

(Fed. Cl. Spec. Mstr. May 26, 2010) (“Dec.”). Petitioner moves for review of that decision, arguing that the special master’s finding regarding causation was arbitrary and capricious. Petitioner’s Motion for Review at 2-3 (docket entry 114, June 24, 2010) (“Pet.’s Mot.”). Because the special master’s decision was based upon factual findings that were rational and supported by substantial evidence in the record, petitioner’s motion for review is **DENIED** and the decision of the special master is **AFFIRMED**.

I. Background

Born on April 22, 1963, petitioner has had a rather “complex medical history” as a result of several ailments, many of which may have “predisposed him to [fibromyalgia].”¹ Dec. at 2; *see also* Transcript of February 21, 2008 Hearing at 8 (docket entry 82, filed Mar. 24, 2008) (“Feb. Tr.”). Prior to the vaccinations at issue, petitioner suffered from “chronic ear infections and sinusitis, perineal pain, allergies, kidney stones, muscle spasms, and back problems associated with disc herniation.” Dec. at 2; *see also* Pet.’s Mot. at 3-4; Respondent’s Memorandum in Response to Petitioner’s Motion for Review at 2 (docket entry 116, July 26, 2010) (“Resp.’s Mem.”). Petitioner’s back pain eventually led to surgery in 1997, which resulted in “a great reduction in the pain,” although petitioner continued to occasionally feel “minor twinges of pain if he was tired.” Pet.’s Mot. at 4; *see also* Dec. at 2-3; Feb. Tr. at 12. In addition, petitioner has a “history of psychological difficulties, including depression, anxiety and sleep disturbances.” Dec. at 3; *see also* Pet.’s Mot. at 4 n.4; Resp.’s Mem. at 2; Feb. Tr. at 13. Petitioner also has a family history of fibromyalgia; both his mother and one aunt were previously diagnosed with that condition. Dec. at 3; *see also* Feb. Tr. at 62; Pet.’s Ex. 4 at 5.²

A. Hepatitis B Vaccinations and Alleged Reactions

1. First Dose of Hepatitis B Vaccine

Petitioner received the first dose of the Hepatitis B vaccine on March 10, 1998.³ Dec. at 3; Pet.’s Mot. at 4; Resp.’s Mem. at 2; Feb. Tr. at 16. After this first dose, petitioner alleges he

¹ Fibromyalgia is a rheumatic condition involving diffuse musculoskeletal pain. *STEDMAN’S MEDICAL DICTIONARY* at 725-26 (28th ed. 2006). Although the specific causes of fibromyalgia are unknown, most experts believe that there is some genetic component. *See, e.g.,* Dan Buskila & Piecarlo Sarzi-Puttini, *Genetic Aspects of Fibromyalgia Syndrome*, *ARTHRITIS RESEARCH & THERAPY* 1, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1779444/pdf/ar2005.pdf> at 1 (2006).

² In his hearings before two separate special masters, petitioner filed voluminous exhibits, including copies of his medical records (docket entry 12, Apr. 16, 2004, as supplemented by docket entry 15, May 28, 2004; docket entry 17, July 2, 2004; docket entry 18, July 16, 2004; docket entry 26, Dec. 14, 2005; docket entry 27, Dec. 14, 2005; docket entry 34, May 4, 2006; docket entry 36, May 25, 2006; docket entry 40, June 16, 2006; docket entry 50, Dec. 6, 2006; and docket entry 55, Jan. 8, 2007). “Pet.’s Ex.” refers to these exhibits.

³ The Hepatitis B vaccine has been commercially available since 1982. *See* Eric Mast et al., *Hepatitis B Vaccine*, in *VACCINES* 299, 312 (Stanley A. Plotkin & Walter A. Orenstein eds.,

“developed diarrhea that went on for about a month[, which] he treated with over-the-counter medication.”⁴ Pet.’s Mot. at 4; *see also* Dec. at 3 (“Petitioner claims to have developed an ongoing bout of diarrhea after his first vaccination, which ‘waxed and waned’ over the summer of 1998.”). According to petitioner’s expert, Dr. Joseph Bellanti, the diarrhea may have been a result of irritable bowel syndrome, which is commonly associated with fibromyalgia. Dec. at 20; Feb. Tr. at 83. However, the special master noted that petitioner did not report his diarrhea to a doctor until March 1999, and in the corresponding medical record, the doctor noted that petitioner reported experiencing diarrhea “during the preceding summer.” Dec. at 4. After being questioned about the inconsistency regarding the date of the onset of petitioner’s diarrhea, Dr. Bellanti conceded that the link between petitioner’s diarrhea and the Hepatitis B vaccine was “more speculative than real.” *Id.* at 20 (quoting Feb. Tr. at 92 (testimony of Dr. Bellanti)).

2. Second Dose of Hepatitis B Vaccine

Petitioner received his second dose of the Hepatitis B vaccine on April 8, 1998. Dec. at 3; Pet.’s Mot. at 4; Resp.’s Mem. at 2; Feb. Tr. at 16. The facts surrounding petitioner’s reaction to the second dose are heavily disputed. Petitioner claims that “[w]ithin a week of this [second] vaccination, [he] had discomfort in his upper extremities beginning in his right arm. He could not lift his left arm above 90 degrees at the shoulder and he had pain in both arms. He [also] had cervical pain and pain in his scapular area.” Pet.’s Mot. at 4-5 (internal citations omitted); *see also* Transcript of December 12, 2008 Hearing at 18 (docket entry 101, filed Jan. 6, 2009) (“Dec. Tr.”) (“Within a week [of the second vaccine], I developed pain and discomfort in my entire right extremity, and I had some muscle tension and pain in the intra-scapular area of my back After about a week, it moved into my left shoulder, and I had pain trying to raise it above 90 degrees so I went to the doctor.”). The special master, however, found that petitioner’s contemporaneous medical records cast doubt on the alleged timing of the onset of his symptoms. Dec. at 21.

4th ed. 2004). The vaccine was initially manufactured from the plasma of persons suffering from chronic Hepatitis B infection. *Id.* Since 1990, however, the vaccine has been synthetically manufactured through recombinant DNA technology, which permits scientists to isolate and alter specific genes. *Id.*; *see also* JAMES D. WATSON ET AL., RECOMBINANT DNA: GENES AND GENOMES—A SHORT COURSE 76 (3d ed. 2007). Petitioner received three doses of the Engerix-B[®] Vaccine, a “noninfectious recombinant DNA hepatitis B vaccine developed and manufactured by GlaxoSmithKline.” GlaxoSmithKline, Engerix-B[®], http://us.gsk.com/products/assets/us_engerixb.pdf at 1 (June 2010); *see also* Pet.’s Ex. 6 at 3. Like most Hepatitis B vaccines, the Engerix-B[®] vaccine is administered through an intramuscular injection in three doses. Engerix-B[®], *supra*, at 10-11; *see also* Mast et al., *supra*, at 314.

⁴ During his hearings, petitioner claimed that his chronic diarrhea started almost immediately after the first dose of the vaccine and continued on and off for approximately two years rather than one month. *See* Dec. at 5 (“Petitioner states that [the] diarrhea, which continued for approximately two years, started within twelve hours of his first Hep B vaccine.”) (citing Affidavit of Petitioner ¶¶ 4-5 (Apr. 27, 2006), *attached as* Pet.’s Ex. 34).

