In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

NORA KENNEY,	*	
	*	No. 11-363V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: January 16, 2015
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SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement, autoimmune epilepsy.
	*	
Respondent.	*	

Ronald C. Homer, Conway et al., P.C., Boston, MA, for petitioner;
Debra A. Filteau Begley, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

At age 18, Ms. Kenney received a series of vaccinations. She alleges that one or more of these vaccines caused her to develop autoimmune epilepsy and seeks compensation through the National Childhood Vaccine Injury Compensation Program. 42 U.S.C. § 300aa—10 to 34 (2006).

None of Ms. Kenney's treating doctors diagnosed her as suffering from epilepsy that originated as an autoimmune reaction. Lacking this diagnosis from

[1] Petitioner filed a motion to redact this decision. That motion was denied and the petitioner did not seek review. This decision is being posted as originally issued, the only change being this footnote. 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 decision on its website. 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.

one of her treating physicians, Ms. Kenney retained Dr. Spencer Weig to opine on her case. Dr. Weig testified at a hearing as did Rajesh Sachdeo, a doctor whom the Secretary hired. Dr. Sachdeo did not agree with Dr. Weig's opinion that Ms. Kenney suffered from autoimmune epilepsy.

Ms. Kenney has failed to establish the persuasiveness of Dr. Weig's opinion that Ms. Kenney suffered from autoimmune epilepsy. Several reasons support this finding. Ms. Kenney's clinical presentation greatly differed from how typical cases of autoimmune epilepsy manifest. Her doctors did not order any tests that, depending on the test's outcome, could have supported a diagnosis of autoimmune epilepsy. Her treating doctors did not include autoimmune epilepsy as among the potential conditions from which she suffered. Moreover, with respect to diagnosing autoimmune epilepsy, Dr. Sachdeo has stronger qualifications than Dr. Weig. Under these circumstances, Dr. Sachdeo's testimony that Ms. Kenney did not suffer from autoimmune epilepsy is more persuasive than Dr. Weig's opinion that she did.

Because a petitioner must prove that she suffers from the condition for which she is seeking compensation, the flaw in Ms. Kenney's proof relating to diagnosis defeats her claim for compensation. The Clerk's Office is directed to enter judgment in accord with this decision.

I. Facts[2]

Ms. Kenney was born in 1989. Exhibit 1 at 1. During her first 18 years, she received a series of routine childhood vaccinations and her pediatrician's office did not record any information about an adverse reaction. Exhibit 6 at 1-5. Ms. Kenney, except for some typical childhood ailments, was healthy. See exhibit 6, passim. In June 2008, Ms. Kenney graduated from high school and was looking forward to beginning college in the fall. Exhibit 12 (Ms. Kenney's affidavit) at 1.

On June 16, 2008, Ms. Kenney had a routine medical examination, in which her doctor did not identify any health problems. During this medical appointment, Ms. Kenney received a dose of the tetanus-diphtheria-acellular pertussis (Tdap) vaccine, meningococcal vaccine, and human papillomavirus (HPV) vaccines.

[2] The parties agree that the medical records created contemporaneously with the events they describe are accurate. See Jt. Prehr'g Submission, filed July 2, 2013, at 2.

Exhibit 6 at 1-2, 35-36. She did not report experiencing a fever after these vaccinations. See Tr. 55.

In the evening of June 20, 2008, Ms. Kenney drank a large amount of alcohol. Alcohol use can decrease a person's threshold for having seizures. Tr. 64-66. After consuming excessive alcohol, Ms. Kenney felt nauseated the following day and had a mild headache that Ms. Kenney "attributed to 'being hung over.'" Exhibit 1 at 2.

Later on June 21, 2008, Ms. Kenney was preparing to go out with friends. She was taking a shower, when her friends "heard a thump in the bathroom and found [Ms. Kenney] unconscious on the floor." Exhibit 1 at 2. Ms. Kenney awoke within a few seconds. Id.

An ambulance brought Ms. Kenney to an emergency department. Before she reached the hospital, Ms. Kenney was given saline via an intravenous line. Exhibit 1 at 2-3, 7; see also Tr. 133-35. The triage nurse noted that Ms. Kenney was alert and oriented to person, place, and time. In addition, the nurse recorded that Ms. Kenney could walk normally. Exhibit 1 at 1. The emergency room doctor examined her. The neurologic aspect revealed that Ms. Kenney had symmetric deep tendon reflexes, normal strength and gait, and good coordination. Exhibit 1 at 2. The doctor diagnosed Ms. Kenney as suffering syncope and dehydration. Id. at 7.[3]

Nearly two months later, on August 13, 2008, Ms. Kenney received a second dose of the HPV vaccine. Exhibit 6 at 24; exhibit 11 at 1. By September 2008, Ms. Kenney was living in a college dormitory. On September 2, 2008, after going shopping, Ms. Kenney was talking with her friends in a "very hot and humid dorm hallway." Exhibit 9 at 3. Although everyone around her was sweating, her skin

[3] Dr. Sachdeo's interpretation of the June 21, 2008 event was consistent with the treating doctor's evaluation --- Ms. Kenney suffered an episode of syncope. Dr. Sachdeo noted that no one reported any tonic-clonic behavior and that Ms. Kenney seemed to be back to normal within seconds of recovering consciousness, something that would not happen so quickly after a seizure. Tr. 134-35.

