

In the United States Court of Federal Claims

No. 98-619V
(Filed February 28, 2012)

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PAUL A. VISCONTINI,

Petitioner,

v.

**SECRETARY OF HEALTH
AND HUMAN SERVICES,**

Respondent.

***** *

* National Childhood Vaccine
* Injury Act, 42 U.S.C. §§ 300aa-1
* to 300aa-34 (2006); motion for
* review of findings of fact of
* special master; proof of
* causation in fact; 42 U.S.C.
* § 300aa-12(d)(3)(A)(I).
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Clifford J. Shoemaker, Vienna, VA, for petitioner.

Lisa A. Watts, Washington, DC, with whom was Assistant Attorney General Tony West, for respondent.

MEMORANDUM OPINION AND ORDER

MILLER, Judge.

This case is before the court on review of a decision by the special master denying compensation to petitioner under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34 (2006) (the “Vaccine Act”). The court has confirmed that the record on review supports the recitation of facts in Special Master Christian J. Moran’s opinion. See Viscontini v. Sec’y of Health & Human Servs., No. 98-619V, 2011 WL 5842577 (Fed. Cl. Spec. Mstr. Oct. 21, 2011). (Unless otherwise noted, the court does not supply its own findings because the special master’s findings have record support. See 42 U.S.C. § 300aa-12(e)(2)(B) (providing that reviewing court may make findings of fact if it first determines that those of special master are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).) The issue before the court is whether the special master’s findings and conclusion that petitioner’s Crohn’s disease was not caused by a vaccine were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Argument is deemed unnecessary.

FACTS

Paul A. Viscontini (“petitioner”) was born on September 17, 1982. Pet’r’s Br. filed Nov. 21, 2011, at 2. As a child, petitioner did not have any significant medical problems. Viscontini, 2011 WL 5842577, at *4. On December 7, 1995, at age thirteen, petitioner received the first of three doses of the Hepatitis B vaccination from his pediatrician, Marcelino DeSantos, M.D. Id. At that time petitioner was 62.5 inches tall and weighed 108.5 pounds. Shortly after he received the vaccination, petitioner suffered a “slight cold” with “flu-like symptoms,” but did not experience nausea or vomiting. Id. Petitioner did not seek medical attention, and no medical record was created to confirm his ailment. Id.

On January 11, 1996, petitioner received the second dose of the Hepatitis B vaccine. Id. According to petitioner and his mother (“Ms. Viscontini”), petitioner developed more severe symptoms shortly after receiving the vaccination. See id. at *4-5. Ms. Viscontini asserted that petitioner experienced “muscle and joint aching, frequent vomiting, and extreme loss of appetite.” Id. at *4. Petitioner confirmed these assertions, explaining that he “was back and forth to the doctor with symptoms of abdominal pain, vomiting and constant nausea.” Id. A January 27, 1996 medical record from Dr. DeSantos reveals that petitioner complained of abdominal pain, pain in both ears, and a headache; the medical record indicates that these problems began two days earlier. Id. at *5.

Petitioner visited Dr. DeSantos again on March 4, 1996, because he had been suffering from a sore throat, intermittent cough, and chest pain for three days. Id. Dr. DeSantos performed an examination that suggested a mild throat infection and discovered pectoral and abdominal discomfort. Id. Dr. DeSantos noted that petitioner, a member of his school’s swim team, had been swimming two miles per day and had recently begun weight training, indicating potential overuse syndrome. Id. Ms. Viscontini confirmed that, until February 15, 1996, petitioner had been practicing four or five days each week and swimming two-and-one-half miles each day. Id. After that time, however, Ms. Viscontini explained that petitioner missed most practices on account of chest and abdominal pain. Id.

On March 26, 1996, petitioner returned to Dr. DeSantos. Id. Petitioner had a low-grade fever, was suffering from fatigue and abdominal pain, and had vomited once the previous weekend. Id. On April 2 and May 10, 1996, petitioner again complained to Dr. DeSantos about experiencing abdominal pain. Id. Petitioner contends that in June 1996 he resumed swim training and running and noticed marked improvement in his health, which continued in July 1996. Pet’r’s Br. filed Nov. 21, 2011, at 2-3. The Special Master did not recite this development in this regard, and the court duly notes that its absence is immaterial.

On July 31, 1996, petitioner received the third and final dose of the Hepatitis B vaccine. Viscontini, 2011 WL 5842577, at *6. On August 4, 1996, petitioner again began

suffering from abdominal pain, cramps, and a stomachache. Id. Dr. DeSantos evaluated petitioner on August 9, 1996, and requested that additional testing be performed. Id. On September 10, 1996, petitioner saw Kevin Kelly, M.D., a pediatric gastroenterologist, and underwent an upper GI series. Id. The results of that test displayed no evidence of Crohn's disease. Id. At the time he saw Dr. Kelly, petitioner was 62.5 inches tall and weighed 99 pounds—nearly 9 pounds less than he weighed in January 1996. Id.

Petitioner was hospitalized from November 9 to November 10, 1996, on account of severe epigastric pain and vomiting. Id. On November 12, 1996, petitioner consulted Kenneth Breslin, M.D., a pediatric gastroenterologist. Id. Dr. Breslin ordered an endoscopy, which was performed on November 14, 1996, and showed results that were consistent with Crohn's disease. Id. Following his diagnosis, petitioner received treatment from various doctors and underwent an operation that improved his condition. Id.

