In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-762V

Filed: October 29, 2015

(Not to be published)

KRISTINA GARRISON,	*	
	*	
Petitioner,	*	Ruling on Record; Trivalent Influenza
v.	*	Vaccine; Narcolepsy; Cataplexy;
	*	Hypocretin.
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Curtis R. Webb, Twin Falls, ID, for petitioner.
Ryan D. Pyles, United States Department of Justice, Washington, DC for respondent.

RULING ON ENTITLEMENT[1]

Gowen, Special Master:

On August 22, 2014, Kristina Garrison ("petitioner" or "Ms. Garrison") filed a petition pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 *et seq.* (2006) ("Vaccine Act"). Petitioner alleges that as a result of receiving a trivalent influenza ("flu") vaccination on October 28, 2011, she developed narcolepsy and cataplexy. See Petition at ¶ 1, 2, docket no. 1, filed Aug. 22, 2014. Petitioner also alleges that she has, and will continue to suffer, effects of her narcolepsy and cataplexy. Id. at ¶ 16. In support of her petition, petitioner filed several medical records; treatment records and medical literature from a narcolepsy expert, Dr. Emmanuel Mignot; an expert opinion from Dr. Marcel Kinsborne; and several pieces of medical literature in support of causation.

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 and note (2006)). In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

On August 2, 2015, respondent filed a Rule 4(c) Report and a motion for a ruling on the record, stating that while she "agrees that petitioner's appropriate diagnosis is narcolepsy with cataplexy," she "concludes that there is insufficient scientific evidence to support a causal relationship between the influenza vaccine and narcolepsy (with or without cataplexy)." Respondent's Report ("Res. Report") at 4, docket no. 21, filed Apr. 2, 2015. Nevertheless, although she recommends against compensation in this case, she "will not expend further resources to contest entitlement in this matter." Id. Respondent moved for a decision on entitlement based on the record. Id.

Based on a review of the entire record, the undersigned finds that petitioner is entitled to compensation.

I. BACKGROUND

A. Procedural History

Along with the petition, petitioner filed twenty-seven exhibits of medical records, an affidavit, and medical literature in support of her petition. See Petitioner's Exhibits ("Pet. Ex(s).") 1-27. An initial status conference was held on September 17, 2014, after which petitioner was ordered to file a Statement of Completion and an expert report addressing the *Althen*[2] factors. See Order, docket no. 12, filed Sept. 23, 2015. Petitioner filed a Statement of Completion on September 29, 2014. On February 2, 2015, petitioner filed an expert report by Dr. Marcel Kinsbourne and several additional exhibits of medical literature. See Pet. Ex. 28-50. Thereafter, respondent was ordered to file a responsive expert report and Rule 4(c) report by April 3, 2015. On April 2, 2015, respondent filed a Rule 4(c) Report indicating that she did not intend to defend this case, and so moved for a ruling on the record. Res. Repot at 4. Respondent did not file a responsive expert report. This matter is now ripe for a decision.

B. Factual History

Petitioner received a flu vaccination at thirty-eight years old on November 9, 2011.[3] Pet. Ex. 4 at 2-3. At that time, petitioner was employed as a Branch Manager at U.S. Bank in Buhl, Idaho, and was married with four children. Pet. Ex. 1 at ¶ 2. In mid-November 2011 petitioner began experiencing excessive daytime sleepiness. Id. at ¶ 5. She noted in her affidavit that around this time, she would become sleepy while interviewing candidates for positions at the bank. Id. In early December 2011, she experienced her first episode of suddenly falling asleep. She fell asleep on the toilet in a bathroom at work. Id. at ¶ 7. When she roused from that episode, she could not remember falling asleep. Id. Also in December 2011, she began to experience sudden collapses, triggered by any strong emotion, which was often stress. Id. at ¶ 8.

A week prior to January 25, 2012, petitioner called her primary care doctor, Dr. Jennifer Preucil, reporting fatigue and feeling "like she was crashing over the last 3 months." Pet. Ex. 5 at

[2] *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

[3] The petition alleges receipt of the flu vaccine on October 28, 2011, however, the medical records indicate that she signed a consent form on that date, and received the vaccine on November 9, 2011.

19. Dr. Preucil ordered lab testing. Id. At the January 25, 2012 appointment with Dr. Preucil, the doctor noted petitioner's history of a uterine infection following a surgery in October 2010, and a history of hypoglycemia. Id. Petitioner's lab tests revealed elevated liver enzymes. She was referred to a gastroenterologist. Pet. Ex. 5 at 20. Dr. Preucil's records also noted that petitioner reported a twenty pound weight gain as a result of not exercising due to her fatigue. Id. at 19. Petitioner reported no depression or emotional distress. Id.