Petitioner visited Dr. Bernard C. Moses, his primary care physician, on April 24, 1998. *See* Dec. Tr. at 18 (pointing to Pet.’s Ex. 6 at 12). Dr. Moses noted that petitioner described right arm and shoulder pain starting two to three weeks before his visit and left-sided pain that began “yesterday.” Dec. at 22; Pet.’s Mot. at 5. Based on this contemporaneous medical report, the special master concluded that the onset of petitioner’s right arm and shoulder pain occurred between April 3 and April 10, a span of time that “includes five days before petitioner’s second [Hepatitis B] vaccination.” Dec. at 21. Dr. Moses told petitioner to take ibuprofen to relieve the pain. *Id.* at 3. Petitioner alleges that his pain “continued until the third vaccination,” Dec. Tr. at 23, but the special master observed that “this [allegation] is only evidenced by [petitioner’s] testimony.” Dec. at 3. Petitioner did not return to Dr. Moses until June 12. *Id.* In that visit, Dr. Moses recorded that petitioner had been experiencing “LS pain,” which petitioner testified referred to left-sided pain.⁵ *Id.*; *see also* Dec. Tr. at 55. In a further follow-up visit in August, petitioner reported “pain in neck.” Dec. at 3 (citing Pet.’s Ex. 52 at 7).

3. Third Dose of Hepatitis B Vaccine

Petitioner received his third and final dose of the Hepatitis B vaccine on September 22, 1998. Pet.’s Ex. 52 at 8; *see also* Resp.’s Mem. at 3. Petitioner was scheduled to start an internship in the occupational therapy field, but alleges that he began developing a severe headache and then body pains two to three days *before* his internship, corresponding to two to three days *after* the third dose of his vaccine.⁶ Dec. at 3-4; Pet.’s Mot. at 5; Feb. Tr. at 20. Petitioner visited Dr. Moses on September 24, where he raised general “somatic” complaints.⁷ Dec. at 3-4.

⁵ The special master observed that “LS” could refer to several things, including “left-sided,” “left shoulder,” or “lumbosacral.” Dec. at 3 n.7. Respondent interpreted the reference to be lumbosacral or lower back pain, because of a later reference to that type of pain in petitioner’s records. Dec. Tr. at 55. The special master apparently took petitioner at his word that this notation referred to left-sided pain. In any event, resolution of this factual issue was not necessary to the ultimate decision.

⁶ During the proceedings before the special master, petitioner asserted that his severe headache began within twenty-four hours of receiving the third dose of the vaccine. Dec. at 3; *see also* Dec. Tr. at 23 (“Within 24 hours, I developed a severe headache.”). Thus, it is unclear from the records whether petitioner’s headache began before or after his September 24 visit to Dr. Moses. However, Dr. Moses’s notes make no mention of petitioner’s reporting a severe headache. Dec. at 3. Respondent observes that the medical records indicate that the purpose of petitioner’s September 24 visit to Dr. Moses was to receive a tuberculin skin test required by his internship. Resp.’s Mem. at 3. The records also indicate that petitioner complained of “generalized anxiety” that had begun to interfere with his work and that Dr. Moses prescribed Xanax. *Id.*

⁷ Petitioner actually referred to “semantic” complaints during the December hearing, which petitioner’s counsel indicated “refer[s] to gastrointestinal, constipation, heartburn, nausea, vomiting, colitis, headaches, migraines, backaches, neck aches, and skin disorders.” Dec. at 4 (quoting Dec. Tr. at 24). The special master concluded that petitioner likely meant “somatic”

4. Subsequent Medical History

On October 28, 1998, petitioner was evaluated by Dr. Steven Kiefer, a surgeon, as a follow up to his back surgery. Dec. at 4; Pet.'s Mot. at 5; Resp.'s Mem. at 3. Dr. Kiefer noted that petitioner had recovered from his surgery but still felt pain, which "has been aggravated by very long work days as an OT intern . . ." Pet.'s Ex. 4 at 25. According to Dr. Kiefer, petitioner also complained "of a one month history of burning neck pain with some extension into his intrascapular region as well as his proximal shoulders." *Id.* Dr. Kiefer diagnosed petitioner with "probable degenerative cervical spine disease as well as known degenerative lumbar disc disease status post lumbar discectomy." *Id.* He recommended physical therapy. *Id.*

In February 1999, petitioner returned to Dr. Moses complaining of lower back pain. Dec. at 4; Pet.'s Mot. at 5; Resp.'s Mem. at 4. Dr. Moses diagnosed bursitis in petitioner's shoulder and referred him to a rheumatologist, Dr. Paul M. Goldfarb. Dec. at 4. Petitioner visited Dr. Goldfarb in March 1999 and the doctor's notes from this visit indicate that petitioner reported "right arm pain [beginning] in spring '98." Pet.'s Ex. 7 at 119. As stated above, it was during this visit that petitioner first described having persistent diarrhea beginning the previous summer. *Id.*; Dec. at 4. He also reported neck, shoulder, and calf pain, as well as difficulty sleeping. Pet.'s Ex. 7 at 119. Petitioner told Dr. Goldfarb he had seen

a show on 20/20 regarding [the] Hepatitis B vaccination and some people who have had problems with [t]his [vaccine]. He had just finished his course when he developed aching all over and wonders if this had anything to do with it. (*I tried to reassure him I did not think this was related.*)

Id. at 120 (emphasis added). Dr. Goldfarb diagnosed probable fibromyalgia even though petitioner did "not quite meet [the] criteria because of the number of tender points."⁸ *Id.* at 122.

On April 14, 1999, petitioner was admitted to a hospital for an apparent drug overdose. Dec. at 4; Pet.'s Ex. 11 at 12. Petitioner later admitted to a social worker that he had taken approximately 50 Elavil tablets and 18 Darvocet tablets, and consumed approximately three beers.⁹ Pet.'s Ex. 11 at 12. According to petitioner, his suicide attempt was the result of the loss of his internship, which petitioner blamed on his fibromyalgia. *Id.*

complaints, which refers to "the soma or trunk, the wall of the body cavity, or the body in general." Dec. at 4 (quoting STEDMAN'S MEDICAL DICTIONARY at 1788); *see also* Pet.'s Ex. 52 at 6 ("somatic complaints").

⁸ The diagnostic criteria established by the American College of Rheumatology require "point tenderness . . . in at least 11 of 18 specified cites." STEDMAN'S MEDICAL DICTIONARY at 725; *see also* Feb. Tr. at 73.

⁹ Elavil, a brand name for Amitriptyline, is an anti-depressant that is also commonly used as an analgesic for chronic pain conditions such as fibromyalgia. *See* Merck Manuals Online Medical Library, *Amitriptyline*, <http://www.merck.com/mmpe/lexicomp/amitriptyline.html> (rev. Jan. 2010). Darvocet, the brand name for Propoxyphene Napsylate, is a narcotic painkiller

Petitioner continued to see various doctors over the next few years, including Dr. William H. Brooks, a neurologist. Dr. Brooks observed that petitioner was “under the impression that [his pains] [are] related to Hepatitis B infection,” and referred him to Dr. Rodney M. Mann, a specialist in infectious diseases. Pet.’s Ex. 4 at 22; *see also id.* at 17. In a report dated April 19, 2001, Dr. Mann observed that “[w]hile it is conceivable that [petitioner] could be a rare serum sickness-like reactor to hepatitis B vaccination, the duration and magnitude of his symptoms seem well out of proportion. In addition, his biochemical assays are not supportive of an ongoing severe inflammatory disorder.” *Id.* at 6.