In contrast, Dr. Weig characterized the June 21, 2008 event as a seizure. However, his explanation was relatively cursory and did not extensively discuss the medical records created on June 21, 2008. See Tr. 38-39.

was pink, warm, and dry. Id.[4] She "started to feel strange and lightheaded." Exhibit 12. Ms. Kenney's friends told the ambulance personnel that Ms. Kenney went down to the ground without striking her head and "actively seized (tonic-clonic) for approximately 30-35 seconds." Exhibit 9 at 3. She was reported to be post-ictal.

An ambulance brought her to another emergency department. The doctor recorded a history of a vasovagal episode in June 2008, and noted no history of alcohol or drug use before the present episode. Exhibit 2 at 2. The examining doctor observed that she "had bit her tongue during the seizure with bleeding controlled at this time." Id.[5] She was "alert and oriented X 3." Id. at 3. Ms. Kenney was administered 1 gram of fosphenytoin IV in the emergency room. Id. at 22. This drug is administered for the treatment of seizures occurring during neurosurgery. Physician's Desk Ref., available at http://www.pdr.net/drug-summary/fosphenytoin-sodium?druglabelid=1730. The emergency room doctor ordered a head CT scan of Ms. Kenney without contrast. The radiologist reported that the reason for the test was that Ms. Kenney "fell and [had a] seizure." No problems were identified on the September 2, 2008 CT scan. Exhibit 2 at 18.

The doctors discharged Ms. Kenney. "While [her] roommate and [Ms. Kenney] were waiting for a ride home, [Ms. Kenney] had another seizure." Exhibit 12 at 2; exhibit 2 at 22, 23, 69. Accordingly, Ms. Kenney was admitted to the hospital for an assessment of her new onset seizures. Exhibit 2 at 13, 21.[6]

On September 3, 2008, Dr. Ming Wang, a neurologist, evaluated Ms. Kenney. His history is in accord with the recitation of facts above. The neurologic exam revealed that Ms. Kenney was "awake, alert and oriented to time, place, person. Speech and language were intact." Dr. Wang's impression was "[n]ew onset of seizure disorder, epileptic versus nonepileptic." Dr. Wang ordered an MRI and an EEG, and prescribed Keppra 500 mg twice per day. Exhibit 2 at

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[4] Dr. Sachdeo stated that the lack of sweating from Ms. Kenney was significant because her temperature could have elevated and a high temperature can lead to a seizure. Tr. 195-96.

[5] Biting one's tongue is consistent with a seizure. Tr. 182 (Dr. Sachdeo).

[6] Dr. Weig and Dr. Sachdeo differed in their opinions regarding whether Ms. Kenney suffered a seizure on September 2, 2008. Dr. Weig accepted the report of a seizure. See Tr. 19.

Contrastingly, Dr. Sachdeo disagreed. Dr. Sachdeo acknowledged that the doctors should have considered seizures as a potential diagnosis. But, Dr. Sachdeo noted that the doctors did not record any tonic-clonic activity. Tr. 136-38.

21,22, 84. Keppra may help with a broad class of epilepsy and was an appropriate choice because of the other pharmaceuticals that Ms. Kenney was taking. Tr. 138.

As ordered by Dr. Wang, Ms. Kenney had a brain MRI with and without contrast. The results were within normal limits. Exhibit 2 at 17, 28.

Ms. Kenney also had an EEG on September 3, 2008. Dr. Wang interpreted the EEG as abnormal "due to the frequent phase reversing sharp wave activity in bilateral temporal areas, left slightly more than right, but otherwise the background was within normal limits." Exhibit 2 at 29 (capitalization changed without notation). At discharge, Ms. Kenney was diagnosed as suffering from hypotension and epilepsy. Id. at 34.

Ms. Kenney had a follow-up examination with Dr. Wang on September 9, 2008. She reported that she was not feeling well and was tired. She did not have any seizures after leaving the hospital. Dr. Wang continued the prescription for Keppra, recommended that Ms. Kenney not drive, and suggested a return appointment in two months. Exhibit 3 at 1. According to information provided to Dr. Wang later, Ms. Kenney stopped taking Keppra by the beginning of October 2008. Id. at 2.

On September 10, 2008, Ms. Kenney's mother wrote a letter to her daughter's pediatricians. Ms. Kenney's mother wanted to let the doctors know about the HPV vaccinations and the seizures because "the CDC recommends notification of any adverse effects to the patient's physician." Exhibit 6 at 51. The doctors later filed a report with VAERS and corresponded with a manufacturer of a vaccine. Exhibit 6 at 52-55; exhibit 8.

Ms. Kenney returned to Dr. Wang on October 31, 2008, and reported that she had discontinued Keppra for one month. Three days before her appointment with Dr. Wang, she had a seizure while sitting, which lasted a minute. Ms. Kenney told Dr. Wang that she bit her tongue, but did not have any incontinence. She was post-ictal for 5-10 minutes. Dr. Wang's impression was "epileptic seizure." He maintained Keppra at 500 Bid, repeated his recommendation not to drive, and scheduled another appointment in two months. Exhibit 3 at 2.

