CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-946V

Filed: August 20, 2021

Corrected: August 23, 2021

JESSE MARTIN, Petitioner,	TO BE PUBLISHED
v.	Human Papillomavirus ("HPV") Vaccine; Narcolepsy and Cataplexy; Dismissal Decision
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	

Danielle Strait, Maglio Christopher & Toale, Seattle, WA, for Petitioner
Catherine Stolar, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On July 13, 2017, Petitioner Jesse Martin[2] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[3] (the "Vaccine

[1] This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*

[2] At the time of filing, Petitioner was under 18 years of age and the Petition was filed by his mother, Ms. Leslie Questel, on his behalf. Petitioner Jesse Martin was named the sole Petitioner on October 1, 2019. ECF No. 54.

[3] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Act" or "Program") alleging that he suffered from narcolepsy and cataplexy as a result of the HPV vaccination he received on August 13, 2014, the HPV vaccination he received on August 18, 2016, or some combination thereof. Pet. at 1, ECF No. 1.

Upon review of the evidence in this case, I find that Petitioner has failed to preponderantly demonstrate that the vaccines he received caused his condition. The petition is accordingly dismissed.

I. Procedural History

Petitioner filed his petition on July 13, 2017. Pet. at 1. He filed medical records in support of his claim on October 31, 2017 (Exs. 1, 2) and March 21, 2018 (Ex. 3). Respondent then filed his Rule 4 Report on June 21, 2018 recommending that entitlement be denied. Resp't's Rep. at 1; ECF No. 23.

Petitioner filed an expert report along with supporting medical literature on September 21, 2018. Exs. 15-34. Respondent filed a responsive expert report and supporting medical literature on February 25, 2019. Exs. A-JJ.

Petitioner filed additional medical records throughout 2019 and 2020. Exs. 42-49. He filed an affidavit on August 26, 2020. Ex. 50. Respondent then filed another expert report and supporting medical literature. Exs. KK-NN.

I held a status conference on February 3, 2021 where I asked the parties whether a Rule 5 conference addressing the issue of onset of Petitioner's symptoms would help to move the case forward. They both indicated that it would. *See* Scheduling Order of February 5, 2021. ECF No. 72. I held a Rule 5 conference on February 18, 2021 where I told the parties that I tentatively found the onset of Petitioner's narcolepsy was in July of 2016. ECF No. 73. Based on my tentative findings, I ordered Petitioner to file a status report by March 19, 2021 indicating how he would like to proceed. *Id.*

On August 11, 2021, Petitioner filed a motion for a decision. ECF No. 79. In this motion, Petitioner indicated that he had filed all the evidence he intends to file in this matter. *Id.* He further stated that "In light of the Court's factual analysis presented in the February 18, 2021 Order, Petitioner's expert is no longer able to support causation given the Court's view on the facts of this particular case." *Id.* Petitioner indicated that he waived his right to a hearing and moved for a decision based on the existing record. *Id.* Finally, Petitioner indicated that he "understands that this motion will likely result in an unfavorable decision by the Special Master, resulting in a judgment against Petitioner. Petitioner has been advised that such an unfavorable judgment will end Petitioner's claim under the Vaccine Act." *Id.*

The parties filed a joint status report on August 17, 2021 indicating that "the record in this matter is complete and a decision by the Court on Petitioner's August 11, 2021 Motion for Decision is appropriate." ECF No. 80. This matter is now ripe for an adjudication.

II. Relevant Medical Records

On August 13, 2014, Petitioner received a Human Papillomavirus ("HPV"), Hepatitis A, Varicella, and meningococcal conjugate vaccination. Ex. 1 at 1.

Petitioner visited the emergency room three times between March and May 2016. He did not mention fatigue at any of these visits. On March 1, 2016, Petitioner visited the ER for "cough and fever since Saturday." Ex. 2 at 29. He went to the ER on May 5, 2016 for a sore throat and fever x 3 days. Ex. 2 at 18. On May 18, 2016 he went to the ER for "left rib pain x2 days." *Id.* at 6. During the May 18 visit, Petitioner specifically denied fatigue. *Id.* at 16.

