In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-834V
Filed: May 15, 2020

P.S., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	To Be Published Dismissal; Ruling on the Record; Hepatitis B Vaccine; Undifferentiated Connective Tissue Disease ("UCTD"); Ankylosing Spondylitis; Autoimmune or Atrophic Gastritis; Significant Aggravation

Richard Moeller, Esq., Moore, Heffernan, et al., Sioux City, IA, for petitioner.
Voris Johnson, Esq., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON THE RECORD AND DECISION DISMISSING PETITION[1]

Roth, Special Master:

On July 14, 2016, P.S. ("petitioner") filed a petition for compensation pursuant to the National Vaccine Injury Compensation Program,[2] alleging that he developed undifferentiated connective tissue disease ("UCTD"), autoimmune or atrophic gastritis, and other injuries, which were either caused or significantly aggravated by hepatitis B vaccinations he received on August 14, 2013, December 17, 2013, and May 16, 2014. *See* Petition ("Pet."), ECF No. 1. Petitioner has filed a Motion for Ruling on the Record. The undersigned finds that petitioner has failed to carry his burden of showing that hepatitis B vaccines caused his UCTD, autoimmune or atrophic gastritis, or any other injuries. The petition is accordingly dismissed.

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[1] This Decision has been formally designated "to be published," which means it will be posted on the Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** However, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id*.

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

I. Background

A. Procedural History

The petition was filed on July 14, 2016, along with several medical records. *See* Petition, ECF No. 1; Pet. Ex. 1-4, ECF No. 3. On July 15, 2016, petitioner filed several articles of medical literature related to the hepatitis B vaccine and UCTD. *See* Pet. Ex. 5-10, ECF No. 4.

An initial status conference was held on August 24, 2016. Scheduling Order, ECF No. 9. Respondent had not yet had an opportunity to review petitioner's records and requested time to determine whether there were any outstanding medical records. *Id.* Petitioner filed additional medical records through September of 2016. *See* Pet. Ex. 11, ECF No. 10; Pet. Ex. 11A, ECF No. 11; Pet. Ex. 12, ECF No. 16; Pet. Ex. 13, ECF No. 17.

On November 17, 2016, respondent filed his Rule 4(c) Report ("Resp. Rpt."), stating the case was not appropriate for compensation. Resp. Rpt., ECF No. 20. Respondent raised several issues including petitioner's lack of a definitive diagnosis for his alleged injury, stating it was the petitioner's burden "to demonstrate that he actually suffers from the injury alleged, UCTD." *Id*. at 17. Additionally, respondent stated "virtually every specialist [petitioner] saw expressed skepticism that the hep B (sic) vaccine was the cause of his symptoms." *Id*. Finally, respondent noted two of petitioner's treating physicians were concerned that petitioner's symptoms related to his mental health and offered referrals to mental health professionals, which petitioner refused. *Id*. at 7-8, 13.

A status conference was held on January 11, 2017 to discuss the issues raised by respondent's Rule 4(c) Report. Scheduling Order at 1, ECF No. 21. Petitioner's counsel advised that petitioner was suffering from UCTD as alleged in the petition and planned to have an expert review petitioner's medical records. *Id*. Respondent's counsel raised reasonable basis in the filing of the petition. *Id*.

Petitioner was ordered to file an expert report or a status report indicating how he intended to proceed by March 13, 2017. *Id*. Petitioner requested and received five extensions of time. *See* ECF Nos. 22, 24, 26, 27, 28. On December 8, 2017, petitioner filed a status report requesting a status conference. Pet. S.R., ECF No. 29. A status conference was held on December 19, 2017 at which time petitioner's claim was again discussed, specifically petitioner's lack of a definitive diagnosis for his alleged injuries, that all objective testing was normal, and there was no temporal relationship between petitioner's receipt of the hepatitis B vaccines and any injury. Scheduling Order at 1, ECF No. 30. Petitioner's counsel advised he had done all he could do to secure an expert report but had been unsuccessful, and that he planned to withdraw as counsel. *Id.* After further discussion, an Order was issued for counsel to file Motions for Attorneys' Fees and Costs and to Withdraw as counsel by February 2, 2018. *Id*. at 2.

Petitioner filed additional medical records on February 1, 2018. Pet. Ex. 14-15, ECF Nos. 31-32. Petitioner's counsel filed Motions for Interim Fees and Costs and to Withdraw as counsel on February 2, 2018. ECF Nos. 33-34. Respondent filed his response to petitioner's Motion for Attorney's Fees and Costs on February 13, 2018 and petitioner filed a reply on March 20, 2018.

See ECF Nos. 36, 41. Based on the filings, the undersigned deferred ruling on the Motion for Attorney's Fees and Costs until after entitlement was decided and granted the Motion to Withdraw as counsel. *See* Order, ECF No. 42; Order, ECF No. 43. The docket reflected the petitioner as *pro se*.

On May 7, 2018, petitioner's current counsel electronically filed a Motion to Substitute Attorney in place of petitioner as *pro se*. ECF No. 45. An Order was issued on May 9, 2018 instructing the pro se petitioner to file his motion via paper filing by May 22, 2018. *See* Order, ECF No. 46. Petitioner's electronically filed Motion to Substitute Attorney was stricken *See id.* On May 18, 2018, petitioner properly filed a Motion to Substitute Attorney substituting Richard Moeller as petitioner's counsel. ECF No. 47.

Petitioner filed additional medical records through July 2, 2018. *See* Pet. Ex. 28-30, ECF No. 49; Pet. Ex. 31, ECF No. 50.

The first status conference with Mr. Moeller as counsel was held on July 24, 2018. *See* Scheduling Order at 1, ECF No. 52. Mr. Moeller advised that he had secured an expert who was willing to review the medical records and advise whether a claim could be supported. *Id.* Petitioner's counsel was reminded that reasonable basis had been raised by respondent and reimbursement of attorney's fees and costs was not guaranteed. Petitioner's counsel was further reminded that any expert should rely on the contemporaneous medical records, which are assumed to be accurate and complete. *See id.* Petitioner was ordered to file an expert report or a status report by October 22, 2018. *Id.* at 2, ECF No. 52. On October 22, 2018, petitioner filed a status report advising that he did not have an expert report. ECF No. 53.

Another status conference was held on December 6, 2018. *See* Scheduling Order at 1, ECF No. 54. Petitioner's counsel stated that neither he nor his client were financially capable of paying the costs for an expert and petitioner believed the Vaccine Program should retain an expert for him. *Id.* As a seasoned attorney in the Program, Mr. Moeller was reminded that it was petitioner's burden to prove his case and retain an expert when necessary. *Id.* The various ways to exit the Program were discussed and 60 days for counsel to discuss the options with petitioner was ordered. *Id.* at 2.

On February 4, 2019, petitioner filed additional medical records and a status report. Pet. Ex. 32, ECF No. 55; ECF No. 56. In his status report, petitioner requested a ruling on the record that should include a "thorough review of the medical records filed in this matter, as well as injuries claimed to have been sustained following the receipt of the allegedly causal vaccinations, and petitioner's claims of ongoing injuries and damages…." ECF No. 56

Petitioner was ordered to file his Motion for Ruling on the Record by April 5, 2019. *See* Non-PDF Order, issued Feb. 4, 2019.

On February 13, 2019, the petitioner made several telephone calls to chambers. Petitioner was informed by my law clerk that all communications were to be made through his attorney of record. *See* Scheduling Order at 1, ECF No. 57.

A status conference was held on February 27, 2019. *See* Scheduling Order at 1, ECF No. 57. Just prior to the scheduled conference call, Mr. Moeller emailed chambers to inform the undersigned that petitioner had questions he wanted answered by the Special Master. *Id.* At the status conference, petitioner's counsel read petitioner's questions which reflected his discontent with the Vaccine Program and the Program's refusal to hire an expert for him or advance the costs for an expert. *Id.* As an experienced attorney in the program, petitioner's counsel was advised that he was well-equipped to provide petitioner with the answers to the questions he posed and the explanations for same. *Id.* at 1-2.

On April 3, 2019, petitioner filed updated medical records. Pet. Ex. 33, ECF No. 58. On April 5, 2019, petitioner filed an unopposed Motion for Extension of Time to file a Motion for Ruling on the Record. ECF No. 58.

Petitioner filed updated medical records and a Motion for Ruling on the Record on April 12, 2019. Pet Ex. 34-44, ECF No. 60; Motion for Ruling on the Record, ECF No. 61. Respondent filed a response on April 22, 2019. Response, ECF No. 62.

On May 3, 2019, petitioner filed a Motion for Extension of Time to file a reply. ECF No. 63. Petitioner further requested "that the special master suspend her consideration and ruling on petitioner's motion for ruling on the record" to allow petitioner time to submit his medical records to a potential expert, Dr. Shoenfeld, for review." *Id*. at 1. Respondent filed a response on May 8, 2019, objecting to petitioner's Motion stating, "Petitioner has had over two-and-a-half years since respondent filed his Rule 4(c) Report to have Dr. Shoenfeld (or some other expert) offer a causal opinion in support of his claim." ECF No. 64 at 3.

The undersigned granted the Motion for Extension of Time, ordering petitioner to file an expert report by June 19, 2019 and a Motion to withdraw his Motion for Ruling on the Record by June 4, 2019. *See* Order at 2, ECF No. 65.

Petitioner filed a status report on June 13, 2019, advising that he would not be withdrawing his original Motion for Ruling on the Record and would not be filing an expert report from Dr. Shoenfeld. ECF No. 67.

This matter is now ripe for ruling.

B. Petitioner's Health Prior to the Hepatitis B Vaccines

The earliest medical record filed by petitioner begins with an examination on February 21, 2011. At that time, petitioner complained of an anal fistula[3] that had "been going on for some time." A colonoscopy was unremarkable. Pet. Ex. 2 at 3-7.

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[3] An anal fistula is "a cutaneous fistula opening on the body surface near the anus; it may or may not communicate with the rectum." *Anal fistula*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 704 (32nd ed. 2012) [hereinafter "DORLAND'S"].

The next record is a little over a year later, on March 22, 2012, when petitioner presented for abdominal ultrasound, which was normal. Pet. Ex. 1 at 12. The record does not contain a reason for why an abdominal ultrasound was ordered.

On May 16, 2012, petitioner presented to Dr. Sami, a dermatologist at the Kirklin Clinic, with a history of itching for the past year and hair loss at the root for the past 15 months. Pet. Ex. 1 at 14; *see also* Pet. Ex. 3 at 147-49. Upon examination, petitioner had diffuse thinning of the hair over the scalp, mild erythema[4] and scaling, and scattered papules and pustules. *Id*. at 15. He was diagnosed with cutis xerosis[5], urticaria[6], seborrheic dermatitis, male pattern hair loss, and folliculitis. *Id*. at 16. Triamcinolone ointment,[7] Allegra, Atarax,[8] medicated shampoo, Rogaine, and panoxyl bar soap were prescribed. *Id*.

On June 14, 2012, petitioner presented to Dr. Dasher, a gastroenterologist at the Kirklin Clinic, with multiple complaints, including upper abdominal pain, some diarrhea, and past rectal bleeding which improved with a better diet. Pet. Ex. 1 at 18; *see also* Pet. Ex. 3 at 143-46. Petitioner reported that he had a complete colon examination 15 months ago, with no major findings. *Id*. Petitioner advised that he had pruritus[9] and perianal itching. *Id*. He was worried about liver disease. *Id*. Upon examination, petitioner had two perianal papillary lesions; it was noted that the lesions seemed to be larger than described during the prior colonoscopy. *Id*. at 20, 21. An esophagogastroduodenoscopy was recommended to determine the cause of petitioner's abdominal pain, but petitioner declined. *Id*. at 21.

On July 30, 2013, petitioner presented to the emergency department at the University of Alabama at Birmingham Medical Center ("UAB") with rectal bleeding and pain ongoing for several weeks. Pet. Ex. 1 at 161, 169. It was noted that petitioner previously saw Dr. Dasher in

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[4] Erythema means "redness of the skin." *Erythema*, DORLAND'S at 636.

[5] Cutis xerosis is also known as "asteatotic eczema." *Xerosis cutis*, DORLAND'S at 2056. It is "a condition resulting from excessive dehydration of the skin, characterized by erythema, dry scaling, fine cracking, and pruritis; it occurs chiefly during cold weather when low humidity in heated rooms causes excessive water loss from the stratum corneum." *Asteatotic eczema*, *id*. at 586.

[6] Urticaria is "a vascular reaction in the upper dermis, usually transient, consisting of localized edema caused by dilatation and increased capillary permeability with wheals." *Urticaria*, DORLAND'S at 1981.

[7] Triamcinolone is a corticosteroid used to reduce inflammation. It can be applied topically as a cream to treat eczema and other forms of dermatitis. *Triamcinolone Acetonide– Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Triamcinolone-Acetonide-Cream-triamcinolone-acetonide-1503.2069#4 (last visited Mar. 27, 2020).

[8] Atarax is the brand name for hydroxyzine hydrochloride, an antihistamine used to treat allergic conditions like chronic urticaria, atopic dermatitis, or contact dermatitis. *Hydroxyzine hydrochloride – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Hydroxyzine-Hydrochloride-Syrup-hydroxyzine-hydrochloride-740.8332 (last visited Mar. 27, 2020).

[9] Pruritis is "an unpleasant cutaneous sensation that provokes the desire to rub or scratch the skin to obtain relief." *Pruritis*, DORLAND'S at 1516.

June of 2012, and at that time was noted to have a 5-6 mm nodule. *Id*. at 169. Routine labs were unremarkable. *Id*. at 171. Petitioner was prescribed Percocet[10] and Colace, a stool softener, and discharged. *Id*. Dr. Heslin, a surgical oncologist, recommended that petitioner return for outpatient follow-up. *Id*.