On February 6, 2009, Ms. Kenney's mother called Dr. Wang to report that Ms. Kenney had a seizure the prior night. Dr. Wang adjusted the medication for Keppra to "500/1000." Exhibit 3 at 2. Dr. Wang saw Ms. Kenney on February 10, 2009. She reported having a seizure at 8:00 am that day. He changed the medication to extended release Keppra tablets. Id.

A new neurologist, Karen Levin, saw Ms. Kenney on June 24, 2009. Ms. Kenney's mother told Dr. Levin that "the seizures started days after her [HPV] vaccine on June 16th." Ms. Kenney also provided information about what happens with her seizures. She indicated that she consumed alcohol before some of the seizures. When the seizures start, Ms. Kenney's voice gets funny and then "she passes out. She is postictal and has a headache and nausea afterwards." Ms. Kenney reported that after the two seizures on September 3, 2008, she was started on Keppra. "She stopped her medications and had another spell in October 2008. In February 2009, she missed a dose and had another spell." Ms. Kenney also said that the current dose of Keppra is controlling her seizures but makes her tired. Exhibit 5 at 4-5.

Dr. Levin conducted a neurologic examination and did not identify any problems. Her impression was that Ms. Kenney has "partial complex seizures with secondary generalization." Dr. Levin recommended Ms. Kenney continue taking Keppra, not drive, and avoid antihistamines, sleep deprivation, and alcohol. Id.

Ms. Kenney's mother called Dr. Levin on September 8, 2009, to recount that Ms. Kenney was telling her mother that she felt like she was going to have a seizure. This was occurring as Ms. Kenney was just returning to school and was "slightly sleep deprived." The doctor's office could not prescribe any medication, but recommended rest. Exhibit 5 at 3.

In the following year, Ms. Kenney experienced relatively few neurologic episodes. See exhibit 5 at 1-2, 9-10. On January 3, 2011, Ms. Kenney saw Dr. Levin and complained about having auras and several seizures. Dr. Levin started to taper Keppra and to begin Trileptal. Exhibit 10 at 3. After a week of taking only Trileptal, Ms. Kenney developed a rash. Consequently, Dr. Levin prescribed Zonegran. Id.

Ms. Kenney had a seizure on April 6, 2011, at the school library. She described herself as very stressed and lacking sleep. Exhibit 10 at 2. She also had a seizure in January 2012. Otherwise, she remained free of seizure while on Zonegran. Exhibit 17 at 4-8.

Ms. Kenney saw another neurologist, Michael Stein, on March 12, 2012.[7] The history that Dr. Stein recorded was consistent with what is described above,

[7] Dr. Stein practices medicine at Rush Epilepsy Center, which is a major medical institution according to Dr. Weig. Tr. 110.

although Dr. Stein did not have access to any medical records. In Dr. Stein's history, Ms. Kenney had her "first seizure in June 2008." Dr. Stein also noted that the roommate who observed Ms. Kenney's behavior in September 2008 said that Ms. Kenney had "grand mal seizures," and was the daughter of a person with epilepsy. Dr. Stein also recorded that Ms. Kenney's mother "feels her seizures are due to receiving 2 HPV vaccinations."[8] Exhibit 17 at 5.

Dr. Stein indicated that Ms. Kenney experienced a qualitatively different seizure about one week before the appointment after she took her morning dose of Zonegran several hours late. Dr. Stein assessed Ms. Kenney as possibly suffering from "right frontal lobe epilepsy." Another possibility was idiopathic primary generalized epilepsy.[9] Dr. Stein wanted to review previous studies and/or to conduct repeat studies. He emphasized strictly complying with the medication schedule and avoiding antihistamines and alcohol. Exhibit 17 at 7-8; see also Tr. 90.

On April 16, 2012, Ms. Kenney underwent an MRI of her brain and an EEG. The MRI was normal. Exhibit 16 at 15-16; see also Tr. 24-25. The EEG, however, was abnormal. It showed "mild but definite focal slowing over the left temporal region consistent with localized cerebral pathology. No epileptiform discharges are noted." Exhibit 18 at 1.[10] In a visit that day, Dr. Stein recommended that Ms. Kenney decrease or eliminate her use of alcohol. Exhibit 18 at 1.

In August 2012, Ms. Kenney had two more seizures. Exhibit 26 at 142-44; exhibit 22 at 1. The doctor after the second seizure added another medication, Lamictal. In September 2012, Dr. Stein noted the two recent seizures and the change in medications. Exhibit 24 at 16-17. In April 2013, Dr. Stein removed Zonegran entirely and maintained Lamictal. Exhibit 24 at 39.

[8] Dr. Weig interpreted Dr. Stein's reciting that the HPV vaccines preceded the seizures as a statement that was "at least associated and possibly causative." Tr. 87.

