In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 13-601V
(Not to be published)

* *	Special Master Corcoran
RONDA MORRIS, *	
Petitioner, *	Filed: May 9, 2017
v. *	
SECRETARY OF HEALTH AND HUMAN SERVICES, *	Hepatitis B ("Hep B") vaccine; Vitiligo; Internal Itching; Onset; Autoimmune Condition
Respondent. *	
* *	

DECISION DENYING ENTITLEMENT[1]

Dan W. Bolton, III, Bolton Law, PLLC, Cary, NC, for Petitioner.

Alexis Babcock, U.S. Dep't of Justice, Washington, DC, for Respondent.

On August 22, 2013, Ronda Morris filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"), alleging that she experienced internal itching and vitiligo after receiving the Hepatitis B ("Hep B") vaccine on October 22, 2010.[2]

[1] This Decision has been designated "not to be published," which means I am not directing it to be posted on the Court of Federal Claims's website. However, because it contains a reasoned discussion of my adjudication of the claim herein, it will nevertheless eventually be available electronically, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (Dec. 17, 2002 (current version at 44 U.S.C. § 3501 (2014)). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) provides that each party has 14 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 decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

An entitlement hearing in this matter was held on January 10, 2017. After considering the record as a whole, and for the reasons explained below, I find that Petitioner has failed to carry her burden in establishing causation, and therefore is not entitled to compensation under the Vaccine Program.

I. FACTUAL BACKGROUND[3]

Medical History Prior to Vaccination

Ms. Morris's filed medical history references few relevant significant health problems prior to the receipt of the vaccine at issue herein, with one notable exception. Ex. 1 at 60. In June 2006 (four years prior to the vaccination at issue in this case), Petitioner saw her general practitioner, Dr. Charles Rhodes at Cabarrus Family Medicine ("CFM") in Mount Pleasant, North Carolina, because she was planning to travel for a mission trip with her church and needed to receive the Hepatitis A ("Hep A") vaccine in order to do so. Ex. 9 at 3. When she returned from her trip about one month later, she reported persistent foot problems that were determined by Dr. Rhodes to be due to infected blisters. *Id*. at 7. On August 14, 2006, she returned to Dr. Rhodes reporting progressive paresthesias in her right lower extremity. *Id*. Over the next year, doctors attempted to determine what caused the paresthesias, ruling out multiple sclerosis (MS), Parkinson's, and other demyelinating conditions. Ex. 1 at 58-62. By February 14, 2007, however, Petitioner's symptoms had resolved completely. Ex. 9 at 15-16.

Vaccination and Subsequent Medical History

In 2010, Ms. Morris was required to receive the Hep B vaccine as part of a medical sciences training program she had begun. Ex. 1 at 7. She expressed concern to Dr. Rhodes about receiving the vaccine, given her seeming to have had a prior reaction to the Hep A vaccine in 2006. *Id*. Dr. Rhodes, however, proposed that it was safe for her to receive the Hep B vaccine, noting that "whatever happened before has resolved - neurology thought this was Parkinson's and not a reaction to vaccine." *Id*. at 24. Thus, on October 22, 2010, Petitioner received the Hep B vaccine, along with a complete physical, in which it was noted that she "c/o [complained of] cough, chest burning, sinus drainage, and fatigue x 3 weeks." *Id.* at 22.

Ms. Morris's next doctor's visit occurred three weeks later, on November 11, 2010, when she presented to her gynecologist, Dr. Natalie Saylor. Ex. 3 at 3. At the visit, she reported "breast tenderness, nipple pain, cramping feeling in her lower pelvis," and expressed concern that although

[3] The following is taken from the medical record filed in this case, as well as the testimony of Ms. Morris at hearing. *See generally* Tr. at 6-47.

she was postmenopausal, she might be pregnant. *Id*. Ms. Morris's testimony at trial mentioned symptoms she recalled experiencing before visiting Dr. Saylor, including one incident "when I was using the bathroom I felt this—just the sensation inside of this irritation, itching." Transcript ("Tr.") at 9. Such symptoms persisted, and so she returned to see Dr. Saylor on November 23, 2010 (one month after vaccination), now reporting that she had begun to experience intermittent "itchiness" in her uterus. *Id*. at 1. After performance of a pelvic examination and ultrasound, Dr. Saylor confirmed that Ms. Morris was menopausal and that pregnancy was not likely. *Id*. at 2. The ultrasound was normal with the exception of the presence of a follicle on Petitioner's left ovary. *Id*. at 7.

On December 17, 2010, Ms. Morris returned to CFM and saw Dr. Amanda Graham, reporting that she was feeling itching on the inside of her lower abdomen. Ex. 1 at 17. The records from this visit are inconsistent regarding the onset of these symptoms, suggesting that they had existed "x3 weeks to a month," but also that they had been "occurring in an intermittent pattern for 6 weeks," and that the sensation had begun after receipt of the Hep B vaccine. *Id*. The impression notes from the visit state "likely a reaction from vaccine," but recommended the use of Benadryl for the itching. *Id*. at 18. Dr. Graham also planned to rule out yeast infections as a cause, and considered referring Ms. Morris to an allergist. *Id*. Ms. Morris underwent a complete blood count and a comprehensive metabolic panel; both were normal, with the exception of a slightly elevated bilirubin level, a slightly low absolute lymphocyte count, and a mildly high mean corpuscular hemoglobin count.[4] *Id*. at 19-20. During this time, Ms. Morris reported taking up to four baths a day to relieve the itching she was feeling when she drank water or ate food. Tr. at 9.

