In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-1725V

Filed: 11 September 2007

JOSEPH WILLIAMS, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	To Be PUBLISHED Hepatitis B, Lupus, Significant Aggravation

Ronald Homer, Esq., Boston, Massachusetts, for Petitioner.
Nathaniel McGovern, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ORDER STRIKING THE PREVIOUS RULING ON ENTITLEMENT AND REVISED ENTITLEMENT RULING[1]

The Court filed an entitlement ruling in this case on 1 August 2006, finding entitlement to compensation for Petitioner. Noting concerns raised by the parties in this case, the Court, *sua sponte*, hereby **STRIKES** that Ruling on Entitlement from the Record in this case, and **RULES** as set forth below, in a revised entitlement ruling.

[1] Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

On 1 December 2004, a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] was filed by Petitioner, alleging that he suffered a vaccine-related injury following the administration of a Hepatitis B vaccination on 15 May 2002.

The Court conducted an evidentiary hearing in this matter on 7 October 2005, which was followed by written argument. The record is now ripe for decision.

The Vaccine Act authorizes the Office of Special Masters to make decisions on petitions which shall include findings of fact and conclusions of law. §12(d)(3)(A)(I).

I. EVIDENCE PRESENTED

This Court may not rule in favor of a petitioner based on his asseverations alone. Rather, a petitioner's claims must be substantiated at the very least by medical records or by medical opinion. § 13(a)(1). Therefore, the Court turns first to the medical records filed in the above-captioned case.

A. Medical Records

On 15 May 2002, the Petitioner, then a fifty-year-old volunteer first-responder for the local fire department, received his first and only recorded Hepatitis B vaccination at the Modoc County Health Department.[3] Petitioner's Exhibit ("Pet. Ex.") 2 at 3.

On 3 June 2002, Petitioner returned to the health department where he complained of:

> having been bothered by joint pains and swelling that began the morning after his first Hepatitis B vaccination that he received at this health department on May 15, 2002. He stated that the swelling was first in his right hand. The injection was given in the left arm. His wife stated that the swelling started in the left hand. He stated that this swelling and painful joint complaint proceeded to involve both wrists and both ankles and that he experienced some stiffness and difficulty getting out of bed in the mornings. He also stated he had stiffness in his fingers and difficulty closing making a fist. The problem was not as bad at other times during the day. He states that it does not seem to be as severe as it was, but that he and his wife are wondering if it might have had anything to do with the Hepatitis shot he received.

Pet. Ex. 2 at 6. The nurse completing the Immunization Incident Report, Linda Nelson, R.N., advised Petitioner to seek medical attention.

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[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq*. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

[3] Petitioner had no medical insurance and lacking the financial wherewithal primarily sought medical care through the Department of Veterans Affairs ("VA"),for his service in the Vietnam War, or at local county health clinics. See Tr. at 7-8.

On 4 June 2002, Petitioner presented at the Modoc Medical Center complaining of a "reaction from Hep[atitis] B shot. Joints are swollen [and] hurt." Pet. Ex. 15 at 1. Dr. Valeska Armisen noted a history of "allergic reaction (swelling of injection site) after Hep B shot 5/15/02. Now [without] swelling joints [illegible] - knees - wrists [symptoms] only started after shot....Joint pain worse in morning better with [movement]." Pet. Ex. 15 at 1. His impression was "Bilateral joint pain" and "Arthritis."[4] Id. Labs ordered by Dr. Armisen, however, while revealing an elevated sedimentation rate, possibly indicating an inflammatory process, were negative for a rheumatoid factor, indicative of rheumatoid arthritis.[5] Id. at 26-27.

Not satisfied with the care and medicines prescribed by Modoc Medical Center, on 12 June 2002 Petitioner sought treatment at the Canby Medical Center in Canby, California. There he saw Dr. Donna Jones who notes,

> He received a hepatitis B shot and with in [sic] 4 hours of receiving the shot he developed left arm swelliing [sic]. Later in the day he began to be affected in his right arm, his knees, and eventually his whole body. He received this injection about 28 days ago and comes in today stating that he is still having swelling, generalized malaise and aching; joint stiffness and difficulty walking. He is concerned because he has no energy and he "hurts everywhere."