II. Procedural history

On July 29, 1998, Ms. Viscontini—on behalf of petitioner, who was then a minor—filed a petition and affidavit alleging that the Hepatitis B vaccination caused petitioner to develop Crohn's disease. Id. at *8. No medical records accompanied the petition. Id. The case was stagnant until August 2001, when petitioner was ordered to file a single medical record. Id. Although medical records were filed, the case was stayed formally in February 2003. Id. The stay was lifted in 2006 when the matter was reassigned to another special master. Id. Thereafter, petitioner filed more medical records, and respondent filed his Rule 4 report on February 28, 2007. Id. Respondent's report indicated that petitioner had not yet submitted an expert report in support of his claim, nor had his physicians determined the cause of his condition. Id.

On November 9, 2007, petitioner submitted an expert report from Joseph A. Bellanti, M.D. Id. Dr. Bellanti explained that individuals with Crohn's disease have certain antibodies ("ASCA") against a type of yeast that is used in the manufacture of the Hepatitis B vaccine. Id. He theorized that, when a person with ASCA is injected with a yeast antigen, an immunologic response is triggered, which can account for the onset and progression of Crohn's disease. Id. Respondent submitted his own expert report from Andrew S. Warner, M.D., who, in challenging Dr. Bellanti's opinion, noted a complete lack of medical and scientific evidence indicating that the Hepatitis B vaccine can cause or aggravate Crohn's disease. Id.

In late 2008 the case was transferred to Special Master Moran, who convened a status conference on October 31, 2008. Id. at *9. Petitioner indicated that he intended to replace Dr. Bellanti with another expert. Id. On October 27, 2009, petitioner filed a report from Meyer Solny, M.D., who expressed the opinion that the Hepatitis B vaccine caused

petitioner's Crohn's disease. Id. The special master noted that the "report omitted any discussion of the appropriate temporal relationship" between receipt of the vaccination and onset of petitioner's Crohn's disease. Id. On March 19, 2010, in response to a request from respondent for more information, petitioner filed a supplemental report from Dr. Solny. Id. Dr. Warner's supplemental report in response to Dr. Solny's was submitted on May 24, 2010. Id. On August 31 and October 4, 2010, petitioner filed various medical articles in support of his position. Id. at *10.

A hearing was held on October 5, 2010. Id. Petitioner called both Drs. Solny and Bellanti as expert witnesses. Id. The special master concluded that Dr. Solny "did not give any persuasive reason for finding that the hepatitis B vaccine caused [petitioner]'s Crohn's disease." Id. As for Dr. Bellanti, the special master noted that he "presented a theory that was quite different from the theory in his report." Id. Cross-examination revealed that Dr. Bellanti no longer was relying on his theory involving ASCA. Id. His new theory was that Crohn's disease occurs when a person with a deficient immune system and a genetic predisposition to developing Crohn's confronts an environmental trigger ("environmental-trigger theory"). Id. at *10-11. According to Dr. Bellanti, the Hepatitis B vaccine could be the environmental trigger. Id. at *11. Dr. Warner responded that, although "the theory made sense in a general sense . . . he did not know whether a trigger was needed. . . .[and] no evidence shows that the hepatitis B vaccine is a trigger." Id. The special master instructed the parties to file post-hearing briefs. Id.

The court next recounts how the special master analyzed the evidence of record. In evaluating the evidence, the special master applied the test set forth in Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005). The Althen test requires that a claimant offer (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. Pursuant to Althen's first prong, the special master examined petitioner's theory that the Hepatitis B vaccine is an environmental trigger that can cause Crohn's disease. Viscontini, 2011 WL 5842577, at *14. In reviewing the evidence and testimony submitted in support of petitioner's theory, the special master applied the standards for admissibility of scientific evidence articulated in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Accordingly, the special master considered whether (1) the theory can be and has been tested, (2) the theory has been subjected to peer review, (3) there is a known or potential rate of error and whether there are standards for controlling the error, and (4) the theory enjoys general acceptance within the relevant scientific community. Viscontini, 2011 WL 5842577, at *14-17; see also Daubert, 509 U.S. at 593-94.

As to the first of the Daubert factors, Drs. Bellanti and Solny testified that, although the environmental-trigger theory could be subjected to testing, it had not been tested to date.

Viscontini, 2011 WL 5842577, at *14. Dr. Bellanti stated that animal models could be used to test his theory, but he was uncertain whether or not such models existed. Id. Dr. Warner confirmed the existence of animal models for Crohn's disease, but, because this particular testing had not been performed, the special master concluded that this factor in the Daubert analysis did "not weigh in favor of accepting or rejecting the theory that hepatitis B vaccine can cause Crohn's disease." Id.

Next, the special master evaluated the theory on the basis of whether or not it had been subjected to peer review and publication, concluding that "this point strongly favors rejecting the theory." Id. at *14-15. Dr. Bellanti testified that he had not authored any articles expounding on his proposed environmental-trigger theory. Additionally, none of the published articles that petitioner submitted supports his claim that the Hepatitis B vaccination causes Crohn's disease. Id. at *15. Moreover, at least one of the submitted articles, recognizing that multiple triggers have been identified, advances the theory that no single trigger or factor independently is responsible for development of Crohn's disease. Id.