Petitioner next visited Dr. Rhodes on March 4, 2011, for a follow up visit and to receive documentation of her previous vaccination reactions. At this time, Dr. Rhodes discussed with Petitioner her reaction and possibly receiving an exemption from further vaccination that might otherwise be required by the medical treatment assistance program she was planning on attending. Ex. 1 at 13. Ms. Morris did not at this visit mention any skin irritation or concerns, however, and the physical exam performed on that day noted her skin to be normal. *Id*. at 14. Ms. Morris returned to Dr. Rhodes three months later, in June 2011, for an evaluation prior to entering school, and again the record indicates that she felt well and had no new or recurring complaints. *Id.* at 9. As a result of the June evaluation, Petitioner was determined to have immunity to measles, mumps, rubella, and varicella viruses, while tests for Hep B antibodies were negative. *Id*. at 11.

[4] None of these results seem to have given Dr. Rhodes or Dr. Graham cause for concern, as there is no records of treatment reacting to or directed at these findings.

Discovery of Skin Problems

The first documented skin problems for Ms. Morris appear from the record of her July 5, 2011 (nine months after vaccination) visit to Dr. Melissa Coale at the Dermatology Group of the Carolinas ("DGC"). After a beach trip, Petitioner had noticed white spots on her skin. *See generally* Ex. 4 at 1. The record from this visit to the dermatologist indicates that Ms. Morris observed the spots over "the past three to four months" (or since April or March). *Id.* At trial, however, Ms. Morris testified that she had begun to notice similar white spots on her back as early as November or December 2010, and that she had called Dr. Rhodes immediately thereafter (although the record contains no proof of that call). Tr. at 39. When asked why she had waited nearly seven months, or until July 2011, to seek treatment, she stated that "I didn't have the money, for one thing, and I was going to school." *Id*. at 40. She further testified that she continued to notice the spots in the first half of 2011 and asked treaters about them, but was told there was not much to be done.[5] *Id*.

At DGC, Dr. Coale took down Petitioner's recited medical history, including the internal itching she reported to have experienced since receipt of the Hep B vaccine. Ex. 4 at 1. She performed an examination of Ms. Morris's body, noting that Petitioner had "numerous nummular, depigmented patches," ranging from 1mm to 4mm in size, on her posterior shoulders and back. *Id*. Dr. Coale concluded that Ms. Morris had "[m]ultiple halo nevi[6] occurring acutely after a hepatitis B vaccine. Whether this stimulated her immune system to react to nevi is unclear." *Id*. Petitioner was instructed to stay out of the sun and to return to Dr. Coale in October for reevaluation. *Id*.

Not long after this dermatology visit, Petitioner was contacted by CFM on July 25, 2011, regarding what needed to be included in another letter to Petitioner's school in order to exempt her from future vaccination. Ex. 9 at 2. Petitioner informed Dr. Rhodes that she needed the letter to explain to the school that she was allergic to all vaccines, including flu, tetanus, and Hep B, and that she would be unable to receive any further vaccination. *Id*. In addition, Ms. Morris indicated that she would be unable to have the necessary tuberculosis test performed given her current skin issues, which had now been diagnosed as vitiligo, and would need a chest x-ray instead.[7] *Id*. Dr.

[5] It is unclear which doctors Ms. Morris is referring to, however, as there is not a record of her reporting the vitiligo symptoms prior to July 2011. However, she stated that her doctor visits during the relevant time period (November 2010-2011) were focused on the itching she was continuing to experience, "I didn't go for vitiligo because, I mean, they—you know, they knew I had it. They could see it." Tr. at 46.

[6] A halo nevi is a melanocytic nevus (mole) surrounded by a halo of depigmentation that may be an immune response to the nevus cells. *Dorland's Medical Dictionary* 373 (32nd ed. 2012) (hereinafter "*Dorland's*").

[7] It is not clear which doctor diagnosed Ms. Morris with vitiligo, or when the diagnosis occurred. Respondent requested that if Ms. Morris visited an additional dermatologist that those records be filed, but no such records were filed and the treater who diagnosed her with vitiligo remains unknown. *See* Respondent's Rule 4(c) Report, filed on Jan. 6, 2014 (ECF No. 14).

Rhodes prepared and signed the exemption letter on July 27, 2011. Ex. 11 at 2. However, Petitioner was unable to continue with her medical assisting degree, and withdrew in the fall of 2011. Ex. 7 at 3.