On August 18, 2016, Petitioner visited Kaiser Permanente. The noted reason for his visit included fatigue and sleep problems. Ex. 1 at 5-7. These records indicate that Petitioner started having difficulties staying asleep "6 weeks ago during school vacation." *Id.* at 5. The medical records note that Petitioner was able to fall asleep quickly but woke up multiple times at night. *Id.* Petitioner was falling asleep during class and at football practice, while at the computer and even when friends were over. *Id*. He reportedly had issues with insomnia prior to this when he would stay up all night and sleep during the day. *Id*. Petitioner was further noted to have irregular eating habits where he would not eat breakfast or lunch, eat dinner after football practice, and then wake in the middle of the night to eat. *Id.* Dr. Lu referred Petitioner to the sleep clinic for further evaluation. Ex. 1 at 6. Petitioner received his second dose of the HPV vaccine at this appointment. *Id.* at 1.

On August 29, 2016, Petitioner presented to KP Fontana Sleep Center for a sleep consultation. Ex. 1 at 17-24. During the visit, Petitioner indicated that he had been experiencing excessive daytime sleepiness for the past four to five months, that was "getting really bad x 6 weeks." *Id.* at 18. The record further notes:

> Prior to this new sleepiness all the time, he would stay up late at night on phone, Eat 3am, go to sleep, get up on time for school, stayed awake in school and football practice fine. Slept in on weekends. This summer took a long road trip through many national parks - Jesse slept day and night through almost all the trip.

Id. Petitioner also indicated that he had experienced sleep paralysis, cataplexy, weakness after being emotional, staring into space blankly, dropping or suddenly falling asleep while taking, eating, or standing, and that he sleepwalks and talks. *Id*. Dr. Hwang's clinical diagnosis was narcolepsy with cataplexy, but he noted that Petitioner needed additional testing to confirm this diagnosis. *Id*. at 20. Dr. Hwang scheduled Petitioner for a polysomnography sleep study and mean sleep latency test. *Id.*

On September 11 and 12, 2016, Petitioner underwent a polysomnogram sleep study and a mean sleep latency test. Ex. 1 at 25-27; 29. The results of the polysomnography sleep study led to a diagnosis of no significant obstructive sleep apnea, upper airway resistance syndrome, and

periodic limb movement syndrome. *Id.* at 27. The mean sleep latency test led to a diagnosis of narcolepsy. *Id.* at 29.

On October 24, 2016, Petitioner was seen by Chelsea Walsh, M.A. for a therapy session at Walsh Therapy Center. Ex. 46 at 26. Petitioner's file states that he was seeking help for "narcolepsy and cataplexy since HPV shot (first dose 2014 and second dose was August 2016)." *Id.* at 28. The records also note "No symtpoms [sic] until HPV shot in 2014" and that "[Petitioner] is a [sic] law suite [sic] against the manufacturer of HPV vaccine." *Id.* at 29, 33.

On November 29, 2016, Petitioner's mother called Dr. Kendra Becker to discuss his narcolepsy/cataplexy. Ex. 3 at 212. Dr. Becker noted that "Patient first excessive daytime sleepiness appeared after first vaccine, and narcolepsy symptoms started one week after second dose." *Id.* Dr. Becker further wrote "Patient is now represented by US federal attorneys – class action suit against Merck Gardasil HPV vaccine. Parent noticed that cataplexy begun about a week and half [sic] after second shot was administered." *Id.*

III. Affidavits

A. Leslie Questel's Affidavit

Petitioner's mother, Leslie Questel signed her affidavit on September 18, 2018. Ex. 5 at 6. Ms. Questel stated that "within a couple months" of his August 13, 2014 vaccinations, she started to notice small changes in Petitioner's sleeping schedule. *Id.* at 2. Specifically, he stayed up very late and had trouble falling asleep. *Id.* Ms. Questel's husband would come home late at night and see Petitioner playing on his game system or phone. *Id.* Petitioner told his step-father that he was not tired or that he couldn't get to sleep. *Id.*

As time went on, Ms. Questel noticed that Petitioner was sleeping during the day and was having difficulty sleeping at night. Ex. 5 at 2. She observed Petitioner to be asleep when his friends came over to the house. *Id.* Petitioner told her that he "couldn't help but fall asleep." *Id.* Ms. Questel thought he was going through a teenage phase. *Id.*

She further described that during the summer of 2016, their family went on a vacation to Montana, with stops in Utah, Wyoming, and South Dakota. Ex. 5 at 2. Petitioner continued with his sleeping issues throughout the trip. *Id.* at 3. During this vacation, Ms. Questel and the rest of the family agreed that Petitioner's condition seemed serious. *Id.*

Petitioner's school started in August and he had issues staying awake during class. Ex. 5 at 3. Ms. Questel decided to bring him to the doctor. *Id.* During the medical appointment on August 18, 2016, Dr. Lu indicated that she believed Petitioner's problems were a result of not being on a proper sleep schedule. *Id.* Petitioner received the second dose of the HPV vaccine at this visit. *Id.*

Ms. Questel stated that after this appointment, Petitioner started getting worse in that he began having issues with his knees buckling during football. Ex. 5 at 3. She began noticing cataplexy in Petitioner's face when he was falling asleep. *Id.* Additionally, Petitioner told them that sometimes he would feel like he was awake but was unable to move. *Id.* at 4. After his sleep

studies, Petitioner was diagnosed with narcolepsy. *Id.* Ms. Questel discussed the difficulties Petitioner's condition has caused for him and for their family. *Id.* at 5-6.