The third factor examines whether the proposed theory has a known rate of error and whether techniques can be employed to account for the rate of error. Noting that "[n]o evidence was introduced on this topic," the special master concluded that "this factor does not constitute affirmative or negative evidence." Id. at *16. The proposed theory met a similar fate when the special master considered the fourth and final factor, which assesses whether the theory enjoys general acceptance within the relevant scientific community. Id. Drs. Warner and Solny both testified that they had not heard other professionals discuss the idea that the Hepatitis B vaccine causes Crohn's disease. Id. Accordingly, the special master found that petitioner's theory is not generally accepted within the relevant scientific community. Id.

Recognizing that the Supreme Court has called for flexibility in determining the admissibility of expert opinion, the special master addressed "additional considerations." Id. He first remarked that Dr. Bellanti's theory "appears to be an opinion developed for this litigation," id. at *18, as opposed to an opinion that grew "naturally and directly out of research [that he had] conducted independent of the litigation," id. at *17. The special master also noted that, when probed as to the basis for his theory, Dr. Bellanti "start[ed] with a result (the vaccine can cause a problem) and reason[ed] to get to that result." Id. at *18. In other words, Dr. Bellanti observed a temporal relationship between petitioner's receipt of the Hepatitis B vaccine and onset of Crohn's disease and concluded that a causative relationship therefore must exist. Id. at *18-19. He was unable, however, to identify what in the Hepatitis B vaccine acts as an environmental trigger or why this vaccine acts as a trigger while others do not. Id. at *19. The special master explained that, because Dr. Bellanti could "not provide any basis for focusing on the hepatitis B vaccine," he could not

support his own theory. Id. at *19-20. Consequently, the special master determined that petitioner “offered no persuasive reason for finding that Dr. Bellanti’s opinion that the hepatitis B vaccine can trigger Crohn’s disease is reliable. His opinion passe[d] none of the Daubert factors.” Id. at *20. The special master thus concluded that petitioner failed to satisfy Althen’s first prong because he did not present a medical theory demonstrating that the Hepatitis B vaccine can cause Crohn’s disease. Id.

Althen’s second prong requires a petitioner to demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury. The special master first explained that petitioner’s failure to proffer a medical theory showing that the Hepatitis B vaccine can cause Crohn’s disease (Althen’s first prong) rendered him unable to satisfy Althen’s second prong, which essentially examines whether the vaccine actually did cause petitioner’s condition. See id. at *20-21. Nonetheless, the special master considered evidence that pertained to the second prong. Id. at *21. He first addressed Ms. Viscontini’s testimony that the doctor who treated petitioner when he visited the emergency room linked the Hepatitis B vaccine to petitioner’s gastrointestinal problems. Id. Despite Ms. Viscontini’s testimony, the emergency room doctor’s report does not mention the vaccine. Id. Because “special masters may not award compensation ‘on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion,’” the special master did not accord much weight to Ms. Viscontini’s testimony. Id. (quoting 42 U.S.C. § 300aa-13(a)).

The special master next considered petitioner’s challenge-rechallenge argument, which notes an adverse reaction to an initial dose of a vaccine (the challenge event) and a worsening of symptoms after receipt of a subsequent dose (the rechallenge event). Id. at *22. Explaining that expert testimony and petitioner’s medical records indicate that petitioner’s Crohn’s disease began in mid-February 1996—two months after the first dose of the Hepatitis B vaccine and one month after the second dose—the special master deemed the second dose to be the “challenge” event and the third dose the “rechallenge” event, thereby weakening petitioner’s argument. Id. at *22-23. The special master further noted that many of petitioner’s assertions as to his symptoms are not supported by medical records created at the time the complained-of symptoms occurred. Id. at *22. Moreover, he noted that petitioner’s symptoms are “very common” and “could . . . represent the onset of Crohn’s disease,” but could also represent other, more common ailments. Id.

Petitioner cited Capizzano v. Secretary of Health & Human Services, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), in support of his contention that, if a rechallenge event is demonstrated, causation is established. Id. at *23. The special master acknowledged that challenge-rechallenge did establish causation in Capizzano, but noted that Capizzano presented a situation in which the petitioner already had demonstrated that the vaccine could cause the injury in question and thus satisfied Althen’s first prong. Id.

As the special master previously had concluded, petitioner was unable to show that the Hepatitis B vaccine can cause Crohn's disease. Accordingly, the special master distinguished this case from Capizzano, remarking that any repetition that may appear to establish challenge-rechallenge "is nothing more than a coincidence." Id. at *24.

Finally, the special master analyzed whether or not petitioner had satisfied Althen's third prong, which requires a "showing of a proximate temporal relationship between vaccination and injury." Id. (quoting Althen, 418 F.3d at 1278). The United States Court of Appeals for the Federal Circuit has held that this prong "requires preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The special master accepted "without critical evaluation" the testimony from petitioner's experts "that symptoms between three days and seven days after a vaccination would be an appropriate interval for which it is medically appropriate to infer that the hepatitis B vaccine caused [petitioner]'s symptoms." Id. at *25. He cautioned that, had the testimony been analyzed, it may have been found lacking because much of it was conclusory. Id. Applying this three- to seven-day time frame to petitioner's case, the special master concluded that petitioner had failed to satisfy Althen's third prong because the medical records indicate that petitioner's abdominal symptoms did not begin until the end of January 1996, which is more than seven days from petitioner's receipt of both the first and second doses of the Hepatitis B vaccine. Id. Furthermore, the onset of petitioner's Crohn's disease did not occur until mid-February 1996—well more than seven days from petitioner's receipt of the vaccine. Id. Accordingly, the special master concluded that petitioner had not demonstrated a temporal relationship between the vaccination and his injury. Id.