Subsequent Vitiligo Treatment

A year later, on July 19, 2012, Petitioner was seen by Dr. Laura Briley at The Dermatology & Skin Cancer Center. This visit was primarily focused on treatment of Ms. Morris's skin conditions, which included starting Clobetasol.[8] *Id*. Ms. Morris's history of vitiligo was reported as scattered all over her body for the prior two years. Ex. 6 at 3. Petitioner returned to Dr. Briley the following month, reporting that the Clobetasol was causing white rings on her body; when the medication was stopped, the color returned in her skin. *Id*. at 1. Due to this reaction, Ms. Morris was taken off Clobetasol and started on Protopic.[9] *Id*. Dr. Briley noted that Ms. Morris voiced her suspicion that preservatives in the Hep B vaccine had caused her vitiligo. Dr. Briley also speculated whether a preservative contained in the Clobetasol could similarly be causing a reaction. *Id*.

On October 14, 2013, Ms. Morris sought treatment at Saddleback Medical Group-Dermatology, with Dr. Daniel K. McKenzie, for a chief complaint of skin discoloration. Ex. 10 at 1. Much of the visit was dedicated to counseling Ms. Morris on treatment options for vitiligo and the lentigines and cherry angiomas that were diagnosed at the visit.[10]

II. EXPERT TESTIMONY

A. Dr. Richard Horan

Dr. Horan, Petitioner's expert, filed three expert reports in this case, and also testified at the hearing. *See e.g.* Expert Report, filed as Ex. 14, on Sept. 10, 2014 (ECF No. 27) ("Horan First Report"); Supplemental Expert Report One, filed as Ex. 16, on March 16, 2015 (ECF No. 32)

[8] Clobetasol is a strong corticosteroid, similar to prednisone, which is used for relief from itching and inflammation. *Dorland's at* 373.

[9] Protopic is the brand name for tacrolimus, which is used topically to help ease severe atopic dermatitis. *Dorland's* at 1868.

[10] Lentigines are small, flat, macular melanosis on the skin, tan to dark brown or black in color. They resemble freckles but are distinguishable by the increased number of normal-appearing melanocytes that do not darken with sun exposure. *Dorland's* at 1022. Cherry Angiomas are bright red/purple, smooth, dome-shaped lesions, usually found on the trunk or proximal end of the limb. *Id*. at 85.

("Horan Second Report"); and Supplemental Expert Report Two, filed as Ex. 3[11] on Nov. 11, 2015 (ECF No. 51) ("Horan Third Report"); Tr. at 49-98.

Dr. Horan graduated from Harvard Medical School in 1980 (after obtaining his bachelor's degree at Harvard as well). Ex. 15 (CV) at 1. He then served as a resident in dermatology at Massachusetts General Hospital, followed by a clinical fellowship in Rheumatology-Immunology at Brigham and Women's Hospital in Boston, Massachusetts. *Id*. He continues to serve as a physician at Brigham and Women's Hospital as well as holding a teaching position in Dermatology at Harvard Medical School. *Id*. Dr. Horan is board-certified in dermatology, allergy/immunology, and internal medicine. *Id*. He currently sees and treats both allergy and dermatologic patients at Brigham and Women's Hospital, as well as writing and researching in those areas. Tr. at 51. Dr. Horan also has a clinical practice in dermatology, in total, seeing patients six days per week. *Id*. at 52. He estimated that he sees several cases of vitiligo every month, whether it be treating for an existing diagnosis or diagnosing the patient himself. *Id*.

Dr. Horan proposed that vitiligo could be the end result of an autoimmune hypersensitivity reaction brought on by receipt of the Hep B vaccine, but manifesting initially through the internal itching Petitioner claims to have experienced. Horan First Report at 3. His testimony began by addressing why, in his opinion, vitiligo was an autoimmune condition. Tr. at 56-58. As Dr. Horan explained, vitiligo was widely understood to be highly associated with other autoimmune conditions, such as alopecia areata, Addison's disease, or pernicious anemia,[12] and is thus viewed to be likely autoimmune in character as well. *Id*. at 57. While this view reflects the consensus of the dermatology community, Dr. Horan admitted that the precise pathophysiology of vitiligo remains somewhat unknown.

Dr. Horan next distinguished between different kinds of "hypersensitivity reactions" in tissues and organs that could reflect the initiation of such an autoimmune process. Tr. at 58-59. He described immediate hypersensitivity as an adverse reaction that occurs quickly, in minutes or hours after exposure, such as a peanut allergy. *Id*. at 59. By contrast, delayed hypersensitive reactions take longer to manifest; Stevens-Johnson syndrome,[13] for example, is typically a weeks or months-long reaction to medication that begins with flu symptoms but ultimately results in a

[11] On November 11, 2015, Petitioner's counsel filed all three expert reports as ECF No. 51 (1-3). He improperly labeled Dr. Horan's third report as Exhibit Three, however, given an existing exhibit was already so designated.

[12]Alopecia areata is patchy, non-scarring, asymmetric hair loss, with an unknown etiology but many patients have an autoimmune component. *Dorland's* at 53. Addison's disease is a condition characterized by hypotension, weight loss, anorexia, weakness, and a bronze-like hyper-pigmentation of the skin. *Id*. at 528. Pernicious anemia a type of anemia caused by impaired intestinal absorption of vitamin B12 due to lack of availability of intrinsic factor. *Id*. at 79.