Pet. Ex. 4 at 25. The Petitioner indicated to Dr. Jones that he had been prescribed the pain medication Celebrex based upon the diagnosis of arthritis, but that it was not working. However, from other contemporaneous records, it is unclear whether he actually took this medication. Pet. Ex. 2 at 4-6. On examination, Dr. Jones noted that Petitioner's range of motion in his extremities was normal but apparently painful. Yet, she noted no active inflammation, ankle swelling, pitting edema, or foot deformity. Pet. Ex. 4 at 27. Her diagnoses included "delayed hypersensitivity to hepatitis vaccine" and "arthritis, allergic (general)." Id. at 28. She reported the same in an occupational injury report, "Hypersensitivity reaction to Hep vaccine." Id. at 24. Dr. Jones continued Petitioner on Celebrex but also added steroid treatment and, at Petitioner's request, ordered a complete Hepatitis profile. Pet. Ex. 4 at 20. Those tests were negative for Hepatitis A antibody, Hepatitis B surface antigen and antibody, Hepatitis B core antibody, and Hepatitis C antibody. Id. at 37. Dr. Jones ordered a battery of other tests, to be discussed infra. Id. at 33-36.

On 26 June 2003, Nurse Nelson filed a report through the Vaccine Adverse Event Reporting System (VAERS) which described "joint pain [and] swelling that began the morning after the first Hep B in a series of three required for job as vol. fire dept. worker[.] The vaccine was given May 15 [and] symptoms not reported until June 3, 02. [Prescribed] Celebrex, but would not take[.] Seen

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[4] Arthritis is inflammation of a joint. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 149.

[5] Rheumatoid Arthritis is "a chronic systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefication of the bones." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 156.

[at] another provider[.] Hep B panel neg[ative] put on prednisone x 6 days (June 6, 02)." Pet. Ex. 2 at 4.

Petitioner was seen by Dr. Jones on 26 June 2002 for "follow-up on his vaccine reaction." Pet. Ex. 4 at 21. Dr. Jones notes that Petitioner was "generally much improved." Id. at 23. The same was reported at a follow-up appointment on 3 July 2002, at which time Dr. Jones noted "patient continues to improve on the steroids." Pet. Ex. 4 at 17. At that visit it was also noted that Petitioner is now taking Vasotec to combat high blood pressure, a condition with which he had struggled for many years. Her diagnoses then read "1. Unspecified adverse effect of drug medicinal and biological substance, not elsewhere classified" and "2. Arthritis, allergic, multiple sites (nonspecific)." Pet. Ex. 4 at 17.

In the early morning of 16 August 2002, Petitioner went to the emergency room of Modoc Medical Center with "tongue grossly swollen" and difficulty swallowing, which was diagnosed as angiodema.[6] Pet. Ex. 3 at 1. He was treated and released but later that morning presented at the Canby Family Practice. There he saw a Dr. Musselman who noted that Petitioner had been seen by the hospital for swelling on the left side of his face including his lips and tongue. The doctor continues, "This is a patient of Dr. Jones' whose [sic] had serum sickness and allergic reaction . . . It all started when he had a Hepatitis shot on 5-15-02. He developed acute shot reaction and edema. On his labs he has an ANA of 1:5000." Dr. Musselman transferred Petitioner to Redding Medical Center for evaluation of the angiodema and for evaluation by a rheumatologist. Pet. Ex. 4 at 3.

On 16 August 2002, Petitioner was seen in an outpatient capacity for the angiodema with tongue swelling, which was thought to be related to the Vasotec blood pressure medication. Pet. Ex. 9 at 7. The doctor noted the patient's history including the vaccine and "[t]here is a report in the packaged literature with the Hepatitis B vaccine of delayed serum sickness-type reaction causing arthritis. This is often self-limited and short-lived. No mention is made of diagnosis or treatment. I will have to look into the literature" and "probable adverse reaction to hepatitis b vaccine." Id. Based on this assessment, Petitioner was converted to inpatient status and referred to a rheumatologist, Dr. Timothy Peters for "Arthritis and possible connective tissue disorder." Pet. Ex. 9 at 9, 23.

The history taken by Dr. Peters is quite thorough and notes that, according to Petitioner, his problems began shortly after the Hepatitis B vaccination on 15 May 2002 at which time he developed "swelling in multiple joints" that started in his left arm and spread from there. Dr. Peters notes how rheumatoid arthritis had at first been suspected but discredited by the negative rheumatoid factor, how the course of steroid treatment had been helpful in many respects but had not resolved Petitioner's complaints, and how Petitioner had lost a great deal of weight in the intervening months going from 310 to 234 pounds. Id. Dr. Peters also noted, "He has had chronic lower extremity

[6] Angiodema is "a vascular reaction involving the deep dermis or subcutaneous or submucosal tissues, representing localized edema caused by dilation and increased permeability of capillaries, and characterized by development of giant wheals." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 83.

nodular lesions and a few also on the back and an ulcer that is chronically located over the left [ankle]. He has been told that this is due to agent orange exposure while he was a soldier in Viet Nam in the 1960's. He is followed through the VAMC for this. However, none of these lesions have been biopsied." Pet. Ex. 9 at 24.[7]

On exam, Dr. Peters did note "hyperpigmented nodules scattered" over the lower back and lower extremities as well as healed ulcers particularly in the left lower extremity along with a "left lateral malleolus ulcer" (on the left ankle). Id. at 26. Dr. Peters also noted that certain lab results were significant for a high titer anti-nuclear antibodies ("ANA") at 5120, a Lyme IgG "positive at 1:256" and evidence of lymphopenia/leukopenia.[8] Id. at 27. See Pet. Ex. 4 at 33-36.