[9] When Dr. Sachdeo was cross-examined about Dr. Stein's assessment, Dr. Sachdeo acknowledged that Dr. Stein was Ms. Kenney's treating physician and he provided excellent care for her. Nonetheless, Dr. Sachdeo was not convinced that Ms. Kenney had epilepsy because, in part, of the results of the second EEG. Tr. 161-63.

[10] Dr. Weig agreed that the second EEG did not show any epileptiform features. Tr. 109.

II. Procedural History

Ms. Kenney filed her petition on June 8, 2011. The following month, she filed her first set of medical records. Ms. Kenney incorporated information from her medical records into an amended petition filed on October 24, 2011. She alleged the vaccines caused her to suffer a "seizure disorder." Am. Pet. at 1 (preamble).

The Secretary reviewed this material and found that Ms. Kenney's evidence did not support an award of compensation. The Secretary noted that none of Ms. Kenney's treating doctors associated the vaccination with her seizure disorder. In addition, Ms. Kenney had not filed a report from an expert. Resp't's Rep't, filed Dec. 21, 2011, at 12.

After approximately six months, Ms. Kenney filed a report from Dr. Weig. She also submitted his curriculum vitae and articles on which Dr. Weig was relying. Exhibits 19-20. Correspondingly, the Secretary filed a report and curriculum vitae from Dr. Sachdeo on October 17, 2012. Exhibits A-B.

With the submission of conflicting reports from two experts, the then-presiding special master set the case for a hearing and ordered submission of various documents to facilitate the hearing. Order, filed January 18, 2013. The parties also explored settlement during this time.

The parties continued to develop their cases. The Secretary filed a supplemental report from Dr. Sachdeo with associated literature on April 24, 2013. Exhibit C. Ms. Kenney filed more medical records in May and June 2013. Exhibits 21-29.

On July 2, 2013, the parties filed their prehearing submissions. The then-presiding special master discussed this material in a pretrial conference held on July 10, 2013. She filed a "Glossary of Terms." Exhibit 1000.

The then-presiding special master conducted a hearing on August 7, 2013. During this hearing, Dr. Weig and Dr. Sachdeo testified. At the conclusion of the hearing, the parties indicated that they did not wish to present additional evidence. Tr. 202. The then-presiding special master advised the parties that she would discuss the content of briefs in a status conference.

Before this status conference was held, the then-presiding special master ended her service as a special master. Her departure created a question as to

whether the parties should retry the case before another special master. Pet'r's Status Rep't, filed Nov. 12, 2013; Resp't's Status Rep't, filed Nov. 13, 2013. While this issue was pending, the case was assigned to the undersigned special master on November 15, 2013.

Upon receiving the case, the undersigned requested more thorough arguments about a second hearing. Order, filed Nov. 20, 2013. The parties presented their positions on January 10, 2014, and February 5, 2014.

After reviewing the transcript and considering the parties' arguments, the undersigned determined that an additional hearing was not required. The evidence was understandable and the parties did not identify any reason that the undersigned needed to observe either Dr. Weig or Dr. Sachdeo while they were testifying. Order, filed Feb. 21, 2014.

In conjunction with the order regarding a possible second hearing, the undersigned issued an order proposing the content of the parties' post-hearing briefs. As promised by the special master who conducted the hearing, a status conference to discuss the parties' briefs was held on March 24, 2014. The parties stated that they did not have any objections or questions about the content of the briefs. Order, filed March 25, 2014.

The parties filed briefs that followed the recommended structure. Ms. Kenney filed her opening brief on May 22, 2014, and a reply on August 8, 2014. In between those submissions, the Secretary filed a brief on July 3, 2014. With those submissions, the case is ready for adjudication.

III. Standards for Adjudication

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is

too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing judgment that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

Here, the parties dispute whether Ms. Kenney suffered the injury for which she seeks compensation. In this circumstance, Ms. Kenney bears the burden of establishing that she suffers from a condition for which she seeks compensation. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1352 (Fed. Cir. 2011) ("under Broekelschen, identification of a petitioner's injury is a prerequisite to an Althen analysis of causation"). In doing so, the special master is "not 'diagnosing' vaccine-related injuries." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Rather, the special master evaluates the evidence presented and determines whether the petitioner has met her burden of establishing that she suffers from the disease. See Lombardi, 656 F.3d at 1353-56 (reviewing evidence that the special master considered in determining whether petitioner suffered from a particular disease and finding that the special master's factual findings were not arbitrary or capricious).

After petitioners establish that they suffer from a particular condition, they must establish that a vaccine caused that injury. For causation-in-fact claims, the Federal Circuit set forth a three-prong test. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). To receive compensation, a petitioner must satisfy the Althen test by a preponderance of evidence.

IV. Autoimmune Epilepsy

Ms. Kenney claims to suffer from autoimmune epilepsy. Pet'r's Br., filed May 22, 2014, at 23-33. Relying upon Dr. Sachdeo, the Secretary argues that Ms. Kenney does not suffer from autoimmune epilepsy. Resp't's Br., filed July 3, 2014, at 13-27. While the parties have relatively little dispute about the diagnostic criteria for autoimmune epilepsy, a basic description of this condition is provided in section A below. This information is the foundation for analyzing, in section B, whether Ms. Kenney actually suffers from autoimmune epilepsy.