[13] Stevens-Johnson syndrome is characterized by a respiratory (often flu-like symptoms) prodromal period before mucocutaneous lesions appear along with other symptoms. *Dorland's* at 1849.

severe rash. *Id*. Dr. Horan proposed that an analogous, more delayed reaction occurred in the instant case. He stated that although rare, there is literature supporting an association between the Hep B vaccine and a cell-mediated autoimmune phenomenon (like Stevens-Johnson syndrome) that can occur with the lymphocytes at the dermal/epidermal junction. He further specified that this case best reflected a Type IV hypersensitivity reaction, beginning with internal itching later developing into vitiligo. *Id*. at 59, 77.

Regarding the timing and onset of Petitioner's vitiligo, Dr. Horan stated that he was unaware of any specific timeframe in which vitiligo would be understood to begin and then develop. Tr. at 66-67. Moreover, like other autoimmune conditions, vitiligo has the possibility of indefinite prolongation, including periods of remittance comingled with periods when new lesions grow. *Id*. at 67. Due to its potentially lengthy and unpredictable clinical course, the first lesion in vitiligo could be very small and remain unnoticed for some time, further complicating efforts to identify the condition's onset. *Id*. at 69. When asked further about the length of an expected immune response, Dr. Horan stated that when a patient receives a vaccine, any reaction could continue for the length of time that the vaccine was meant to remain effective, or possibly even longer. *Id.*at 69. He thus proposed that the onset of Ms. Morris's itching, in the three to four weeks post-vaccination, was consistent with what would be expected for a vaccine-induced reaction. *Id*. at 71.

During cross examination, Dr. Horan was confronted with some of the unknown variables of his theory as applied to the Hep B vaccine. *See generally* Tr. at 81-90. He admitted that he could not specify a biologic mechanism by which the Hep B vaccine would result in vitiligo. *Id*. at 82. Moreover, he agreed that there is no scientific or medical literature linking the two, nor has there been a single case report of vitiligo occurring as a documented reaction to the Hep B vaccine. *Id.* at 85-86. Dr. Horan further acknowledged that Ms. Morris did not report any vitiligo-like skin symptoms during the first few months after vaccination. *Id*. at 83. He noted, however, that the presence of a halo nevi can be the first initial presenting symptom of vitiligo but may not be observed for some time; affected individuals often only notice them after a trip to the beach, because other parts of the skin have tanned but those spots remain without pigment. *Id*. at 94.

Although Dr. Horan stated that it would be relatively rare for a patient with vitiligo to experience internal itching as an initial symptom, he proposed that her November symptoms were related to the vitiligo she eventually developed, reflecting the start of an immune response that is not completely understood by the medical community. Tr. at 92. He admitted, however, that immunology is not his specialty, and he could not rely on his own expertise to posit other mechanisms that are common in the Program to explain an autoimmune reaction, such as the upregulation of cytokines. *Id.* at 96. He also confirmed that there was no testing in the record that would indicate an ongoing autoimmune process in the time period between vaccination and Ms.

Morris's discovery of her vitiligo. *Id.* at 97. And he admitted the absence of markers of autoimmunity, but stated that "[s]uch markers are inconsistently present in vitiligo." Horan Second Report at 1.

Accompanying Dr. Horan's reports were several pieces of medical literature, but most were focused on describing vitiligo and supporting Dr. Horan's contention that vitiligo is an autoimmune condition, rather than establishing a possible relationship between injury and vaccination based upon the facts of this case. Dr. Horan did, however, offer one piece of medical literature indicating that a DNA vaccine had induced vitiligo in mice. Zhou, Q, *et al. Down Regulation of Prdx6 Contributes to DNA Vaccine-Induced Vitiligo in Mice,* 2011 Molecular Biology Syst. 809-16, filed as Ex. 14, Tab I ("Zhou Article"). He also offered a second study focusing on an injection that was designed to kill cancer cells in the body (specifically melanoma) but which appeared to have caused vitiligo as a byproduct. Cecline Lane, *et al. Vaccination-Induced Autoimmune Vitiligo is a Consequence of Secondary Trauma to the Skin,* Am. Ass'n for Cancer Research, http://cancerres.aacrjournals.org/content/64/4/1509.long (last accessed April 14, 2017), filed as Ex. 6 of Prehearing Submissions. ("Lane Article").

Some of Dr. Horan's testimony and expert reports addressed the alternative causes proposed by Respondent's expert to explain Petitioner's symptoms. Horan Second Report at 1. The first was Gilbert's syndrome, a condition present in 15 percent of the population and characterized by elevated bilirubin levels in the blood. Tr. at 73. Dr. Horan suggested that Gilbert's syndrome could not convincingly explain the itching Mr. Morris experienced, because there is no literature that associates itching with the condition, adding that Gilbert's syndrome is most often diagnosed incidentally. *Id.* at 73-74. The other two proposed alternative causes were xerosis (dry skin) or a psychiatric condition. *Id.* at 74-75. Dr. Horan rejected both of those as well, stating that dry skin would not explain her internal itching or vitiligo, nor in his opinion did the record suggest that Petitioner was then experiencing stressors sufficient to have caused her symptoms. *Id.*

B. Dr. Emil Bardana

Dr. Bardana, Respondent's expert, submitted one expert report in this case, accompanied by four pieces of medical literature, and also testified at hearing.[14] *See e.g.* Ex. A, filed on Nov. 10, 2014 (ECF No. 28) ("Bardana Report"); Tr. 99-176.