Based on his examination coupled with the lab results, Dr. Peters suspected "a connective tissue disorder along the lines of systemic lupus initially."[9] Id. at 27. At that time he also noted that the apparent skin lesions might be pyodermagangrenosum.[10]

On discharge from hospital, the diagnosis read as follows: 1) probable lupus, 2) angiodema secondary to Vasotec, 3) hypertension and 4) "Iron-deficiency anemia and pancytopenia."[11] Pet. Ex.

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[7] In 2000, the Veteran's Hospital scheduled a biopsy of those lesions; however, Petitioner neglected to attend that testing.

[8] Leukopenia is "reduction in the thember of leukocytes in the blood," and lymphopenia also known as lymphocytopenia is "reduction in the number of lymphocytes in the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1022, 1078.

[9] At trial, Respondent's expert, Dr. Alan Brenner, described Lupus in the following manner:

> Lupus, the best way to define it is an immunologic condition, where the immune system appears to be reacting against antigenic particles that are primarily from the nuclei of our cells. It's our DNA and several other nuclear particles that appear to be participating.
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> Lupus is a classic medical immune complex disease. When these antigen antibody complexes get together, and they deposit in what I call filter areas -- the smallest of blood vessels; the little blood vessels in the joints, the little blood vessels in the skin, the little blood vessels in the kidney, the lungs, the central nervous system. That's why Lupus is a disease of protein manifestations.
>
> Anyway, wherever they deposit in any given patient then, the different antigens may determine some of where they deposit in any given patient. They elicit a local inflammatory response by fixing components of the inflammatory helper system called the Compliment System.
>
> It looks like Lupus begins because one part of the immune system goes a bit haywire, and over-produces antibodies against these nuclear factors.

Transcript, 7 October 2005 ("Tr.") at 38-39.

[10] Pyodermagangrenosum is "a rapidly evolving, idiopathic, chronic debilitating skin disease that usually accompanies a systemic disease." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1551.

[11] Pancytopenia is a "deficiency of all cellular elements of the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1356.

9 at 5. On discharge the doctor noted that Petitioner's hepatitis B antibody titer was low despite the recent vaccination. Pet. Ex. 9 at 6.

Petitioner followed up with Dr. Jones on 19 August 2002 two days after discharge from the hospital. According to that record, while hospitalized, "the patient was evaluated by rheumatologist and was told that he probably had [systemic lupus erythematosis[12] or "SLE"] most likely triggered by the vaccine." Pet. Ex. 4 at 10. According to Dr. Peters' notes, however, "I am not sure about the relationship (if any) of the hepatitis vaccine with the onset of his disease." Pet. Ex. 5 at 2.

Petitioner next saw Dr. Peters on 30 August 2002. At that time, the doctor noted that Petitioner was doing better with occasional "aches and pains." Id. His assessment is "unequivocal SLE with arthritis, leukopenia/lymphopenia, positive ANA, positive double stranded DNA, mild hypocomplementemia.[13] I think the diagnosis is clear. Prognosis is good without major organ involvement." Pet. Ex. 5 at 2. Doctor Peters further indicated "I do wonder if the nodular/ulcerative lesions on his lower extremity have anything to do with the lupus." Id. Adding to the doctor's suspicions was the fact that the lesions cleared up on the steroid treatment. Id.

On 29 August 2002, in conjunction with a claim for worker's compensation, Petitioner was evaluated by Dr. Donald Downs, a qualified medical evaluator in the fields of occupational and sports injuries, with the Sacramento Knee & Sports Medicine Corporation. Pet. Ex. 7 at 14. In taking Petitioner's history, Dr. Downs adds, "He associates the onset of his symptoms with receiving the hepatitis B shot. He implies quite strongly that his treating physicians feel this is also causative." Pet. Ex. 7 at 15. Dr. Downs did not review laboratory or diagnostic records, and he had only partial medical records on hand at that time. Id. Regardless, Dr. Downs opines "his musculoskeletal disability secondary to his arthralgias[14] and myalgias[15] is reasonably medically probable to have been

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[12] Systemic Lupus Erythematosus is defined as:

> a chronic, remitting, relapsing, inflammatory, often febrile multisystemic disorder of connective tissue, acute or insidious in onset, characterized principally by involvement of the skin (*cutaneous l. erythematosus*), joints, kidneys, and serosal membranes. It is of unknown etiology, but is thought to represent a failure of regulatory mechanisms of the autoimmune system, as suggested by the high level of numerous autoantibodies against nuclear and cytoplasmic cellular components. It is marked by a wide variety of abnormalities, including arthritis and arthralgias, nephritis, central nervous system manifestations, pleurisy, pericarditis, leukopenia or thrombocytpopenia, hemolytic anemia, elevated erythrocyte sedimentation rate, and positive LE-cell preparations.