A. Diagnostic Criteria

At the simplest level, a person who suffers from autoimmune epilepsy suffers from seizures. A seizure is a "paroxysmal transient disturbance [] of the brain function." Dorland's Illustrated Medical Dictionary at 633 (32d ed. 2012).

Seizures are classified into two broad groups, generalized and partial seizures. A partial seizure, which is also known as a focal seizure, arises in one area of the brain and can be mild. Examples of partial seizures include auras (abnormal sensations), a sensory disturbance, and a motor disturbance. In partial seizures, the person does not lose consciousness. Tr. 11-13; see also Dorland's at 1688.

In contrast, a person who suffers a generalized seizure may lose consciousness and sometimes has convulsions. Generalized seizures affect more than one area of the brain. Tr. 11-14; see also Dorland's at 1688. Seizures can be detected using an electroencephalogram. An EEG can sometimes present evidence of a subclinical seizure. Tr. 125. Seizures have various causes. Common causes of seizures include lack of sleep, metabolic disturbances, fever, alcohol, and some medications. Tr. 65-66 (Dr. Weig), 124-28 (Dr. Sachdeo).

While all epilepsies involve seizures, not all seizures are manifestations of epilepsy. Tr. 14, 124. "Epilepsy is a condition where an individual is prone to having repeated, unprovoked seizures." Tr. 14; accord Tr. 124, Dorland's at 633. Consistent with the classification of seizures, epilepsy can be classified as either partial epilepsy or generalized epilepsy. Tr. 14, 128; see also Dorland's at 633. Another way of classifying epilepsy is to label epilepsy as symptomatic or idiopathic. In symptomatic epilepsies, the cause is known. In contrast, in idiopathic epilepsies, the cause is not known. Dorland's at 633; see also Tr. 16, 128. As many as one third of all epilepsies are idiopathic. Exhibit 19, tab C (Anne T. Berg et al., Revised terminology and concepts for organization of seizures and epilepsies: Report of the ILAE Commission on Classification and Terminology, 2005-2009, 51 Epilepsia 681 (2010)).

Within the group of symptomatic epilepsies (epilepsies with a cause) is an entity known as autoimmune epilepsy. In autoimmune epilepsy, the body produces antibodies that attack cells located in the grey matter of the brain. Tr. 27, 139, 167. Patients with autoimmune epilepsy usually test positive for certain neural antibodies, once they are tested. Exhibit 30 (Tanja Brenner et al., Prevalence of neurologic autoantibodies in cohorts of patients with new and established epilepsy,

54 Epilepsia 1028 (2013)), exhibit 19, tab F (Sarosh R. Irani et al., *N*-methyl-D-asparate antibody encephalitis: temporal progression of clinical and paraclinical observations in a predominantly non-paraneoplastic disorder of both sexes, 133(6) Brain 1655 (2010)), exhibit 19, tab G (Caroline Hofmann et al., Anti-NMDA receptor encephalitis after TdaP-IPV booster vaccination: cause or coincidence, 258 J. Neurol. 500 (2011)), exhibit 19, tab H (K. McNight et al., Serum antibodies in epilepsy and seizure-associated disorders, 65 Neurology 1730 (2005)).

Doctors typically order tests for neural antibodies only when a patient's clinical presentation warrants that testing. Tr. 155. The clinical picture is a "key" part of diagnosing autoimmune epilepsy. Tr. 34-35. Some of the symptoms associated with autoimmune epilepsy include high seizure frequency, resistance to antiepileptic drugs, physical and mental illness beyond the seizures, and improvement of the epilepsy after administration of immunotherapy such as intravenous immunoglobulin. A prominent sign of autoimmune epilepsy is the presence of inflammation as detected by MRIs, EEGs, and/or cerebral spinal fluid studies.

When treating a patient with these symptoms and signs, a doctor may order a test for neural antibodies.[11] A positive test for neural antibodies can support a diagnosis of autoimmune epilepsy. Tr. 30-36, 100, 139, 168, 191, 196. However, a diagnosis of autoimmune epilepsy may be appropriate even in the absence of a positive test for neural antibodies. Tr. 171.

B. Ms. Kenney's Presentation

The parties' briefs have presented their respective positions with respect to the various signs and symptoms associated with autoimmune epilepsy. In accord with that structure, the following sections review those signs and symptoms. It should be emphasized that although the analysis is divided into discrete sections, a diagnosis of autoimmune epilepsy depends upon the entire picture. Tr. 171.

[11] While autoimmune epilepsy has appeared in the literature since 1987, in Dr. Weig's view, it has risen in clinical significance only in the past few years. Tr. 27, 94; see also Tr. 139. Before doctors knew about autoimmune epilepsy, they could not have ordered testing for neural antibodies. Tr. 78, 101.

1. Neural Antibodies

Ms. Kenney was not tested for the presence of neural antibodies. See Tr. 35-36. In the Secretary's view, the lack of a treating doctor's order to test for neural antibodies suggests that none of Ms. Kenney's treating doctors suspect she has autoimmune epilepsy. Resp't's Br. at 18.