On August 1, 2013, petitioner presented to the emergency department at UAB, complaining that his rectal pain and bleeding had not resolved. Pet. Ex. 1 at 197. He did not want to eat or use the restroom due to the pain. *Id*. Petitioner was seen by Dr. Foster, who noted that petitioner had been referred to surgical oncology for evaluation and had an appointment for August 8.[11] *Id*. at 203. He presented to the ER with increasing abdominal pain with defecation. *Id*. An abdominal CT was negative for metastatic disease but did show thickening and irregularity of the anorectal region. *Id*. at 209; *see also* Pet. Ex. 12 at 4. An underlying mass could not be excluded. *Id*. Petitioner was prescribed lactulose[12] and Miralax, a stool softener, and discharged. *Id*. at 205.

C. Petitioner's Health After the First Hepatitis B Vaccine

Petitioner received three hepatitis B vaccinations on August 14, 2013; December 17, 2013; and May 16, 2014, respectively.

On August 14, 2013, petitioner presented to Dr. Landen, a family medicine physician at the Kirklin Clinic, for follow up of his ER visit for rectal pain. Pet. Ex. 3 at 139; *see also* Pet. Ex. 13 at 9-12. Dr. Landen noted the prior history of rectal pain "over the last couple of years." *Id*. Also noted were the results of petitioner's CT scan in the ER with questionable mass; petitioner reported that he had seen the surgical oncologist and was scheduled for a repeat colonoscopy and exam under anesthesia with possible biopsy. *Id*. Dr. Landen wrote, the patient was "very concerned and has a lot of questions." *Id*. at 141. Dr. Landen referred petitioner to a gastroenterologist and advised that he needed to receive the hepatitis B vaccine series. *Id*. Petitioner's ongoing conditions were listed as rectal mass, vitamin D deficiency, eczema, and hypertriglyceridemia, among other issues.[13] *Id*. at 140. Dr. Landen noted petitioner wanted to come back for the hepatitis B vaccine "on Friday."[14] Pet. Ex. 3 at 142. Other records document petitioner's receipt of the first hepatitis B vaccine at the August 14, 2013 visit. Pet. Ex. 1 at 177.

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[10] Percocet is the brand name for a combination of acetaminophen and oxycodone. It is a strong opiate agonist used to treat acute, severe pain. *Acetaminophen/oxycodone – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Percocet-acetaminophen-oxycodone-2483.1051 (last visited Mar. 27, 2020).

[11] The record for the August 8 visit to surgical oncology was not filed.

[12] Lactulose is a laxative used to treat constipation. *Lactulose – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Constulose-lactulose-1544 (last visited Mar. 27, 2020).

[13] Hypertriglyceridemia means "excessive triglycerides in the blood." *Hypertriglyceridemia*, DORLAND'S at 886.

[14] "Friday" would be August 16, 2013. There are no records of a medical visit on this date.

On August 20, 2013, petitioner presented to Dr. Heslin, a surgical oncologist at Kirklin Clinic, for a proctoscopy.[15] Pet. Ex. 1 at 575-76. Dr. Heslin performed incision and drainage of the perianal fistula under anesthesia and biopsy. *Id*. Upon discharge, petitioner was prescribed Dilaudid[16] and Colace; he was also given instructions for sitz baths as well as ways to avoid constipation. *Id*. at 578.

On September 5, 2013, petitioner returned to Dr. Heslin for post-operative care. Pet. Ex. 3 at 137. Biopsy results showed "moderate to severe acute and chronic inflammation with ulceration" compatible with a fistula. *Id*. No granulomas were identified. *Id*. Petitioner reported less pain and doing well. *Id*. at 138. Dr. Heslin advised petitioner to schedule a follow-up visit with Dr. Landen. *Id*.

There were no medical records filed of any medical visits between September 5, 2013 and December 17, 2013, and no complaints of any adverse events following the August 14, 2013 hepatitis B vaccine.

D. Petitioner's Health After the Second Hepatitis B Vaccine

On December 17, 2013, petitioner received a second hepatitis B vaccine. Pet. Ex. 1 at 177. There were no medical records filed between December 17, 2013 and May 16, 2014, for any medical care generally or specifically related to any complications or adverse events associated with the December 17, 2013 hepatitis B vaccination.

E. Petitioner's Health After the Third Hepatitis B Vaccine

On May 16, 2014, petitioner received a third hepatitis B vaccine. Pet. Ex. 1 at 176. There were no records filed for any medical care between May 16, 2014 and February 19, 2015.

On February 19, 2015, petitioner presented to Dr. Salser at Kirklin Clinic. Pet. Ex. 3 at 131. He reported developing a cough and sore throat on February 3, 2015. *Id*. The cough was lingering. *Id*. He also complained of left-sided abdominal pain that started a week ago but had improved over the past three or four days. *Id*. He requested imaging to evaluate it. *Id*. Dr. Salser documented petitioner's history of perianal fistula, eczema, vitamin D deficiency, and hypertriglyceridemia, among other issues. *Id*. at 131-32. Abdominal ultrasound and liver function tests were ordered. *Id*. at 135. Petitioner was advised to use Mucinex DM for his cough. *Id*. at 136.

Three months later, on May 18, 2015, petitioner returned to Kirklin Clinic and was examined by Dr. Davuluri for chief complaints of mid-back and neck pain. Pet. Ex. 3 at 126. He

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[15] A proctoscopy is the "inspection of the rectum with a proctoscope" *Proctoscopy*, DORLAND'S at 1498. A proctoscope is a "speculum or tubular instrument with appropriate illumination for inspecting the rectum." *Proctoscope*, *id*. at 1498.

[16] Dilaudid is the brand name for hydromorphone hydrochloride. It is a strong opiate agonist used to treat acute or chronic moderate to severe pain. *Hydromorphone hydrochloride – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Dilaudid-Liquid-and-Tablets-hydromorphone-hydrochloride-489 (last visited Mar. 27, 2020).

reported receiving a hepatitis B vaccine a year prior in May of 2014, left knee pain beginning in June of 2014, and a cold in February of 2015 with bloody sputum and ear "fluttering" that lasted 10 days, which was unusual for him as his colds normally lasted one to three days. *Id*. He then developed left-sided neck, upper back, and spine pain at the beginning of May 2015 which was initially severe but lessened when he started swimming. *Id*. Currently, his neck and back pain were a 3/10, worse in the morning when he got up and easing as the day went on. *Id.* He had no radiculopathy. *Id.* "Last night," he felt transient electric shocks while asleep and when he moved his extremities, he felt his head was "shivering," and he could not sleep. *Id*. Dr. Davuluri wrote:

> [Petitioner's] main concern is that he assumes all these above event (sic) which happened are related to adverse reaction caused from his last hepatitisvaccination. (sic) he informs me that he reviewed a number [of] articles which relayed similar symptoms [after] the vaccination he is worried about "weakened immune system, transvermyelitis, (sic) MS[17], requests blood test, MRI of spine, brain, knee" to avoid worsening injury to his spine or worsening assumed side effects from vaccination[.]

Id. at 127. On the day of his visit, he reported a cracking noise in his neck when he turned to the right, but no neck pain, no upper or lower extremity weakness, no trouble walking, no bowel or bladder issues, no sensory abnormalities, no visual issues, and no hearing loss. *Id*. Dr. Davuluri suggested that petitioner use topical anti-inflammatories, Advil, and heating pads for his neck pain. *Id*. at 130. She wrote:

> I am unable to relate his symptoms/clinical conditions as an adverse effect to hepatitis B vaccination, infact (sic) I am unaware of this at this time. But based on his symptoms and normal neurological exam there is no indication for MS or Transever (sic) myelitis. I am not aware of what caused the transient electric shock like symptoms last night. At this time I recommend no further tests or imaging unless symptoms become more frequent/worsening/progressing. I encouraged him to keep a log of his symptoms and if they become frequent or recurrent to inform us. He seem (sic) dissatisfied with the answer today, I suggested that he discuss with his PCP Dr Salser about this.

Id.

On May 23, 2015, petitioner presented to UAB Emergency Department with paresthesias.[18] Pet. Ex. 1 at 336-41, 349-50. Petitioner described his symptoms as "pain in back, left eyelid

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[17] Transverse myelitis is an inflammation of the spinal cord in which the functional effect of the lesions spans the width of the entire cord at a given level. *Transverse Myelitis*, DORLAND'S at 1201; *myelitis*, *id.* Multiple sclerosis is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years…the etiology is unknown." *Multiple Sclerosis*, *id* .at 1653.

[18] Paresthesia means "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus" *Paresthesia*, DORLAND'S at 1362.

flickering, hearing crackling when he turn (sic) neck, 'shock' type sensations at times in extremities at night, spots of itching on legs, left knee pain, numbness in arms and fifth...finger at times when he awakens." *Id.* at 342. He claimed onset of these symptoms after receiving the hepatitis B vaccine. *Id.* He stated he came to the Emergency Department because his primary care physician was "unable or unwilling to further evaluate his symptoms." *Id.* at 348. The physician, Dr. Gilford, listed the differential diagnosis as "Peripheral neuropathy vs MS vs other neurological condition vs anxiety." *Id*. at 349. A "[p]hysical exam reveal[ed] no significant findings." A CT scan was normal. *Id.* at 349, 350, 354-55. He was instructed to follow-up with a neurologist. *Id*. at 350.

On May 29, 2015, petitioner returned to Dr. Salser, reporting neck pain and bilateral arm "shocks" and numbness. Pet. Ex. 3 at 120. He stated his neck pain began on the left side in May of 2014. *Id.* He reported on May 16, 2014, he had a "paralytic attack" with inability to get out of bed. *Id.* On May 17, 2014, he "began to have [an] electric shock sensation followed by numbness in bilateral hands and arms." *Id*. at 121. He reported a recent URI that lasted for 10 days, which he claimed was due to the vaccine. Pet. Ex. 13 at 24-25. Dr. Salser wrote petitioner was "convinced" of the connection between the vaccines and all of his musculoskeletal problems and neurological complaints and was becoming frustrated at the delay of "necessary tests" to diagnose him. *Id.* at 29. Dr. Salser described petitioner's behavior as "Agitated, Belligerent, Compulsive, Pressured speech" and noted "Abnormal/Psychotic thoughts: Ideas of influence, Misinterpretations, Obsessions." *Id.* at 27.

On June 2, 2015, petitioner presented to Dr. Agnihotri, a neurologist, with concerns he had transverse myelitis connected to the hepatitis B vaccine. Pet. Ex. 13 at 32. He brought a written chronology of all his symptoms. *Id.* He complained of convulsions and electrical shock sensations while sleeping, weakness, numbness and stiffness in both arms, a "cracking noise" when moving his neck, and neck pain while sleeping. *Id.* at 33-36. His neurological exam was normal. *Id.* at 37-38. Petitioner reported that his review of the literature suggested he had suffered adverse effects from the vaccine; Dr. Agnihotri wrote he seems "very convinced" the vaccine was the cause of his symptoms. *Id.* at 38. She further noted petitioner's "symptoms localize poorly." She did not believe they were related to the hepatitis B vaccine. *Id.* at 38.

Petitioner had an MRI of his cervical spine with and without contrast on June 11, 2015, which revealed "[m]ild multilevel degenerative changes of the cervical spine, without evidence of spinal cord compression or significant neural foraminal narrowing" and "[l]eft paracentral disc extrusion contacting the spinal cord at the T1-2 level, incompletely evaluated in this cervical spine exam." Pet. Ex. 12 at 9-10. An MRI of the thoracic spine on June 23, 2015 revealed "[l]eft paracentral protrusion at T1-2 with cephalad extruded component deforming the left anterior cord. No cord signal abnormalities appreciated at this time." *Id*. at 11-12.

On June 26, 2015, petitioner returned to Dr. Salser for generalized joint and nerve pain. Pet. Ex. 13 at 42. Petitioner reported pain and a "cracklin (sic)" noise in his neck, numbness and weakness of both arms, shoulder pain that "[c]omes and goes," left knee pain and popping causing discomfort and instability, fatigue in the morning, and shortness of breath. *Id.* at 42-43. He was still working out, walking, and running daily, despite his knee pain. *Id.* at 42. Dr. Salser ordered a

blood panel, including an intrinsic factor[19] antibody test, which was negative. *Id.* at 46-47. Petitioner was diagnosed with fatigue and a vitamin B12 deficiency. *Id*. at 46.

On June 30, 2015, petitioner returned to Dr. Agnihotri. Pet. Ex. 13 at 49; *see also* Pet. Ex. 3 at 102. His paresthesias had improved significantly since taking vitamin B12 and D supplements. *Id.* He continued to be concerned about the etiology of his B12 deficiency, complained he was still fatigued in the morning with diffuse joint pain, and voiced concerns that his vitamin B12 deficiency was an indication of MS. *Id.* He wanted to know "if there's anything else that could be studied," due to "significant concern about his symptoms." *Id.* at 49-50. Dr. Agnihotri wrote petitioner has "significant focus and concern on his symptoms" and had "been reading a lot about them and has many questions and theories, including the association with his last HBV vaccine." *Id.* at 52. Dr. Agnihotri wrote most symptoms could be explained by his vitamin B12 deficiency and "reinforced that there's no evidence of MS since this is one of his main concerns." *Id.* at 52-53. Dr. Agnihotri suggested testing petitioner for pernicious anemia.[20] *Id*. at 52. She further indicated that somatization[21] and somatoform[22] disorders should be considered, along with stress and anxiety, as a possible cause of petitioner's symptoms. *Id.*

Petitioner underwent MRI of his left knee on July 6, 2015, which showed "[f]ocal patellar chondromalacia overlying the mid sagittal ridge" but was otherwise unremarkable. Pet. Ex. 12 at 13-14.

On July 8, 2015, petitioner presented to Drs. Weber and Black at UAB's gastrointestinal clinic. He complained of "ongoing fatigue and subjective weakness in his arms," but denied memory problems, confusion, gait abnormalities, diarrhea, constipation, bloating, or abdominal pain. Pet. Ex. 13 at 55. He was a vegetarian and drank milk. *Id.* The record documents, "His B12 deficiency is due to pernicious anemia (autoimmune[23] gastritis[24]) – low B12 level combined with

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[19] Intrinsic factor is a mucoprotein required for adequate absorption of vitamin B12; a deficiency in intrinsic factor results in pernicious anemia. *Intrinsic factor (IF)*, STEDMAN'S MEDICAL DICTIONARY 317050, accessed via westlaw.com (last visited May 7, 2020) [hereinafter "STEDMAN'S"].