[14] Yu, H, *et al. Surveillance for adverse events following immunization from 2008 to 2011 in Zhejiang Provence, China*, Clinical Vaccine Immunology, 20: 211-217 (2013); Grimes, P, *New Insights and New Therapies in Vitiligo,* JAMA 293:730-735 (2005); Gots, R, *Epidemiology: Its Application to Environmental Toxicology*, In: Toxic Risks: Science, Regulation and Perception. Lewis Publishers, Boca Raton (1993); and Manga, P. *et al.*, *Recent Advances in Understanding Vitiligo*, F1000 Research (2016).

Dr. Bardana completed his medical degree at McGill University in Montreal, Quebec, Canada (after receiving his undergraduate degree from Georgetown University in Washington, DC). Ex. E (CV) at 1. His residency was completed at Oregon Health Sciences University in Portland, Oregon in internal medicine and later in the division of immunology, allergy, and rheumatology. *Id*. Dr. Bardana spent most of his career as a professor in the Division of Allergy and Clinical Immunology at Oregon Health and Science University, while also maintaining a clinical practice. *Id*. at 2. He holds board certifications in allergy and immunology, and currently consults on worker's compensation cases specifically related to asthmatic conditions and occupational allergies. Tr. at 104. Dr. Bardana retired from his clinical practice in 2014, and now sees patients as an independent medical examiner performing evaluations for workers' compensation claims. *Id*. at 130. He stated that it would be unusual to see a patient with vitiligo in the performance of his present duties, and has likely seen only one such patient since his retirement. *Id*. at 131. While he was in clinical practice, however, he would occasionally see patients with vitiligo as an incidental disorder to an existing autoimmune condition. *Id*. at 134.

The Hep B vaccine, Dr. Bardana opined, had nothing to do with Petitioner's internal itching or vitiligo. Tr. at 108. His report and opinion separately discussed the conclusions he drew for each symptom of Ms. Morris's injury, beginning with her reported internal itching. Dr. Bardana stated that he did not find any evidence in the medical records of a generalized inflammatory process that could initially provoke such itching, given that there were no skin lesions of any kind, and that the testing that was ordered by Dr. Graham in December 2010 did not detect any inflammatory process. *Id*. at 109-10. Although Dr. Bardana admitted that itching after vaccination is fairly common, that itching typically begins within 24-48 hours and is localized to the injection site. *Id*. at 110. Dr. Bardana was not aware of any literature that associated generalized internal itching, or internal itching of the uterus, with the Hep B, or with any other vaccine. *Id*.

Dr. Bardana agreed that vitiligo is properly considered an autoimmune condition, if only due to its broader association with other autoimmune disorders. Tr. at 114. However, he stated that Ms. Morris never had any testing performed to determine if she was in fact experiencing an autoimmune process. *Id*. at 115. He also emphasized that, as Dr. Rhodes's findings indicated, Ms. Morris did not have immunity to Hep B – meaning it would be unlikely that she had experienced an autoimmune process at all post-vaccination. *Id*. at 116. Moreover, even if Petitioner had experienced a hypersensitive reaction after vaccination, that reaction would have occurred sooner than four to six weeks later, or when her itching reportedly began (and certainly sooner than when the vitiligo was officially observed as set forth in the medical records). *Id*. at 118.

As mentioned previously, some of Dr. Bardana's testimony was dedicated to suggesting three other causes that could explain Ms. Morris's condition. He stated that the most likely alternative cause in his opinion for her itching was external stress happening in Ms. Morris's life,

such as her divorce, a new career path, caring for an ailing mother, and navigating new relationships. Tr. 124-125. He supported this contention by generally referencing literature that found that patients can experience generalized itching when dealing with stress. *Id*. at 125. He also briefly mentioned Gilbert's disease and xerosis as alternative causes, but seemed to admit in his testimony that they were less likely to have occurred here. *Id*. at 124.

Dr. Bardana rejected the Zhou article offered by Dr. Horan to support the conclusion that the Hep B vaccine could cause vitiligo. Bardana Report at 14. The vaccine used in that study was a DNA vaccine still in the experimental phase of development, and not currently used on humans either (Zhou was a study involving mice). *Id*. Similarly, he argued that the Lane article offered by Dr. Horan finding a skin reaction after receiving an injection of cancer cells intended to induce an immune response to a melanoma tumor was likewise irrelevant to the Hep B vaccine. Tr. at 122. That injection was *intended* to provoke a response in skin cells, making the vitiligo associated with it distinct from vitiligo alleged to have resulted from the immune response induced by a different vaccine (and one directed at a different kind of infection in any event).