Ms. Kenney attempts to explain away the lack of testing for neural antibodies by saying that in 2008, autoimmune epilepsy "'was probably not on most people's radar.'" Pet'r's Br. at 28 n.14 (quoting Tr. 78 (Dr. Weig)). However, this explanation works for only a few years at best. As the Secretary pointed out, one of Ms. Kenney's current treating doctors could still order testing for neural antibodies. Resp't's Br. at 18 n.9. Moreover, a test could still detect neural antibodies years after onset and this identification could lead to treatment improving Ms. Kenney's condition. Exhibit 19, tab I (Amy M.L. Quek et al., Autoimmune Epilepsy: Clinical Characteristics and Response to Immunotherapy, 69 Arch Neurol 583-85 (2012)).

When given a chance to address this argument, Ms. Kenney simply repeated her argument relating to the state of knowledge in 2008. See Pet'r's Reply at 4. In doing so, Ms. Kenney left unanswered the Secretary's persuasive argument that she could have been tested at any time.

2. High Seizure Frequency and Resistance to Antiepileptic Drugs

In advocating that she fulfills the diagnostic criteria for autoimmune epilepsy, Ms. Kenney pays little attention to the frequency of her seizures and whether they were controlled by antiepileptic drugs. In this context, Ms. Kenney argues that "none of [her] treating physicians agreed with Dr. Sachdeo that [her] seizures were provoked by alcohol, sleep deprivation, or noncompliance with respect to medications." Pet'r's Br. at 31. Contrastingly, the Secretary presented a thorough review of Ms. Kenney's seizures. Resp't's Br. at 19-22.

An analysis shows that Ms. Kenney routinely went more than two months between seizures. Additionally, virtually all of her seizures were associated with lapses in taking her anti-epilepsy drugs, consuming alcohol, lack of sleep, and/or stress. The Secretary overwhelmingly refuted Ms. Kenney's argument that "none of [her] treating physicians agreed with Dr. Sachdeo that [her] seizures were provoked by alcohol, sleep deprivation, or noncompliance with respect to medications." Undeterred by the Secretary's detailed showing of the context of her

seizures, Ms. Kenney argued that it is "purely speculative" that her seizures were well-controlled when she avoided activities that trigger seizures, like "alcohol, sleep deprivation, and antihistamine medications." Pet'r's Reply at 7.

Ms. Kenney fails to cite any examples of seizures that took place outside of the context of either a problem with medication compliance or seizure-triggering behaviors. In fact, the evidence provides ample support for the Secretary's argument. Dr. Levin and Dr. Stein commented when Ms. Kenney took her antiepileptic drugs as recommended and also avoided activities that could trigger seizures, her seizures were controlled. Exhibit 15 at 1-2, exhibit 18 at 2. Dr. Sachdeo agreed with the evaluation of these treating doctors. Tr. 156-57.[12] Dr. Weig, too, stated that "there were problems . . . that the patient was not always compliant with medication." Tr. 21-22. Dr. Weig also acknowledged that Dr. Stein recommended that Ms. Kenney decrease her alcohol consumption. Tr. 90.

3. Objective Signs of Inflammation

The autoimmune basis for autoimmune epilepsy is that the body's own antibodies attack brain cells, prompting inflammation. The inflammation is detectable on MRIs, on EEGs, and in the cerebral spinal fluid. Exhibit 19, tab I (Quek at 583); Tr. 191, 197-98.

On an EEG, disruptions to the grey matter appear as a change in background. Exhibit C, tab 1 (Josep Dalmau et al., Clinical experience and laboratory investigations in patients with anti-NMDAR encephalitis, 10(1) Lancet Neurol. 64-65 (2011)); Tr. 132, 139, 142, 192, 195, 200. In addition, spikes on an EEG strongly support a diagnosis of epilepsy. Tr. 131-32. EEG spikes are not the same as EEG sharp waves. While sharp waves on an EEG are consistent with epilepsy, sharp waves have other causes, such as trauma, dehydration, and headaches. Tr. 59, 111, 131, 154.

Ms. Kenney underwent two EEGs, one on September 3, 2008, and the other on April 16, 2012. The parties dispute the significance of both EEGs.

[12] Ms. Kenney also noted that her treating doctors prescribed four antiepileptic drugs. Pet'r's Reply at 7. However, Ms. Kenney fails to offer any argument that the number of drugs relates to whether the seizures were controlled. This omission is especially notable because Ms. Kenney was taken off Trileptal because the medication appeared to produce a rash.

The September 3, 2008 EEG showed "frequent phase reversing sharp wave activity in bilateral temporal areas, left slightly more than right." Exhibit 2 at 29. In addition, "the background of this EEG consists of 8.5-9 hertz with about 20-30 microvolts in amplitude which was posteriorally located and blocked with eye opening." Id.