Petitioner visited gastroenterologist, Dr. Seth Wheeler, on March 12 and 19, 2012, for a chronic history of elevated AST with a history of Hellp Syndrome[4] with each pregnancy. Id. at 23. Dr. Wheeler noted fatigue in his assessment of petitioner. Id. at 25. Dr. Wheeler noted that her likely diagnosis was nonalcoholic steatohepatitis,[5] as "this is the most common source of LFT elevations when other etiologies [are] ruled out." Id. at 28.

Petitioner's excessive daytime fatigue and sleepiness continued and became progressively severe in the subsequent months. Pet. Ex. 1 at ¶ 10. She would fall asleep at work, she could not remember conversations she had, and she was unable to concentrate at work. Id. On May 17, 2012, she sought treatment from Dr. Dan Nofzinger, who recommended a liver biopsy. Pet. Ex. 7 at 2. Petitioner's liver biopsy showed minimal chronic hepatitis. Pet. Ex. 5 at 53. On June 8, 2012, Dr. Nofzinger ordered an EEG. Id. The EEG was unusual, so the doctor ordered a sleep study. Pet. Ex. 1 at ¶ 12. Based on the sleep study, Dr. Nofzinger diagnosed petitioner with narcolepsy and prescribed her Provigil. Pet. Ex. 7 at 2-3. The doctor's July 18, 2012 medical records noted that due to petitioner's episodes of falling asleep at work, she was required to take a leave of absence. Id. at 2.

On September 21, 2012, Dr. Nofzinger noted that petitioner's narcolepsy was not well controlled with Provigil. Id. at 3. He documented that "within the last month she [] had episodes of falling asleep[,] once while waiting on a customer and once while driving." Id. On October 1, 2012, Dr. Nofzinger referred petitioner to neurologist, Dr. Richard Hammond. Id. Petitioner visited Dr. Hammond on December 27, 2012, who noted that petitioner experienced decreased awareness since December 2011. Pet. Ex. 5 at 3. Petitioner reported to Dr. Hammond that her narcolepsy "was usually preceded by a very odd sensation that would come up the back of her neck," followed by lessened awareness. Id. She reported that if she could take a ten to twenty minute nap while at work during the day, it would enable her to be alert for hours afterwards. Id. She also reported that she could sleep up to fifteen hours a day. Id. Additionally, there were episodes where she would fall to ground but would not fall asleep, "her knees would just buckle and she would fall." Id. She preferred to treat her condition with regular napping, as her medications caused her terrible side effects. Id. at 3, 5-6; Pet. Ex. 1 at ¶ 14-16. An MRI of her brain was normal. Pet. Ex. at 5. Dr. Hammond confirmed her diagnosis of narcolepsy with cataplexy, prescribed Effexor for her cataplexy, and Nuvigil for her narcolepsy. Id. at 5-6, 8.

On a June 11, 2013 visit to Dr. Hammond, the doctor noted that petitioner's Nuvigil was stopped a week prior because it failed to improve her condition and caused her to become moody

[4] A condition of hemolysis, elevated liver enzymes, and low platelet count. See Neil M. Davis, Medical Abbreviations 155 (15th ed. 2011).

[5] A liver disease characterized by a fatty liver with inflammation. See Dorland's Medical Illustrated Dictionary 1768 (32d ed. 2012).

and hallucinate. Id. at 10. Dr. Hammond documented that her narcolepsy and cataplexy had become "quite profound[,] and she had multiple falls during the day." Id. "It did not take hardly any emotion at all to push her over the edge of having a cataplectic attack." Id. Petitioner's performance at work continued to suffer as a result of her condition. Id.; Pet. Ex. 1 at ¶ 18. She frequently fell asleep at work, sometimes while with a customer. Pet. Ex. 1 at ¶ 18. In May 2013, she was asked to take a paid leave of absence to pursue more effective treatment for her condition. Id. at ¶ 21. In June 2013, Dr. Hammond tried treating her with Pristiq to improve her cataplexy and also decreased her dose of Nuvigil. Pet. Ex. 5 at 10. Also during this visit, Dr. Hammond noted that he will complete her disability forms because she could not work. Id. at 10-11. Up until that point, petitioner had been an employee at U.S. bank for thirteen years. Pet. Ex. 1 at ¶ 19.