III. PROCEDURAL BACKGROUND

This case was filed on August, 22, 2013. Relevant medical records were filed through the end of that year, and Respondent's Report contesting entitlement was filed on January 6, 2014. Shortly thereafter, the case was transferred to me, and Petitioner continued to file medical records. I set a deadline for the summer of 2014 for her to file her expert report, and she did so on September 10, 2014, followed in two months by Respondent's expert report.

In the ensuing year, the parties engaged in settlement discussions, but they ended unsuccessfully on September 16, 2015, after Petitioner obtained a new counsel of record. Thereafter, I set a deadline for Petitioner to file a supplemental expert report, and a hearing was scheduled in the case for January 10-11, 2017, in Washington, DC. *See* Prehearing Order filed on Dec. 17, 2015 (ECF No. 57). The parties timely filed their prehearing briefs, and the hearing was held as scheduled.

The parties elected not to file post-hearing briefs, so this matter is ripe for a decision. Tr. at 186.

IV. PARTIES' RESPECTIVE ARGUMENTS

In her prehearing brief, Petitioner argued that the Hep B vaccine was more likely than not the cause of her internal itching and vitiligo. *See* Petitioner's Prehearing Brief, filed on Feb. 15, 2016 (ECF No. 64)("Pet'r's Brief"). She supports that argument with the confirmation of treating

physicians like Dr. Rhodes, who independently opined that the vaccine (through a hypersensitive immune response) was the cause of her condition. *Id*. at 6-7. Petitioner also pointed to the IFNgama driven inflammatory pathway as a possible pathogenesis for her condition. *Id*. at 7; *see also* Rork, *et al.*, *Understanding Autoimmunity of Vitiligo and Alopecia Areata*, Wolters Kluwer Health, Vol. 28, 463 (2016), filed as Ex. 4 ("Rork Article").

In addition, Petitioner argued that the knowledge and experience of her treating physicians, the lack of intervening factors that could have caused her vitiligo, and the existence of no persuasive alternative diagnosis all supported her position. Pet'r's Brief at 7. Petitioner also relied heavily on the package inserts for the Hep B vaccine that warn against autoimmune reactions generally. While Petitioner recognized that her causation theory relied upon what she characterized as "out of box" medical reasoning due to what she characterized as the non-linear progression of her post-vaccination symptoms, she maintained that vitiligo is a condition that varies greatly with a somewhat unknown incubation period, prodromal period, clinical course, and cause, thereby making it possible that it occurred in her case despite gaps in the record (especially in the temporal sense). *Id*. at 8. She particularly acknowledged that there is no known, established timeline for the development of autoimmune vitiligo, but maintained that in this case the temporal relationship can established by "deductive and inductive reasoning alone." *Id.* at 10.

Respondent argued in opposition that Petitioner could not prove a medically plausible theory connecting the Hep B to vitiligo. *See* Respondent's Prehearing Brief, filed on Nov. 21, 2017 (ECF No. 62) ("Respondent's Brief"). Further, Respondent maintained that there was no evidence in the record that any inflammatory or immune response was occurring in Petitioner in the months after vaccination. *Id*. at 6. In addition, Respondent argued that the time that passed between vaccination and injury was too long to support a theory that Petitioner had experienced a hypertensive reaction to the Hep B vaccine. *Id*. Petitioner subsequently filed a short reply brief (ECF No. 64, dated December 15, 2016) emphasizing Petitioner's prior reaction to the Hep A vaccine as establishing a sensitivity that was corroborated by her subsequent experience with the Hep B vaccine, and otherwise reiterating her prior points that she had met her burden of proof.

V. APPLICABLE LAW

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; §

11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274 (Fed. Cir. 2005): "(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 proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

[15] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[16]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a

[16] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less than the other two, there is ample contrary authority for the more straightforward proposition that the first *Althen* prong (as a component of the overall test) simply requires application of a preponderance evidentiary standard when evaluating if a reliable and plausible causation theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

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

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88

Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

ANALYSIS

I. *Althen* Prong One

In order for Petitioner to succeed on the first *Althen* prong, she was required to offer a theory based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d 543 at 548. Petitioner's theory began with the generalized proposition that vaccines have been associated with a variety of autoimmune conditions, and that vitiligo is reasonably viewed to be autoimmune in character. Both points are correct or undisputed – but they are too broad to satisfy the preponderant evidence test alone, especially given the absence in this case of more direct evidence (*i.e.,* case reports or epidemiologic studies) linking the Hep B vaccine to vitiligo, or some analogous skin condition. Of course, Program petitioners are not *required* to offer any particular category of evidence, or even file any medical or scientific literature at all in support of their claim. *Andreu*, 569 F.3d at 1378-79. Petitioners may also rely on circumstantial evidence to carry their burden. But Mrs. Morris's generalized observations about autoimmunity, vaccination, and vitiligo do not, without more, constitute a scientifically reliable causation theory sufficient to meet the preponderant evidentiary test.