[20] Pernicious anemia is a chronic progressive anemia of older adults, occurring more frequently during the fifth and later decades, due to failure of absorption of vitamin B12, usually resulting from a defect of the stomach and associated with lack of secretion of "intrinsic factor." It is characterized by numbness and tingling, weakness, and a sore smooth tongue, as well as dyspnea after slight exertion, faintness, pallor of the skin, anorexia, diarrhea, weight loss, and fever. *Pernicious anemia*, STEDMAN'S at 36730.

[21] Somatization is "the conversion of mental experiences or states into bodily symptoms." *Somatization*, DORLAND'S at 1705.

[22] Somatoform is a term used to describe "physical symptoms that cannot be attributed to organic disease and appear to be of psychic origin." *Somatoform*, DORLAND'S at 1705.

[23] Autoimmune means "characterized by a specific humoral or cell-mediated immune response against constituents of the body's own tissues (self antigens or autoantigens)." *Autoimmune*, DORLAND'S at 178.

[24] Gastritis is an "inflammation of the stomach." *Gastritis*, DORLAND'S at 754.

an elevated parietal cell antibody. We explained to him that negative intrinsic factor antibody can be seen with pernicious anemia. Since starting B12 supplementation his neurologic symptoms have improved." *Id.* at 58. Petitioner was instructed to continue supplementing his diet with vitamin B12. *Id.*

On July 13, 2015, petitioner presented to Dr. Salser with complaints of worsening elbow joint crepitus,[25] polyarthralgia,[26] pain in his thumb when moving his right hand, chronic knee pain, and crepitus of the left knee. Pet. Ex. 13 at 59; 63. Petitioner's fatigue had improved on vitamin D supplements. *Id.* at 59. Dr. Salser planned to recheck inflammatory labs and referred petitioner to a rheumatologist. *Id.* at 63.

On July 22, 2015, petitioner returned to Dr. Weber, reporting ongoing atrophic gastritis,[27] multiple myalgias, and arthralgia. Pet. Ex. 1 at 44. Dr. Weber concluded his symptoms were likely due to pernicious anemia rather than the hepatitis B vaccine. *Id.* at 47.

On July 23, 2015, petitioner presented to Dr. Smith at Highlands Rheumatology complaining of body fatigue, knee pain, and elbow pain caused by hepatitis B vaccines. Pet Ex. 1 at 34-35; Pet. Ex. 3 at 84-85. Irritable bowel syndrome was ruled out. Dr. Smith could not find any evidence of inflammatory arthritis. *Id.* at 35, 39. An MRI confirmed mild osteoarthritis.[28] *Id.* at 39. Dr. Smith did not see a connection between the hepatitis B vaccine and osteoarthritis. *Id.* at 39. Petitioner expressed concerns for his symptoms becoming disabling. *Id.* at 40.

On July 24, 2015, petitioner underwent colonoscopy that found hemorrhoids[29] but was otherwise normal. Pet. Ex. 1 at 25, 27.

On July 29, 2015, petitioner returned to Dr. Weber with complaints of intermittent rectal bleeding, diarrhea, fever, and inflammatory signs. Pet. Ex. 1 at 29. Petitioner advised of his multiple rheumatological complaints, stating the rheumatologist did not think a rheumatological

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[25] Joint crepitus is "the grating sensation caused by the rubbing together of the dry synovial surfaces of joints." *Joint crepitus*, DORLAND'S at 424.

[26] Polyarthralgia is pain in many different joints. *Polyarthralgia*, DORLAND'S at 1464; *arthralgia*, *id.* at 154.

[27] Atrophic gastritis is a "type of chronic nonerosive gastritis characterized by infiltration of the lamina propria by inflammatory cells, similar to superficial gastritis but involving the entire mucosa. The amount of chief cells and parietal cells decreases, lymphoid nodules may be present, the total thickness of the mucosa decreases, and intestinal metaplasia may develop." *Atrophic gastritis*, DORLAND'S at 754.

[28] Osteoarthritis is a "noninflammatory degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes in the synovial membrane. It is accompanied by pain, usually after prolonged activity, and stiffness, particularly in the morning or with inactivity." *Osteoarthritis*, DORLAND'S at 1326.

[29] A hemorrhoid is a "prolapse of an anal cushion, resulting in bleeding and painful swelling in the anal canal." *Hemorrhoid*, DORLAND'S at 832.

disorder was causing his symptoms. *Id.* Dr. Weber attributed petitioner's anemia to hypochlorhydria[30] from autoimmune gastritis and/or pernicious anemia. *Id.*

On August 12, 2015, petitioner returned to Dr. Salser with ongoing knee "tissue disorder," or "connective tissue disease [is] connected to Hep B vaccine" and requested referral to a rheumatologist who specialized in muscular disorders. Pet. Ex. 3 at 64. Dr. Salser documented petitioner's mood and behavior as "flat" and "restless." *Id*. at 68.

On August 18, 2015, petitioner returned to Dr. Agnihotri. Pet. Ex. 3 at 59; Pet Ex. 1 at 60. He complained of crackling joints and stiffness in his muscles and arms "focus[ed] on how this could be Hep vaccine related." *Id*. at 60. He worried his joint problems were secondary to muscle weakness due to MS. *Id*. Dr. Agnihotri noted EMG results with no significant abnormalities and normal physical exam. *Id*. at 62-63. Dr. Agnihotri wrote symptoms could be due to his vitamin B12 deficiency and "reinforced that there's no evidence of MS…" *Id*. Dr. Agnihotri agreed to order a brain MRI at petitioner's request, which she "expected to be normal." *Id.* at 63. She "remain[ed] concerned about some degree of somatization or somatiform (sic) disorder." *Id.* She discussed how anxiety and stress could contribute to his symptoms but petitioner "firmly denie[d] that." *Id*.

Petitioner had a brain MRI with and without contrast on August 26, 2015, which showed "[s]mall nonspecific abnormal signal foci in the left frontal white matter" which "may represent chronic microvascular disease and do not have the classic appearance expected for demyelinating disease. No acute intracranial abnormality." Pet. Ex. 12 at 15-16.

Petitioner had an abdominal MRI on August 27, 2015, which showed no evidence of inflammatory bowel disease or small bowel mass. Pet. Ex. 12 at 17-18.

On August 28, 2015, petitioner returned to Dr. Smith with complaints of joint pain in his left elbow with popping and cracking in both knees. Pet. Ex. 3 at 70. Petitioner reported being unable to run, but upon further questioning by Dr. Smith, admitted that "he actually had not tried to run because he is concerned that this may be painful or possibly cause injury." *Id*. at 71. Dr. Smith wrote petitioner "still expressed concern that his symptoms are the result of 'hepatitis B vaccine injury,'" stating "I feel the autoimmune reaction," as well as "twitching of the muscles." *Id.* at 70. He "described articles that indicate long term chronic joint damage related to a hepatitis B vaccination." *Id*. at 71. He requested muscle biopsy as well as synovial biopsy to investigate his symptoms. *Id.* Physical examination was normal with no evidence of an inflammatory arthritic condition. *Id*. at 76. Dr. Smith agreed with Dr. Agnihotri that petitioner's symptoms were likely due to somatization. *Id*. at 77.

Dr. Smith wrote, "[petitioner] told me, 'I expect aggressive diagnostics and appropriate treatment.'" Pet. Ex. 3 at 71. He provided contact numbers for Merck and suggested that Dr. Smith call them to discuss his condition. *Id.* He was concerned he was "deteriorating," and requested

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[30] Hypochlorohydria is a "deficiency of hydrochloric acid in the gastric juice." *Hypochlorohydria*, MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/medical/hypochlorhydria (last visited Mar. 27, 2020).

MRIs of all of his painful joints, which Dr. Smith refused to order but did order a separate list of tests and "emphasize[d] that [the] labs tests (sic) are non-specific and would neither rule in or rule out any disease." *Id*. at 76. Dr. Smith wrote petitioner "expressed desire to see someone else in my department who is an expert in hepatitis B vaccine injury." *Id.* Additionally, petitioner "strongly expressed a desire" that Dr. Smith immediately review the case with the clinic director, Dr. Chatham. *Id*. When Dr. Smith advised that would take a few weeks "to allow for a more productive assessment," petitioner became "upset" and "insisted that he should get an immediate appointment" with Dr. Chatham. *Id.* Dr. Smith notified Dr. Chatham of the situation and told petitioner "there is no need for further follow up with me." *Id.*

On September 8, 2015, petitioner returned to Dr. Salser with complaints of joint pain in both knees and left elbow as a result of a hepatitis B vaccine he received in 2013. Pet. Ex. 3 at 53. Dr. Salser described petitioner as "Anxious, Angry," his behavior as "Belligerent, Compulsive," and flagged petitioner as having "Abnormal/Psychotic thoughts." *Id*. at 57. Petitioner demanded "Urgency at the highest level" and requested a "specialist who understands Hep B adverse effects." *Id*. Petitioner was very upset because "Nobody [was] helping [him] discover the diagnosis on this" and "[he had] to continue to research this because nobody [was] helping [him]." *Id*. at 53. Dr. Salser noted that a recent abdominal MRI showed no evidence of inflammatory bowel disease. *Id*. at 54.

On October 1, 2015, petitioner returned to Dr. Weber complaining of recurrent rectal bleeding. Pet. Ex. 3 at 48. Dr. Weber wrote petitioner has "significant rheumatologic complaints with no defined diagnosis" though "he does seem to blame this on a hepatitis B vaccine." *Id*. "The symptoms are intermittent but he worries about them constantly—although more so his rheumatologic complaints." *Id.* An abdominal MRI was normal, though petitioner did have a modest iron deficiency. *Id*. at 49. Dr. Weber's diagnoses were chronic atrophic gastritis without bleeding, unspecified iron deficiency anemia, unspecified vitamin D deficiency, and possible somatization. *Id*. at 51.

At his insistence, Dr. Chatham head of rheumatology at Kirklin Clinic examined petitioner on October 12, 2015. Pet. Ex. 3 at 42. Petitioner reported good health until the past year, when he began to experience increasing difficulties with joint pain, muscle twitches, and crepitation in his neck, elbows, shoulders, and knees with generalized myalgia and weakness that significantly interfered with function. *Id.* Dr. Chatham wrote, "[petitioner] has had numerous serologic as well as imaging evaluations done in the past year all of which have been unrevealing for any evidence of acute phase response, autoantibody titer elevations, rheumatoid factor elevation or any evidence of inflammatory changes referable to his knees." *Id*. Additionally, all MRIs have been unremarkable. *Id*. at 42-43. "It is possible his arthralgias were accentuated by adjuvants in the administered HBV vaccine, but there is no objective evidence of chronic joint inflammation presently. Current objective findings on exam and imaging are all easily explained by evolving osteoarthritis" *Id*. at 46. Petitioner tested positive for HLA-B27, which is a gene found in 90% of patients with ankylosing spondylitis. *Id*. at 47; *see also Histocompatibility complex*, STEDMAN'S at 194270. Dr. Chatham prescribed sulfasalazine.[31] *Id.*

[31] Sulfasalazine is an anti-inflammatory drug used to treat ulcerative colitis, Crohn's disease, and rheumatoid arthritis. *Sulfasalazine – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Azulfidine-sulfasalazine-1862#14 (last visited Mar. 27, 2020).

On October 15, 2015, petitioner returned to Dr. Salser for follow-up of ongoing knee, elbow, and shoulder pain. Pet. Ex. 3 at 37. He reported a "twitching" sensation in both upper arms and expressed interest in seeing an integrative medicine physician. *Id*. Petitioner was scheduled for a capsule endoscopy with his gastroenterologist later that day. *Id*. Dr. Salser agreed to refer him to Dr. Allen. He was to follow-up in two months. *Id*. at 41.

On October 16, 2015, petitioner was admitted to UAB by Dr. Vander Noot for a suspected gastrointestinal bleed and inability to pass the capsule from an endoscopy the prior day despite multiple bowel movements.[32] Pet. Ex. 1 at 399, 457, 465. The capsule endoscopy was done to determine if a source other than pre-existing hemorrhoids was the cause of his bleeding. *Id.* at 470. Petitioner reported abdominal pain and rectal bleeding for four hours and was admitted for two days. *Id.* at 465, 579-82. There was blood observed in petitioner's stool, but no apparent source was located. *Id*. at 467. Petitioner was kept under observation. He was concerned that the capsule had broken and irritated his bowels. *Id.* at 467, 470, 478. Radiology found no evidence of a bleed within the intestines and a CT scan identified the capsule in an appropriate position. *Id.* at 467, 477, 480-81, 485, 486, 492-93; Pet. Ex. 12 at 20-24. The minimal amount of blood was explained by a pre-existing hemorrhoid. *Id.* at 467. Petitioner was advised that the capsule would pass uneventfully and to follow-up with his primary care physician and gastroenterologist. *Id.* at 418, 486.

On November 18, 2015, petitioner returned to Dr. Salser following his admission to UAB for what he reported as a "gastrointestinal bleed." Pet. Ex. 1 at 105; Pet. Ex. 3 at 31-36. Petitioner was taking sulfasalazine for ten days and claimed it helped with twitching, stiffness, and his B12 deficiency. *Id.* at 105. Dr. Salser noted, "Patient feels this is connected to his HLA B27 and Hep B vaccination." *Id.* at 106.

On December 22, 2015, petitioner returned to Dr. Salser with complaints of neck and knee pain. Pet. Ex. 3 at 25. He was worried about an adjuvant reaction to the hepatitis B vaccine and requested his aluminum level be checked. *Id.* Bloodwork was ordered. *Id*. at 29-30.