On August 9, 2013, petitioner had a follow-up visit with Dr. Hammond. See Pet. Ex. 5 at 12. Dr. Hammond noted that petitioner was being treated with Pristiq and Nuvigil, which enabled her to better stay awake during the day and had reduced the frequency of her cataplexy." Id. The medical record noted that petitioner was in good spirits and in no distress during that visit, but that she would become tearful when talking about work. Id. Dr. Hammond recommended that she not return to work, as she still became sleepy if she sat down for a lengthy period of time. Id. The doctor also noted that he would like to treat petitioner with a prescription of Xyrem, however there was difficulty with insurance approval of the medication. Id.

On a follow-up visit with Dr. Hammond on October 4, 2013, petitioner reported that she became paralyzed for about eight minutes in a cataplectic event after experiencing anger. Pet. Ex. 5 at 14. She could only move her eyes during that episode. Id. Petitioner reported that she had missed her dose of Pristiq the day before. Id. She reported that she still had episodes of "significant sleep attacks" with a frequency of about one a day. Id. Whenever she sat down, she would fall asleep. Id. She stopped driving for fear of falling asleep. Id. Dr. Hammond noted continued difficulty with insurance approval of petitioner's medications. Id.

On November 20, 2013, petitioner saw a neurologist and sleep specialist, Dr. Emmanuel Mignot at Stanford Medical Center. Pet. Ex. 8 at 3-7. Dr. Mignot is a board certified sleep Specialist and expert in narcolepsy. Id. at 20. He has been the director of the Center for Narcolepsy at Stanford University for over nineteen years, and a director of the Stanford Sleep Division in the Psychiatry Department. Id. Dr. Mignot noted that petitioner received an influenza vaccination and developed excessive daytime sleepiness and sleep attacks, followed by cataplexy with knee buckling. Id. at 2.[6] Dr. Mignot noted that petitioner was still having "excessive daytime sleepiness," and that her sleep attack and cataplexy were not under control yet. Id. at 5. He documented that petitioner had a forty-five pound weight gain since 2010 and dysmenorrhea. Id. at 2. He also noted petitioner's "difficulty organizing, planning, and making judgment," and that she had disrupted nighttime sleep. Id. Dr. Mignot recommended treatment with Xyrem, as it was the "most effective medication for narcolepsy with cataplexy . . . ." Id. at 5. The doctor believed the medication provided "a good chance for [petitioner] to regain her function." Id.

[6] In his records, Dr. Mignot incorrectly documented petitioner's vaccination date and onset of symptoms. Notwithstanding this error, the undersigned finds his medical records are otherwise reliable and credible.

On December 13, 2013, petitioner reported improvement of her condition with Xyrem. Pet. Ex. 8 at 17. On December 17, 2013, it was noted that she had started Xyrem two weeks prior. As a result of that medication, her cataplexy was "considerably better," she was no longer experiencing the frequent "zingers" associated with her cataplexy, and that she was feeling less sleepy during the day. Id. Dr. Mignot recommended that she increase her dose of Xyrem from 2.5 grams to 3.0 grams. Id.

On January 9, 2014, Dr. Mignot wrote to petitioner's insurance carrier, Blue Cross Blue Shield, in support of her appeal of the decision to deny coverage of Xyrem. Pet. Ex. 8 at 20-25. Dr. Mignot wrote that "[petitioner] first developed symptoms of narcolepsy in January of 2011 [sic] after flu vaccination in December of 2010 [sic]." Id. at 20. He summarized her subsequent medical history and noted that she had been unable to work since May 6, 2013 "due to the lack of adequate control of cataplexy and continued daytime sleepiness." Id. at 21. He noted that her current prescriptions, Ritalin, Provigil, Effexor, and Pristiq did not adequately control her condition, and caused side effects like headaches, negative personality effects, and severe mood swings. Id. He wrote that petitioner had been able to receive Xyrem through a voucher program for patients who are unable to get coverage, however the voucher only provided a short trial. Id. He advocated for her appeal, noting that her symptoms "have improved considerably" on Xyrem, and that "Xyrem is the only approved medication for the purpose of treating cataplexy." Id.