To put meat on the bones of her theory, Petitioner offered discrete items of literature showing that vitiligo has occurred after certain kinds of vaccination or injection. However, the vaccines from those studies are immediately distinguishable from the Hep B vaccine. One such vaccine was a DNA vaccine used in animal experiments. Zhou Article at 809. As Dr. Bardana pointed out, however, that vaccine was highly experimental, and has not been shown to contain components similar to those in the Hep B vaccine. Tr. at 121. The other allegedly vaccine-related case of vitiligo, as discussed in the Lane Article, involved a cancer-fighting injection targeting melanoma in the skin—far different from the Hep B vaccine, and more specific to the injury in question as well. Lane Article at 1. Accordingly, both of these items of literature, while interesting, are of limited utility in helping Petitioner establish her causation theory.

In addition, Petitioner relied on the package inserts included with the Hep B vaccine to show that the vaccine is known by its manufacturers to have potential autoimmune effects. However, as I have previously observed in other cases, package inserts do not constitute probative causation evidence. *Sullivan v. Sec'y of Health & Human Servs.,* No. 10-398, 2015 WL 1404957 at*20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015)(" [s]tatements contained in vaccine package inserts do not constitute reliable proof of causation, and cannot be deemed admissions that the vaccines in question have the capacity to harm a particular petitioner in a specific manner"); *see also Werderitsh v. Sec'y of Health & Human Servs.*, No. 99–319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as saying "[a] report or information submitted by a licensed manufacturer ... does not necessarily reflect a conclusion by the licensed

manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect").

Petitioner also failed to offer sufficient persuasive evidence establishing that internal itching could reflect an initial hypersensitivity reaction to a vaccine that would later develop into an autoimmune condition such as vitiligo. There is some evidence that itching can occur after vaccination, but it appears to be limited to the injection site, and occurs immediately after vaccination, which was not the case here. In addition, no persuasive evidence was produced that internal itching has ever been associated with vitiligo – or with any other vaccine. I acknowledge that there are unknown factors relating to vitiligo – in particular, its etiology and how it progresses—but such unknowns cannot be invoked to excuse an absence of reliable scientific or medical grounds for linking internal itching (reports of which are inherently subjective in any event) and a diagnosis of vitiligo weeks to months later. Absent reliable scientific or medical proof linking internal sensations of itching to vitiligo, it requires speculation to make such a connection.

Ms. Morris attempted to remedy such evidentiary deficiencies in her theory through the testimony of Dr. Horan, who opined that vitiligo could be the end-result result of an autoimmune reaction that initially presented with internal itching (as some kind of initial, but slow-burning, hypersensitivity reaction), caused in turn by a vaccine. Dr. Horan did not, however, present a reliable medical or scientific theory connecting the Hep B vaccine to the itching, then vitiligo, by showing how one would inherently be expected to lead to the other. He also acknowledged that he could not propose a biologic mechanism either (again, not something a petitioner *must* do to prevail – but something that petitioners often attempt to show, especially when stronger direct proof of their theory is absent).[17]

At best, his opinion shed light on the nature of vitiligo from his perspective as a dermatologist who treats many patients suffering from that condition. While Dr. Horan was well qualified to testify on such topics specific to his experience, he lacked a sufficient immunologic grounding to establish a reliable medical theory connecting the Hep B vaccine and internal itching or vitiligo. His testimony and report did not persuasively fill the large evidentiary gaps in Petitioner's theory.

All in all, Petitioner's theory was simply too unreliable from a scientific or medical standpoint to find it meets the "more likely than not" test, and it was not salvaged by Dr. Horan's testimony.

[17] Petitioner did offer the Rork article discussing a proposed shared mechanism of vitiligo and alopecia areata (another autoimmune condition causing hair loss). Rork at 463. But that article did not discuss or associate any vaccine, let alone the Hep B vaccine, with initiating such a mechanism, and therefore I did not find it persuasive in this context.

II. ***Althen* Prong Two**

Even if I had found that Petitioner had provided a reliable medical theory that the Hep B vaccine could cause vitiligo, there would still be insufficient evidence in the evidentiary record to conclude that Ms. Morris's overall course of symptoms reflected the theory "in action."

In particular, Ms. Morris's medical history reveals no evidence of any inflammatory response, reflective of an ongoing autoimmune process, after the vaccination – either during the fall of 2010 or the following summer. *See, e.g.*, *Dillon v. Sec'y of Health & Human Servs.*, No. 10-850V , 2013 WL 3745900, at *16 (Fed. Cl. Spec. Mstr. June 25, 2013) ("[i]f petitioner's condition had been an autoimmune one, systemic or prodromal symptoms would have been expected prior to the onset of petitioner's condition. Such symptoms would include fever and a significantly elevated white blood cell count") (internal citations omitted). Rather, the record establishes that Petitioner received the vaccine, complained for a time thereafter of unexplained internal itching, and then had some temporal hiatus before her vitiligo was discovered or treated. She can point to no objective evidence (whether in the form of a medical test or diagnosis) from the entire period corroborating her assertion that the vaccine was affecting her as alleged, or that it was having a physiologic impact upon her consistent with her causation theory. While Petitioner alleges that she noticed the vitiligo far sooner than her July 2011 dermatology treatment visit indicates, those statements are not corroborated with any independent proof; but even if I accept such testimony, the record is still relatively bare of evidence supporting the proposition that the vaccine was stimulating an autoimmune condition.