On January 29, 2016, petitioner returned to Dr. Chatham for "[s]uspected (undifferentiated) spondyloarthropathy.[33]" Pet. Ex. 3 at 19. Petitioner complained of ongoing myalgia but stated that his overall joint pain had improved, though crepitation of the left elbow and both knees was still present. *Id.* Laboratory results were "unremarkable." *Id*. at 24.

On February 15, 2016, petitioner returned to Dr. Salser with ongoing pain in his elbow, knee, neck, and upper shoulder as well as "muscle fatigue" which "[c]omes and goes". Pet. Ex. 3 at 13-14. Dr. Salser wrote petitioner "did literature search – Vitamin D helps with symptoms of Hepatitis B Vaccine." *Id*. At the request of the petitioner, autoimmune tests were reordered. *Id*. at 17.

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[32] Records documenting the capsule endoscopy could not be located.

[33] Spondyloarthropathy is a "[d]isease of the joints of the spine." *Spondyloarthropathy*, DORLAND'S at 1725.

On February 26, 2016, petitioner returned to Dr. Agnihotri with complaints of intermittent muscle fatigue. Pet. Ex. 3 at 7-8. He reported pain in the left side of his body, from his shoulder to his upper hip, the week prior. *Id*. at 8. He also reported having short term memory loss after receiving a hepatitis B vaccination, which had since improved. *Id*. Petitioner worried he could have macrophagic myofasciitis[34] associated with aluminum adjuvants; Dr. Agnihotri wrote, "he again focuses on how this could be Hep vaccine and the adjuvants in the vaccine." *Id*. Petitioner advised that he was taking cilantro and chlorella supplements to counteract aluminum toxicity. *Id*. Petitioner further expressed concern for myopathy secondary to the hepatitis B vaccine and presented related literature. *Id*. at 11. Dr. Agnihotri assured him there was no evidence of myopathy on the EMG, and therefore no need for a muscle biopsy. *Id*. Petitioner was "reassured multiple times and again today that there is no evidence of MS at this time," as he was diagnosed with a significant vitamin B12 deficiency which would explain most of his symptoms. *Id*. Dr. Agnihotri wrote there was no objective neurological evidence that petitioner developed an autoimmune reaction after the hepatitis B vaccination. *Id*. Dr. Agnihotri again expressed concern that petitioner was suffering from "some degree of somatization or somatiform (sic) disorder," and suggested counselling or therapy, which petitioner refused. *Id*.

On March 18, 2016, petitioner returned to Dr. Salser with complaints of chronic fatigue and multiple musculoskeletal complaints, including "tissue discomfort" on the left side of his body, "which he relates to receiving 'all 3 Hep B injections in my left arm.'" Pet. Ex. 3 at 1. Petitioner was worried about hair loss he stated began after the hepatitis B vaccinations. *Id*. at 2. "Patient states he needs my opinion on whether this is truly a Hepatitis B Vaccination injury." *Id*. Dr. Salser wrote petitioner "presented multiple articles about Hep B vaccination injury" and "continued to insist on treatment plans, literature researches (sic) and treatment for Hep B vaccination injury." *Id*. at 6. Dr. Salser advised petitioner that his anxiety was exacerbating his complaints and offered a referral to a psychiatrist, but petitioner "adamantly refused any psych meds or referral." *Id*.

On April 12, 2016, petitioner returned to Dr. Chatham, complaining of possible gluten sensitivity, left-side chest wall pain, and ocular discomfort. Pet. Ex. 13 at 68. His joint pain had improved, and he no longer had swelling, though crepitation was noted in the left elbow. *Id.* He was diagnosed with osteoarthritis of the neck, knee, and left elbow along with myalgias. *Id.* at 72. Possible uveitis[35] was noted. *Id.*

On May 31, 2016, petitioner visited Dr. Gewin, a specialist in family and internal medicine, reporting multiple rheumatologic complaints, diagnoses of pernicious anemia, atrophic gastritis, positive HLA-B27, vitamin B12 deficiency, and "undifferentiated connective tissue disease by his rheumatologist Dr. Chatham." Pet. Ex. 15 at 5. Petitioner questioned Dr. Gewin whether these problems were caused by the hepatitis B vaccine. *Id.* Petitioner described worsening hair loss and itching as well. *Id.* He wanted testing for celiac disease and Hashimoto's thyroiditis. *Id.* Bloodwork revealed normal TSH, normal antibodies, and normal tissue transglutaminase. *Id.* at 4.

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[34] Myofasciitis is an "inflammation of a muscle and its fascia, particularly of the fascial insertion of muscle to bone." *Myofasciitis*, DORLAND'S at 1205.

[35] Uveitis is "an inflammation of part or all of the uvea, commonly involving the other tunics of the eye (sclera, cornea, and retina)." *Uveitis*, DORLAND'S at 1983.

On July 26, 2016, petitioner returned to Dr. Chatham for ongoing myalgias and occasional fasciculations.[36] Pet. Ex. 13 at 76. He had mild pruritus but no rash, and his overall joint pains had further improved. *Id.* An x-ray of his elbow was performed and did not show fracture, dislocation, or swelling. *Id.* at 83. Early osteoarthritis signs were observed from the knee exam and probable osteoarthritis of the left elbow was indicated. *Id.* at 79. Petitioner was "[t]olerating sulfasalazine well." *Id.* at 76.

On August 19, 2016, petitioner returned to Dr. Gewin complaining of worsening arthralgias in his left elbow and knee. Pet. Ex. 15 at 5. He again related the arthralgias to his hepatitis B vaccines because they were given when he had extreme pruritis, crepitus, and pain in his joints. *Id.* Dr. Gewin noted a possible immune response to the vaccines, including arthralgias and allergic dermatitis that had since resolved. *Id.* Dr. Gewin ordered a rheumatoid profile with serologic markers, including the sedimentation rate[37] and CRP.[38] *Id.* The bloodwork revealed negative ANA,[39] abnormally low ferritin,[40] normal rheumatoid factor, and normal TSH. *Id.* at 6.

On August 26, 2016, petitioner returned to Dr. Gewin reporting when he tried to discontinue the vitamin D supplements, he noticed more pain and spasticity in his joints. Pet. Ex. 15 at 4. Dr. Gewin instructed petitioner to continue the vitamin D supplement and planned to test petitioner's vitamin D 25-hydroxy level at the next appointment. *Id.* Petitioner apparently did not return to Dr. Gewin, as there are no further records.

On August 29, 2016, petitioner presented to Dr. Nozaki for a second opinion of whether the hepatitis B vaccine caused his myalgias. Pet. Ex. 13 at 84-85. Dr. Nozaki wrote that petitioner contacted a physician in France who thinks hep B vaccination can cause MS and myopathy." *Id.* at 84. He was concerned he could have macrophagic myofasciitis from the aluminum adjuvants in the vaccine. *Id.* at 85. Petitioner also complained of muscle fatigue that was "on and off." *Id.* On examination he was found to have normal strength, sensory response, and DTRs.[41] *Id.* at 87. There

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[36] Fasciculations are involuntary contractions of groups of muscle fibers. *Fasciculation*, STEDMAN'S at 321740.

[37] Sedimentation rate is a non-specific test used to detect illnesses associated with acute and chronic infection, inflammation, and tissue necrosis or infarction. *See Mosby's Manual of Diagnostic and Laboratory Tests* 199 (Pagana eds., 6th ed. 2018) [hereinafter *Mosby's*].

[38] C-reactive protein ("CRP") is a protein used to indicate an inflammatory illness. It is elevated in patients with a bacterial infectious disease, tissue necrosis, or an inflammatory disorder. A positive test result indicates the presence, but not the cause, of the disease. *See Mosby's* at 165-66.

[39] "ANA" stands for "anti-nuclear antibody." It is an antibody showing an affinity for nuclear antigens including DNA and found in the serum of a high proportion of patients with systemic lupus erythematosus, rheumatoid arthritis, and certain collagen diseases. *Anti-nuclear antibody (ANA)*, STEDMAN'S at 47140.

[40] Ferritin is an iron-protein complex which regulates iron storage and transport. *Ferritin*, STEDMAN'S at 324990.

[41] "DTR" stands for deep tendon reflex. *DTR*, STEDMAN'S at 267760. Deep tendon reflexes are involuntary contractions of skeletal muscle that occur as a result of stimulation of stretch receptors in the muscles. *Deep tendon reflex*, *id*. at 767400; *myotatic contraction*, *id*. at 201140.

was no evidence of myalgias, rashes, or joint swelling. *Id.* Dr. Nozaki concluded petitioner may have had a systemic autoimmune reaction to the vaccine, but ongoing myopathy was unlikely due to his normal strength and lack of myalgia. *Id.* at 88.

On October 14, 2016, petitioner returned to Dr. Chatham with noted "suspected (undifferentiated) spondyloarthropathy." Pet. Ex. 19 at 137. Petitioner reported Dr. Weber advised him he has atrophic gastritis with anti-parietal cell abnormality. *Id.* Bloodwork was ordered and was unremarkable. *Id.* at 141-42.

On December 14, 2016, petitioner presented to Dr. McLain, a specialist in internal medicine reporting that he had UCTD, positive HLA-B27, joint pain, and a "Hepatitis B vaccine reaction." Pet. Ex. 28 at 1. Dr. McLain wrote he has "a number of symptoms that he links to hepatitis B vaccination." *Id.* at 5. Petitioner was taken off sulfasalazine and placed on Plaquenil.[42] *Id.*

On January 31, 2017, petitioner returned to Dr. Chatham, for "suspected (undifferentiated) spondyloarthropathy." Pet. Ex. 19 at 114. He complained of ongoing knee pain, elbow arthralgia, crepitation referable to left elbow and both knees, and no rash or joint swelling but ongoing stiffness in his elbow. *Id*. He was tolerating sulfasalazine and had no diarrhea, weight loss, or new ocular complaints. *Id*. He was feeling better overall. *Id*. He was minimizing gluten in his diet and adhering to a regular exercise program. *Id*. Dr. Chatham's impression was cervical, knee, and left elbow osteoarthritis, and myalgia. *Id*. at 118.

On February 3, 2017, petitioner underwent an MRI of his left elbow to evaluate for synovitis[43]/enthesitis.[44] Pet. Ex. 19 at 110. The MRI was "[e]ssentially unremarkable" and "[n]o abnormality [was] identified to account for patient's elbow pain." *Id*.

On April 11, 2017, petitioner presented to Dr. Massey at Alabama Allergy complaining of itchy legs, skin rash, knee and elbow discomfort, intermittent eye discomfort, hair loss, and atrophic gastritis connected to the hepatitis B vaccine. Pet. Ex. 29 at 2. Petitioner was not hypersensitive to any of the following allergens: corn, egg white, milk, peanut, soybean, or wheat. *Id.* at 1. Zyrtec was recommended to aid with itching. *Id.* at 2.

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[42] Plaquenil is the brand name for hydroxychloroquine sulfate, an anti-rheumatic drug used to treat rheumatoid arthritis, systemic lupus erythematosus, lupus nephritis, and malaria. *Hydroxychloroquine sulfate – Drug Summary*, PDR.NET, https://www.pdr.net/drug-summary/Plaquenil-hydroxychloroquine-sulfate-1911 (last visited Mar. 27, 2020).

[43] Synovitis is "inflammation of a synovial membrane; it is usually painful, particularly on motion, and is characterized by a fluctuating swelling due to effusion within a synovial sac." *Synovitis*, DORLAND'S at 1826.

[44] Enthesitis is "inflammation of the muscular or tendinous attachment to bone." *Enthesitis*, DORLAND'S at 620.

On April 13, 2017, petitioner presented to Callahan Eye Clinic for an eye evaluation on referral by Dr. Chatham. Pet. Ex. 18 at 1. He complained of halos and pain around his eyes. No ocular etiology was found. *Id.* at 5. The pain was attributed to dry eyes or sinus problems. *Id.*

On April 25, 2017, petitioner returned to Dr. Chatham with ongoing knee and left elbow arthralgia and crepitation. Pet. Ex. 19 at 87. He reported overall improvement in joint pain but had twitching and stiffness. *Id.* There was no sign of uveitis. Petitioner was concerned that he had an allergy to proteins due to his pruritis and occasional rashes. *Id.* Petitioner was "[s]till submitting claim to vaccine injury board (sic) alleging his medical problems arose from previous HBV vaccine." *Id.* at 87.

On May 7, 2017, Dr. Chatham sent an email to petitioner which stated: "Subject: RE: Chatham, Walter Winn – Rheumatology: Diagnosis – Right elbow crepitation in 2015. As previously stasted (sic) your diagnosis(sic) are: seronegative spondyloarthropathy[45] osteoarthritis of the cervical spine, knees." Pet. Ex. 14.[46]

On August 7, 2017, petitioner presented to Dr. Wilcox, a gastroenterologist, with "numerous complaints" which petitioner "link[ed]…to a series of hepatitis B injections in 2015." Pet. Ex. 19 at 57. He reported his knees and elbows "pop" with movement, but an MRI of his left elbow was unremarkable. *Id.* at 60, 62. Petitioner was "concerned about "leaky gut" caused by the vaccination." Dr. Wilcox was unable to "link any of his complaints to some specific bowel disease." *Id.* at 62. Petitioner requested an investigation into inflammatory bowel disease. Dr. Wilcox ordered tissue transglutaminase and antiparietal cell antibody panels. *Id.* Tissue transglutaminase was negative. *Id.* at 63-64. Anti-gastric parietal cell antibodies were positive; Dr. Wilcox concluded the result "may reflect the presence of atrophic gastritis." *Id.* at 62-63.

On January 5, 2018, petitioner returned to Dr. Wilcox for flexible sigmoidoscopy of the colon. Pet. Ex. 19 at 7-10. Minimal amounts of chronic inflammation were observed. *Id*. at 8. Skin tags and a healed fistula were also found. *Id.* at 9. There was minor irritation at the dentate line, but no bleeding present. *Id.* Petitioner was advised to use fiber supplements. *Id.* at 10.