B. Petitioner's Affidavit

Petitioner signed his affidavit on August 18, 2020. Ex. 50 at 6. He stated that he does not remember having any issues with "getting to sleep, staying asleep, or being abnormally sleepy during the day" from the fall through mid-November of 2014. *Id.* at 2. Petitioner described that he began to have the urge to sleep during the day shortly after football season ended. *Id.* This was during his seventh grade school year. *Id.* He also developed difficulty sleeping at night. *Id.*

Petitioner described that in 2015, his nighttime sleep was irregular. Ex. 50 at 3. In early 2016, he began getting up in the middle of the night to have a bowl of cereal, chips and a sandwich. *Id.* During this time, when he fell asleep in class, Petitioner described feeling "a sudden urge to sleep, whether I was tired … or not." *Id.* His teachers blamed him sleeping in class on his attitude. *Id.*

During the summer of 2016, Petitioner went on a road-trip vacation with his family. Ex. 50 at 3. Petitioner stated that he does not remember much of the trip because he was sleeping all the time. *Id.* Petitioner described experiencing one episode of cataplexy during this 2016 vacation. *Id.* He stated, "I remember waking up at my grandparents' home in Montana, not being able to move, and being really terrified of something. I was staring down their hallway and I could only move my eyes." *Id.*

Petitioner received his second HPV vaccine on August 18, 2016. Ex. 50 at 4. Approximately three days later, Petitioner stated that he went out to breakfast with his family and kept dropping his fork. *Id.* He stated this was the first time he felt weakness and lost control over his body during the daytime. *Id.*

Petitioner stated that it seemed like "everything went off a cliff" after his second HPV vaccine. Ex. 50 at 4. Within a couple of weeks, his cataplexy worsened. *Id.* He continued to try to play freshman football but was unable to continue because he would fall asleep when he was not active. *Id.* at 5.

IV. Respondent's Expert Opinion

Respondent filed two expert reports from Dr. Maryann Deak. (Ex. A (hereinafter "First Deak Rep.") and Ex. KK, (hereinafter "Second Deak Rep.")). Respondent also filed an expert report from Dr. J. Lindsay Whitton.[4] Ex. C.

[4] Dr. Whitton opined that "the vaccines administered to J.M. on 8/13/2014 and 8/18/2016 played no demonstrable role in the initiation, or subsequent evolution, of his reported symptoms." Whitton Rep. at 17. The majority of his report focuses on rebutting Dr. Steinman's expert opinion. Because Dr. Steinman has indicated he is unable to provide a supportive opinion in Petitioner's case, given my tentative findings in the Rule 5 conference regarding the onset of Petitioner's narcolepsy, I have not provided a summary of either Dr. Steinman's or Dr. Whitton's expert opinion.

A. Dr. Maryann Deak

Dr. Deak is board-certified in both neurology and sleep medicine; she is currently employed at eviCore healthcare, where she performs clinical case reviews in sleep medicine. Ex. B (hereinafter "Deak CV"). Dr. Deak graduated from Georgetown University School of Medicine in 2004. Deak CV at 2. She completed residencies in neurology at New York University and University of Massachusetts, and then served as a clinical and research fellow in sleep medicine at Brigham and Women's Hospital at Harvard Medical School. *Id.* Dr. Deak has written several articles and book chapters in the area of sleep disorders. *Id.* at 2-3. She has significant experience treating sleep disorders, to include narcolepsy. First Deak Rep. at 1.

Dr. Deak outlined the criteria for a diagnosis of narcolepsy type I. These criteria include excessive daytime sleepiness, and one or both of the following two criteria 1) cataplexy[5] and a positive mean sleep latency test (mean sleep latency less than or equal to 8 minutes and two or more sleep onset-REM periods); 2) cerebrospinal fluid hypocretin-1 less than 110 pg/ml or less than 1/3 of the mean values in normal subjects. First Deak Rep. at 3-4.