Dr. Mignot also wrote a letter to the employee benefits analyst at the Minneapolis Claims Office on January 9, 2014 to request an extension of petitioner's short term disability benefits. Pet. Ex. 8 at 23. He wrote that "we are confident that with the proper medication and minor accommodations, [] Ms. Garrison will be able to return to full time employment. Id. He reported that the persistent symptoms which make it difficult for her to go back to work include: slurred words and the inability to communicate due to cataplexy, the inability to drive due to cataplexy, daytime sleepiness due to disrupted nighttime sleep, and the inability to maintain focus or make reliably good judgment. Id. at 24-25.

In her affidavit, signed on August 13, 2014, petitioner averred that Dr. Mignot informed her that persons with a particular genetic susceptibility can experience an autoimmune reaction after receiving an H1N1 vaccination (which is included in the trivalent influenza vaccination she received), whereby neurons which produce hypocretin are destroyed, resulting in narcolepsy and cataplexy. Pet. Ex. 1 at 5. Dr. Mignot's medical records note that petitioner tested positive for the genetic HLA marker DQB1*0602, which predisposes her to narcolepsy. Pet. Ex. 8 at 14. Also in her affidavit, petitioner stated that Dr. Mignot was able to persuade her health insurance company to pay for Xyrem, but for only six months. Pet. Ex. 1 at 6. She further stated that Xyrem has "eliminated the cataplexy attacks, improved her nighttime sleep, and has reduced her sleep attacks to one a day. Id. She noted that before a sleep attack, she has approximately a 60 to 120 second warning before she falls into REM sleep for about twenty minutes. Id. She further noted that she continues to have episodes of micro-sleep, where she does not remember any conversation and her communication is slow and sometimes incoherent. Id.

Petitioner avers that her condition has profoundly affected her life. Pet. Ex. 1 at 6. She is unable to help her family pay bills or drive her four children to their activities. Id. She relies on

her family to transport her for her activities. Id. She lives on a farm with her husband and is unable to contribute to their farming duties. Id.

II. ANALYSIS

A. Legal Standard

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of HHS*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

In order to prevail under the Program, a petitioner must prove either a "Table" injury or that a vaccine listed in the Table was the cause in fact of an injury (an "off-Table" injury). Here, petitioner is not alleging a Table injury, but rather that her influenza vaccination on November 9, 2011 caused-in-fact her narcolepsy and cataplexy, off-Table injuries.

An "off-Table" injury is established when the petitioner demonstrates, by a preponderance of the evidence: (1) that she received a vaccine set forth on the Vaccine Injury Table; (2) that she received the vaccine in the United States; (3) that she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months. § 13(a)(1)(A).

The record is clear that petitioner received a vaccine listed on the Vaccine Injury Table and that she was vaccinated in the United States. See Pet. Ex. 4. The medical records also document that petitioner experienced narcolepsy and cataplexy for more than six months.

To satisfy her burden of proving causation in fact, petitioner must establish each of the three *Althen* factors by preponderant evidence: (1) a medical theory causally connecting the vaccination and her injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278; see *de Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec'y of HHS*, 100 Fed. Cl. 119, 132 (2011), aff. per curiam, 463 Fed. Appx. 932 (Fed. Cir. 2012) (specifying that each *Althen* factor must be established by preponderant evidence). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. See *Moberly v. Sec'y of HHS*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991).

In determining whether petitioner is entitled to compensation, a special master must consider the entire record and is not bound by any particular piece of evidence. § 13(b)(1) (stating a special master is not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record). Thus, a special master must weigh and evaluate opposing

expert opinions, medical and scientific evidence, and the evidentiary record in deciding whether petitioners have met their burden of proof.

B. Petitioner's Expert Opinion and *Althen* Analysis

Petitioner filed an expert opinion from Dr. Marcel Kinsbourne. Dr. Kinsbourne is a research professor at the Center for Cognitive Studies at Tufts University. Pet. Ex. 31 at 2. He is also a professor of psychology at New School University, in New York. Id. Previously, he was the director of the Behavioral Neurology Unit at Sargent College of Allied Health Professions at Boston University. Id. Dr. Kinsbourne received medical degrees from Oxford University in England, and Duke University in North Carolina. Id. at 1.

Dr. Kinsbourne opined that petitioner's sleep disorder began after receipt of a trivalent flu vaccination containing the H1N1 strain. Pet. Ex. 29 at 2-3. He opined that petitioner meets the behavioral and objective criteria for narcolepsy. Respondent does not dispute that petitioner's correct diagnosis is narcolepsy with cataplexy. Res. Report at 4.