On March 26, 2018, petitioner returned to Dr. Chatham. Pet. Ex. 31 at 11. Petitioner had stopped using sulfasalazine and only used NSAIDs and glucosamine, as needed. *Id.* He denied any ocular complaints and had no new gastrointestinal complications. *Id.* Dr. Chatham wrote petitioner has "early [osteoarthritic] changes referable to knee by exam, MR; cervical disc disease by cervical radiogrpahs (sic), MR; probably component of post-traumatic [osteoarthritis] of the left elbow." *Id.* at 13.

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[45] Ankylosing spondylitis, also referred to as seronegative spondyloarthropathy, is "a general term comprising a number of degenerative joint diseases having common clinical, immunologic, pathologic, and radiographic features, including synovitis of the peripheral joints, enthesopathy, bony ankylosis of the large peripheral joints, lack of rheumatoid factor, and, in many cases, a positive status for the human leukocyte antigen HLA-B27." *Seronegative spondyloarthropathy*, DORLAND'S at 1725.

[46] The request to Dr. Chatham that resulted in this email was not filed.

On April 10, 2018, an MRI of petitioner's hips revealed a right acetabular labral tear but no evidence of synovitis. Pet. Ex. 31 at 18. An MRI of the thoracic spine on April 11, 2018 revealed persistent disc protrusion at the T1-2 and decreased mass effect on the thoracic cord, but no focal cord signal abnormalities. *Id.* at 20.

On January 30, 2019, petitioner presented to Dr. Lolley, an ophthalmologist at Callahan Eye Hospital Clinic, for pain behind the left eye and light sensitivity. Pet. Ex. 32 at 1. Petitioner "believe[d] these symptoms are related to dx (sic) of Ankylosing spondylitis that he developed after receiving a Hep B vaccine." *Id.* Dr. Lolley diagnosed petitioner with keratoconjunctivitis sicca[47] and myopia[48] with presbyopia[49] in both eyes. *Id.* at 4. Petitioner expressed concern that his vision would change but was informed his condition was common in patients who had Lasik surgery performed in 1998. *Id.* at 5. Petitioner noted frequent tears, despite the diagnosis of keratoconjunctivitis sicca. *Id.* Allergies to "Hepatitis B virus vaccine" and oxycodone were reported. *Id.* at 1-2.

On February 26, 2019, petitioner presented to Dr. Read, an ophthalmologist at Callahan Eye Hospital Clinic for evaluation. He reported receipt of a hepatitis B vaccine after which "he suffered severe damage from this…he had 2 in 2013…last shot in 2017." Pet. Ex. 33 at 1. He reported light sensitivity, headaches, blurred vision and halos at night. *Id*. He had vitamin B12 deficiency and "some other auto immune disorders that he feels may be affecting OU. He had a follow up with Dr. Lolley and received a new prescription for glasses. *Id*. at 1-2. Dr. Read's assessment was ankylosing spondylitis, unspecified site of spine; HLA-B27 positive; history of assisted *in situ* keratomileusis; blepharitis[50] of both eyes unspecified eyelid, unspecified type; keratoconjunctivitis sicca of both eyes. *Id.* at 4. The plan was to return as needed. *Id*.

No further medical records were filed.

F. Letters from Dr. W Winn Chatham, Professor of Medicine

On March 8, 2018, Dr. Chatham submitted a letter with the salutation "To whom it may concern."[51] Pet. Ex. 17 at 1. Dr. Chatham wrote that he first examined petitioner on October 12, 2015, when petitioner presented with a history of symmetric joint pain and stiffness referable to his elbows, knees and cervical. *Id*. Petitioner reported onset of symptoms subsequent to "initiation

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[47] Keratoconjunctivitis sicca is "a condition marked by hyperemia of the conjunctiva, lacrimal deficiency, thickening of the corneal epithelium, itching and burning of the eye, and often reduced visual acuity." *Keratoconjunctivitis sicca*, DORLAND'S at 968.

[48] Myopia is "an error of refraction in which rays of light entering the eye parallel to the optic axis are brought to focus in front of the retina, as a result of the eyeball being too long from front to back, or of an increased strength in refractive power of the media of the eye." *Myopia*, DORLAND'S at 1207.

[49] Presbyopia is "impairment of vision due to advancing years or to old age." *Presbyopia*, DORLAND'S at 1488.

[50] Blepharitis is "inflammation of the eyelids." *Blepharitis*, DORLAND'S at 221.

[51] To whom or why this letter was written is unclear.

of an immunization series with Hepatitis B vaccine." *Id*. Evaluation was negative for serologic evidence for developing rheumatoid arthritis or a lupus-related autoimmune disease. *Id*. He was confirmed to be a positive HLA-B27 carrier. *Id*. He also had iron deficiency and a history of previous rectal fistula. *Id*. Developing spondyloarthropathy related to inflammatory bowel disease was considered but not confirmed after an extensive work-up. *Id*. There were no skin lesions to implicate developing psoriatic arthritis or gastrointestinal or genitourinary infection to implicate developing reactive arthritis. *Id*. Due to the above and recent symptoms of inflammatory lower back pain, he was being treated with sulfasalazine and NSAIDs for developing spondyloarthropathy, most consistent with ankylosing spondylitis. *Id*. Dr. Chatham concluded that his symptoms had only been present for three years, so he had not yet developed any radiographic footprints characteristic of this disorder. *Id*.

On April 27, 2018, Dr. Chatham generated a second letter, again directed "To whom it may concern." Pet. Ex. 30 at 1. He wrote:

> This patient continues to be followed in the UAB Rheumatology Clinic for developing ankylosing spondylitis that presented with seronegative symmetric arthritis, axial pain, stiffness in the context of HLA-B27 positive haplotype. He presented to our clinic with this complex of symptoms in 2015 following initiation of immunization with hepatitis B vaccine in 2014. As such, it is more likely than not that the vaccine triggered the onset of his disease.

Id.

G. Affidavit of P.S.

The only Affidavit submitted by the petitioner can be found at the end of the Petition, in which the petitioner affirms that the statements contained in the Petition are true except where the statements are made "upon information and belief," in which case they are true based on the information "now available to me." Pet. at 13, ECF No. 1.

II. Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he or she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Alternatively, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may bring an "off-Table" claim. § 11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii)(II). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is

sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[52]

To prove causation, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. Under the first *Althen* prong, petitioner must provide a "reputable medical theory" demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, a theory must be sound and reliable. A petitioner's "plausible" or "possible" causal theory does not satisfy the standard of proof in Vaccine Act cases. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1360 (Fed. Cir. 2019). This theory need only be "legally probable, not medically or scientifically certain." *Id*. at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Secretary of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs*., 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id*. at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

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[52] The Vaccine Act also requires petitioners to show by preponderant evidence the vaccine suffered from the "residual effects or complications" of the alleged vaccine-related injury for more than six months, died from the alleged vaccine-related injury, or required inpatient hospitalization and surgical intervention as a result of the alleged vaccine-related injury. § 11(c)(1)(D). It is undisputed that this requirement is satisfied in this case.

The third *Althen* prong requires that petitioner establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe 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). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id*. However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id*.; *see also Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

A petitioner may also be eligible for compensation if he or she had a preexisting condition which was significantly aggravated by a vaccine. *See* § 11(c)(1)(C). For a significant aggravation claim for an off-Table injury, the petitioner's burden is raised, requiring petitioner to show, by preponderant evidence, proof of

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving ex rel. Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009). The fourth, fifth, and sixth factors are derived from *Althen* prongs one, two, and three, respectively. *Id*. The Federal Circuit has agreed with this approach. *See W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) ("We hold that the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims.") Due to the requirement to prove causation, one special master has recommended evaluating "the last three *Loving* factors first." *Hennessey v. Sec'y of Health & Human Servs*., No. 01–190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), *motion for review denied*, 41 Fed. Cl. 126 (2010).

However, the third *Loving* factor, determining whether the person suffered a "significant aggravation" of his or her condition, leads to the question of what constitutes a significant aggravation. Based on the legislative history and the language of the statute, it appears that Congress intended for a "significant aggravation" of a condition to present rather dramatically. *See* H.R. Rep. 908, 99th Cong.2d Sess. 1, reprinted in 1986 USCCAN 6287, 6356 ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as preexisting (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)); *see also* 42 U.S.C. § 300aa-33(4) ("The term "significant aggravation" means any change for the worse in

a preexisting condition which results in *markedly greater* disability, pain, or illness accompanied by *substantial deterioration* of health" (emphases added)).

Once a petitioner has established that his or her condition worsened post-vaccination, the special master must determine "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the preexisting condition. *Hennessey*, 2009 WL 1709053 at *42. In doing so, special masters have relied on evidence supporting the "typical" clinical course of the petitioner's condition. *See, e.g.*, *Locane*, 685 F. 3d at 1381-82 (Special master's determination that petitioner's Crohn's disease was not significantly aggravated by her hepatitis B vaccinations where her disease flare-ups after her first and third vaccinations were typical of frequent flares in adolescents' expected course of Crohn's disease was reasonable); *Faoro v. Sec'y of Health & Human Servs*., No. 10-704V, 2016 WL 675491, at *27 (Fed. Cl. Spec. Mstr. Jan. 29, 2016), *mot. for review denied*, 128 Fed. Cl. 61 (Fed. Cl. Apr. 11, 2016) (finding that "the vaccinations would not have changed her clinical course and thus, the vaccinations did not significantly aggravate her preexisting condition").

Finally, although this decision discusses much but not all of the evidence filed in detail, the undersigned reviewed and considered all of the evidence filed in this matter, including but not limited to the medical records and literature that was filed. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

III. Discussion

A. Defined and Recognized Injury

The first step in any case is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1343, 1353 (Fed. Cir. 2011). It is the petitioner's burden to demonstrate that he actually suffers from the injuries he has alleged. *Hibbard v. Sec'y of Health & Human Servs*., 698 F.3d 1358, 1364-65 (Fed. Cir. 2012). "In the absence of a showing of the very existence of any specific injury[,]…the question of causation is not reached." *Lombardi*, 656 F.3d at 1353; *Broekelschen*, 618 F.3d at 1346 (explaining that a vaccine-related injury "has to be more than just a symptom or manifestation of an unknown injury."); *Stillwell v. Sec'y of Health & Human Servs*., 118 Fed. Cl. 47, 56 (2014) ("[I]f the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the *Althen* test for causality."). Thus, petitioner has the burden of demonstrating what medically-recognized injury he suffers. *Broekelschen*, 618 F.3d at 1348; *see also Lasnetski v. Sec'y of Health & Human Servs*., 128 Fed. Cl. 242 (2016), *aff'd*, 696 Fed. Appx. 497 (Fed. Cir. 2017).

To determine whether a petitioner has adequately proven a demonstrable injury, a special master must analyze the complete medical records filed into the record by petitioner. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are

presumed to be accurate and complete providing all relevant information on a petitioner's health problems. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.3d 1525, 1528 (Fed. Cir. 1993). Subsequent statements made by third parties that contradict contemporaneous medical records are less persuasive to special masters than the medical records. *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006).

In his petition, petitioner alleged that he suffered from "undifferentiated connective tissue disease ("UCTD"), autoimmune or atrophic gastritis, and other injuries" as a result of the hepatitis B vaccinations. *See* Petition at 1.

In his Motion for Ruling on the Record, petitioner claims the vaccinations "caused him to develop auto-immune gastritis, pernicious anemia (an auto-immune disease), ankylosing spondylitis (an auto-immune disease), and ongoing injuries and damages…" Motion at 1. He relied on the literature he filed to "show that his medical course and current illness are consistent with a diagnosis of post-vaccination ankylosing spondylitis;" that the "[m]edical literature discusses the pathogenesis of ankylosing spondylitis as including intestinal disorders, and therefore provides a link between [petitioner's] diagnosed illnesses – pernicious anemia associated with elevated anti-gastric parietal cell anti-bodies/B12 deficiency, and ankylosing spondylitis;" and provides "the association of rheumatic diseases with the hepatitis b (sic) vaccine, and therefore provides a link between [petitioner's] diagnosed illnesses – ankylosing spondylitis – with the vaccine…" *Id*. at 4, 7, 11.

In response to the petitioner's Motion for Ruling on the record, respondent pointed to the medical records stating petitioner's treating physicians "did not settle on a consensus diagnosis for his condition" and therefore, "petitioner arguably has not proven any particular diagnosis in accordance with the preponderance standard." Response at 5.

It is unclear when, from whom, or if petitioner was ever suspected of having UCTD. UCTD appears in petitioner's records for the first time on October 15, 2015 when he reported it to Dr. Salser as a condition from which he suffered. Pet. Ex. 1 at 101-04. Dr. Salser included UCTD in petitioner's list of ongoing problems, but not in his list of diagnoses. *Id*. at 102, 104. Petitioner later reported to Dr. Gewin on May 31, 2016, Dr. Nozaki on August 26, 2016, and Dr. McLain on December 14, 2016, that was he was diagnosed with UCTD by Dr. Chatham. *See* Pet. Ex. 13 at 84; Pet. Ex. 15 at 5; Pet. Ex. 28 at 1. Though UCTD is included in petitioner's list of ongoing problems at visits with Dr. Chatham on January 29, 2016; October 14, 2016; and January 31, 2017; none of his office visits mention UCTD, and Dr. Chatham never included UCTD among petitioner's diagnoses. *See* Pet. Ex. 3 at 19-24, 42-47; Pet. Ex. 13 at 68-72, 76-83; Pet. Ex. 19 at 115-18, 137-42; Pet. Ex. 31 at 11-13. Moreover, Dr. Chatham specifically diagnosed petitioner with osteoarthritis and spondyloarthropathy. *See* Pet. Ex. 14 at 1. Dr. Chatham's records repeatedly provided the diagnoses of osteoarthritis and spondyloarthropathy, up through the last office visit filed on March 16, 2018. Pet. Ex. 31 at 11, 13.

