR vaccine can cause febrile seizures. But, the more complicated questions are the appropriate temporal interval and what are the consequences, if any, to an MMR-induced febrile seizure? These questions are taken up in the following sections.

II. Prong three - Timing

In addition to presenting a reliable medical theory explaining how the MMR vaccine can cause febrile seizures, the Quinoneses must also show that Y.Q.'s first febrile seizure occurred in a medically appropriate timeframe to infer causation. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). To satisfy the third Althen prong, the petitioners' burden is to present "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." Id. ; accord Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), reconsideration denied after remand, 105 Fed. Cl. 353 (2012), aff'd without opinion, 503 Fed. App'x 952 (Fed. Cir. 2013).

A. Onset of Neurologic Problem

Of the two parts to the temporal prong, the easier-to-resolve part addresses when Y.Q. began to have neurologic problems. Dr. Shafrir opined that the onset of Y.Q.'s neurologic problem was her febrile seizure. Tr. 176. This opinion is persuasive.

In contrast, Dr. Holmes asserted that Y.Q. started having neurologic problems the day after vaccination. Tr. 398, 404. Dr. Holmes grounded his opinion on an affidavit that Y.Q.'s mother submitted for this litigation. See exhibit A at pdf 6-7 (Dr. Holmes's first report citing Donna Quinones's affidavit, exhibit 1). Dr. Holmes's acceptance of this affidavit seems opportunistic in that, in the undersigned's experience, the Secretary's experts typically do not rely upon assertions found in affidavits, uncorroborated by medical records created contemporaneously. Regardless, Dr. Shafrir persuasively pointed out that the normal process by which a vaccine can make a child feel discomfort a day later

differs from the unexpectedly adverse process by which a vaccine causes a neurologic problem. Tr. 353-55.

B. Appropriate Temporal Interval

While the IOM determined that the MMR vaccine can cause febrile seizures, the IOM did not define the amount of time for which an inference of causation is appropriate. See Court Exhibit 1001. Similarly, the Secretary's Notice of Proposed Rulemaking did not set out any temporal limits on this question.

The IOM's analysis warrants a more detailed examination. The IOM made slightly different statements about the timing found in studies, depending on whether the studies were epidemiologic or mechanistic. In the mechanistic studies, the "latency between vaccination and the development of symptomology … ranged from hours to 28 days after administration of a vaccine containing measles, mumps, and rubella alone or in combination; however, most of the cases discussed above presented between 7 and 14 days after vaccination." Court Exhibit 1001 at 132. The epidemiologic studies "found an increase in seizures within 7 to 14 days following MMR vaccination." Id. at 124.

While the epidemiologic studies reached a consensus that seizures were increased in the second week after the MMR vaccination, two studies found some evidence of an increased incidence within the first week. In the first study, researchers from the Centers for Disease Control and Prevention Vaccine Safety Datalink Working Group consulted information contained in the Vaccine Safety Datalink project, which collects information from health maintenance organizations. These researchers determined that the relative risk for experiencing a febrile seizure within 1-7 days of an MMR vaccination was 1.73 with a 95% confidence interval of 0.72-4.15. Exhibit 24 (William E. Barlow et al., The Risk of Seizures after Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine, 345 No. 9 N. Engl. J. Med. 656 (2001)) at 659 (table 1).

In the second study, Danish researchers analyzed more than a half million computerized medical records of children born in Denmark from 1991 through 1998. This group found that the relative risk for febrile seizures in the week after MMR vaccination was 2.46 with a 95% confidence interval of 2.22-2.73. Exhibit NN (Mogens Vestergaard et al., MMR vaccination and febrile seizures: evaluation of susceptible subgroups and long-term prognosis, 292 No. 3 JAMA 351 (2004)) at 353.

In response to the studies, the Secretary offered some criticisms through the report and testimony of Dr. Holmes. Exhibit CCC; Tr. 406-08, 489-90. This critique shows that the studies are not perfect, but perfection is not the standard. Epidemiologic studies can undermine a petitioner's claim that a vaccine caused an injury. See, e.g., Heddens v. Sec'y of Health & Human Servs., No. 15-734V, 2018 WL 5726991, at *3 (Fed. Cl. Spec. Mstr. Oct. 5, 2018), mot. for rev. denied, 143 Fed. Cl. 193 (2019). Here, these two studies support a finding that the MMR vaccine can cause febrile seizures toward the end of the first week following vaccination.