Noting that petitioner "failed to demonstrate the reliability of a theory that causally connect[ed] the hepatitis B vaccine to Crohn's disease," id., and that "evidence on the other two prongs from Althen was also lacking," id. at *26, the special master concluded that petitioner was not entitled to compensation. The special master's decision issued on October 21, 2011. Thereafter, petitioner filed his Motion for Review in the United States Court of Federal Claims on November 21, 2011. Respondent replied on December 19, 2011.

DISCUSSION

I. Standards

1. Standard of review

The Vaccine Act specifies three alternative courses of action available to the Court of Federal Claims in reviewing a special master's decision. The court may

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2).

In Capizzano the Federal Circuit observed that, in appeals of Court of Federal Claims decisions in Vaccine Act cases, the Federal Circuit “‘review[s] the trial court’s legal determination that the special master acted in a manner not in accordance with law *de novo*,” Capizzano, 440 F.3d at 1323-24 (quoting Althen, 418 F.3d at 1277-78), and also “‘determine[s] anew whether the . . . special master’s findings of fact were arbitrary or capricious,” id. at 1324 (citing Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000)). This scope of review necessarily results in the Federal Circuit’s applying the same standard of review to a special master’s decision as the Court of Federal Claims does in reviewing the same. Id. at 1323-24 (“In an appeal from a decision of the Court of Federal Claims in a Vaccine Act case, we apply the same standard of review that the Court of Federal Claims applied to the special master’s decision.”). More recently, in Lombardi v. Secretary of Health & Human Services, 656 F.3d 1343, 1350 (Fed. Cir. 2011), the Federal Circuit recognized that, although it was reviewing the Court of Federal Claims’s decision under the non-deferential *de novo* standard on both legal and factual issues, it was actually reviewing the special’s master’s factual findings under the deferential arbitrary and capricious standard—the same standard applied by the Court of Federal Claims when it first reviews the special master’s decision. Id. All this is a prelude to reciting the degree of deference accorded to special masters’ findings of fact that is a product of their special expertise as administrative factfinders who are not bound to apply the Federal Rules of Evidence or otherwise engage in traditional trial-type proceedings.

The deferential “arbitrary and capricious” standard, see 42 U.S.C. § 300aa-12(e)(2)(B); de Bazan, 539 F.3d at 1350-51 (citing 42 U.S.C. § 300aa-12(e)(2)), is “uniquely deferential.” Doe v. Sec’y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing Hodges v. Sec’y of Dep’t of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); see also Masias v. Sec’y of Health & Human Servs., 634 F.3d 1283, 1287 (Fed. Cir. 2011) (noting that “[a]rbitrary and capricious is a highly deferential standard of review”); Munn v. Sec’y of Dep’t of Health & Human Servs., 970 F.2d 863, 869-70 (Fed. Cir. 1992) (noting that arbitrary and capricious standard is “well understood to be the most deferential possible”); Hines v. Sec’y of Dep’t of Health & Human Servs., 940 F.2d 1518, 1528 (Fed.

Cir. 1991) (upholding Court of Federal Claims’s conclusion that special master’s decision was not arbitrary and capricious, noting that “‘arbitrary and capricious’ is a highly deferential standard of review”). The Federal Circuit in Broekelschen v. Secretary of Health & Human Services, 618 F.3d 1339, 1345 (Fed. Cir. 2010), cited the standard applied in Hines with approval, agreeing that the standard of review was highly deferential. See Broekelschen, 618 F.3d at 1348 (explaining the “‘extreme[] difficult[y]’” of demonstrating reversible error “if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision’” (quoting Hines, 940 F.2d at 1528)).

Discretionary rulings of the special master, such as the exclusion of evidence, are reviewed under the abuse of discretion standard. Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Munn, 970 F.2d at 870 n.10. While the special master may apply the standards for admissibility of scientific evidence articulated in Daubert, 509 U.S. at 593-94 (interpreting trial judge’s role in admitting scientific evidence offered under Fed. R. Evid. 702), the special master may not cloak credibility determinations as exclusions under Daubert or thereby render his findings arbitrary and capricious. See Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1326 (Fed. Cir. 2010) (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence. What [is] prohibited [i]s for the finder of fact to reject evidence based on an unduly stringent legal test while characterizing the rejection as based on the reliability of particular evidence or the credibility of a particular witness.”); see also Lombardi, 656 F.3d at 1354 (finding that special master acted within his discretion in evaluating credibility of witnesses and concluding that respondent’s experts were more persuasive than petitioner’s); Cedillo, 617 F.3d at 1338 (opining that special masters may apply Daubert factors to evaluate reliability of expert witnesses’ opinions and methodologies); Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1317 (Fed. Cir. 1999) (finding no error in special master’s use of Daubert factors as tool for evaluating reliability of scientific evidence in Vaccine Act cases); Hodges, 9 F.3d at 967 (Newman, J., dissenting) (stating that special master erred in failing to apply Daubert and consider scientific evidence, explaining that “[w]hen resolution of a legal issue requires the finding of scientific fact, the trier of fact must assess the methodology on which the scientific evidence and opinion is grounded, and ascertain the weight to which the finding is entitled). Compare Broekelschen, 618 F.3d at 1350 (affirming special master’s decision despite fact that special master may have improperly considered expert’s demeanor because special master provided a number of additional reasons why that expert’s opinion was “better supported by sound medical explanation”), with id., 618 F.3d at 1353 (Mayer, J., dissenting) (“[C]redibility determinations can be used to determine if an expert is reliable, but weighing the persuasiveness of the competing medical theories is a separate analysis. Once the special master determined both experts were highly qualified and