1. *Althen* Prong One

Under the first prong of *Althen*, petitioner is required to set forth a reliable medical theory that explains how a particular vaccination can cause the injury in question. *Althen*, 418 F 3d at 1279. Scientific certainty is not required to establish causation under the Vaccine Act. Id. at 1280 (holding that the purpose of the Vaccine Act's preponderance of the evidence standard "is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body"). However, a causation theory or mechanism must be proposed and supported by a sound and reliable medical or scientific explanation. *Knudsen v. Sec'y, HHS*, 35 F.3d 543, 548 (Fed Cir. 1994).

Petitioner's theory, provided by Dr. Kinsbourne, is consistent with Dr. Mignot's explanation to petitioner regarding her condition. Dr. Kinsbourne explained that hypocretin, a neurotransmitter, contributes to a person's waking state by an excitatory effect on several brainstem loci that control the level of arousal. Pet. Ex. 29 at 5. Conversely, "inhibitory neurotransmitters lower the brain's arousal level and counteract hypocretin and other excitatory neurotransmitters." Id. at 5-6. This infrastructure of excitatory and inhibitory neurotransmitters imposing opposite effects in the brainstem is known as the "sleep switch hypothesis." Id. at 6. More fully explained, "[w]ake promoting and sleep-promoting loci in separate regions of the hypothalamus inhibit each other, constituting an 'opponent system.' Inactivation of either system leaves the other in relative control, resulting in insomnia or in narcolepsy." Id.

According to Dr. Kinsbourne, people with narcolepsy have been shown to be deficient in hypocretin levels in the cerebrospinal fluid, and to also have greatly diminished numbers of hypocretin-producing neurons in the dorsolateral hypothalamus. Pet. Ex. 29 at 6 (citing Nishino et al., Hypocretin (orexin) Deficiency in Human Narcolepsy, 355 The Lancet 39 (2000) [Pet. Ex. 45]). Hypocretin deficiency in persons with narcolepsy is believed to be a consequence of a destructive autoimmune attack on hypocretin-producing neurons. Pet. Ex. 29 at 6 (citing Mahlios et al., The Autoimmune Basis of Narcolepsy, 23 Current Opinion in Neurobiology 767 (2013)

[Pet. Ex. 39]). Dr. Kinsbourne commented that depletion of hypocretin-producing neurons is "'seemingly selective,'" as the other cells intermingled with hypocretin-producing cells are left unaffected, whereas the cells producing hypocretin are destroyed—leading to the "hypothesis that narcolepsy is an autoimmune-driven process within the hypothalamus, presumably mediated by CD4+ T cells." Pet. Ex. 29 at 6; see also Pet. Ex. 39 at 767.

According to Dr. Kinsbourne and the medical literature, current thinking is that the H1N1 vaccine activates CD4+ T cells, which have a peptide mimic with self-epitopes in hypocretin releasing neurons. Pet. Ex. 29 at 8-9; see also Pet. Ex. 42 at 315[7] (noting that "narcolepsy is characterized by the presence of autoreactive CD4+ T cells to hypocretin fragments when presented by DQ0602," a narcolepsy gene). Autoimmunity involving the CD4+ T cells triggers the destruction of neurons producing hypocretin, which then leads to the development narcolepsy. Id. According to Dr. Kinsbourne and the medical literature, in autoimmune subjects with verified low hypocretin activity, almost all have a genetic susceptibility. See Pet. Ex. 6 at 6; Pet. Ex. 42. A genetic susceptibility for narcolepsy was found in the petitioner here. See Pet. Ex. 8. Dr. Kinsbourne noteed that current research is exploring a molecular mimic between epitopes of hypocretin and proteins from an H1N1 infection or vaccination. Pet. Ex. 29 at 7; see Pet. Exs. 33, 34, 49.

Epidemiological studies in China, Finland, Sweden, France, Norway, Ireland, and Canada, found a "significant increase in the prevalence of narcolepsy" in those populations after receipt of the pandemic H1N1 influenza vaccine and also after H1N1 infections. Pet. Ex. 29 at 4. Dr. Kinsbourne noted that, although those studies involved a formulation of the H1N1 vaccine (Pandemrix) which contains an adjuvant, and the vaccine in question here did not contain an adjuvant, these studies are nevertheless significant as "it is unlikely" that the adjuvant in Pandemrix "is solely responsible for the causal autoimmune reaction." Pet. Ex. 29 at 7. Petitioner submitted multiple epidemiological studies on the increased incidence of narcolepsy following receipt of the pandemic H1N1 influenza vaccine and also after epidemic H1N1 infections. See Pet. Exs. 31, 41, 43, 44, 46, 47.