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1072.

[13] Hypocomplementemia is defined as "abnormally low levesls of complement in the blood." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 893.

[14] Arthralgia is joint pain. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 149.

[15] Myalgia is muscular pain. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1205.

an adverse reaction to the hepatitis B vaccine." Id. at 17. As to the basis for this opinion, Dr. Downs indicates:

> Mr. Williams presents as a somewhat moderate historian, but in the records that I have and his verbal report to myself, he presents a consistent clinical history of initially a local, then very rapidly a generalize [sic] reaction to the hepatitis B vaccine. These types of reactions occur rarely, but are described and in absence of documentation of pre-existing rheumatologic disease, it is reasonable that Mr. William's reaction is secondary to the injection with the information that I have at this point.

Id.

Doctor Downs indicated that access to the complete medical records could result in an alteration of his opinion. Hence, he was later presented with additional records including those from the hospital visit on 16 August 2002. Based on this more complete body of records, he notes:

> The information provided in these records does indicate reason for the assignment for the diagnosis of lupus being a very high ANA as well and elevated sedimentation rate. Again, the association with hepatitis B vaccine is documented in the records. This is a very unusual reaction if it is related to the hepatitis B vaccine and frankly the best opinion that I can render is that it is possible that Mr. Williams' autoimmune disorder was triggered by the vaccine. It is based upon the history presented by Mr. Williams given the onset of symptoms being associated directly with a vaccine that industrial causation of his autoimmune disorder may be reasonable. However, I would suggest that a more expert opinion may come through a sophisticated rheumatologist or immunologist.

Pet. Ex. 7 at 6. Notably, however, after reviewing yet another set of records, Dr. Downs indicated that the information provided therein did not alter his original opinion tying the injury to the vaccination. Rather, he notes, "The information provided in these records tends to support Mr. Williams' arthralgias and myalgias[16] being secondary to an adverse reaction to the hepatitis B vaccine." Pet. Ex. 7 at 2

Perhaps because Dr. Downs expressed a necessity for Petitioner to be evaluated by an immunologist or rheumatologist, Petitioner was seen by Dr. Stephen Nagy, an allergist and immunologist, for yet another workers' compensation evaluation.[17] Dr. Nagy saw Petitioner on 11 November 2002. His history is as complete as any proffered in this case. Pet. Ex. 8 at 8-9. In conducting his evaluation and investigation, Dr. Nagy researched the medical literature "on the

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[16] Arthralgia is defined as "pain in a joint" and myalgias as "pain in a muscle or muscles." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 249, 1205.

[17] The referral letter indicates that Mr. Williams asserts that he had been given the Hepatitis B vaccine years ago while in the military. Pet.. Ex. 8 at 1. However, that claim is lacking in other more medical histories, and this source is not sufficient of itself for the Court to find more likely than not that such occurred.

association of hepatitis B immunization with the initiation/exacerbation of connective tissue disorders; there is considerable controversy as regards the possible association of a hepatitis B immunization either initiating a connective tissue disorder, including lupus, and/or exacerbating an undiagnosed case of same, i.e. lupus." Pet. Ex. 8 at 10. Yet, even so, Dr. Nagy reaches the following conclusion, the pertinent paragraphs of which are reprinted here in full:

> In my opinion, the immunization with hepatitis B which was given to the claimant in the left upper arm on 5/14/02 [sic] either initiated *de novo* a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder. In either case, this is an occupational-related illness. The most persuasive aspect of the history is the fact that within hours of the immunization he developed an obvious immunologic response manifested by local swelling/erythema which progressed to the illness as defined over the ensuing four months. Although there is still controversy in the literature as regards an association between all immunizations and connective tissue disorders, there are any number of cases of lupus-like syndromes being associated with a hepatitis B immunization. Furthermore, hepatitis B itself can be associated with arthritis/arthralgia. Lastly, the claimant's medical history prior to the hepatitis B immunization in question is virtually nonexistent. For the previous 20 years he states he was quite well; he only visited a physician at the Reno VA on two occasions for mild hypertension.
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> The nature of this patient's current illness is still not clear; although Dr. Peters, his rheumatologist, feels he has unequivocal lupus, I feel the abnormalities associated with his illness are primarily laboratory; that is, he had an elevated sedimentation rate/double-stranded DNA; on the other hand, he does not have any of the end-organ involvement that we commonly associate with lupus; there is no evidence of major hypertension/renal disease/liver disease/muscle disease, nor does he have any evidence of true arthritis; he primarily experiences arthralgia. I feel the problem of weakness/muscle wasting is secondary to a steroid myopathy[18] secondary to the large amounts of steroids with which he has been treated over the last four months. It is possible that this represents an unusual connective tissue disorders, i.e. overlap syndrome, [illegible] could be a manifestation of a persistent serum sickness reaction. If this is, in fact, the diagnosis, the prognosis is much more optimistic as the illness could gradually clear spontaneously over the course of 6-12 months.