Petitioner was definitively diagnosed as having fibromyalgia in January 2000.¹⁰ Dec. at 4. Petitioner also saw a psychiatrist who diagnosed generalized anxiety disorder. *Id.* The available medical records after 2001 indicate “widespread constant pain” and fatigue associated with his fibromyalgia as well as continued treatment of his back problems. Pet.’s Mot. at 5; *see also* Dec. at 5.

B. *Vaccine Petition and Proceedings Before the Special Master*

1. Petitioner’s Theory of the Case

Petitioner filed his Vaccine Act petition on March 8, 2001 (docket entry 1). His theory, principally presented through the expert opinion of Dr. Bellanti, was that the Hepatitis B vaccines, in combination with his preexisting conditions, caused his fibromyalgia. *See* Expert Report of Dr. Joseph A. Bellanti at 9-10 (Dec. 12, 2005) (docket entry 27-2, filed Dec. 14, 2005) (“Bellanti Rep.”); Supplemental Report of Dr. Joseph A. Bellanti at 7-8 (June 17, 2009) (docket entry 108-2, filed June 18, 2009) (“Bellanti Supp. Rep.”). Specifically, Dr. Bellanti opined that petitioner’s case fits the “challenge-rechallenge model.” Bellanti Rep. at 1; *see also* Bellanti Supp. Rep. at 7.

The challenge-rechallenge model is a logical tool used to demonstrate that a vaccine (or any other event) caused an injury. *See* Dec. at 18 & n.22; *Nussman v. Sec’y of Health & Human Servs.*, 83 Fed. Cl. 111, 119-20 (2008). Under this model, an individual who has had an adverse reaction to the initial vaccine dose (the “challenge event”) “suffers [a] worsening [of] symptoms after a second or third injection” (the “rechallenge event”).¹¹ Dec. at 19 (quoting Feb. Tr. at 91 (testimony of Dr. Bellanti)) (alterations in original).

normally combined with acetaminophen. *See* Xanodyne Pharmaceuticals, Inc., *Darvocet-N*, http://www.xanodyne.com/pdf/Darvocet_N_50.pdf (2006).

¹⁰ Respondent did not dispute petitioner’s fibromyalgia diagnosis. *See* Dec. at 14.

¹¹ The special master discussed a minor discrepancy between Dr. Bellanti’s description of the challenge-rechallenge model and previous cases using this term. In the *Nussman* case, for example, Judge Sweeney stated that “[c]hallenge-rechallenge happens when a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly.” 83 Fed. Cl. at 119 (quoting *Nussman v. Sec’y of Health & Human Servs.*, No. 99-500, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008)) (alterations in original). This definition does not appear to require the

Dr. Bellanti presented two possible theories of what could be considered the “challenge event” in petitioner’s case. The first possibility was petitioner’s persistent diarrhea that he allegedly experienced after the first dose of the vaccine. *See* Bellanti Rep. at 8, 10; Dec. at 20; Feb. Tr. at 92. After the special master pointed out to Dr. Bellanti the lack of documentation in the medical record regarding the timing of petitioner’s diarrhea, Dr. Bellanti shifted his focus to the other potential challenge event: the arm and shoulder pain petitioner allegedly experienced after his second dose of the Hepatitis B vaccine. *See* Bellanti Supp. Rep. at 7; Dec. at 20. Dr. Bellanti described this potential challenge event as follows:

[Petitioner] received a second Hepatitis B virus vaccine, and within a week of developing or of receiving [this], he developed, first, pain [i]n the right arm, and the right shoulder. Then it became more diffuse in the scapular area, . . . in the back, and in the cervical area. Then it went to his left shoulder, and his left arm, with inability to raise it beyond 90 degrees.

Dec. at 20 (quoting Feb. Tr. at 84) (first and second alterations in original).

If petitioner’s diarrhea were the challenge event, then the first bout of arm and shoulder pain after the second dose of the vaccine would be the rechallenge event. If the arm and shoulder pain after the second dose of the vaccine were the challenge event, then the pain petitioner experienced after the third dose of the vaccine would be the rechallenge event. In either case, Dr. Bellanti opined, petitioner’s reaction to the doses of the Hepatitis B vaccine fit the challenge-rechallenge model.

2. Special Master’s Decision

The special master found both of Dr. Bellanti’s challenge-rechallenge theories to be unsupported by the facts of record. Dr. Bellanti’s opinion relied on petitioner’s own account of his symptoms as presented through affidavits. Dec. at 6 n.10. The special master found this reliance on “petitioner’s affidavits” to be problematic because petitioner’s version of events was inconsistent with the medical records in many significant ways. *Id.* at 9. Thus, after petitioner’s second round of testimony, the special master found that because of the inconsistencies between petitioner’s testimony and the medical records, the latter “will be relied upon for the facts of this case.” Order at 1 (docket entry 99, Dec. 16, 2008) (“Dec. 16 Order”); Dec. at 9. The special master continued:

While petitioner’s testimony was in many ways consistent with the medical records in a global sense, the detailed nuances of petitioner’s complex medical

rechallenge event to involve more severe symptoms than the challenge event. But Judge Sweeney also stated: “Typically, the second reaction is faster and more severe.” *Id.*; *see also Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006) (“A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine.”). The special master reviewed petitioner’s case in a manner consistent with Dr. Bellanti’s approach, and the Court has done likewise.

history were in several key areas presented differently between the records and testimony. Given that the medical record history was given by petitioner himself ten years ago, the [special master] finds it unnecessary to re-write that history ten years later. Stated another way, petitioner's memory ten years ago of the timeline of his symptoms is vastly more reliable than his memory of those events today.

Dec. 16 Order at 1-2. The special master gave Dr. Bellanti the opportunity to submit a supplemental expert report relying on the medical records when they differed from petitioner's affidavits. Dec. at 7, 10. However, the bulk of Dr. Bellanti's June 18, 2009 supplemental report "mirror[ed] the first" report and did not rely on the medical records as the special master directed. *Id.* at 7.

As a factual matter, the special master found that petitioner did not prove by a preponderance of the evidence that his symptoms occurred *after* having received the doses of the Hepatitis B vaccine. By failing to establish this basic temporal relationship, petitioner was unable to prove that the vaccines could have caused the symptoms.

First, there was no corroborating evidence that petitioner's persistent diarrhea occurred immediately after the first vaccine. Dec. at 20. In light of Dr. Bellanti's concession that petitioner's suffering from diarrhea as a result of the first dose of the vaccine was "more speculative than real," the special master found that petitioner's persistent diarrhea could not be considered a challenge event. *Id.*

Second, as to the arm and shoulder pain, the special master concluded that the record did not support a finding that this pain occurred as a result of the second dose of the Hepatitis B vaccine. *Id.* Dr. Moses's notes from the April 24 visit indicate right arm pain beginning two to three weeks before the visit, which is consistent with the right arm pain having begun five days *before* the second Hepatitis B vaccine.¹² *Id.* at 21. The medical records indicated that the left arm pain began a day before the April 24 visit—one day after the second vaccine. Dr. Bellanti initially relied heavily on petitioner's development of right-side pain *after* the second dose of the vaccine in order to causally connect petitioner's fibromyalgia with the vaccine. Dec. at 20. After being challenged by the special master about the onset date of the right shoulder pain, he "inexplicably dropped his reliance on the right-sided pain and relied wholly on the left-sided pain." *Id.* at 21.