In so finding, I acknowledge (as Dr. Horan opined) that the kind of testing that might establish the existence of an ongoing immune response would not necessarily be performed by a medical treater considering Petitioner's complaints. At the same time, however, indirect testing that could have corroborated an immune response consistent with Petitioner's theory *was* performed, and it suggested an absence of an autoimmune response relating to the Hep B vaccine. In particular, in June 2011, Ms. Morris was tested by Dr. Rhodes for immunity to diseases she had previously been vaccinated against, but she did not display the existence of Hep B antibodies. Tr. at 121; Ex. 1 at 11. If the vaccine Ms. Morris received did not produce the result for which it was administered, it is difficult to conclude that it nevertheless also triggered an autoimmune reaction. Accordingly, there is more evidence in the medical record contrary than favorable to Petitioner's theory of an autoimmune response.

Petitioner places great stock in the fact that certain treating physicians and dermatologists, such as Dr. Rhodes, proposed a causal connection between vaccination and her condition. Although treater opinions are entitled to some weight and warrant close consideration, in this case I do not find them particularly persuasive support for the second *Althen* prong. First, those

physicians do not appear to be sufficiently experienced in treatment or study of autoimmune diseases to make such a correlation on a scientifically or medically reliable basis, and the opinions on causation they propose also do not appear to arise from their treatment of Petitioner and what they learned as a result. Second, as the records reveal, Ms. Morris was often the principal advocate for the view that the Hep B vaccine was causally related to her condition, with her treaters repeating what she told them, or acceding to her view, rather than endorsing it after independent analysis. *See* Ex. 9 at 2 ("Pt. wants the letter [exempting her from future vaccination] to state: Ronda Morris is allergic to all vaccine, including flu shorts, tetanus, and hepatitis B"). The records thus do not suggest that any particularly robust evaluation was performed by such treaters before they concluded that the vaccine had been a factor in causing Petitioner's itching and subsequent vitiligo.

A related point about treater views in this case also undermines a different argument Petitioner makes: that she possessed some underlying sensitivity to vaccination generally, as established by her prior experience after receiving the Hep A vaccine in 2006, that the 2010 vaccination stimulated. Although Dr. Rhodes (who was her primary caregiver in 2006 as well as during the time relevant herein) later agreed to provide Ms. Morris a letter exempting her from future vaccination based in part on this prior experience, the actual records from the 2006 vaccination suggest that he had been skeptical of a connection between the Hep A vaccine and Petitioner's paresthesia. Ex. 1 at 24. Nor do those records support such a determination in any event, and no other records or reliable medical evidence have been offered to establish this point.

Overall, Petitioner's *Althen* prong two showing relies mostly on the temporal association between her receipt of the Hep B vaccine and her subsequent symptoms. But it is well understood that this kind of temporal relationship is insufficient to meet a claimant's preponderant burden of proof. *Althen*, 418 F.3d at 1278.

III. ***Althen* Prong Three**

As noted above, a petitioner must show that her injury occurred in a medically acceptable timeframe consistent with her causation theory. *de Bazan*, 539 F.3d at 1352. Here, both experts agreed that the exact timing of the onset of Ms. Morris's vitiligo remains unknown, making it difficult for the Petitioner to show that the onset of her condition was medically acceptable. Tr. at 94. Certainly the date the vitiligo was first observed by a treater (nine months from vaccination) is temporally too attenuated from the vaccine's administration to constitute a persuasive proximate temporal relationship. Tr. at 179.

But even if onset is presumed closer in time to the vaccination, as reflected in Ms. Morris's claims of internal itching in November 2010, with the vitiligo beginning around the start of 2011 or a little before (as Ms. Morris testified), the medical appropriateness of the overall timeframe in

this case remains unexplained. Beyond Dr. Horan's conclusory assertions, Petitioner has not provided a reliable scientific or medical explanation for the temporal course a treater would expect a hypersensitivity autoimmune reaction of the kind allegedly experienced herein to take. The record does not explain, from a biologic standpoint consistent with Petitioner's causation theory, why itching one month after vaccination would then manifest as halo nevi a month or so after.

Indeed – Petitioner's itching symptoms, reported to have begun three to four weeks after vaccination, might themselves be too attenuated from the October 22, 2010, date of her receipt of the Hep B vaccine, to reflect even the slowest onset form of hypersensitivity reaction, as Dr. Bardana testified. Tr. at 118 (even a "delayed hypersensitivity of a cellular nature" would occur within a week, but "not four to six weeks, certainly not nine months"). And Petitioner's inability to establish a reliable scientific/medical link between her initial reported itching and the vitiligo also prevents me from concluding that the temporal relationship between the two was medically acceptable.

CONCLUSION

I appreciate the suffering Ms. Morris has experienced in coping with her vitiligo, and the corresponding difficulties it has imposed on her life. But my sympathies for her personal struggles are not grounds for a Program award. Rather, the Vaccine Act permits me to award compensation only if a Petitioner alleging a "non-Table Injury" can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. Here, the weight of the evidence does not support Petitioner's causation theory, and there is insufficient evidence to support an award of compensation, leaving me no choice but to hereby **DENY** this claim.

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 accord with this decision.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master