Pet. Ex. 8 at 10 (emphasis added). Of notable significance, Dr. Nagy went on to serve as Petitioner's expert witness, opining in support of the instant Petition. See *infra*.

Nearly two years later, Petitioner was again seen for a workers' compensation evaluation, this time by Dr. Adam Duhan with the Evaluation Resource Group. Dr. Duhan states, "Certainly, as reported by numerous treating physicians, taking the Hepatitis B vaccine triggered his Lupus." Pet. Ex. 13 at 67.

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[18] Myopathy is "any disease of a muscle." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1215.

Petitioner remains under the care of Dr. Peters and Dr. Jones. But according to Petitioner's affidavit, he continues to suffer from the alleged vaccine-related injuries which manifested four hours after onset. See Pet. Ex. 10 at 3; Pet. Ex. 19 at 2-3; Pet. Ex. 13 at 67, 100; and Pet. Ex. 21 at 9. Moreover, on 25 November 2003, Dr. Jones wrote in a letter regarding Mr. Williams' workers' compensation claim that he would "never be able to return to active work" due to "ongoing problems as a result of his reaction to hepatitis B and ensuing systemic lupus that he had because of it."

B. Medical Opinion

As noted *supra*, a petitioner may substantiate his claim either via the medical records or medical opinion. And, in fact, the Vaccine Act adjures this Court to consider any diagnosis, conclusion, medical report or impression contained in the record. However, that being said, the act says quite explicitly that these "shall not be binding on the special master" but must be considered based on the entirety of the record and the course of the injury. §13(b)(1). Therefore, while this Court has always shown appropriate deference to the opinions, impressions, or diagnoses of treating physicians and other medical experts, that is not to say that such are perforce binding on the Court. Bearing this in mind, the Court now turns to the medical opinions proffered in this case.

In addition to the medical records mentioned above, Petitioner proffered additionally the live testimony of Dr. Nagy, a long-time professor at the University of California's Davis campus and who is board-certified in internal medicine and allergy immunology. Tr. at 6. Respondent offered the testimony of Dr. Alan Brenner, who is board certified in internal medicine and immunology and has practiced for more than three decades as a clinical rheumatologist. Tr. at 37-38. Both are quite familiar with connective tissue disorders such as lupus, which Dr. Nagy has diagnosed in several patients (Tr. at 35), and which Dr. Brenner has treated in many patients within his rheumatology practice (Tr. at 38).

Prior to the hearing, Dr. Nagy opined in his medical expert opinion report that the vaccination "either initiated de novo a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder," Pet. Ex. 8 at 10. At the hearing, Dr. Nagy outlined a medical theory in support of the Petition, that the Hepatitis B vaccination administered on 15 May 2002 initiated a process, beginning within four hours of the administration, that would eventually result in Petitioner's current connective tissue disorder.

Dr. Nagy began and ended his testimony in the Hearing by cautioning that the exact etiology of Lupus is still an open question in the current state of medical knowledge. However, he noted that it is medically plausible for an Hepatitis B vaccine to act as an environmental trigger in precipitating or "stimulating" the symptoms of the illness, for which an individual may be genetically predisposed. He explained that, although the complete etiological mechanism of Lupus is uncertain, "it's presumed that it's a combination of the susceptibility genes and an environmental factor, most like[ly] some sort of an infection. That's the current theory; that the gene is stipulated [sic] to produce, by the antigen, a pathologic antibody." Tr. at 11. Dr. Nagy explained further that often, even where such a trigger is believed to be at work, it is not particularly identified. Tr. at 36. He summarized his theory thusly:

> [T]here is a plausible explanation for this entire sequence of events, from a biochemical standpoint, and from what we know immunologically about the nature of Lupus, it's predisposing factors, and what usually tends to trigger the disease.

Tr. at 17. Dr. Nagy addressed the course of Petitioner's condition, from an initial localized reaction, quickly to a more severe acute reaction–all within a relatively brief window–and leading inexorably to a disease affecting his connective tissues:

> I mean, the illness begins within four hours of getting that injection, and progresses inexorbitently [sic] to a classical -- what I won't call serum sickness -- but a classical antigen antibody mediated reaction with swelling, fever, joint aches, and so forth -- to three weeks later, where the man has developed, essentially, laboratory evidence of a major connective tissue disorder.