Petitioner further claims he suffers from ankylosing spondylitis. Ankylosing spondylitis is defined in the literature as part of a larger group of diseases generally termed

"spondyloarthropathies," Pet. Ex. 20 at 1;[53] Pet. Ex. 25 at 1;[54] Pet. Ex. 23 at 1,[55] characterized by inflammatory back pain, restricted spinal mobility, peripheral arthritis, enthesitis, and uveitis. Pet. Ex. 25 at 1; Pet. Ex. 22 at 1.[56] The difficulty in diagnosing patients with ankylosing spondylitis is exemplified by the numerous changes that have been made to diagnostic criteria since the initial criteria were developed in 1961. *See* Pet. Ex. 24 at 2[57] (Discussing the evolution of criteria for ankylosing spondylitis and noting that revised criteria were issued in 1966, 1977, and 1984). Despite the importance of early diagnosis, many patients have symptoms for years before receiving a diagnosis of ankylosing spondylitis. *See* Pet. Ex. 20 at 2 (Study finding an average diagnosis delay was six years); Pet. Ex. 21 at 2[58] (Noting that "eight to 11 years may pass between the first symptoms of [ankylosing spondylitis] and its definitive diagnosis"); Pet. Ex. 22 at 2 (Study finding an average diagnosis delay was six years); Pet. Ex. 23 at 1 (Noting that the diagnosis of ankylosing spondylitis "is often delayed by 5-10 years"); Pet. Ex. 25 at 1 (Noting that "an average interval of 8-11 years has been reported" between "the onset of symptoms and the time of diagnosis"). This delay is likely due to the diagnostic criterium requiring radiographic evidence of changes in the sacroiliac joint. Pet. Ex. 20 at 1-2; Pet. Ex. 22 at 1; Pet. Ex. 23 at 1; Pet. Ex. 25 at 1.

Petitioner also submitted several articles on the relationship between a positive HLA-B27, as "a major risk factor for ankylosing spondylitis." Pet. Ex. 37 at 6;[59] *see also* Pet. Ex. 40 at 2[60] associated with spondyloarthropathy, including…ankylosing spondylitis"); Pet. Ex. 44 at 3[61] (Stating that ankylosing spondylitis is "strongly associated" with HLA-B27).

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[53] Umit Dincer et al., *Diagnosis Delay in Patients With Ankylosing Spondylitis: Possible Reasons and Proposals For New Diagnostic Criteria*, 27 CLIN. RHEUMATOL. 457-62 (2008), filed as "Pet. Ex. 20."

[54] Finbar O'Shea et al., *The Challenge of Early Diagnosis in Ankylosing Spondylitis*, 34 J. RHEUMATOL. 5-7 (2007), filed as "Pet. Ex. 25."

[55] Salih Ozgocmen & Muhammad Asim Khan, *Current Concept of Spondyloarthritis: Special Emphasis on Early Referral and Diagnosis*, 14 CURR. RHEUMATOL. REP. 409-14 (2012), filed as "Pet. Ex. 23."

[56] Mehrzad Hajialilo et al., *Ankylosing Spondylitis in Iran; Late Diagnosis and Its Causes*, 16 IRAN RED CRESCENT MED. J. e11798 (2014), filed as "Pet. Ex. 22."

[57] Martin Rudwaleit et al., *The Challenge of Diagnosis and Classification in Early Ankylosing Spondylitis: Do We Need New Criteria?*, 52 ARTHRITIS RHEUMATOL. 1000-08 (2005), filed as "Pet. Ex. 24."

[58] J. Martindale & L. Goodacre, *The Journey to Diagnosis in AS/Axial SpA: The Impact of Delay*, 12 MUSCULOSKELET. CARE 221-31 (2014), filed as "Pet. Ex. 21."

[59] Mary-Ellen Costello et al., *Intestinal Dysbiosis in Ankylosing Spondylitis*, 67 ARTHRITIS RHEUMATOL. 686-91 (2015), filed as "Pet. Ex. 36."

[60] James T. Rosenbaum et al., *Does the Microbiome Cause B27-related Acute Anterior Uveitis?*, 24 OCUL. IMMUNOL. INFLAMM. 440-44 (2016), filed as "Pet. Ex. 40."

[61] James T. Rosenbaum & Mark Asquith, *The Microbiome and HLA-B27-Associated Acute Anterior Uveitis*, 14 NAT. REV. RHEUMATOL. 704-13 (2018), filed as "Pet. Ex. 44."

Petitioner's medical history prior to his hepatitis B vaccinations includes hair loss, itching, cutis xerosis, urticaria, seborrheic dermatitis, folliculitis, upper abdominal pain, diarrhea, history of rectal bleeding, rectal mass/fistula, vitamin D deficiency, eczema, and hypertriglyceridemia. Pet. Ex. 1 at 14, 16, 18; Pet. Ex. 3 at 141-49. There were no medical records filed documenting any reactions following the August 14, 2013 and/or the December 17, 2013 hepatitis B vaccinations. Petitioner received the third hepatitis B vaccine on May 16, 2014. There were no medical records filed between May 16, 2014 and February 19, 2015, when petitioner presented with a cough, sore throat, and left-sided abdominal pain. There was no mention of any events associated with his hepatitis B vaccinations at that medical visit. Pet. Ex. 3 at 135-37. At his next medical visit on May 18, 2015, petitioner presented with neck and back pain, which he associated with the hepatitis B vaccine received one year prior. *Id*. at 127-30.

Over the next four years, petitioner presented to and received numerous differential and possible diagnoses from multiple specialists including Drs. Davuluri, Salser, and Gewin (family medicine), Agnihotri (neurology), Gillford (emergency medicine), Weber, Black, and Wilcox (gastroenterology), Smith and Chatham (rheumatology), Nozaki (neuromuscular medicine), McLain (internal medicine), Massey (allergy and immunology), and Lolley and Read (ophthalmology).

The diagnoses included vitamin B12 and vitamin D deficiency (existing prior to the vaccinations); pernicious anemia (autoimmune gastritis) due to vitamin B12 deficiency; mild osteoarthritis and myalgias; somatization or somatoform disorder; possible atrophic gastritis without bleeding (ruled out on sigmoidoscopy); unspecified iron deficiency anemia; polyarthralgia and bilateral shoulder pain; suspected (undifferentiated) spondyloarthropathy; possible uveitis (ruled out); dry eyes or sinus problems; seronegative spondyloarthropathy osteoarthritis of the cervical spine and knees; right labral tear of the hip; *in situ* keratomileusis; blepharitis of both eyes, unspecified eyelid, unspecified type; and keratoconjunctivitis sicca of both eyes. *See* Pet. Ex. 1 at 39; Pet. Ex. 3 at 7, 11, 19, 41, 46, 51, 62-63, 70; Pet. Ex. 13 at 47, 49, 58; Pet. Ex. 14 at 1; Pet. Ex. 31 at 13, 18; Pet. Ex. 18 at 5; Pet. Ex. 19 at 7-10, 62-63, 114, 118, 137, 141; Pet. Ex. 33 at 4.

Petitioner underwent extensive testing, including but not limited to, MRIs of his cervical spine with and without contrast on June 11, 2015 showing degenerative changes; an MRI of the thoracic spine on June 23, 2015, with no cord signal abnormalities appreciated; an MRI of his left knee on July 6, 2015, which was unremarkable; an MRI of the left shoulder on February 3, 2017 for synovitis/enthesitis, deemed "[e]ssentially unremarkable" and noting that"[n]o abnormality [was] identified to account for patient's elbow pain;" an MRI of the hips on April 10, 2018, which showed a right acetabular labral tear but no evidence of synovitis; an MRI of the thoracic spine on April 11, 2018, which showed persistent disc protrusion; a negative intrinsic factor antibody test; a colonoscopy on July 24, 2015 which found hemorrhoids but was otherwise normal; an August 18, 2015 EMG with normal findings; an August 26, 2015 brain MRI with and without contrast, finding no acute intracranial abnormality; an August 27, 2015 abdominal MRI, showing no evidence of inflammatory bowel disease or small bowel mass; December 22, 2015 blood work, which was "unremarkable;" May 31, 2016 blood work, negative for celiac and Hashimoto's thyroiditis, with normal TSH, normal antibodies, and normal tissue transglutaminase; a July 26, 2016 x-ray of the left elbow, which was negative; August 19, 2016 blood work with serologic markers, including sedimentation rate and CRP, which was negative for ANA factor, abnormally

low for ferritin, normal for rheumatoid factor, and normal for TSH; October 14, 2016 blood work, which was unremarkable; August 7, 2017 blood work, which was negative for tissue transglutaminase but positive for anti-gastric parietal cell antibodies which "may reflect the presence of atrophic gastritis;" and a January 5, 2018 flexible sigmoidoscopy of colon showing minimal amounts of chronic inflammation, skin tags, and a healed fistula but no bleeding. *See* Pet. Ex. 1 at 25, 27; Pet. Ex. 3 at 24, 29-30, 62-63; Pet. Ex. 12 at 9-18; Pet. Ex. 13 at 46-47, 76; Pet. Ex. 15 at 4, 6; Pet. Ex. 19 at 10, 62-64, 110, 141-42; Pet. Ex. 31 at 18, 20;

None of petitioner's medical records mention ankylosing spondylitis as a diagnosis, not even Dr. Chatham's office records. "Ankylosing spondylitis" appears for the first time in Dr. Chatham's March 8, 2018 letter. Prior to generating this letter, Dr. Chatham had not seen petitioner for almost a year; his last examination of petitioner was April 25, 2017. Pet. Ex. 19 at 87. Subsequent to the April 25, 2017 visit, Dr. Chatham sent petitioner an email confirming petitioner's diagnosis as seronegative spondyloarthropathy and osteoarthritis of the cervical spine and knees. Pet. Ex. 14 at 1. However, in his letter dated March 8, 2018, Dr. Chatham wrote that he treated petitioner "with sulfasalazine and NSAIDs as needed for developing spondyloarthropathy, which at this time is most consistent with developing ankylosing spondylitis." Pet. Ex. 17 at 1. A week later, on March 16, 2018, Dr. Chatham examined petitioner and made no mention of ankylosing spondylitis or its development in the medical record for that visit. *See* Pet. Ex. 31 at 11, 13. A little over a month later, Dr. Chatham wrote a second letter dated April 27, 2018, stating petitioner "continues to be followed at the UAB Rheumatology Clinic for developing ankylosing spondylitis that presented with seronegative symmetric arthritis, axial pain, [and] stiffness in the context of HLA-B27 haplotype." Pet. Ex. 30 at 1. "He presented to our clinic with this complex of symptoms in 2015 following initiation of immunization with hepatitis B vaccine in 2014. As such, it is more likely than not that the vaccine triggered the onset of his disease." *Id*. Contrary to his office records, Dr. Chatham again mentioned developing ankylosing spondylitis and added "seronegative symmetric arthritis," another diagnosis that is not contained in any medical records. *Id*. Notably, Dr. Chatham mentioned hepatitis B vaccinations initiated in 2014 rather than 2013 with the final vaccine administered in May of 2014. *Id*.

The diagnoses contained in Dr. Chatham's opinion letters are contradicted by his office records. On October 12, 2015, Dr. Chatham wrote, "[petitioner] has had numerous serologic as well as imaging evaluations done in the past year all of which have been unrevealing for any evidence of acute phase response, autoantibody titer elevations, rheumatoid factor elevation or any evidence of inflammatory changes referable to his knees." Pet. Ex. 3 at 42. Additionally, all MRIs have been unremarkable. *Id*. at 42-43. "It is possible his arthralgias were accentuated by adjuvants in the administered HBV vaccine, but theree (sic) is no objective evidence of chronic joint inflammation presently. Current objective findings on exam and imaging are all easily explained by evolving osteoarthritis" *Id*. at 46. He prescribed sulfasalazine. *Id*. at 47. On January 29, 2016, Dr. Chatham documented petitioner's lab results as "unremarkable." *Id*. at 19, 24. On April 12, 2016, Dr. Chatham diagnosed osteoarthritis of the neck, knee, and left elbow along with myalgias and possible uveitis. *Id*. at 72. On July 26, 2016, Dr. Chatham diagnosed early osteoarthritis signs observed from the knee exam and probable osteoarthritis of the left elbow. *Id.* at 76, 79. On January 31, 2017, Dr. Chatham's impression was cervical, knee, and left elbow osteoarthritis and myalgia. Pet. Ex. 19 at 118. On April 25, 2017, Dr. Chatham confirmed no sign of uveitis. *Id*. at 87. In May 7, 2017, Dr. Chatham confirmed his diagnosis in an email to petitioner, "Diagnosis – Right elbow

crepitation in 2015. As previously stasted (sic) your diagnosis(sic) are: seronegative spondyloarthropathy osteoarthritis of the cervical spine, knees." Pet. Ex. 14 at 1.

The inconsistencies between the diagnoses Dr. Chatham rendered throughout his treatment of the petitioner and the email he sent to petitioner, when contrasted with the contents of the two letters he wrote on March 8, 2018 and April 27, 2018, make the diagnoses contained in those letters unsupportable and unreliable.

Further, petitioner received numerous diagnoses including vitamin B12 deficiency, vitamin D deficiency, pernicious anemia, and osteoarthritis from multiple physicians. Petitioner has not been diagnosed with enthesitis or uveitis,[62] characteristic of ankylosing spondylitis and in fact these conditions were ruled out by objective testing. While the records do reflect complaints of back pain on occasion, the records do not reflect inflammatory back pain or restricted spinal mobility, also characteristic of the condition. An MRI of petitioner's hips from 2018 showed no signs of sacroiliac changes. The only mention of symptoms associated with or characteristic of ankylosing spondylitis are contained in Dr. Chatham's April 27, 2018 letter when he wrote petitioner has inflammatory back pain and seronegative symmetric arthritis despite Dr. Chatham consistently referring to petitioner as suffering from osteoarthritis, which is very different than seronegative arthritis,[63] in his examination records. Pet. Ex. 30 at 1; Pet. Ex. 13 at 72, 79; Pet. Ex. 19 at 118; Pet. Ex. 14 at 1; Pet. Ex. 31 at 13.