reliable, there was no reason for him to give any additional weight to the background or demeanor of the government's expert.”).

2. Proving causation in Vaccine Act cases

To be compensated under the Vaccine Act, petitioners must prove that an injury was caused by a vaccine listed on the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14. See *id.* § 300aa-11(c)(1)(A), (C); *de Bazan*, 539 F.3d at 1351. The Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), “lists symptoms and injuries associated with each listed vaccine and a timeframe [*sic*] for each symptom or injury.” *de Bazan*, 539 F.3d at 1351. Petitioners can meet the causation burden in one of two ways. *Walther v. Sec’y of Health & Human Servs.*, 485 F.3d 1146, 1149 (Fed. Cir. 2007). If a petitioner demonstrates that the injury falls under the Vaccine Injury Table within the time frame prescribed by the Table (a “Table injury”), causation is presumed. See 42 U.S.C. § 300aa-14(a); *Walther*, 485 F.3d at 1149. Alternatively, if the injury is not included on the Vaccine Injury Table, or falls outside the prescribed time frame for the symptom to occur (an “off-Table injury”), a petitioner must prove by a preponderance of the evidence that the vaccine was the cause in fact of the injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); *Walther*, 485 F.3d at 1149; see also *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1350 (Fed. Cir. 1999). The case *sub judice* is of this latter type, involving an off-Table injury requiring petitioner to prove causation in fact. To meet this burden, a claimant must satisfy the *Althen* test by offering (1) a medical theory causally connecting the vaccination and the injury, (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and (3) a showing of a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278.

II. Petitioner’s assignments of error

1. Whether the special master ignored the weight of the evidence

Petitioner’s first of two assignments of error is that the special master ignored the weight of medical evidence in the record that the onset of petitioner’s Crohn’s disease was within a medically accepted time frame. Petitioner notes the special master’s observation that various testimonial assertions from both petitioner and Ms. Viscontini relating to petitioner’s symptoms are not memorialized in any of petitioner’s medical records. The special master acknowledged that medical records are presumed to be complete because, “when people are ill, they see a medical professional . . . [and] report all of their problems to the doctor . . . [who then] records what he (or she) was told.” *Viscontini*, 2011 WL 5842577, at *2. Petitioner contends that, in light of this acknowledgment, the special master disregards much of petitioner’s testimony regarding his symptoms, while at the same time recognizing that “[i]t seems unlikely that a typical 13 year old would seek medical attention

for a ‘slight cold’” or other mild ailments. Pet’r’s Br. filed Nov. 21, 2011, at 9-10 (quoting Viscontini, 2011 WL 5842577, at *4).

Specifically, petitioner explains, the special master rejected testimony that established that petitioner’s symptoms occurred within a medically accepted time frame. See id. at 9. Petitioner and Ms. Viscontini both testified that within days of receiving the first and second doses of the Hepatitis B vaccine, petitioner began experiencing symptoms that ranged from “flu-like” following the first dose to abdominal pain and vomiting following the second dose. See id. at 10. Because his symptoms following the first dose were mild, petitioner did not seek medical attention, explaining the lack of a medical record documenting his claims. See id. at 10-11. Acknowledging petitioner’s age and the mild nature of his symptoms, the special master accepted petitioner’s testimony as to his symptoms following the first dose despite the absence of a medical record verifying occurrence of the symptoms. Viscontini, 2011 WL 5842577, at *4.

Petitioner and Ms. Viscontini also testified that within four days of receiving the second dose—January 15, 1996—petitioner began experiencing abdominal pain and vomiting. A medical record dated January 27, 1996, reveals that petitioner saw Dr. DeSantos on account of abdominal pain, pain in both ears, and a headache on that date. Pet’r’s Br. filed Nov. 21, 2011, at 10; Viscontini, 2011 WL 5842577, at *5. The special master stated that the context of the January 27, 1996 record indicates that petitioner’s symptoms began two days earlier—January 25, 1996. Viscontini, 2011 WL 5842577, at *5. The special master then relied on various medical records from March through May 1996 in finding that petitioner began experiencing symptoms of Crohn’s disease in mid-February 1996. See id. In challenging the special master’s rejection of the testimony indicating that petitioner’s abdominal problems began just days after he received the second dose, petitioner explains that, although he did not seek medical attention until the symptoms began interfering with his activities in mid-February, the symptoms were present earlier. Pet’r’s Br. filed Nov. 21, 2011, at 11. He then emphasizes that an otherwise healthy teenager likely would not visit the doctor until the symptoms became worrisome. Id. Accordingly, petitioner contends that the special master’s rejection of testimonial assertions establishing that the onset of petitioner’s symptoms occurred within a medically accepted time frame was arbitrary and capricious, “particularly in light of [the special master’s] earlier acceptance of [petitioner’s and Ms. Viscontini’s] testimony without corroborating medical records, based on what a typical 13 year old would do.” Id. at 12.