Tr. at 16-17. Dr. Nagy expressed his belief that this temporal proximity between the vaccination and the onset of the initial symptoms is very persuasive, if not most persuasive, in relating Petitioner's injury to that vaccination. Id.

Dr. Nagy explained that what began initially as a "classical" reaction to the vaccine, such as swelling and a fever, culminated into a less acute, but more serious, long-term illness, such that "there was an immediate antigen antibody reaction in that four hours, and it simply initiated a cascade of events, which just didn't stop." Tr. at 23. Dr. Nagy opined that the initial reaction therefore could have acted as the environmental trigger for the illness which has continued to affect Petitioner since that time, such that "this reaction itself facilitated the stimulation of these pathogenic genes," in which case the vaccination at issue would be a factor "instrumental in that activation." Tr. at 23-24.

Dr. Nagy continued this explanation at the biological level, by addressing one of the major points of contention between the expert witnesses in this case: why the response was so strong after the first administration (of three planned administrations) of the Hepatitis B vaccine:

> Now the presumption there is that the very first immunization produced antibody. Then on the second immunization, you're now exposing someone to a protein antigen, which is the immunization. You're exposing them to someone who's already made antibody. Then all of a sudden, that antibody is now complexing with the antigen and initiating a response, which subsequently leads to, in some fashion, activation of the pathogenic [antigen]. But that's the plausible medical explanation.
>
> Now my interpretation of what happened to this man was that he had probably contracted, at some point, Hepatitis B in the past. Now Hepatitis B is [not] something that persists in most patients. Most patients who develop Hepatitis B naturally, the wild disease, they deal with the disease. They make antibodies, and they get rid of the virus. It only those few patients that develop chronic Hepatitis, that persistence of what they [call] antigen damage in the system.

Tr. at 14. Dr. Nagy opined that this interpretation was entirely reasonable, given Petitioner's extensive life history, which included extended stints in localities where contracting Hepatitis B would be quite facile:

> So this man had lived -- you know, I don't mean to knock him. But he was 15 years in New York and 50 or 60 years old. I mean, I didn't go into his major sociological history. But it's entirely possible that this man had already had Hepatitis B. Therefore, I'm presuming that this initial response was secondary to the fact that there was antibody there; the way he got the reaction. That initiated this whole response.

Tr. at 15. When asked for support in the factual record for this presumption within his medical opinion, Dr. Nagy continued in this vein:

> Well, my support is that he was in Vietnam. I mean, he's 50 years old. I mean, frankly, Hepatitis B is epidemic in Southeast Asia. It's also epidemic in certain parts of Los Angeles and New York, where he spent a good part of his life. I think one can presume someone may have had Hepatitis. It can be a relatively asymptomatic disease.

Tr. at 27.

Dr. Nagy explained that, if one were to accept that Petitioner had been previously exposed to Hepatitis B, it is logical to conclude that the reaction experienced by Petitioner could be a natural sequela thereto:

> I mean, within four to six hours, you develop this antigen antibody reaction, because they already have the antibody. But they do develop this immediate response when there is an antibody present.

Tr. at 16.

Dr. Nagy responded to the absence of Hepatitis B antibodies in the tests performed on Petitioner by saying that Petitioner's body, either over time or as a result of the acute immune reaction following vaccination, may have eliminated, or used up, any discernable Hepatitis B antibodies that might otherwise have been present. Tr. 17-18.

> [A]ntigen only persists in some patients. Most patients with Hepatitis B -- I don't know whether you've read the literature or not, or even just the standard textbooks -- but most patients who develop Hepatitis B don't have persistent antigens.

Tr. at 28-29.

Dr. Nagy responded sharply to the medical opinion offered by Respondent, that Petitioner's connective tissue disorder preexisted the vaccination, and that such is evidenced by the presence of hypertension and skin nodules alone, without further symptoms:

> So we're talking about some nodules on his feet that have been there at least 12 years, and possibly for over 20 years.

> I know Dr. Brenner is using this as evidence that the man has some evidence of a connective tissue disorder, along with the fact that a man who's black and who weighs 280 pounds has some hypertension. These two facts seem to suggest that the man has had Lupus for years.
>
> I mean, I just can't accept that. I personally have never seen nodules. I didn't examine this man's feet; I'm sorry. But I just have never heard that nodules on the feet would be a sign of Lupus. I mean, I've seen a number of patients with Lupus. This is just not one of the manifestations of the disease.

Tr. at 20. A short while later, Dr. Nagy gave his explanation for the persistent presence of the nodules on Petitioner's feet.