However, the special master observed that Dr. Bellanti's theory was based upon a "progression of . . . pain," and that progression required one to take into account the onset of the

¹² Respondent states that "[a]t least one record . . . documents the onset of petitioner's joint pain as April 4, 1998, four days *before* his second vaccination." Resp.'s Mem. at 12 n.8 (citing Pet.'s Ex. 6 at 2). As respondent readily admits, however, this "record" was a Spontaneous Adverse Event Report Form completed in February 2001, several years after the administration of the vaccine. *Id.* The special master only briefly referred to this report and did not rely upon it for the onset date of pain after petitioner received his second dose of the vaccine. *See* Dec. at 5; *see also Analla v. Sec'y of Health & Human Servs.*, 70 Fed. Cl. 552, 558 (2006) (questioning reliability of Vaccine Adverse Event Reporting System reports).

right arm pain. *Id.*; Dec. Tr. at 19; *see also* Feb. Tr. at 93-94 (testimony of Dr. Bellanti) (“There was a *progression of this pain syndrome*, which hadn’t occurred before, and which was totally unrelated to his [back] problem.”) (emphasis added). Furthermore, there were references in the medical records to pain before, during, and after the administration of the three doses of the Hepatitis B vaccine. Dec. at 20; *see also* Feb. Tr. at 111 (describing indication in medical record that petitioner experienced “muscular skeletal pain” several weeks before the first dose of the vaccine). Finally, contrary to petitioner’s allegation, Dr. Moses’s notes indicate “no [point] tenderness of either shoulder” and a “full range of motion.” Pet.’s Ex. 6 at 12; Resp.’s Mem. at 12 n.9. Therefore, the special master concluded that there was limited evidence that petitioner’s shoulder pain temporally followed his second dose of the vaccine. Dec. at 23.

Furthermore, the special master found the theory of the cause of petitioner’s fibromyalgia presented by the Government’s expert, Dr. Alan I. Brenner, to be more convincing than Dr. Bellanti’s theory. *Id.* at 22; *see also* Report of Alan I. Brenner (Sept. 25, 2006) (docket entry 47-1, filed Sept. 25, 2006) (“Brenner Rep.”). Dr. Brenner stated that petitioner’s symptoms of fibromyalgia actually began in the summer of 1998 when “petitioner’s pain complex began and *did not abate* after this time.” Dec. at 22 (emphasis in original). The onset of pain, according to Dr. Brenner, was likely caused by the physical and psychological stress associated with petitioner’s recent back surgery and his return to occupational therapy school. *See* Brenner Rep. at 11-12 (stating that “[t]here is ample literature to support” that “psychological stressors as well as the possible physical stressors of recent back injury, surgery and return to a physical OT internship” were much more likely the cause of petitioner’s fibromyalgia). Dr. Brenner’s “convincing reasoning for placing onset at this time was based upon his experience with treating fibromyalgia; that experience being that [fibromyalgia] typically does not cease after it begins.” Dec. at 22 (citing Feb. Tr. at 142). Thus, while Dr. Bellanti’s theory was “conclusory,” Dr. Brenner’s theory found support in both the medical records and Dr. Brenner’s experience in working with fibromyalgia patients.¹³ *Id.* at 23.

The special master determined that Dr. Bellanti’s reasoning was conclusory and failed to temporally connect petitioner’s symptoms with his fibromyalgia. Therefore, Dr. Bellanti’s opinion alone could not support a finding that there was a “medically-accepted temporal relationship between the vaccination and the alleged injury,” *i.e.*, the third element of the *Althen* test. Dec. at 17, 24; *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The special master found that petitioner’s proof of the first and second elements of the *Althen* test relied on Dr. Bellanti’s having established the applicability of challenge-rechallenge. However, the special master found that “Dr. Bellanti’s muddled evidence of a plausible

¹³ Dr. Brenner also rejected the applicability of a challenge-rechallenge model entirely. Dr. Brenner testified that challenge-rechallenge is an immunological theory, but there was no evidence that fibromyalgia was an “immune-mediated condition.” Dec. at 7, 22; *see also* Brenner Rep. at 10 (“It is generally accepted that [fibromyalgia] is not a condition mediated by immune inflammatory processes . . .”). The special master, however, did not rely on this aspect of Dr. Brenner’s opinion, focusing instead on the persuasiveness of Dr. Brenner’s views regarding the onset of pain in light of the medical records.

[medical] theory and a logical sequence of cause and effect” was unpersuasive.¹⁴ Dec. at 28. Thus, the special master held that petitioner failed to prove a prima facie case and dismissed his petition.

Petitioner timely filed his motion for review of the special master’s decision on June 24, 2010. 42 U.S.C. § 300aa-12(e)(1); *see also* Pet.’s Mot. at 1. Respondent filed its memorandum in response to petitioner’s motion on July 26, 2010. Resp.’s Mem. at 1.

II. Jurisdiction and Standard of Review

The court possesses jurisdiction to review a special master’s decision under the Vaccine Act pursuant to 42 U.S.C. § 300aa-12(e). *See Capizzano*, 440 F.3d at 1320. This court will uphold the special master’s findings of fact and conclusions of law unless they are “found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” and may “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)(A) - (C); *Saunders v. Sec’y of Dep’t of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994). The special master’s legal conclusions are reviewed *de novo*. *Euken v. Sec’y of Dep’t of Health & Human Servs.*, 34 F.3d 1045, 1047 (Fed. Cir. 1994); *Gardner-Cook v. Sec’y of Health & Human Servs.*, 59 Fed. Cl. 38, 44 (2003), *aff’d per curiam*, 97 F. App’x 332 (Fed. Cir. 2004). Findings of fact of the special master are reviewed under the arbitrary and capricious standard, and discretionary rulings are reviewed under the abuse of discretion standard. *Saunders*, 25 F.3d at 1033; *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 & n.10 (Fed. Cir. 1992) (observing that the arbitrary and capricious standard is “well understood to be the most deferential possible”).

It is particularly difficult for a petitioner to satisfy the arbitrary and capricious standard “with respect to an issue that turns on the weighing of evidence by the trier of fact.” *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). “In general, reversible error is ‘extremely difficult to demonstrate’ if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” *Id.* (quoting *Hines v. Sec’y of Dep’t of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Indeed, the reviewing court does not “reweigh the factual evidence, or . . . assess

¹⁴ The special master also noted that petitioner’s expert “hinted at other arguments” but that these arguments were also unpersuasive. Dec. at 25. First, the special master stated that petitioner did not present evidence linking fibromyalgia “to any of the conditions associated with the [Hepatitis B] vaccine in the submitted literature.” *Id.* Further, there was limited evidence that the “symptoms of [fibromyalgia] are caused by similar disease processes that result in the symptoms of those conditions” traditionally associated with the Hepatitis B vaccine. *Id.* Finally, the special master found the medical literature relied upon by Dr. Bellanti to be unhelpful because “[o]ther than suggesting [fibromyalgia] somehow affects or is affected by the immune system, Dr. Bellanti does nothing to develop a theory relying on these articles[;] he simply proposes the [Hepatitis B] vaccine affected” petitioner’s neurological, endocrine or immunological systems, which is what Dr. Bellanti postulated would link the vaccine to fibromyalgia. *Id.* at 27-28. The special master therefore concluded that Dr. Bellanti’s theory was not supported by the facts, viewing the record “as a whole.” *Id.* at 28.