As of August 7, 2017, Dr. Wilcox was unable to link any of petitioner's complaints to some specific bowel disease, and, finding anti-gastric parietal cell antibodies to be positive, concluded the result "may reflect the presence of atrophic gastritis." Pet. Ex. 19 at 62-64. The diagnosis was not definitive, and a subsequent sigmoidoscopy showed only mild inflammation. *Id*. at 7-10.

Petitioner's most recent records from Dr. Read in 2019 reflect the history petitioner provided to him of ankylosing spondylitis. However, at the time of the writing of this decision, no contemporaneous medical records or objective testing have been filed providing any definitive illness or conditions suffered by petitioner. Petitioner does have pernicious anemia, which has been related to his vitamin B12 deficiency, and specifically not to his hepatitis B vaccinations by his treating physicians. *See* Pet. Ex. 1 at 29, 47; Pet. Ex. 13 at 58.

Dr. Chatham's contemporaneous medical records, the multitude of tests conducted on petitioner since May of 2015, the diagnoses and opinions of the physicians of various specialties who treated or were consulted by petitioner all argue against a diagnosis of ankylosing spondylitis, seronegative symmetric arthritis, UCTD, autoimmune or atrophic gastritis or any other condition associated with the hepatitis B vaccinations received by petitioner. Dr. Chatham said it best when he wrote, "[petitioner] has had numerous serologic as well as imaging evaluations done in the past year all of which have been unrevealing for any evidence of acute phase response, autoantibody

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[62] Although petitioner presented for several eye issues and received diagnoses of blepharitis and keratoconjunctivitis sicca, he was not diagnosed with uveitis. Uveitis is a condition affecting the eyeball itself, whereas blepharitis and keratoconjunctivitis sicca are conditions affecting the eyelids.

[63] Seronegative arthritis occurs when a patient has symptoms of arthritis but does not test positive for rheumatoid factor. *Seronegative*, STEDMAN'S at 812110; *rheumatoid arthritis (RA)*, *id*. at 75730.

titer elevations, rheumatoid factor elevation or any evidence of inflammatory changes referable to his knees." Pet. Ex. 3 at 42. "It is possible his arthralgias were accentuated by adjuvants in the administered HBV vaccine, but there is no objective evidence of chronic joint inflammation presently. Current objective findings on exam and imaging are all easily explained by evolving osteoarthritis" *Id*. at 46.

Based on a thorough review of the medical records, I can find no support for any condition associated with the hepatitis B vaccine and specifically cannot find any support that petitioner was definitively diagnosed with ankylosing spondylitis, UCTD, or atrophic gastritis/autoimmune gastritis. Because petitioner has failed to establish a defined and recognized injury, he has failed to meet his burden to show that the hepatitis B vaccinations significantly aggravated a preexisting condition. Nevertheless, I will address the requirements for an off-Table significant aggravation claim.

B. Petitioner's Theory of Causation

Petitioner filed extensive medical records, medical literature, and two letters from Dr. Chatham in support of his claim. As set forth above at length and in detail, in his letters, Dr. Chatham diagnosed petitioner with developing ankylosing spondylitis that has not yet developed any radiographic footprint characteristic of the disorder and seronegative symmetric arthritis following initiation with hepatitis B vaccine in 2014 that "more likely than not" triggered the onset of disease. Pet. Ex. 17 at 1; Pet. Ex. 30 at 1. Dr. Chatham provided nothing more.

Petitioner received hepatitis B vaccines in August 14, 2013, December 17, 2013, and May 16, 2014. There are no medical records filed after any of the vaccinations that document any complaints, reactions, untoward events or medical visits associated with petitioner's receipt of any of hepatitis B vaccinations. Dr. Chatham made note of this in his medical record of January 31, 2017. Pet. Ex. 19 at 115.

Though I have found no support in the record for ankylosing spondylitis, seronegative symmetric arthritis, UCTD, pernicious anemia, or any other condition alleged by petitioner to be associated with the hepatitis B vaccinations he received, because Dr. Chatham wrote two opinion letters in support of petitioner's claims, an *Althen* analysis is appropriate.

C. Analysis of *Althen* and *Loving* Factors

Typically, "[i]n the absence of a showing of the very existence of any specific injury of which petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1353. However, even if petitioner had shown some definable injury, he would be unable to sustain his burden of proving causation under the three prongs of *Althen* or significant aggravation under the six-factor test established in *Loving,* in this case. 86 Fed. Cl. at 144.

1. *Althen* Prong 1/*Loving* Factor 4: Petitioner Failed to Advance a Medical Theory

Petitioner has failed to offer a reputable medical theory of causation to show that hepatitis B vaccine can cause or significantly aggravate any of the conditions he alleges that he suffers from.

In his first letter dated March 8, 2018, Dr. Chatham discussed petitioner's history, claim that the hepatitis B vaccinations were the cause of his symptoms, and tests that have ruled out various diagnoses, including developing spondyloarthropathy related to inflammatory bowel disease, which was not confirmed after an extensive work-up. There were no skin lesions to implicate developing psoriatic arthritis or gastrointestinal or genitourinary infection to implicate reactive arthritis. Dr. Chatham then concluded petitioner had recent "developing inflammatory lower back pain" and was treated with sulfasalazine and NSAIDS for developing spondyloarthropathy, most consistent with ankylosis spondylitis stating he only had symptoms for three years, so he had not yet developed any radiographic footprints characteristic of the disorder. Pet. Ex. 17 at 1. In this letter, Dr. Chatham offered no association between the hepatitis B vaccines and petitioner's conditions.

A little over two weeks later, on March 26, 2018, Dr. Chatham examined petitioner for the first time in 11 months. Petitioner denied ocular complaints and had no new gastrointestinal complications. Pet. Ex. 31 at 11. Dr. Chatham concluded that petitioner had early osteoarthritic changes referable to the knee, cervical disease, and probable post-traumatic osteoarthritis of the left elbow. *Id*. at 13. There was no mention of inflammatory lower back pain, ankylosing spondylitis or hepatitis B vaccine related injuries or illness.

One month later, on April 27, 2018, Dr. Chatham generated a second letter, which stated that petitioner had seronegative symmetric arthritis, axial pain, stiffness, and a positive HLA-B27 after immunization with hepatitis B vaccine in 2014. Pet. Ex. 30 at 1. Dr. Chatham opined that "it is more likely than not that the vaccine triggered the onset of his disease." *Id*.

Dr. Chatham's letters and records provide no scientific support or sound and reliable theory for how the hepatitis B vaccines can cause ankylosing spondylitis, seronegative symmetric arthritis, osteoarthritis, or any other conditions claimed by petitioner.

When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." *Kreizenbeck v. Sec'y of Health & Human Servs.*, No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. June 22, 2018), *review denied, decision aff'd*, 141 Fed. Cl. 138 (2018), *aff'd*, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Prokopeas v. Sec'y of Health & Human Servs.*, No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 571, 596 (2009), *aff'd*, 592 F.3d 1315 (Fed. Cir. 2010)). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. *See id.*

Dr. Chatham's letters are conclusory in nature and provide no evidence linking petitioner's hepatitis B vaccinations to UCTD or ankylosing spondylitis or to any of petitioner's other co-morbidities. Dr. Chatham's conclusion that "it is more likely than not that the vaccine triggered the onset of his disease," Pet. Ex. 30 at 1, without any further medical explanation or analysis is insufficient to provide a sound and reliable medical theory of causation. *See R.V. v. Secretary of Health & Human Services*. No. 08-504V, 2016 WL 3882519, at *38-39 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *review denied, decision aff'd*, 127 Fed. Cl. 136 (2016).

Further, Dr. Chatham's letter fails to provide any scientific support or explanation of whether hepatitis B vaccine can cause any of petitioner's conditions or specifically, ankylosing spondylitis or seronegative symmetric arthritis, UCTD, autoimmune gastritis, or atrophic gastritis. To simply state it is more likely than not that it did, without more, is insufficient to establish causation. *See Garner v. Sec'y of Health & Human Servs.*, No. 15-63V, 2017 WL 1713184, at *16 (Fed. Cl. Spec. Mstr. Mar. 24, 2017), *review denied, decision aff'd*, 133 Fed. Cl. 140 (2017) (providing the petitioner's expert provided conclusory reasoning for "possible" vaccine causation is "not sufficient").

Because Dr. Chatham's letter is conclusory and provides no "sound and reliable" theory associating the hepatitis B vaccinations he received with any condition from which he allegedly suffers or claims to suffer, the undersigned finds petitioner failed to provide preponderant evidence to support the first prong of *Althen* and the fourth factor of *Loving*.

2. *Althen* Prong 2/*Loving* Factor 5: Lack of Logical Connection

Even if petitioner had been able to show that the hepatitis B vaccine or vaccines could cause or significantly aggravate ankylosing spondylitis, seronegative symmetric arthritis, UCTD, atrophic/autoimmune gastritis, or any of the conditions petitioner reports that he suffers, his medical records do not support that it did so in this case.

The majority of petitioner's treating physicians stated that there was no connection between the hepatitis B vaccine and petitioner's symptoms. Pet. Ex. 1 at 39; Pet. Ex. 3 at 11, 62-63, 130; Pet. Ex. 13 at 38, 52-53. Furthermore, petitioner's treaters suggested alternate causes for his symptoms; his gastroenterologist, Dr. Weber, concluded that petitioner's symptoms were more likely due to pernicious anemia than the hepatitis B vaccine, while others noted that his symptoms could be explained by his vitamin deficiencies. Pet. Ex. 1 at 44-47; Pet. Ex. 3 at 11, 62-63; Pet. Ex. 13 at 52-53, 58, 59; Pet. Ex. 15 at 4. These physicians also expressed concerns with petitioner's preoccupation with the hepatitis B vaccine and believed that he was suffering from somatization or a somatic disorder. *See* Pet. Ex. 3 at 6, 51, 63, 77; Pet. Ex. 13 at 52.

Dr. Chatham stated that, while it was possible petitioner's arthralgias were temporarily caused by adjuvants in the vaccine, all objective findings were easily explained by evolving osteoarthritis. Pet. Ex. 3 at 46. At his January 31, 2017 visit, Dr. Chatham noted no reaction to the hepatitis B vaccine was ever documented in petitioner's medical records and his symptoms were simply due to arthralgia and spondyloarthropathy. Pet. Ex. 19 at 115, 118.

On May 30, 2015, June 2, 2015, June 30, 2015, and August 12, 2015, petitioner's neurologist, Dr. Agnihotri, noted normal neurological examination despite petitioner's reports of vitamin B12 deficiency, fatigue, joint pain, and transverse myelitis connected to the hepatitis B vaccine. Pet. Ex. 1 at 60; Pet. Ex. 3 at 102; Pet. Ex. 13 at 32-36, 37-38. Dr. Agnihotri wrote that petitioner's symptoms were not related to the hepatitis B vaccine. Pet. Ex. 13 at 38. MRIs of the cervical and thoracic spine showed degenerative changes. Pet. Ex. 12 at 9-12. An MRI of his left knee was unremarkable. *Id*. at 13-14. Dr. Agnihotri documented her concern with petitioner's research on hepatitis vaccine and his theories about how his complaints were associated with the vaccine. She noted somatization and somatoform disorders, along with stress, as possible causes

of his symptoms. Pet. Ex. 13 at 52-53; Pet. Ex. 1 at 63. A brain MRI was negative. Pet. Ex. 12 at 15-16. On February 26, 2016, petitioner complained to Dr. Agnihotri of left-sided body pain from shoulder to upper hip, short term memory loss since the hepatitis B vaccination, now improved, and concern for "macrophagic myofasciitis" from aluminum adjuvants and myopathy secondary to hepatitis B vaccination according to the literature. Pet. Ex. 3 at 7-8. Dr. Agnihotri assured petitioner that the EMG showed no myopathy, there was no need for tissue biopsy, and his vitamin B12 deficiency could explain his symptoms. The doctor again expressed concern over somatization or somatoform disorder and suggested counseling, which was refused. *Id*. at 11.

On July 8, 2015, Drs. Weber and Black, petitioner's gastroenterologists, noted the history petitioner provided of ongoing fatigue, subjective weakness in his arms, vitamin B12 deficiency due to pernicious anemia, and improvement of symptoms with vitamin B12 supplements. Pet. Ex. 13 at 55, 58. Dr. Weber concluded on July 22, 2015, that petitioner's symptoms were likely due to pernicious anemia rather than hepatitis B vaccine. Pet. Ex. 1 at 44, 47. An abdominal MRI on August 27, 2015 ruled out inflammatory bowel disease or mass. Pet. Ex. 12 at 17-18. A colonoscopy on July 24, 2015 revealed only hemorrhoids. In follow-up on July 29, 2015 and October 1, 2015, Dr. Weber attributed petitioner's symptoms to anemia from autoimmune gastritis/pernicious anemia. Pet. Ex. 1 at 29; Pet. Ex. 3 at 48-49, 51.

On August 12, 2015 and September 8, 2015, petitioner reported to his primary care physician that his ongoing knee pain "tissue disorder" was connective tissue disease connected to hepatitis B vaccine. Pet. Ex. 3 at 64. He was again noted to be agitated, anxious, and angry, with belligerent, compulsive, and abnormal/psychotic thoughts. *Id*. at 57, 64.

Dr. Smith, a rheumatologist, found no evidence of inflammatory arthritis, but evidence of osteoarthritis was confirmed by MRI at his July 23, 2015 and August 28, 2015. Pet. Ex. 1 at 34-35, 39; Pet. Ex. 3 at 70-71, 76. Dr. Smith did not see a connection between hepatitis B vaccine and osteoarthritis and agreed with Dr. Agnihotri that it was likely somatization. *Id*. at 40; Pet. Ex. 3 at 77. Petitioner demanded to see the head of the department, Dr. Chatham.

On October 12, 2015, Dr. Chatham wrote "[petitioner] has had numerous serologic as well as imaging evaluations done in the past year all of which have been unrevealing for any evidence of acute phase response, autoantibody titer elevations, rheumatoid factor elevation or any evidence of inflammatory changes referable to his knees." Additionally, all MRIs have been unremarkable. Pet. Ex. 3 at 42-43. "It is possible his arthralgias were accentuated by adjuvants in the administered HBV vaccine, but there is no objective evidence of chronic joint inflammation presently. Current objective findings on exam and imaging are all easily explained by evolving osteoarthritis" *Id*. at 46.