The parties argue whether the "sharp wave activity" indicates epilepsy. Compare Pet'r's Br. at 29 and Pet'r's Reply at 5 with Resp't's Br. at 22-23. Dr. Wang, Ms. Kenney's first neurologist, diagnosed her as suffering "[n]ew onset seizure disorder, epileptic versus nonepileptic" and prescribed Keppra. Exhibit 2 at 21-22. Although Dr. Sachdeo questioned the diagnosis of epilepsy, Tr. 130-32, 154-55, the better question is whether the EEG showed evidence of an autoimmune process.

According to the unrebutted testimony from Dr. Sachdeo, an autoimmune process would produce an abnormal background on the EEG. Dr. Sachdeo stated that Ms. Kenney's September 3, 2008 EEG had a normal background. Tr. 142; see also Tr. 138, 152-54, 195-97. Dr. Weig was also asked about this EEG and he said that the sharp waves were the only abnormalities. Tr. 106. Similarly, when Dr. Weig was questioned whether the EEG showed inflammation, he said that it did not. Tr. 108-09.

Ms. Kenney's second EEG was on April 16, 2012. It showed "mild but definite focal slowing over the left temporal region consistent with localized pathology." Exhibit 18 at 1. Dr. Stein, who was then Ms. Kenney's treating neurologist, asserted that Ms. Kenney "most likely" had "left temporal lobe epilepsy (left v. bilateral) with secondary generalization." Exhibit 25 at 7. Again, Dr. Sachdeo questioned the diagnosis of epilepsy, remarking that a "focal slowing is absolutely not consistent with epilepsy." Tr. 165-66.

Ms. Kenney relies upon Dr. Stein's diagnosis of epilepsy. Pet'r's Br. at 30. However, a diagnosis of epilepsy, even if persuasive, only gets Ms. Kenney so far. Her claim is that she suffers from a particular type of epilepsy, autoimmune epilepsy. Ms. Kenney has presented no argument that the April 16, 2012 EEG supports a diagnosis of autoimmune epilepsy.

Besides the EEGs, another test that could show inflammation in Ms. Kenney's brain is an MRI. See exhibit 19, tab I (Quek) at 583 (63 percent of 32 patients with presumed autoimmune epilepsy had MRIs showing inflammation), Tr. 167, 197-98.

Ms. Kenney had two MRIs. The first was done on September 3, 2008. It was normal. Exhibit 2 at 17. The second was done on April 16, 2012. It, too, was normal. Exhibit 16 at 15. Neither showed signs of inflammation.

Ms. Kenney points to the normal results on the MRIs as helping her rule out other potential causes for her epilepsy, such as stroke, trauma, vascular malformations, a tumor, and mesial temporal lobe sclerosis. Pet'r's Br. at 29, citing Tr. 24-25, 35. The MRIs do help exclude these other potential causes. But, the normal results on the MRIs are inconsistent with how the majority of people with autoimmune epilepsy presented in the Quek report.[13]

A final source of information about inflammation is the cerebral spinal fluid. Dr. Weig acknowledged that a logical place to look for inflammation would be a spinal tap, but the doctors did not order one. Tr. 101. Consequently, Ms. Kenney cannot point to any test that shows she suffered inflammation in her brain.

4. Clinical Course

People with autoimmune epilepsy may have a fever, psychiatric problems, lethargy, decreased alertness, abnormal movements, and cognition problems. Tr. 141 (Dr. Sachdeo).[14] On the other hand, one article indicates that autoimmune epilepsy "can have a much milder course." Tr. 30 (Dr. Weig discussing exhibit 19, tab F (Irani)).

Ms. Kenney's health, except for her seizures, has been fine. She graduated from college and is working. When Dr. Weig was asked which symptoms of autoimmune epilepsy listed in the Irani article Ms. Kenney had, Dr. Weig responded "none of them." Tr. 75.

[13] Ms. Kenney argues that her presentation is similar to the 37 percent of people in the Quek study who were presumed to have autoimmune epilepsy with a normal MRI. Pet'r's Reply at 5-6.

[14] Dr. Weig drew analogy between autoimmune epilepsy and another illness affecting people's brains caused by antibodies. Tr. 33. These patients have a multitude of problems. Exhibit C, tab 1 (Dalmau) at 63-64. The four patients with this encephalitis whom Dr. Weig treated were all "critically ill… at risk of death." Tr. 36-37.

5. Treating Doctors

Although the parties did not discuss the views of treating doctors separately, their opinions are important. Ms. Kenney puts forward the proposition that three treating neurologists diagnosed her with epilepsy. Pet'r's Br. at 32. The problem however, is that neither Dr. Wang, nor Dr. Levin, nor Dr. Stein have ever taken the additional step of diagnosing Ms. Kenney's epilepsy as autoimmune. As previously noted, the lack of a specific autoimmune diagnosis from Dr. Wang is perhaps understandable because of an assumed lack of awareness. However, this explanation seems inappropriate for Dr. Stein because he practices at a major medical center.

C. Overall Finding

Diagnosing autoimmune epilepsy is not as simple as following an algorithm. Tr. 102. The diagnosis is complicated because there is a great amount of variability in the signs and symptoms of autoimmune epilepsy. Nevertheless, there are enough common factors to consider whether Dr. Weig or Dr. Sachdeo is more persuasive.