Based on her review of the medical records filed in this case, Dr. Deak opined that Petitioner's symptoms are not related to the HPV (or varicella) vaccines he received because the time course of his illness is inconsistent with a vaccine related event, and further because there is no probable causal link between HPV vaccine and narcolepsy. First Deak Rep. at 2.

Dr. Deak opined that Petitioner developed narcolepsy six weeks prior to his August 18, 2016 visit with Dr. Lu. First Deak Rep. at 2. She stated that:

> In the summer of 2016, J.M. was experiencing the following symptoms: 1) sleep maintenance insomnia, without difficulty initiating sleep 2) excessive daytime sleepiness, independent of nighttime sleep duration 3) sleep paralysis 4) cataplexy (Ex. 3 at 152-153). These most likely represent the first symptoms of narcolepsy experienced by J.M.

Id. She does not believe that the sleep-related symptoms that Petitioner reported four to five months before his worsening in the summer of 2016 represented the onset of his narcolepsy for two main reasons. *Id.* at 3. First, Petitioner did not report that he was experiencing significant daytime sleepiness. *Id.* Second, the delayed onset of sleep is not a symptom of narcolepsy. *Id.*

Dr. Deak commented that "[f]or 4-5 months prior to 8/2016, the notes recount a history of 'staying up late at night on the phone' (Ex. 42 at 340) and 'stay[ing] up all night' (Ex. 42 at 300), resulting in 'sleep[ing] during the daytime' (Ex. 42 at 300), but still permitting J.M. to 'get up on time for school, stay[] awake in school and football practice fine' (Ex. 42 at 340)." Second Deak

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[5] Cataplexy is characterized by brief bilateral sudden loss of muscle tone while maintaining consciousness and is typically precipitated by strong emotions. First Deak Rep. at 3.

Rep. at 1. Accordingly, in Dr. Deak's opinion, "the 4-5 month history of delayed sleep onset is most consistent with delayed sleep phase, behaviorally induced insufficient sleep or a combination of both, which are common in adolescence." First Deak Rep. at 3.

Dr. Deak additionally stated that even if Petitioner's narcolepsy did develop four to five months before his August 2016 appointment with Dr. Lu, "this would still be > 1 year after vaccination on 8/13/14 and not appropriate for a causal relationship with any of the vaccinations alleged." *Id.*

With respect to vaccines and narcolepsy, Dr. Deak stated that to her knowledge "there is no evidence that the HPV, meningococcal, or varicella zoster vaccine has been linked with narcolepsy." First Deak Rep. at 5.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, when a petitioner suffers an alleged injury that is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

In attempting to establish entitlement to a Vaccine Program award of compensation for a off-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (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." *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at

1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs*., No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

Petitioner's medical records are presumed to be accurate and complete and are afforded substantial weight. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs*., 95 Fed. Cl. 598, 608 (2010); *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted").

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of

evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Factual Finding Regarding Onset of Petitioner's Narcolepsy

Petitioner filed several medical records that were particularly pertinent with respect to the issue of onset.

On August 18, 2016, Petitioner presented to Kaiser Permanente Medical Center. These records indicate: "6 weeks ago during school vacation, started having difficulties staying asleep." Ex. 1 at 5. Dr. Loan Thuy Lu's notes also indicate that "prior to this, [Petitioner] had issues with insomnia and would stay up all night and sleep during the day time." *Id.*

On August 29, 2016, Petitioner presented to Dr. Dennis Hwang for a follow up regarding his sleep issues. Ex. 1 at 18. Dr. Hwang noted Petitioner's "excessive daytime sleepiness duration: 4-5 months, getting really bad x 6 weeks." *Id.* Dr. Hwang further noted that "Prior to this new sleepiness all the time, he would stay up late at night on phone, Eat 3am, go to sleep, get up on time for school, stayed awake in school and football practice fine." *Id.*

On October 24, 2016, Petitioner was seen by Chelsea Walsh, M.A. for a therapy session at Walsh Therapy Center. Ex. 46 at 26. Petitioner's file states that he was seeking help for "narcolepsy and cataplexy since HPV shot (first dose 2014 and second dose was August 2016)." *Id.* at 28. The records also note that "[Petitioner] is a [sic] lawsuite [sic] against the manufacturer of HPV vaccine." *Id.* at 33.