Respondent rejoins that the special master permissibly accorded greater weight to the medical records and expert opinions than to petitioner’s testimony. Even if the court concludes that the special master erred, respondent argues, petitioner still would not be entitled to compensation. Respondent explains first that, although the special master accepted for the sake of argument and “without critical evaluation” that symptom onset

within three to seven days constituted a medically appropriate time frame, he cautioned that the experts' testimony in this regard was conclusory and might not survive if analyzed. See Viscontini, 2011 WL 5842577, at *25; Resp't's Br. filed Dec. 19, 2011, at 19. Second, respondent argues that if further analysis revealed that this proposed time frame was medically acceptable, petitioner would be found to have satisfied only prong three; he still would need to satisfy prongs one and two in order to establish his entitlement to compensation.

The Vaccine Act states that special masters may not award compensation "on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a). Notwithstanding, the court agrees with petitioner that the special master should have credited petitioner's and Ms. Viscontini's testimony regarding the onset of symptoms despite the absence of a medical record memorializing such testimony. The court notes that the special master did accept testimonial assertions regarding petitioner's symptoms following the first dose of the Hepatitis B vaccine despite the absence of corroborating medical records. The special master explained that, given the mild nature of the symptoms, it was not troubling that petitioner—who was thirteen years old at the time—did not seek medical attention.

Similarly, petitioner did not seek immediate medical attention when he began experiencing symptoms following his second dose of the vaccine. According to petitioner and Ms. Viscontini, although petitioner had abdominal pain and vomited within four days of receiving the second dose, he did not visit his pediatrician until the symptoms worsened and began interfering with his activities. See Viscontini, 2011 WL 5842577, at *5. The records memorializing these severe symptoms subsequently attributed to his Crohn's disease were dated between March and May 1996. See id. This led the special master and other treating physicians to conclude that petitioner developed Crohn's disease in mid-February 1996. See id. at *5-6.

Had the special master accepted petitioner's and Ms. Viscontini's testimony that petitioner actually began experiencing symptoms sometime between January 15 and January 19, 1996, it would have been more likely that the special master would have found that petitioner demonstrated a proximate temporal relationship between the vaccination and the injury. Without more, the special master's refusal to credit this testimony is arbitrary and capricious because petitioner has explained that he did not regard the symptoms as requiring medical attention until they began interfering with his activities. In justifying his refusal to accept the testimony, the special master recited the rule that medical records are presumed complete. Although true, this rule applies where present-day testimony conflicts with contemporaneous documentary evidence. See Ricci v. Sec'y of Health & Human Servs., 101 Fed. Cl. 385, 390 (2011) (citing Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (Ct. Cl. 1980)). In this case the rejected testimonial assertions involve

a time period for which a medical record is unavailable. Accordingly, the testimony does not conflict with a medical record; rather, the testimony—from the two individuals most familiar with petitioner’s condition—fills in gaps between medical records and provides a comprehensive picture of petitioner’s health. Although the testimony may not have altered the ultimate outcome, the special master should have accepted and considered it to ensure that his review included all available, relevant evidence. Nonetheless, as respondent noted, the special master’s acceptance of the testimonial assertions would have aided petitioner only in satisfying Althen’s third prong. For the reasons set forth below, petitioner still would not be able to satisfy Althen’s first and second prongs and thus would not be entitled to compensation.

2. Whether the special master required petitioner to prove an elevated evidentiary burden

Petitioner’s second assignment of error is that “[t]he Special Master’s decision based on requiring Petitioner[] to prove an elevated evidentiary burden expressly rejected in *Althen* . . . was not in accordance with law.” Pet’r’s Br. filed Nov. 21, 2011, at 2 (footnote omitted). Petitioner’s argument hinges on his assertion that the special master’s decision was based on the absence of medical literature and studies supporting the theory advanced by Dr. Bellanti. Id. at 19-20. Petitioner explains that, although a previous test applied in Vaccine Act cases required a petitioner to present medical literature and studies confirming acceptance by the medical community of the theory advanced by the petitioner, the Federal Circuit now resoundingly rejects such a burden of proof. Pet’r’s Br. filed Nov. 21, 2011, at 17 (citing Stevens v. Sec’y of Dep’t of Health & Human Servs., No. 99-594V, 2001 WL 387418, at *23-26 (Fed. Cl. Spec. Mstr. Mar. 30, 2001), overruled by Althen v. Sec’y of the Dep’t of Health & Human Servs., 58 Fed. Cl. 270 (2003), aff’d, 418 F.3d 1274 (Fed. Cir. 2005)); see also Althen, 418 F.3d at 1280-81 (holding that requiring medical literature contravenes Vaccine Act’s requirement that petitioner present either medical literature or opinion to satisfy his burden of proof).