whether the special master correctly evaluated the evidence.” *Munn*, 970 F.2d at 871. Nor does the reviewing court “examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.” *Id.*

III. Discussion

Petitioner’s motion for review is at its core a disagreement about the facts underlying the special master’s rejection of the applicability of petitioner’s challenge-rechallenge theory. First, petitioner argues that the special master erred in discounting petitioner’s live testimony when it was contradicted by his contemporaneous medical records. Pet.’s Mot. at 3. Second, petitioner contends that the special master’s conclusion regarding the applicability of the challenge-rechallenge model was arbitrary and capricious. *Id.* at 12-13. Finally, petitioner maintains that the special master erred in failing to follow his own decision in a previous case, *Lee v. Secretary of the Department of Health and Human Services*, No. 03-2479, 2005 WL 1125672 (Fed. Cl. Spec. Mstr. Apr. 8, 2005), in which the special master found that the Hepatitis B vaccine *did* cause the petitioner to develop fibromyalgia. *Id.* at 17. None of these arguments provide a basis for reversing the special master’s decision.

A. *The Special Master Correctly Afforded the Contemporaneous Medical Records More Weight Than Petitioner’s Testimony When They Were in Conflict*

Initially, petitioner challenges the special master’s decision to credit the contemporaneous medical records over petitioner’s live testimony. Pet.’s Mot. at 3-4 & n.2. Petitioner first argues that, as a matter of law, petitioner’s testimony was uncontested through two hearings and therefore should have been relied upon by the special master. *Id.* at 3.

However, the special master correctly placed more reliance on the contemporaneous medical records than petitioner’s live testimony. In the Vaccine Act context, the Federal Circuit has specifically held that “oral testimony in conflict with contemporaneous documentary evidence deserves little weight.” *Cucuras v. Sec’y of Dep’t of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 365, 396 (1948) and *Montgomery Coca Cola Bottling Co. v. United States*, 615 F.2d 1318, 1328 (Ct. Cl. 1980)); *see also Burns v. Sec’y of Dep’t of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Doe/17 v. Sec’y of Health & Human Servs.*, 84 Fed. Cl. 691, 706 (2008); *Nordwall v. Sec’y of Health & Human Servs.*, 83 Fed. Cl. 477, 486 (2008), *appeal dismissed*, 331 F. App’x 720 (Fed. Cir. 2009). The Federal Circuit explained:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras, 993 F.2d at 1528. Therefore, the special master correctly gave more weight to petitioner’s contemporaneous medical records when they were in conflict with petitioner’s live testimony. Petitioner fails to cite to any law or articulate any reason why the special master’s application of Federal Circuit precedent was incorrect.

Petitioner next argues that factually, the special master's conclusion that petitioner's testimony was inconsistent with the medical records was unsupported by the record.¹⁵ Pet.'s Mot. at 5 n.5. But the special master's decision to rely less on petitioner's live testimony was not arbitrary or capricious because petitioner's testimony was at odds with the medical record in several significant ways. For example, petitioner testified that he developed chronic diarrhea almost immediately after he received the first dose of the vaccine, but there is no report in his medical records of diarrhea until a year after the administration of the vaccine. Furthermore, that record indicated that petitioner's diarrhea commenced in the previous summer, not in March 1998 as petitioner testified. *Compare id.* at 4 *with* Pet.'s Ex. 7 at 119. Petitioner also testified that the pain in his shoulders after the second dose limited his movement. But in the notes from his visit after his third dose of the vaccine, Dr. Moses indicates that petitioner had a full range of motion with no point tenderness. *Compare* Pet.'s Mot. at 4-5 *with* Pet.'s Ex. 6 at 12.

Finally, and most damaging to Dr. Bellanti's challenge-rechallenge theory, petitioner was adamant that he began experiencing right-arm pain after having received the second dose of the vaccine, and that the pain then progressed into left-arm pain. Pet.'s Mot. at 4, 10-11. But the record was far from clear on this timeframe, indicating that the right arm pain may have begun before petitioner received his second dose of the vaccine. *See* Pet.'s Ex. 6 at 12. Given the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law.

B. The Special Master's Finding That Petitioner's Progression of Symptoms Did Not Fit the Challenge-Rechallenge Model Was Rational and Supported by the Record

Petitioner principally relied on the challenge-rechallenge model to establish causation. However, the special master found that the facts of petitioner's case did not fit the challenge-rechallenge model; consequently, the special master determined that petitioner failed to sustain his burden on causation. *See* Dec. at 17.

Petitioner's remaining arguments aim to persuade the Court that petitioner's reactions to the Hepatitis B vaccine did, in fact, fit the challenge-rechallenge model. These arguments are unavailing.

¹⁵ At one point in his motion, petitioner appears to argue the contrary, namely, that "the primary record relied on by the special master is *not at all consistent* with Petitioner's testimony." Pet.'s Mot. at 3 (emphasis added). Petitioner might be suggesting that the medical records should be considered less reliable than petitioner's testimony. As described above, such a view is contrary to Federal Circuit precedent—and common sense—which dictates that contemporaneously recorded documents are more trustworthy than recollections ten years later. *See Cucuras*, 993 F.2d at 1528.

1. Causation in Vaccine Act Cases

To prove his “off-Table” case,¹⁶ petitioner was required to demonstrate by a preponderance of the evidence that: (1) he received a vaccine set forth on the Vaccine Injury Table; (2) he received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the problem has persisted for more than six months. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A), 300aa-11(c)(1). Only the third element—causation—was contested by respondent. *See* Dec. at 10 n.16.

Petitioner was therefore required to prove “by preponderant evidence that the vaccination brought about [the] injury.” *Althen*, 418 F.3d at 1278. Petitioner can satisfy this burden by showing “(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 proximate temporal relationship between vaccination and injury.” *Id.*; *see also Broekelschen*, 618 F.3d at 1345. The three *Althen* “prongs must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To prove his claim by a preponderance of the evidence, petitioner must show that it is “more probable than not” that the vaccine caused petitioner’s injury. *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec’y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993) (Newman, J., concurring)).

The special master must decide whether the petitioner has carried his burden by evaluating the entire record, which may consist of expert testimony, medical literature, or other circumstantial evidence. *See Capizzano*, 440 F.3d at 1325. However, petitioner need not identify and prove a *specific* biological mechanism that caused his injury because “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen*, 418 F.3d at 1280. Nor must petitioner show that the vaccination was the sole cause or even the predominant cause of the injury or condition. In determining causation under the *Althen* test, the Federal Circuit has explicitly adopted the approach to legal causation expressed in the Restatement (Second) of Torts. *Shyface v. Sec’y, Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also*

¹⁶ The Secretary of Health and Human Services maintains a Vaccine Injury Table by regulation that lists the types of vaccines and the “injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines.” *See* 42 C.F.R. § 100.3(a) (2009). If petitioner demonstrates that he suffered an injury described on the Vaccine Injury Table as being associated with the vaccine he received, causation is presumed. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1341 (2010), *pet. for rehearing filed*, No. 09-5132 (Fed. Cir. Oct. 21, 2010). But if petitioner’s injury is not listed on the Vaccine Injury Table, he does not get the benefit of this presumption and must demonstrate by a preponderance of the evidence that his injury was actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A), 300aa-11(c)(1); *Capizzano*, 440 F.3d at 1320. Fibromyalgia is not listed on the Vaccine Injury Table as a condition commonly resulting from the Hepatitis B vaccine, and, therefore, petitioner was required to prove that his fibromyalgia was caused by the Hepatitis B vaccine he received. *See* 42 C.F.R. § 100.3(a)(VIII); *see also* Dec. at 2; Pet.’s Mot. at 6-7; Resp.’s Mem. at 9.