On November 29, 2016, Petitioner's mother called Dr. Kendra Becker to discuss his narcolepsy/cataplexy. Ex. 3 at 212. Dr. Becker noted that "Patient first excessive daytime sleepiness appeared after first vaccine, and narcolepsy symptoms started one week after second dose." *Id.* Dr. Becker further wrote "Patient is now represented by US federal attorneys – class action suit against Merck Gardasil HPV vaccine. Parent noticed that cataplexy begun about a week and half [sic] after second shot was administered." *Id.*

In her first expert report, Dr. Deak noted that: "I do not believe that delayed sleep initiation reported several months prior to the onset of narcolepsy represent a symptom of narcolepsy, because 1) significant daytime impairment was not reported and 2) delayed sleep onset is not a symptom of narcolepsy." First Deak Rep. at 4.

In examining these medical records, I find the records from August 18, 2016 and August 29, 2016 to be more persuasive than the October 24, 2016 and November 29, 2016 records. I find

this to be true for two primary reasons. First, the August records were created contemporaneously with Petitioner's recognition of his sleep issues. Petitioner and his mother provided information to medical providers in order to facilitate diagnosis and treatment. In general, contemporaneous medical records are presumed to be accurate and complete. *Cucuras v. Sec'y of Health & Hum. Servs.*, 933 F.2d 1525, 1528 (Fed. Cir. 1993). Second, the August records are persuasive because there is no indication they were created in anticipation of litigation. *See, e.g.*, *Sheets v. Sec'y of Health & Hum. Servs.*, No. 16-1173V, 2019 U.S. LEXIS 587 at *56 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (later-in-time statements whether made to treaters or prepared for purposes of litigation do not suffice to contradict contemporaneous records). The same cannot be said of the October and November records, which each make specific mention of litigation. The August 18, 2016 and August 29, 2016 records both indicate that Petitioner's symptoms began six weeks prior to these visits, or approximately in the July 2016 timeframe. While these notes indicate some degree of sleepiness beginning in approximately April-May of 2016, I find Dr. Deak's discussion on this point to be persuasive.

In making these factual determinations, I have also concluded that the medical records and medical histories provided close-in-time to Petitioner's injury are more persuasive than the affidavits drafted between approximately two and four years after the fact.[6] Special Masters in the Vaccine Program "have traditionally declined to credit later testimony over contemporaneous records." *Sturdivant v. Sec'y of Health & Hum. Servs.,* No. 07-788V, 2016 WL 552529, at *15 (Fed. Cl. Spec. Mstr. January 21, 2016). *See, e.g., Stevens v. Sec'y of Health & Hum. Servs*., No. 90–221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. December 21, 1990); *see also Vergara v. Sec'y of Health & Hum. Servs*., No. 08–882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); *See also, Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

I will add that regardless of whether onset of narcolepsy occurred in April-May of 2016 or July of 2016, both of these dates occurred more than one year after Petitioner's first HPV vaccine, and before his second. For the reasons discussed above, I find the contemporaneous records created on August 18, 2016 and August 29, 2016 to be more persuasive than the October and November records and the affidavits filed in this case. I further find that Dr. Deak effectively explained Petitioner's daytime sleepiness four to five months prior to the August 29, 2016 appointment as unrelated to his subsequent narcolepsy diagnosis. I therefore find that the onset of Petitioner's symptoms associated with narcolepsy more likely than not began in July 2016.

B. Petitioner Has Not Carried His Burden of Proof

In a motion for a decision filed on August 11, 2021, Petitioner stated that based on my factual finding regarding the onset of his narcolepsy, Dr. Steinman "is no longer able to support

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[6] The affidavits drafted by Petitioner and his mother which claim onset of excessive daytime sleepiness shortly after the 2014 HPV vaccine are also belied by the medical records from March and May 2016 where Petitioner visited the ER three times and did not mention fatigue. *See* Ex. 2 at 16, 18, 29.

causation…" ECF No. 79. Without an expert opinion, Petitioner cannot sustain his burden of proof. *Althen*, 418 F.3d at 1278.

To receive compensation under the Vaccine Program, a petitioner must prove either (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to his vaccination, or (2) that he suffered an injury that was actually caused by a vaccine. *See* §§ 13(a)(1)(A) and 11(c)(1). Moreover, under the Vaccine Act, a petitioner may not receive a Vaccine Program award based solely on his claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent medical expert. § 13(a)(1). In this case, however, there is insufficient evidence in the record for Petitioner to meet his burden of proof. Petitioner's claim therefore cannot succeed and must be dismissed. § 11(c)(1)(A).

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, I conclude that Petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[7]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

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