Petitioner explains that the special master unduly relied on the Daubert factors and failed to consider that Dr. Bellanti was presenting a novel theory that may not yet be ripe for a Daubert analysis. Id. at 12, 17-18. The special master found that two Daubert factors—that addressing whether a theory had been subjected to peer review and that examining whether a theory is generally accepted within the relevant scientific community—counsel against accepting Dr. Bellanti’s theory. Viscontini, 2011 WL 5842577, at *15-16. Given that Dr. Bellanti presented a theory that never before had been advanced, petitioner contends that the special master’s reliance on the outcome of the Daubert analysis essentially required petitioner to satisfy the rejected elevated burden—i.e., the special master required petitioner to proffer literature from the medical community confirming the medical plausibility of Dr. Bellanti’s theory. Pet’r’s Br. filed Nov. 21, 2011, at 17. The Vaccine Act,

however, explicitly recites that a petitioner can satisfy his burden through the use of medical records or medical opinion. See 42 U.S.C. § 300aa-13(a)(1).

Moreover, petitioner challenges that the special master found respondent's expert—Dr. Warner—more credible than Dr. Bellanti merely because Dr. Bellanti could offer no literature on which to base his theory. Pet'r's Br. filed Nov. 21, 2011, at 18. According to petitioner, the special master was attempting to “cloak an impermissible burden under the guise of a credibility assessment”—a tactic that was “strenuously rejected” in Andreu v. Secretary of the Department of Health & Human Services, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (“While considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.” (citation omitted)). Id. This deference to Dr. Warner is apparent, given Dr. Warner's testimony that he did not know what causes Crohn's disease and could not provide “a medically appropriate time frame for the onset of Crohn's following an environmental trigger.” Id. at 18-19. As petitioner explains it, the special master accepted Dr. Warner's opinion that he “doesn't know what causes Crohn's[,] he just knows it's not the Hep B vaccine” instead of Dr. Bellanti's “exhaustive testimony” explaining the onset of Crohn's disease following an environmental trigger. Id. at 19.

Therefore, petitioner argues that the special master did not act in accordance with law when he rejected Dr. Bellanti's medical theory because it was not accompanied by medical literature and studies. He also contends that the special master failed to act in accordance with law when he “cloak[ed] an impermissible burden under the guise of a credibility assessment” and opted to accept Dr. Warner's uncertainty over Dr. Bellanti's plausible medical theory. Id. at 18-19.

Respondent disputes that the special master applied an elevated evidentiary burden by requiring petitioner to produce medical literature in support of his claim in contravention of the Federal Circuit's holding in Althen. Resp't's Br. filed Dec. 19, 2011, at 14. The special master's opinion sets forth the opinions expressed by petitioner's experts and the bases for those opinions. Viscontini, 2011 WL 5842577, at *8-11. To assess the reliability of these opinions, the special master evaluated them pursuant to the standards enunciated in Daubert. Although petitioner contends that the special master relied too heavily on the Daubert analysis and failed to consider that the burden of proof in Vaccine Act cases is lower than that in traditional tort litigation, respondent notes that the Federal Circuit has approved use of the Daubert analysis in Vaccine Act cases. In Cedillo the Federal Circuit explained that

Special Masters may look to the Daubert standards in evaluating expert testimony. Vaccine Rule 8(b)(1) provides that the special master will

“consider all relevant and reliable evidence.” By inclusion of the terms “relevant and reliable,” Vaccine Rule 8(b)(1) necessarily contemplates an inquiry into the soundness of scientific evidence to be considered by special masters.

617 F.3d at 1338-39 (footnote omitted) (quoting RCFC App. B, Vaccine R. 8(b)(1) (2011)). Accordingly, respondent argues that the special master’s use of the Daubert factors to evaluate the experts’ testimony was in accordance with law.

This evaluation revealed that neither of petitioner’s experts offered a persuasive basis for concluding that the Hepatitis B vaccine can cause Crohn’s disease. Resp’t’s Br. filed Dec. 19, 2011, at 14-15. Specifically, the special master found that Dr. Bellanti began with the conclusion that the Hepatitis B vaccine could trigger Crohn’s disease and then reasoned to arrive at that conclusion. Viscontini, 2011 WL 5842577, at *18. Dr. Bellanti was entirely unable to explain the basis for his belief that the Hepatitis B vaccine could trigger the onset of Crohn’s disease and “his responses to pointed questions regarding the underpinnings of his testimony were circuitous.” Resp’t’s Br. filed Dec. 19, 2011, at 15. Respondent notes that “the special master was quite clear in explaining that the theory advanced by petitioner need not reflect scientific certainty, nor must it be corroborated by medical literature or epidemiologic evidence.” Id. at 16. Nonetheless, the special master was entitled to require “some indicia of reliability to support the assertion of the expert witness,” id. (quoting Moberly, 592 F.3d at 1324), and to reject any opinion that “is supported by only . . . “*ipse dixit*” of the expert,” id. (quoting Viscontini, 2011 WL 5842577, at *13 (citation omitted)).