Further support for the finding that the MMR vaccination can cause an adverse event in as few as five days after the vaccination is found within the Vaccine Injury Table. There, the Secretary has indicated that the MMR vaccination is the presumptive cause of an encephalopathy — as defined in the regulation — that develops 5-15 days after vaccination. 42 C.F.R. § 100.3(a) ¶ (III)(B) (2011). The regulatory definition of encephalopathy does not encompass Y.Q.'s presentation on April 1, 2008. For instance, Y.Q. did not suffer an extended loss of consciousness. However, it seems likely that the process by which MMR vaccine can cause an injury as severe as an encephalopathy in five days could also cause a less severe injury (a febrile seizure) in 4.5 days. As Dr. Shafrir explained, there is not much biological difference between an injury appearing four days after vaccination and five days after vaccination. Tr. 137-38, 176. The analogy between febrile seizures and encephalopathy is strengthened by decisions of special masters that found febrile seizures were a manifestation of an encephalopathy under the earlier and broader definition of the term "encephalopathy." Fuller v. Sec'y of Health & Human Servs., No. 90-3709V, 1996 WL 65734, at *8 (Fed. Cl. Spec. Mstr. Jan. 31, 1996) (respondent's expert conceded that the child-vaccinee "suffered seizures following her DPT vaccination and that these seizures constituted an encephalopathy"); Cepeda v. Sec'y of Health & Human Servs., No. 90-2664V, 1994 WL 390352, at *5 (Fed. Cl. Spec. Mstr. July 12, 1994) (citing cases).

Finally, non-binding precedent supports a finding that four days is an appropriate interval to infer that MMR vaccine caused a febrile seizure. One example is Cusati v. Sec'y of Health & Human Servs., No. 99-492V, 2005 WL 4983872, at *2-3 (setting out chronology of events), *10 (finding entitlement) (Fed. Cl. Spec. Mstr. Sept. 22, 2005).

For all these reasons, the petitioners have established that the MMR vaccine can cause febrile seizures appearing as early as four days after the vaccination.[19] And, because Y.Q.'s febrile seizure occurred approximately 4.5 days after vaccination, the petitioners have established the third prong of Althen.

III. Prong two - Logical Sequence of Cause and Effect

The remaining prong from Althen is to demonstrate that the MMR vaccine did cause Y.Q.'s febrile seizure. The undersigned has already found that the MMR vaccine can cause febrile seizures on the fourth day after vaccination. Therefore, it is a relatively short step to finding that the MMR vaccine was causal in Y.Q.'s case. Dr. Shafrir's testimony on this point carries the burden of proof. Tr. 178-90.

IV. Sequela

Although the Quinoneses, by establishing the Althen prongs, have demonstrated that the MMR vaccine was the cause-in-fact of Y.Q.'s febrile seizure, the Quinoneses also must demonstrate that Y.Q.'s injury lasted for more than six months. In other words, the Quinoneses bear the burden of proving that the febrile seizure caused a lasting consequence. Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1570 (Fed. Cir. 1993) (once the initial injury has been established, petitioner must establish by a preponderance of the evidence that the initial injury caused the sequela). This question is the most beguiling issue in the case.

Citing the same two epidemiologic studies that analyzed the rate of febrile seizures in the first week after MMR vaccination, the Secretary stated that: "The long-term rate of epilepsy was not increased in children who had febrile seizures

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[19] Drawing lines between an appropriate temporal interval and an inappropriate temporal interval is difficult. See Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 482 (2012) (ruling that the special master should not have set a "hard and fast" deadline of two weeks), aff'd, 786 F.3d 1373, 1384 (Fed. Cir. 2015) (holding that the special master erred in setting a "hard and fast" deadline of three weeks).

However, the evidence, while nearly balanced, tips in favor of a finding that four days is appropriate. Having made this finding, the undersigned is not sure that three days would be appropriate. See Austin v. Sec'y of Health & Human Servs., No. 10-362V, 2012 WL 592891, at *6 n.15 (Fed. Cl. Spec. Mstr. Jan. 24, 2012) (deferred ruling on motion for interim fees and noting that a claim that MMR vaccine caused a seizure 24-48 hours later may not be supported by reasonable basis); but see Austin v. Sec'y of Health & Human Servs., No. 10-362V, 2013 WL 659574, at *11 (Fed. Cl. Spec. Mstr. Jan. 31, 2013) (granting motion for final fees and concluding that there was an "extremely weak" reasonable basis until petitioner could not obtain a favorable expert report).

following MMR vaccination compared with children who had febrile seizures of a different etiology." 80 Fed. Reg. at 45139 (citing Vestergaard and Barlow). The Secretary declined to list febrile seizures on the proposed Vaccine Injury Table because they "only very rarely have long term consequences." Id. at 45140. Of course, petitioners can be awarded compensation on off-Table claims before the Secretary determines than a vaccine-injury combination has reached the threshold to be included on the Vaccine Injury Table.