> One of the interesting things is, remember now, he is a mason. Masons get a lot of silicon into their feet. I mean, they're constantly working with cement and limes and things like this. These things get into their shoes.
>
> I don't know if you've ever done any masonry work. I have. You just get full of cement and stuff like that. It wouldn't surprise me -- I mean, if some of this wasn't a granulomonous[19] response to his long-term work as a mason.

Tr. at 22. This explanation remains consistent, explained Dr. Nagy, when one considers that those nodules resolved with Petitioner's treatment course with steroids.

> Yes, that's because it was inflammatory. A granulomonous condition would respond. That simply means it was an inflammatory condition. It doesn't necessarily mean it was related to the Lupus.

Tr. at 30.

Beyond an explanation of the manifestly preexisting conditions affecting Petitioner, Dr. Nagy was emphatic–even indignant–in confronting the proposition given by Respondent's expert, that the symptoms experienced by Petitioner since his vaccination are equivalent with his condition prior to vaccination:

> I mean, if all you're hanging your hat on is some hypertension in a heavy black man and some nodules on his feet, with no other history, I can't believe there's a rheumatologist in America that would accept that as evidence of connective tissue disorder [preexisting at the time immediately preceding vaccination].

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[19] A granuloma is a general term for:

> (1) any small nodular delimited aggregation of mononuclear inflammatory cells, or (2) such a collection of modified macrophages resembling epithelial cells [], usually surrounded by a rim of lymphocytes, often with multinucleated giant cells. Some granulomas contain eosinophils and plasma cells, and fibrosis is commonly seen around the lesion. Granuloma formation represents a chronic inflammatory response initiated by various infectious and noninfectious agents.

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 795.

Tr. at 29.

During the hearing, the dispute did not center on the question of whether Hepatitis B vaccination *can* trigger a connective tissue disorder. Rather, Respondent's expert, Dr. Alan Brenner, concededly explained the theory that Hepatitis B antibodies, produced as a result of the first or second vaccine administration, given the right conditions, may interact with Hepatitis B antigen from a latter (second or third) administration, thereby forming antigen antibody complexes that can wreak all sorts of mischief. Tr. at 57. The difficulty in this particular case, according to Dr. Brenner, is the timing of onset. It takes time for the immune system to react to the Hepatitis B antigen introduced by the vaccination in order to create Hepatitis B antibodies. This process usually takes "days and days" or two to three weeks. Tr. at 50-52. And this timetable for that process is borne out in the anecdotal literature and case studies. Respondent's Exhibit ("R. Ex.") I at 131; see also R. Ex. A at 8.

Dr. Brenner explained it thusly:

> [T]he literature that exists, based on case reports and temporal association, is quite clear on showing that the temporal association is one to three, predominantly two to three weeks, following vaccination, to onset of clinical symptoms.
>
> The second point that's important is the literature is also clear that if there is an association, it's a secondary association; by which I mean, in the case of Hepatitis B, the cases, in the main, are reported after second and third administrations, not after primary vaccination.

Tr. at 52. Dr. Nagy agreed with this timing in general but pointed to one anecdotal report in the medical literature, and that in a letter to the editor and not in a peer reviewed portion of the medical journal, where a connective tissue disorder was noted within two weeks after the first administration of Hepatitis B. Tr. at 13-14; Pet. Ex. 32. However, according to Dr. Brenner, "[I]t would be very, very unusual to have any sort of chronic immunopathy or chronic immune process that began four hours after vaccination. You know, it defies logic. It even defies the literature that's out there." Tr. at 45.

In order to account for Petitioner's unusually fast onset, Dr. Nagy presupposes that Hepatitis B antibodies must have already been present. Tr. at 34. It is possible, explains Dr. Nagy, given Petitioner's history, he may have contracted the disease during the course of his life, and in particular, during a tour to Southeast Asia courtesy of the United States government and international Communism. Dr. Nagy acknowledges that, despite testing done both contemporaneously and after a period of time, no evidence was ever found of Hepatitis B antibodies. But, says Dr. Nagy, the antigen-antibody complex reaction post-vaccination may have "used up" those antibodies and, furthermore, argues Petitioner, subsequent medical treatment may have suppressed their later resurgence.

Dr. Nagy's theory militates for the existence of a fact, in this case that Hepatitis B antibodies were present prior to the 15 May 2002 vaccination, the burden of which is Petitioner's to prove. It

must be noted that a test for Hepatitis B core antigen was never conducted. Tr. at 44. In this instance, the medical records are silent on whether Hepatitis B antibodies were present prior to the injection or have ever been present since, despite three separate tests that were conducted both contemporaneous to the event and many months out. However, as Respondent's expert admits, the most conclusive test to determine the presence of Hepatitis B was not performed upon Petitioner, so evidence on this point remains inconclusive: "Unfortunately, the very best test for core antigen wasn't done, and it wasn't done because nobody considered the possibility that he had underlying Hepatitis B." Tr. at 44-45. Although Dr. Brenner argued that this neglected investigation was proof that Petitioner's theory was one "totally unsubstantiated by the medical record" (Tr. at 45), he himself admitted that "When people have chronic Hepatitis B, the really bad actor turns out not to be surface antigen. The really bad actor in chronic Hepatitis B turns out to be core antigen." Tr. at 60.