Respondent also challenges petitioner’s assertion that the special master found Dr. Warner to be more credible than Dr. Bellanti because Dr. Bellanti did not proffer medical literature in support of his theory. Id. at 17 n.14. According to petitioner, in doing so, the special master “cloak[ed] an impermissible burden under the guise of a credibility assessment.” Id. (quoting Pet’r’s Br. filed Nov. 21, 2011, at 18). Respondent explains that a similar attack mounted in Lombardi was found to be without merit because “[t]he special master spent significant effort in deciding Lombardi’s case, holding three separate hearings, analyzing Lombardi’s extensive medical record, resolving conflicting expert opinions, and reviewing a gamut of evidentiary materials submitted by both parties to rule on multiple factual and legal issues in a significantly difficult case.” 656 F.3d at 1356. Likewise in this case, respondent explains, the special master carefully and thoroughly reviewed the arguments and evidence and evaluated them in accordance with applicable legal standards set forth in his opinion. Resp’t’s Br. filed Dec. 19, 2011, at 17 n.14. The special master was entitled to rely on the testimony of Dr. Warner, a practicing gastroenterologist who actively sees and treats patients with Crohn’s disease, over that of Dr. Bellanti, a professor who only occasionally sees patients with Crohn’s disease. See id. at 17. In response to petitioner’s characterization of Dr. Bellanti’s theory as novel and thereby not yet ripe for evaluation

under the Daubert framework, respondent counters that “Crohn’s disease is not new and vaccines have been around for decades.” Id. Consequently, more weight should be given to Dr. Warner’s observation that, “given that Crohn’s disease has been studied over the last fifty years, it is striking that there is no data even facially asserting that Crohn’s disease could be due to vaccination.” Id. at 17-18.

As for Dr. Solny’s opinion, the special master concluded that Dr. Solny “did not give any persuasive reason for finding that the hepatitis B vaccine caused Mr. Viscontini’s Crohn’s disease.” Id. at 14-15 (quoting Viscontini, 2011 WL 5842577, at *10). Respondent concludes that petitioner agrees with this assessment because petitioner “does not even mention Dr. Solny’s involvement in this case in his entire twenty-one page M[otion] F[or] R[eview].” Id. at 15.

The court does not agree with petitioner that the special master required petitioner to prove an elevated evidentiary burden. Petitioner is correct that, in evaluating the reliability of Dr. Bellanti’s theory under the Daubert factors, the special master did note the absence of medical literature and studies in support of Dr. Bellanti’s theory; however, the special master considered that the novel nature of Dr. Bellanti’s theory may explain the lack of published research in support of it, noting that “[t]he Supreme Court, in Daubert, cautioned against finding [that] a theory did not satisfy the minimal standards for admissibility/reliability solely because the theory was new.” See Viscontini, 2011 WL 5842577, at *17. Despite the special master’s willingness to heed this cautionary instruction, the literature that petitioner submitted, to the extent that it was on point, did not reflect that the theory was considered novel.

Thus, the special master credited evidence that persuasively challenged the reliability of Dr. Bellanti’s theory. The special master explained that, although the specific theory may be new, “[t]he fact that for decades, researchers have been investigating Crohn’s disease and have not proposed that any vaccine functions as an environmental trigger suggests that the theory that the hepatitis B vaccine causes Crohn’s disease does not fall within the mainstream.” Id. Moreover, Dr. Bellanti could not explain the basis for his theory; rather, he identified a temporal relationship between petitioner’s receipt of the vaccine and onset of symptoms and assumed a causative relationship. He was unable to articulate why a causative relationship exists or otherwise “provide any basis for linking the hepatitis B vaccine to the onset of Crohn’s disease.” Id. at *19; see also id. at *18 (“It does not advance the proof to say, as Dr. Bellanti essentially does, that the evidence supporting that causative relationship is that we have established a causative relationship.”).

Finally, although the special master does appear to have found Dr. Warner more credible than Dr. Bellanti, it is not true that the special master was cloaking an impermissible burden in the guise of a credibility determination. Dr. Bellanti, unlike Dr. Warner, does not

regularly treat patients with Crohn's disease. See id. at *17. In fact, Dr. Bellanti "estimat[ed] that he ha[d] seen 30-40 cases of Crohn's disease in his 47-year career," id., as compared to Dr. Warner, who is a practicing gastroenterologist specializing in inflammatory bowel diseases, including Crohn's disease, id. at *16. Moreover, the special master did not place undue reliance on Dr. Warner's testimony. To the contrary, the special master painstakingly reviewed the medical records and journal articles that petitioner submitted, and his opinion reflects that he weighed all of the evidence. As noted in Lombardi, such a comprehensive effort diminishes a claim that a special master is holding a petitioner to an elevated burden and shrouding that action in a credibility determination.

Accordingly, the court finds that the special master neither required petitioner to submit medical literature proving his theory nor discounted Dr. Bellanti's theory solely on the basis of a lack of such literature. Rather, Dr. Bellanti's inability to expound on his conclusion that the Hepatitis B vaccine caused petitioner's Crohn's disease largely was responsible for the special master's decision that petitioner had failed to satisfy Althen's first and second prongs. Because the special master did not base his conclusion on the absence of medical literature or studies, nor require petitioner to submit such evidence, the court concludes that the special master acted in accordance with law.

CONCLUSION

The court concludes that the special master applied the correct legal standard and that he examined petitioner's medical records and reports and set forth his findings leading to his ultimate conclusion that petitioner had failed to provide preponderant evidence that the Hepatitis B vaccine caused petitioner's condition. Giving no more than appropriate deference to the special master's findings of fact, this court concludes that the decision denying compensation was neither arbitrary nor capricious. Accordingly, petitioner's motion for review is denied, and the Clerk of the Court shall enter judgment in accordance with the special master's decision.

IT IS SO ORDERED.

No costs on review.

/s/ Christine O.C. Miller

Christine Odell Cook Miller
Judge