Hopkins v. Sec’y of Dep’t of Health & Human Servs., 84 Fed. Cl. 517, 522-23 (2008). Thus, the vaccine will be considered the legal cause of the injury if it was “a substantial factor in bringing about the harm.” RESTATEMENT (SECOND) OF TORTS § 431(a) (1965). The vaccine is “not a substantial factor in bringing about the harm if the harm would have been sustained” in the absence of the vaccine. *Id.* § 432(1); *see also Pafford*, 451 F.3d at 1355.

2. The Special Master’s Decision Regarding Causation Was Not Arbitrary or Capricious

The special master understood that Dr. Bellanti’s theory of causation was based on his showing a “distinct pattern of reaction” to the vaccines via the challenge-rechallenge model. Dec. at 20. Petitioner’s argument boils down to a factual disagreement with the special master’s rejection of Dr. Bellanti’s theory.¹⁷ The special master found that petitioner had not established causation by a preponderance of the evidence because neither of his expert’s proposed “challenge events” had the necessary temporal connection to the first or second dose of the vaccine.¹⁸ *Id.* at 20-24; *see also Pafford*, 451 F.3d at 1361 (requiring proof of a temporal relationship).

¹⁷ According to petitioner, the special master also disregarded a scientific study that Dr. Bellanti relied upon which hypothesized that fibromyalgia involves the immune system and can be triggered by vaccination. Pet.’s Mot. at 11. However, the special master specifically discussed this article, Dec. at 8 n.14, 28, and found that “when pressed regarding [this article], Dr. Bellanti state[d] the article is only indirectly relevant to petitioner’s case as he is not identifying [fibromyalgia] as an autoimmune disease.” *Id.* at 28; *see also* Feb. Tr. at 120 (“THE COURT: But you are not identifying fibromyalgia as an autoimmune disease. THE WITNESS: Not as an autoimmune disease. THE COURT: Is this article relevant at all then to your opinion today? THE WITNESS: Only peripherally, and I think indirectly.”). The special master then specifically found that Dr. Bellanti did not provide any way to link the suggestion that fibromyalgia *affects* the immune system to a theory that the Hepatitis B vaccine *caused* petitioner’s fibromyalgia. Dec. at 28. Thus, that finding is not arbitrary, capricious, or an abuse of discretion.

¹⁸ Petitioner also asserts in conclusory fashion that “Dr. Bellanti testified that genetics play a large role in [fibromyalgia], especially those on the maternal side.” Pet.’s Mot. at 11. However, the special master acknowledged petitioner’s genetic predisposition to fibromyalgia, Dec. at 2, and both experts commented on the link between genetics and fibromyalgia. Feb. Tr. at 79-80 (testimony of Dr. Bellanti); *id.* at 133, 137 (testimony of Dr. Brenner). Although petitioner was predisposed to fibromyalgia, this fact alone does not assist in determining whether the Hepatitis B vaccine caused petitioner’s fibromyalgia in this case. *See Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (discussing petitioner’s burden to “provide a reputable medical or scientific explanation that pertains *specifically to the petitioner’s case*”) (emphasis added); *Stapleford v. Sec’y of Dep’t of Health & Human Servs.*, 89 Fed. Cl. 456, 459 (2009) (“[T]he second prong [of the *Althen* test] focuses on whether the vaccine *did* cause the petitioner’s particular injury.”).

The Court finds that the special master’s rejection of persistent diarrhea as the challenge event was reasonable and well founded in the record. The only mention in petitioner’s medical records of persistent diarrhea occurs a year after he received the first dose of the vaccine and then described this symptom as having occurred the previous summer—long after he had completed the vaccine series. Dec. at 20. Moreover petitioner’s own expert admitted the causal relationship was “more speculative than real.” *Id.*

Regarding petitioner’s right and left arm and shoulder pain—Dr. Bellanti’s second potential challenge event—the special master was faced with a medical record that documented pain occurring before, during, and after the second dose of the vaccine. *See, e.g.*, Feb. Tr. at 31 (describing “muscle spasms [and] pain [in] right leg” approximately “three weeks prior” to the first dose of the vaccine); Dec. Tr. at 36 (“Q. In the month or two prior to the vaccination, did you have any problems with any muscle or joint pain? . . . A. I might have had some tightness or a little burning . . . in the thigh area.”). As to the right-sided pain, petitioner’s statements to his doctors “place[d] the onset of those pains between April 3 and April 10, a span that includes five days before petitioner’s second” dose of the vaccine. Dec. at 21. Because the right-sided pain could have commenced *before* the vaccine, Dr. Bellanti shifted his focus to the left-sided pain as the challenge event. But this type of “transient arm and shoulder pain[] do[es] not fit the characterization of [fibromyalgia] given by the experts; both described the [fibromyalgia] pain as widespread and diffuse.” *Id.* Dr. Brenner, on the other hand, reviewed the medical records and observed frequent reports of pain—potentially related to petitioner’s disc surgery—followed by the onset of fibromyalgia in the summer of 1998, after which “petitioner’s pain complex began and *did not abate* after this time.” Dec. at 22 (emphasis in original); *see also* Feb. Tr. at 142-44 (describing most likely onset of fibromyalgia to be in the summer of 1998).

The special master carefully analyzed the theories of the two experts—Dr. Bellanti for petitioner and Dr. Brenner for respondent—and found that the theory of respondent’s expert was better supported by the record.¹⁹ That finding was well documented and was based upon factual determinations supported by substantial testimonial and documentary evidence. The special master’s decision is rational, thorough and well supported by the record; it therefore merits affirmance. *See Lampe*, 219 F.3d at 1360.

¹⁹ At one point, petitioner observes that the Federal Circuit has emphasized the importance of “the opinions of treating physicians contained in *documentary* evidence.” Pet.’s Mot. at 7-8. However, two of petitioner’s treating physicians, Dr. Kiefer and Dr. Mann, expressed skepticism that petitioner’s fibromyalgia was caused by the Hepatitis B vaccine and attempted to convince petitioner that such was not the case. *See* Pet.’s Ex. 4 at 6; Pet.’s Ex. 7 at 120; Dec. at 15 (“In fact, two of petitioner’s treating physicians dismissed a connection between the vaccine and petitioner’s [fibromyalgia].”); *see also Reed v. Sec’y of Health & Human Servs.*, No. 07-794, 2010 WL 1732230, at *2 (Fed. Cl. Spec. Mstr. Mar. 30, 2010) (citing treating physician’s opinion that petitioner’s “symptoms were unrelated to any vaccinations” in dismissing petition).