The Secretary's acknowledgment that febrile seizures produce long-term consequences "very rarely" implies that febrile seizures can lead to lasting problems. In his Notice of Proposed Rulemaking, the Secretary did not define the situation or situations in which febrile seizures could cause long-term consequences. Instead, the Secretary left this determination to be made on a "case-by-case basis," again with the implication that some cases can establish long-term consequences from febrile seizures. Id.[20]

Here, the Secretary retained an expert, Dr. Holmes, who opined that the April 1, 2008 febrile seizure did not carry a lasting consequence for Y.Q. In contrast, the Quinoneses's expert, Dr. Shafrir, saw the April 1, 2008 febrile seizure as a turning point in her life. Overall, both parties could have advanced their positions more effectively by developing evidence in more detail.[21]

Sources of information about Y.Q.'s functioning after the April 1, 2008 febrile seizure include records from Kids Care Pediatric, Dr. Palevsky, Stony Brook University Hospital, and Y.Q.'s mother's testimony. The earliest material comes from Y.Q.'s traditional pediatrician. The day after the febrile seizure, the doctor recorded a chief complaint that Y.Q. was "cranky [with] different behavior." Exhibit 6 at 11. Yet, at the same time, her neurologic exam was normal.

More details are found in the records Dr. Palevsky created. The Quinoneses's decision to have Y.Q. treated by a holistic doctor, Dr. Palevsky, increases the difficulty in determining whether the April 1, 2008 febrile seizure caused lasting consequences. Nevertheless, Dr. Palevsky's records show that by

[20] Because this case does not present a legal question about the meaning of a regulation, this case does not implicate deference to an agency's interpretation. See Kisor v. Wilkie, 139 S. Ct. 2400 (2019).

[21] The relative thinness of the parties' evidentiary development is consistent with the parties' post-hearing memoranda in which each party devoted less than one page to this issue. See Pet'rs' Br. at 11; Resp't's Resp. at 7.

May 5, 2008 (or slightly more than one month after the febrile seizure), Y.Q. had "tantrums, fevers, aggression less interaction, restlessness [and] does not cuddle." Exhibit 7 at 20. Y.Q. continues to be plagued by tantrums and aggressiveness years later.

To be sure, Dr. Palevsky's records note some improvements with Y.Q. See, e.g., exhibit 7 at 12 (June 10, 2008: "good eye contact, interactive"). However, this improvement is tempered by the presence of "head banging," "biting," and "hair pulling." Id.; see also id. at 13 (July 7, 2008: "head banging … continues").

In addition, when Y.Q. was discharged following her second seizure, the discharge report indicates that the neurologists considered her to be neurologically "intact." Exhibit 9 at pdf 24-26. Similarly, after the third seizure on April 3, 2009, the treating neurologist found her neurologically normal. Exhibit 11 at pdf 99 / 284; see also Tr. 245, 447.

Y.Q.'s improvements do not preclude a finding that the April 1, 2008 febrile seizure carried long-term consequences. Dr. Shafrir explained that the symptoms in a person with autoimmune epilepsy or autoimmune encephalitis wax and wane. Tr. 283, 514-15. This testimony is persuasive. See Moriarty v. Sec'y of Health & Human Servs., 130 Fed. Cl. 573, 575 (2017) ("After [the vaccinee's] seizures ended, she continued to receive treatment for deficits in language, attention, memory, and other skills"); Fuller, 1996 WL 65734, at *10 ("While "[the vaccinee's] developmental delay was not immediately apparent [following her encephalopathy],[] by the time she was called upon to express herself verbally, all care providers noted [her] language delay. Later, her attention deficit disorder and hyperactivity, as well as behavior problems, and some fine and gross motor deficits were noted"); Lurtz v. Sec'y of Health & Human Servs., No. 90-1703V, 1998 WL 321926 (Fed. Cl. Spec. Mstr. June 4, 1998); Clark v. Sec'y of Health & Human Servs., No. 90-537V, 1991 WL 33243, at *6 (Cl. Ct. Spec. Mstr. Feb. 25, 1991); but see Finley v. Sec'y of Health & Human Servs., No. 00-405V, 2002 WL 1488758, at *11 (Fed. Cl. Spec. Mstr. May 29, 2002), mot. for rev. denied, 55 Fed. Cl. 355 (2003), app. dismissed, 60 F. App'x 801 (Fed. Cir. 2003).

In short, the evidence about any sequela to Y.Q.'s April 1, 2008 febrile seizure is relatively thin. While the evidence is not especially conclusive, "clear and convincing" is not the evidentiary threshold. Instead, the evidentiary threshold is merely a preponderance of the evidence and the Quinoneses have passed that measure. Cf. Althen, 418 F.3d at 1280 ("close calls regarding causation are resolved in favor of injured claimants"). The sequela have satisfied the six-month severity requirement. Accordingly, the Quinoneses are entitled to compensation.

Conclusion

The Federal Circuit has stated that compensation is appropriate when a petitioner can provide evidence of a reputable medical theory attributing the vaccinee's injury to the vaccination, evidence of an appropriately proximate temporal relationship between the two, and evidence that the causal association is logical. The Quinoneses have met this standard and, therefore, are entitled to compensation on behalf of Y.Q. under the Vaccine Act.

An order regarding damages will be issued shortly.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master