Based on a review of the evidence, petitioner has met her burden of setting forth a reliable medical theory by preponderant evidence. Reliable medical literature and petitioner's expert opinion demonstrates that the H1N1 component of the trivalent flu vaccine can cause autoimmunity in a susceptible individual, whereby an attack on neurons which produce hypocretin causes disruption in the sleep/arousal centers of the brain, leading to narcolepsy.

2. *Althen* Prong Two

Proof of *Althen* prong two requires a logical explanation as to how the vaccine did cause the injury in the petitioner. "A logical sequence of cause and effect' means what it sounds like—the claimant's theory of cause and effect must be logical." *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The proof need not rise to the level of scientific certainty but rather to the Vaccine Act's preponderance standard under the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.'" *Andreu*, 569 F.3d at 1378.

[7] Emmanuel J.M. Mignot, History of Narcolepsy at Stanford University, 58 Immunological Research 315-39 (May 14, 2014).

In this case, petitioner's treating physician, Dr. Mignot, at all times maintained that petitioner's narcolepsy and cataplexy were attributable to her flu vaccination, which contained immunization against the H1N1 influenza virus. See Pet. Ex. 8 at 20; Pet. Ex. 1 at 5. Additionally, Dr. Mignot found petitioner had tested positive for the genetic HLA marker DQB1*0602, which indicated a genetic susceptibility to narcolepsy. Pet. Ex. 8 at 14. Dr. Mignot's medical records and medical literature on narcolepsy are particularly persuasive and compelling in this case.

Additionally, Dr. Kinsbourne opined that:

> [a] role in the causation of narcolepsy for H1N1 vaccine is widely considered to be biologically reasonable. Ms. Garrison was diagnosed [with narcolepsy] by the premier expert physician in the field of narcolepsy as having experienced a vaccine injury, by a neurobiological mechanism that has been largely elucidated. She has the HLA risk factor for narcolepsy. She had the onset of the illness within a medically reasonable temporal interval of a vaccination that included H1N1 vaccine . . . . Thus the trivalent influenza vaccine did cause or significantly contribute[d] to the cause of her narcolepsy.

Pet. Ex. 29 at 9-10. The undersigned agrees with Dr. Kinsbourne and finds his opinion persuasive for all the reasons he articulated. Accordingly, petitioner has met her burden of establishing a logical explanation of how her vaccination caused her injury under *Althen* prong two.

3. *Althen* Prong Three

Prong three of *Althen* requires a showing that the timing of the onset of petitioner's condition was reasonable. Petitioner must show a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278.

The timing in this case is reasonable in light of the evidence. Dr. Kinsbourne noted that "[t]he documented time intervals between H1N1 vaccination and the onset of narcolepsy have ranged up to six months," citing Dr. Mignot's article which found a peak in narcolepsy cases in China about four to six months after the peak of H1N1 infections. Pet. Ex. 29 at 9; Pet. Ex. 42 at 327. Additionally, Dr. Kinsbourne noted that "Dauvilliers [and others, including Dr. Mignot] documented the range of vaccination to onset intervals in their sample[,] and found it to vary between two days and twenty weeks." Pet. Ex. 29 at 9. Dr. Kinsbourne went on to note that in petitioner's case, the interval was approximately two weeks." Id.; see also Pet. Ex. 1 (averring that petitioner began experiencing excessive daytime sleepiness in mid-November 2011, and that in early December 2011, she experienced her first episode of suddenly falling asleep and sudden collapses triggered by any strong emotion).

Although the vaccination date alleged in the petition and petitioner's affidavit are inconsistent with the date provided in medical records, in either event, the timing of the onset of petitioner's condition is supported by the medical literature. The onset of petitioner's condition appears to be in the range of one to two weeks, whether the date of onset is calculated based on the alleged October 28, 2011 vaccination date (on which Dr. Kinsbourne based his opinion), or

calculated based on the vaccination date of November 9, 2011 (noted in the medical records). Both time frames are consistent with the medical literature provided, which notes an onset of two days to up to five months.

Accordingly, petitioner has met her burden under *Althen* prong three.

III. CONCLUSION

Petitioner has provided reliable and persuasive evidence under all three prongs of *Althen*. Although respondent does not recommend compensation in this matter, she stated an intent not to defend this case and presented no evidence refuting petitioner's case. Based on a review of the evidence, the undersigned finds that petitioner is entitled to compensation from this Program.

A damages order will be issued separately.

IT IS SO ORDERED.

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