C. *The Special Master Was Not Bound By His Prior Decision*

Petitioner also argues that the special master disregarded one of his own prior decisions, *Lee*, 2005 WL 1125672, at *1. Invoking the doctrine of stare decisis, petitioner contends that the special master must “be bound by his previous decisions, in order to assure fair treatment of all petitioners.” Pet.’s Mot. at 10; *see also* 18 MOORE’S FEDERAL PRACTICE § 134.01[1] (3d ed. rev. 2010) (“[T]he doctrine of stare decisis ‘is derived from considerations of stability and equal treatment.’”) (quoting *Ute Indian Tribe v. Utah*, 935 F. Supp. 1473, 1509 (D. Utah 1996)). In *Lee*, the same special master found that “petitioner . . . satisfied her burden of proof [to show] that the hepatitis B vaccines that she received . . . more likely than not caused her to develop a headache and sleeplessness which subsequently led to her fibromyalgia.” 2005 WL 1125672, at *16. Petitioner’s contention that the special master was bound by *Lee* is unpersuasive both as a matter of law and on the facts of this case.

Trial judges regularly afford deference to the decisions of judges of the same district; this deference is a matter of intra-court comity, *not* of stare decisis. *Am. Silicon Techs. v. United States*, 261 F.3d 1371, 1381 (Fed. Cir. 2001); 18 MOORE’S FEDERAL PRACTICE § 134.02[1]; *see also State Farm Mut. Auto. Ins. Co. v. Bates*, 542 F. Supp. 807, 816 (N.D. Ga. 1982) (“By comity and tradition, judges of the same district customarily follow the others’ decisions.”). And this principle applies, *a fortiori*, to a trial court’s treatment of its own prior decisions.

But “[t]he doctrine of stare decisis does not compel one district court judge to follow the decision of another.” *Starbuck v. City & Cnty of S.F.*, 556 F.2d 450, 457 n.13 (9th Cir. 1977); *see also Am. Silicon Techs.*, 261 F.3d at 1381 (“[J]udges of a unified federal district . . . are not constitutionally or legally bound to march in lockstep. The responsibility for maintaining the law’s uniformity is a responsibility of appellate rather than trial judges.”). More specifically, “special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.” *Guillory v. United States*, 59 Fed. Cl. 121, 124 (2003) (quoting *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998)). Thus, as a purely legal matter, petitioner’s argument fails: the special master was not bound by his prior decision.

Additionally, stare decisis “does not apply to the determination of the facts of a case.” 18 MOORE’S FEDERAL PRACTICE § 134.05[3]. The special master, like any trial judge, must be free to find facts based on the evidence of each case before him. To the extent petitioner contends the facts in his case are similar enough to those in *Lee* to dictate that the application of the facts to the law in this case should yield the same result as *Lee*, that argument fails.

Lee is readily distinguishable from this case. To begin with, unlike the medical records relating to petitioner, Ms. Lee’s medical records corroborated her testimony regarding the onset of her symptoms. *Lee*, 2005 WL 1125672, at *2. The evidence in *Lee* demonstrated that two days after her second dose of the Hepatitis B vaccine, Ms. Lee experienced a severe headache and sleeplessness for which she sought medical treatment. *Id.* While painkillers alleviated her pain, the headache would return. *Id.* Ms. Lee then sought treatment from a rheumatologist who found that she “may have had an aseptic meningitis from the hepatitis B vaccine that set off a

cascade which has led to what appears to be now mainly fibromyalgia.”²⁰ *Id.* at *3. Unlike petitioner here, Ms. Lee’s treating physician testified on her behalf, and stated that “anything that causes pain can potentially cause fibromyalgia. More specifically, the ‘current thinking’ is that ‘regional pain syndromes, viral infections, trauma, anything that sets off the cascade of pain[,] and not sleeping . . . can trigger the syndrome.” *Id.* at *7 (quoting testimony of Ms. Lee’s expert). Ms. Lee’s expert proffered evidence, including medical studies and citations to Ms. Lee’s contemporaneous medical records, that the Hepatitis B vaccine can and did cause severe headache and sleeplessness, which then triggered fibromyalgia. *Id.* at *8, 10. The special master found that Lee had proved by a preponderance of the evidence that the Hepatitis B vaccine caused her headache, which then led to fibromyalgia.²¹ *Id.* at *17.

Lee involved facts that were undisputed and supported by contemporaneous medical records, coupled with a dispute over whether the Hepatitis B vaccine could (and did) cause petitioner’s headache. In this case, on the other hand, petitioner’s medical records cast doubt on the sequence and timing of his symptoms. Moreover, contrary to petitioner’s contention, his theory in this case was *not* “the same theory of causation” as in *Lee*. Pet.’s Mot. at 12. Petitioner argued that the Hepatitis B vaccine directly caused his fibromyalgia, while the petitioner in *Lee* argued that the Hepatitis B vaccine caused her headache and sleeplessness, which then caused fibromyalgia. *Compare* Feb. Tr. at 83-84 (describing petitioner’s diarrhea and shoulder pain symptoms as “typical symptoms of fibromyalgia”) *with* 2005 WL 1125672, at *8 (“In essence, [petitioner’s expert] does not directly link the hepatitis B vaccination to petitioner’s fibromyalgia; rather, [she] believes that petitioner had a reaction to the hepatitis B vaccine with the pain and headache and that set off her fibromyalgia.”) (quotations and alterations omitted). This difference in theories of causation is significant.²²

²⁰ Meningitis is the “[i]nflammation of the membranes of the brain or spinal cord.” STEDMAN’S MEDICAL DICTIONARY at 1183. A disease is “aseptic” when it is not caused by a “pathogenic organism,” *e.g.*, bacteria or a virus. *Id.* at 165.

²¹ Petitioner observes that Dr. Brenner, the Government’s expert in this case, was also the Government’s expert in *Lee*. Pet.’s Mot. at 9; *see also Lee*, 2005 WL 1125672, at *8. In *Lee*, Dr. Brenner agreed that fibromyalgia, a “functional somatic syndrome,” could have been caused by petitioner’s headache, but disagreed whether petitioner’s headache (*not* her fibromyalgia) was caused by the vaccine. Thus, Dr. Brenner’s opinions in the two cases are consistent.

²² In addition to *Lee*, several previous Vaccine Act petitioners have “successfully shown causation” between a vaccine and fibromyalgia. *See Zatuschni v. Sec’y of Health & Human Servs.*, 69 Fed. Cl. 612, 623 (2006) (finding that petitioner satisfied burden to prove that measles, mumps and rubella vaccination caused, *inter alia*, fibromyalgia), *on remand at* No. 94-58, 2006 WL 1499982 (Fed. Cl. Spec. Mstr. May 10, 2006), *aff’d in part*, 73 Fed. Cl. 451 (2006), *aff’d*, 516 F.3d 1312 (Fed. Cir. 2008); *Doe/68 v. Sec’y of Dep’t of Health & Human Servs.*, 2010 WL 2300592, at *35 (Fed. Cl. Spec. Mstr. May 24, 2010) (petitioner satisfied burden to show that Hepatitis B vaccine caused her fibromyalgia); *Jane Doe/52 v. Sec’y of Dep’t of Health & Human Servs.*, 2009 WL 5206199, at *16 (Fed. Cl. Spec. Mstr. Dec. 15, 2009) (same).