The evidence shows that Ms. Kenney has failed to carry her burden of showing that she suffers from autoimmune epilepsy. Ms. Kenney's clinical course is not the course of most people suffering from autoimmune epilepsy. Her seizures have been largely controlled, especially when she was compliant in taking her anti-epilepsy drugs and avoided behaviors that could trigger a seizure. In addition, her seizures have, fortunately, not impaired other aspects of her health.

Likewise, the objective tests for inflammation (EEG and MRI) have not shown any evidence for inflammation. Ms. Kenney's normal results, therefore, are inconsistent with the results that usually appear on EEGs and MRIs of patients with autoimmune epilepsy.

Ms. Kenney's treating doctors appear not to have considered autoimmune epilepsy as a potentially appropriate diagnosis for her. Ms. Kenney has not cited any medical records in which a physician included autoimmune epilepsy on a differential diagnosis. Ms. Kenney's treating doctors did not order a spinal tap, did not prescribe any treatments for autoimmune conditions (intravenous immunoglobulin), and also did not order testing for neural antibodies, which could have assisted in reaching a diagnosis.

Since the information from Ms. Kenney's treatment points away from the diagnosis of autoimmune epilepsy, her argument that she suffers from that condition is uphill. The strongest force behind Ms. Kenney's claim is the opinion of Dr. Weig. But, even with respect to the weight to be given to expert testimony, Ms. Kenney's claim falters.

To answer whether Ms. Kenney suffers from autoimmune epilepsy, Dr. Sachdeo has a stronger background than Dr. Weig. Dr. Sachdeo's entire practice is devoted to treating epilepsy and he estimated that he has seen more than 10,000 patients (adults and children) with epilepsy. He has treated approximately 30-40 patients with autoimmune epilepsy. Tr. 118-21. This experience makes him well suited to opine that Ms. Kenney did not suffer autoimmune epilepsy. See Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 726-27 (2011) (finding that special master was rational in relying upon an expert with greater experience with a particular disease), aff'd, 685 F.3d 1375, 1380 (Fed. Cir. 2012).

Dr. Weig's background is not quite as stellar. His practice was in pediatric neurology, generally, and not in epilepsy, specifically. While he has treated several hundred patients with epilepsy, Tr. 17, this experience is at a smaller magnitude than Dr. Sachdeo's experience with epilepsy.

Ms. Kenney has not persuasively demonstrated that Ms. Kenney suffers from autoimmune epilepsy. Rather, the Secretary has effectively shown that it is quite likely that Ms. Kenney does not suffer from autoimmune epilepsy.[15] This finding resolves Ms. Kenney's claim that a vaccine caused her to suffer autoimmune epilepsy.

[15] Dr. Sachdeo's opinion that Ms. Kenney does not suffer from any form of epilepsy is questionable because her treating doctors have diagnosed her as suffering from epilepsy. However, resolving whether Ms. Kenney suffers from any epilepsy is not necessary because her claim is premised on having autoimmune epilepsy. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) (holding special master did not err in requiring that petitioner establish that she suffered an autonomic neuropathy despite agreement that petitioner suffered from dysautonomia when petitioner's claim was the vaccination caused an autonomic neuropathy). On the specific question of whether Ms. Kenney suffered autoimmune epilepsy, the evidence is overwhelming against the proposition.

V. Causation

If Ms. Kenney had met her burden of establishing that she suffers from autoimmune epilepsy, then the next step would be to determine whether she established that the vaccines were the cause-in-fact of her autoimmune epilepsy. This evaluation would require an assessment of the evidence in light of the Federal Circuit's three-prong test set forth in Althen, 418 F.3d at 1278. See Broekelschen, 618 F.3d at 1346, 1350.

The parties submitted evidence in support of their respective positions. This evidence included the reports from the experts, medical literature, and testimony from the experts. The parties summarized this evidence in their briefs. See Pet'r's Posthr'g Br. at 34-46; Resp't's Posthr'g Br. at 27-38; Pet'r's Reply Br. at 7-12. The undersigned has considered the evidence and arguments.

Nevertheless, the undersigned declines to determine, strictly as a hypothetical matter, how the causation evidence preponderates. As the Federal Circuit has explained, "[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Lombardi, 656 F.3d at 1353.

In addition, the inquiry into causation is "frequently more difficult." Hibbard, 698 F.3d at 1365. Since any analysis would necessarily be counter-factual in that it would assume that Ms. Kenney suffered from autoimmune epilepsy when preponderant evidence shows that she does not, exploring the more challenging question of whether any relevant vaccine can cause autoimmune epilepsy is not necessary to decide Ms. Kenney's case. Therefore, no findings are made regarding Ms. Kenney's proof under Althen.

VI. Conclusion

After Ms. Kenney was vaccinated, she started to have seizures. Her doctors have indicated that these seizures are manifestations of underlying epilepsy. Ms. Kenney claims that the vaccinations caused her to develop the epilepsy through an autoimmune process.

Ms. Kenney has not established that her epilepsy is autoimmune in origin. Without this showing, Ms. Kenney cannot prevail. The Clerk's Office is instructed to enter judgment in accord with this decision.

IT IS SO ORDERED.

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