Petitioner then reported a need for his aluminum level to be checked as a result of the adjuvant in the hepatitis B vaccine. Pet. Ex. 3 at 29-30. In March of 2016, petitioner advised that the left side of his body hurt from all three hepatitis vaccines received in his left arm, demanding testing and treatment. Dr. Salser advised petitioner that his anxiety was exacerbating his complaints and suggested a psychiatrist. *Id*. at 6.

On January 29, 2016, Dr. Chatham wrote "suspected (undifferentiated) spondyloarthropathy, lab results are unremarkable." Pet. Ex. 3 at 19, 24. On April 12, 2016, he documented a diagnosis of osteoarthritis of the neck, knee, and left elbow with myalgias. Pet. Ex. 13 at 72. An elbow x-ray on July 26, 2016 was negative. Dr. Chatham wrote early osteoarthritis signs observed from knee exam and probably left elbow. *Id*. at 76, 79. On October 14, 2016, Dr. Chatham noted bloodwork was unremarkable. Pet. Ex. 19 at 137, 141-42. Dr. Chatham's impression on January 31, 2017 remained neck, knee and left elbow osteoarthritis and myalgia. *Id*. at 118. An MRI of his left elbow was unremarkable. *Id*. at 110. On April 25, 2017, Dr. Chatham noted no signs of uveitis. *Id*. at 87. On May 7, 2017, Dr. Chatham emailed petitioner with a diagnosis of seronegative spondyloarthropathy, osteoarthritis of the cervical spine and knees. Pet. Ex. 14 at 1. Dr. Chatham next saw petitioner on March 26, 2018, at which time he had no ocular complaints or gastrointestinal complications. Dr. Chatham wrote "early [osteoarthritic] changes referable to knee by exam, MR; cervical disc disease by cervical radiogrpahs (sic), R; probably component of post-traumatic [osteoarthritis] of the left elbow." Pet. Ex. 31 at 11.

In 2016, Dr. Gewin, an internist, was advised by petitioner that he had been diagnosed with UCTD by Dr. Chatham and by others as well as with atrophic gastritis and vitamin B12 deficiency associated with hepatitis B vaccine. Bloodwork conducted at that time was normal for TSH, antibodies, tissue transglutaminase, ANA factor, and rheumatoid factor. Pet. Ex. 15 at 4, 6. His ferritin level was low. *Id*. Petitioner advised Dr. Gewin he was administered the hepatitis B vaccines when he already had painful joints.[64] *Id*. at 5.

Petitioner presented to Dr. Nozaki in August of 2016, reporting myalgias caused by hepatitis B and advising that he contacted a doctor in France that thinks hepatitis B can cause MS and myopathy. Pet. Ex. 13 at 84. He was concerned he had macrophagic myofasciitis from aluminum adjuvants. *Id*. at 85. Dr. Nozaki found no evidence of myalgias, rashes, or joint swelling. *Id*. at 87. Based on the history provided by petitioner, Dr. Nozaki concluded that he may have had a systemic autoimmune reaction to the vaccine, but an ongoing myopathy was unlikely due to his normal strength and lack of myalgia. *Id*. at 88.

Petitioner visited several other doctors, including ophthalmologists, who documented the history that petitioner provided, but did not diagnose any conditions related to hepatitis B vaccine. Pet. Ex. 18 at 1, 5; Pet. Ex. 19 at 7-10, 57-62; Pet. Ex. 28 at 1; Pet. Ex. 29 at 2; Pet. Ex. 32 at 1-5; Pet. Ex. 33 at 1.

The undersigned is compelled to objectively weigh the contemporaneous medical records. In doing so, the consistent opinions of petitioner's physicians that his complaints and symptoms are unrelated to the hepatitis B vaccines he received are more persuasive than two letters written by Dr. Chatham which are inconsistent with his impressions and contemporaneous medical records from visits with the petitioner in which he documented his hesitancy in attributing petitioner's symptoms to the vaccine. Contemporaneous medical records are assumed to be "complete," and

[64] There were no records filed documenting any complaints of joint pain in 2013 or 2014 prior to or at the time of his vaccinations; however, if so, petitioner has admitted to the onset of joint pain prior to his vaccinations. His records do, however, show complaints of abdominal pain, referral to a gastroenterologist and need for objective testing dating back to 2012, as well as vitamin D deficiency. Pet. Ex. 1 at 8; Pet. Ex. 3 at 140, 143-46.

none of petitioner's other treating physicians provided a causal link between the vaccine and any of petitioner's symptoms.

There is insufficient proof to support a logical sequence of cause and effect connecting petitioner's alleged development of or significant aggravation of UCTD, ankylosing spondylitis, seronegative symmetric arthritis, vitamin B12 deficiency, or any other condition to the hepatitis B vaccinations he received. Accordingly, petitioner has not satisfied the second prong of *Althen* and the fifth factor of *Loving*.

3. *Althen* Prong 3/*Loving* Factor 6: No Proximate Temporal Relationship

To satisfy the sixth factor of *Loving*, which requires petitioner show a proximate temporal relationship between his hepatitis vaccinations, which he received on August 14, 2013, December 17, 2013, and May 16, 2014, and his alleged symptoms and/or conditions, petitioner would need to demonstrate an appropriate timeframe for causation or significant aggravation of those conditions following a hepatitis B vaccine. Since petitioner cannot show that the hepatitis B vaccine can cause or significantly aggravate any of his claimed conditions, petitioner cannot show what a reasonable timeframe for the cause or significant aggravation of such conditions following hepatitis B vaccination would be. *Langland v. Sec'y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013) ("[T]o satisfy the 'proximate temporal relationship' prong of the *Althen* test, petitioners must demonstrate, by a preponderance of the evidence, that the onset of symptoms occurred within a time frame for which it is medically acceptable to infer causation-in-fact….With no reputable theory as to how the vaccination could cause the injury, this exercise is not possible.") (citing *De Bazan*, 539 F.3d at 1352).

The facts and timeframe upon which Dr. Chatham based his opinions were factually inaccurate and inconsistent with the medical records. In any event, Dr. Chatham's letters state that petitioner developed ankylosing spondylitis "after" or "subsequent to" his hepatitis B vaccinations. As a function of time and place, petitioner certainly received his vaccinations in 2013 and 2014, and saw Dr. Chatham for the first time in October of 2015, so petitioner's alleged injuries would undoubtedly be at some time "after" or "subsequent to" his vaccinations from Dr. Chatham's perspective based on the history provided by petitioner. However, Dr. Chatham did not discuss a medically appropriate timeframe between the receipt of the hepatitis B vaccination(s) and the onset of ankylosing spondylitis, seronegative symmetric arthritis or any other condition if the hepatitis B vaccines could or did cause these conditions. Further, petitioner's medical providers, within their respective specialties in diagnosing petitioner's other conditions, specifically discounted his insistence that any of these medical conditions were related to hepatitis B vaccinations. Moreover, petitioner had no documented complaints after any of his hepatitis B vaccination. His first reported complaints that he associated with his August and December 2013 and May of 2014 hepatitis B vaccinations was reported in May of 2015 as knee pain in June of 2014 and a cold in February of 2015 that lasted too long. Then in June of 2015, he reported a "paralytic attack" with inability to get out of bed on May 16, 2014. *Id.* Then on May 27, 2014, he "began to have [an] electric shock sensation followed by numbness in bilateral hands and arms." *Id.* at 121. Petitioner sought no medical care following these alleged reactions and offered no support for how hepatitis B vaccine can be temporally associated with any of these events.

Accordingly, petitioner has failed to present preponderant evidence to support the third prong of *Althen* and the sixth factor of *Loving*.

4. *Loving* Factor 1: Petitioner's Condition Prior to the Hepatitis B Vaccinations

Prior to petitioner's receipt of the hepatitis B vaccinations, he suffered from upper abdominal pain, diarrhea, anal fistula, rectal pain and bleeding, and perianal papillary lesions with itching. *See* Pet. Ex. 1 at 18, 20-21, 161, 169, 197; Pet. Ex. 2 at 3-7; Pet. Ex. 3 at 143-46. He worried about liver disease. Pet. Ex. 1 at 18. He presented to the emergency room for abdominal pain and rectal bleeding. *Id.* at 161, 169, 171, 197, 203, 205, 209. He was referred to a gastroenterologist due to his ongoing issues and a lot of questions. Pet. Ex. 3 at 141. He also suffered from male pattern hair loss, with erythema, folliculitis, and cutis xerosis of the scalp, seborrheic dermatitis and vitamin D deficiency. *See* Pet. Ex. 1 at 14-16; Pet. Ex. 3 at 147-49.

5. *Loving* Factor 2: Petitioner's Condition Following the Hepatitis B Vaccinations

At the time that he received his first hepatitis B vaccination on August 14, 2013, petitioner was noted to have a rectal mass, vitamin D deficiency, eczema, and hypertriglyceridemia, among other conditions. *See* Pet. Ex. 3 at 139-41. One week later, petitioner underwent incision and drainage of a preexisting perianal fistula. *See* Pet. Ex. 1 at 575-76. The records reflect that petitioner did not receive any medical care between a post-op follow-up visit on September 5, 2013, and his receipt of the second hepatitis B vaccination on December 17, 2013. *See* Pet. Ex. 3 at 137-38; Pet. Ex. 1 at 177. The records further reflect that petitioner did not receive any medical care between his second hepatitis B vaccination and his third hepatitis B vaccination on May 16, 2014. *See* Pet. Ex. 1 at 176.

Petitioner's next medical visit was on February 19, 2015, nine months after his third hepatitis B vaccination, when he presented for cough, sore throat, and left-sided abdominal pain. *See* Pet. Ex. 3 at 131-36. On May 18, 2015, approximately one year after his third hepatitis vaccination, petitioner presented with knee pain in June of 2014. *See id.* at 126. He also reported in June of 2015 that he had a paralytic attack and was rendered paralyzed after his May 2014 vaccination but sought no medical care. Pet. Ex. 13 at 24-27.

Thereafter, petitioner spent over four years, presenting to many physicians of varying specialties, undergoing numerous tests, most of which ruled out diseases and conditions, with few definitive diagnoses made. He was found to have degenerative changes on MRI of his cervical and thoracic spine; modest iron deficiency; chronic atrophic gastritis without bleeding; unspecified iron deficiency anemia; unspecified vitamin D deficiency and possible somatization; anemia due to hypochlorhydria from autoimmune gastritis and/or pernicious anemia; mild osteoarthritis of the neck, left knee, and left elbow; hemorrhoids; HLA-B27; vitamin B12 deficiency; low ferritin level; polyarthralgia and bilateral shoulder pain; suspected undifferentiated spondyloarthropathy; seronegative spondyloarthropathy; osteoarthritis of the cervical spine and knees; labral tear of the right hip with no evidence of synovitis; disc protrusion at T1-2 with no focal cord abnormalities; dry eyes and sinus problems; keratoconjunctivitis sicca and myopia with presbyopia in both eyes; and blepharitis of both eyes. *See* Pet. Ex. 1 at 29, 34-35, 39, 44, 47; Pet. Ex. 3 at 11, 19, 41-43, 46-

51, 75; Pet. Ex. 12 at 9-12; Pet. Ex. 13 at 72, 79; Pet. Ex. 14; Pet. Ex. 15 at 6; Pet. Ex. 18 at 5; Pet. Ex. 19 at 114, 137; Pet. Ex. 31 at 18, 20; Pet. Ex. 32 at 4; Pet. Ex. 33 at 4.

As of August 7, 2017, Dr. Wilcox was unable to link any of his complaints to some specific bowel disease and finding anti-gastric parietal cell antibodies to be positive, concluded the result "may reflect the presence of atrophic gastritis." Pet. Ex. 19 at 62-64. The diagnosis was not definitive, and a subsequent sigmoidoscopy showed only mild inflammation. *Id*. at 7-10.

6. *Loving* Factor 3: Petitioner's Condition Was Not "Significantly Aggravated" by the Hepatitis B Vaccinations

The statute describes "significant aggravation" as "substantial deterioration" or "markedly greater" illness or disability, neither of which petitioner experienced following his hepatitis B vaccinations. *See* 42 U.S.C. § 300aa-33(4).

Petitioner suffered from gastroenterological and dermatological conditions prior to receiving the allegedly causal hepatitis B vaccinations; he also had a vitamin D deficiency. Based on the medical records filed, petitioner did not experience "substantial deterioration" secondary to any of these conditions after receiving the hepatitis B vaccinations. Beginning nine months after his third hepatitis B vaccination, petitioner complained of a wide variety of symptoms. In the years following, he received many diagnoses including vitamin B12 deficiency, possible pernicious anemia, possible chronic atrophic gastritis, and osteoarthritis of the neck, elbow and knee. None of these conditions were connected to his hepatitis B vaccinations. The medical records as a whole fail to support petitioner's allegation that he experienced "significant deterioration" as a result of his hepatitis B vaccinations.

IV. Conclusion

The petitioner herein undoubtedly lives with pain in his neck, left elbow and left knee as well as with many gastrointestinal issues he has had for years. He is certainly convinced the hepatitis vaccinations he received have caused him to suffer based on his extensive research and this has caused him a great deal of stress. It is hoped that he finds solace in the results of numerous objective tests that have ruled out any of the diseases and conditions he has found in the literature and he fears. To that end, there is no support in the record that petitioner suffers from any disease or condition causally related to the receipt of hepatitis B vaccinations.

Therefore, upon careful evaluation of all of the evidence submitted in this matter—including the medical records, Dr. Chatham's letters, medical literature, submissions by the parties and affidavit of petitioner—the undersigned concludes that petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. The petition is therefore dismissed.

In the absence of a timely filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[65]

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[65] Pursuant to Vaccine Rule 11(a), if a motion for review is not filed within 30 days after the filing of the

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

special master's, the clerk will enter judgment immediately.