In the present motion, petitioner attempts to recast Dr. Bellanti's theory to be more consistent with the indirect causation theory presented in the *Lee* case. *See* Pet.'s Mot. at 10-11. According to petitioner, "Dr. Bellanti's theory in this case was that the Petitioner had a systemic reaction after each of the vaccinations he received and it was these reactions that subsequently triggered the Petitioner's [fibromyalgia] . . ." *Id.* However, after a thorough review of the record, the Court concludes that this theory was never presented to the special master—petitioner exclusively argued that the Hepatitis B vaccine "triggere[d] fibromyalgia." Petitioner's Pre-Hearing Memorandum at 11 (docket entry 64, June 22, 2007); *see also id.* ("There is a clear-cut temporal relationship between the second Hepatitis B vaccination and the onset of the first symptoms of Fibromyalgia."); *id.* at 12 ("While there is a possibility that a number of factors may have come together to result in [petitioner's] Fibromyalgia, [petitioner] would not have developed this condition but for the Hepatitis B vaccines that he received.") (emphasis added); Petitioner's Pre-Hearing Submissions at 2 (docket entry 98, Dec. 2, 2008) (listing as the issues remaining for decision: "1. The onset of Petitioner's symptoms after his Hepatitis B vaccination; 2. Does the Hepatitis B vaccination cause Fibromyalgia and [are] the symptoms the Petitioner is claiming . . . a result of the Hepatitis B vaccination; and 3. Did the Hepatitis B vaccinations the Petitioner received cause the Petitioner's Fibromyalgia and the symptoms the Petitioner is claiming are a result of the Hepatitis B vaccinations?") (emphasis added); Amended Petition ¶ 83 (docket entry 51, Dec. 13, 2006) ("After receiving his Hepatitis B vaccinations, petitioner experienced new ailments that he never had prior to receiving the vaccination, including but not limited to Fibromyalgia.").

Dr. Bellanti's expert reports and testimony rely almost exclusively on his opinion that "[t]his sounds . . . like a case of challenge/rechallenge." Bellanti Rep. at 8; *see also* Bellanti Supp. Rep. at 8; Feb. Tr. at 83-84. The special master found that Dr. Bellanti "hinted at other arguments," Dec. at 25, and, as discussed above, found these arguments to lack merit. *See supra* note 14. All of these arguments attempt to prove that the Hepatitis B vaccine caused petitioner's fibromyalgia directly, not that the vaccines caused symptoms that *subsequently* triggered fibromyalgia. *Id.* To the extent that petitioner raises this argument for the first time, the Court may not consider the argument because it was not raised before the special master. *See* RCFC App. B, Rule 8(f)(1) ("Any fact or argument not raised specifically in the record before the

However, other petitioners have been unsuccessful because in their cases, the evidence was insufficient to demonstrate causation. *See, e.g., Born v. Sec'y of Dep't of Health & Human Servs.*, No. 06-392, 2010 WL 2473576, at *5 (Fed. Cl. Spec. Mstr. May 10, 2010) (denying petition because of lack of evidence linking tetanus vaccine with fibromyalgia); *Szekeres v. Sec'y of Dep't of Health & Human Servs.*, No. 01-197, 2006 WL 3725134, at *8, 10-12 (Fed. Cl. Spec. Mstr. Nov. 29, 2006) (finding that petitioner's medical records did not demonstrate a "logical sequence of cause and effect" or a "proximate temporal relationship" between Hepatitis B vaccines and development of fibromyalgia and other diseases); *Smith v. Sec'y of Dep't of Health & Human Servs.*, No. 08-874, 2009 WL 4020253, at *3 (Fed. Cl. Spec. Mstr. Oct. 30, 2009) (finding lack of evidence that influenza vaccine caused fibromyalgia); *Tiufekchiev v. Sec'y of Health & Human Servs.*, No. 05-437, 2008 WL 3522297, at *1, 10 (Fed. Cl. Spec. Mstr. July 24, 2008) (holding that petitioner failed to present sufficient evidence to demonstrate causal relationship between Hepatitis B vaccine and fibromyalgia and did not adequately demonstrate challenge-rechallenge).

special master will be considered waived and cannot be raised by either party in proceedings on review of a special master's decision."); see also *Hellenbrand-Sztaba v. Sec'y of Health & Human Servs.*, 35 Fed. Cl. 222, 225 (1996) (citing *Weddel v. Sec'y of Dep't of Health & Human Servs.*, 23 F.3d 388, 390 n.2 (Fed. Cir. 1994) and *Jay v. Sec'y of Dep't of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993)), *aff'd per curiam*, 106 F.3d 426 (Fed. Cir. 1997) (unpublished table opinion).

The special master did not err in distinguishing petitioner's case from *Lee* given the differing factual records in the two cases and the proof in the *Lee* case of a distinct medical theory of causation. The special master is vested with significant discretion in this area, *Munn*, 970 F.2d at 870 & n.10, and the Court will not second-guess the special master's findings, which are rational and well supported in the record.²³ See *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) ("[O]n review, the Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. . . . That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.") (internal citations omitted).

²³ In one case involving similar facts, a different special master reached the same conclusion regarding the adequacy of the challenge-rechallenge model in proving causation. In *Tiufekchiev*, within two weeks of her first dose of the Hepatitis B vaccine, petitioner began "experiencing itching on her arms and pain in her knees that occurred when she was seated for over an hour." 2008 WL 3522297, at *1. Approximately two weeks after the second dose, petitioner "noticed itching on her arms and 'an odd tingling sensation in both [her] pinkies, mostly in the left.'" *Id.* (alteration in original). Petitioner, however, had a "history of neck pain with upper extremity tingling and pain, possibly secondary to cervical radiculopathy." *Id.* She was later diagnosed with fibromyalgia and filed a vaccine petition on that basis. *Id.* at *3. Petitioner's expert, also Dr. Bellanti, relied on the temporal relationship between the vaccines and petitioner's symptoms as well as the challenge-rechallenge model to demonstrate causation. The special master, as in this case, found that Dr. Bellanti's theory was inadequate under *Althen*, because the "problem with the challenge-rechallenge paradigm in Ms. Tiufekchiev's case is that it isolates a small number of events from Ms. Tiufekchiev's complex medical picture. . . . [A]lthough the challenge-rechallenge model can be persuasive in some cases, it is not always dispositive and it is not persuasive in this case." *Id.* at *10-11.

While it is certainly a pertinent factor in determining causation, *Pafford*, 451 F.3d at 1361, "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Moberly*, 592 F.3d at 1323 (quoting *Grant v. Sec'y of Dep.'t of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)); see also *Gardner-Cook*, 59 Fed. Cl. at 47. In addition to the factual uncertainty regarding when petitioner's symptoms occurred, Dr. Bellanti's reliance on the challenge-rechallenge model in this case evidences the same problem as in *Tiufekchiev*. Here, the special master accepted Dr. Bellanti's challenge-rechallenge model as a theoretical matter, but found that the applicability of the theory was not supported by the facts, including the facts reflected in petitioner's medical records. The Court concludes that the special master's factual findings and analysis were not only rational, but were, indeed, eminently reasonable.

CONCLUSION

For the foregoing reasons, petitioner's motion for review is **DENIED** and the special master's May 26, 2010 decision is **AFFIRMED**. The Clerk is directed to enter judgment in favor of respondent accordingly.

IT IS SO ORDERED

s/ George W. Miller
GEORGE W. MILLER
Judge