Nevertheless, Dr. Brenner acknowledged that Mr. Williams suffered "an acute reaction, which is probably allergic mediated" within four hours of the vaccination, although he cannot conjure a theory or "understand the mechanism" whereby such a reaction could cause the a chronic immune process; such a phenomenon "defies logic" and "defies the literature that's out there." Tr. at 44-45.

The relationship between the immediate reaction and Petitioner's long-term, residual symptoms was very controversial, and never decisively addressed. The following exchange with Dr. Brenner is exemplary of this point:

> THE COURT: Something presumably happened to Mr. Williams about four hours after the vaccination. We have a description of the symptomalogy; what happened?
>
> THE WITNESS: Oh, I think that, you know, this sort of reaction has been very well studies [sic] in vaccinology. A four hour time frame for vaccination to acute local reaction is not uncommon. As a matter of fact, it's probably the most common reaction.
>
> You know, I mean literally, any place from minutes to six to eight hours, it looks like, according to the vaccine literature, it's basically the same immunologic mechanism.
>
> Now what happened next is a whole other question. Because what happens next is muscular skeletal pain. What happens next is not documented in the medical record to represent arthritis. Only in the barest of circumstances, when he was hospitalized in August, did Dr. Peters make any mention of joint problems. That aside, every examination before and every examination subsequent, where joint exam was done, showed no evidence of articular inflammation.

So the real question is, what happened? You know, this has been defined as an Arthritis. But you can't define Mr. Williams' condition as arthritis. In my opinion, that's impossible.

THE COURT: Okay, then, what is it?

THE WITNESS: It's Arthralgia. Then the question becomes, you know, why would an acute reaction, which is probably allergic mediated, then, in and of itself, lead to chronic muscular/skeletal pain? I don't have an explanation for that, because I don't understand the mechanism. It doesn't make sense.

THE COURT: Okay, but I gather from what you're indicating, that the acute reaction that occurred about four hours post-vaccinal, in and of itself was sequela to the vaccination?

THE WITNESS: Well, you know, my only problem is, you know, the idea of having some sort of objective medical record that documents what patients tell us. Having said that, the answer is yes.

Tr. at 43-44.

Dr. Brenner further hypothesizes that the acute, immediate reaction, occurring four hours post vaccination, had nothing to do with Petitioner's latter diagnosed connective tissue disorder; instead, he asserts that Petitioner had a pre-existing underlying autoimmune disorder for which the chronic ulcerating rash and nodules were a manifestation. In support, Dr. Brenner offers his not insubstantial three decades as a rheumatologist and points to the statements of the treating rheumatologist in the Medical Record, who likewise suspected that the nodules were representative of lupus. Dr. Brenner argued that, were proper tests conducted before the vaccine was administered, Petitioner would have been diagnosed with lupus prior to the vaccination. Tr. at 47. Dr. Brenner stated his belief "that there was a clinical manifestation [of Lupus] that had been going on for a very long time." Tr at 46. When asked by the Court when he believed the onset of Lupus occurred, Dr. Brenner thought that Petitioner "first manifested Lupus whenever he actually began developing those nodules on his feet and his back. If that's 1971, so be it." Tr. at 46-47.

Puzzled by his nuanced stance and diagnosis of Petitioner's progression, the following exchange occurred between the Court and Dr. Brenner:

THE COURT: Is his condition today significantly worse than what it was prior to the vaccination?

THE WITNESS: I don't know; subjectively, perhaps -- objectively, no. I mean, objectively, the chances are overwhelming. The only reason that we see high grade inflammation following vaccination and not before vaccination is because nobody looked before vaccination. So that's the first thing.

> The second thing is, we know from recent studies, wonderful studies that have been done, both in Lupus and in Rheumatoid Arthritis, that auto-immune antibodies long precede clinical manifestations of either disease to begin with.
>
> We also know that his high blood pressure, one of his major clinical manifestations, long preceded vaccination or the other problems that he developed. So what he has that's worse is muscular skeletal pain. Now that's a subjective complaint of diverse ideology, likely not Arthritis; likely not on an immune basis.

Tr. at 47.

Petitioner's counsel eventually followed up on this line of reasoning during cross examination:

A He already had Lupus.

Q Now he has Lupus?

A No, he had Lupus then. That's my point.

Q Yes, but he was asymptomatic, aside from the nodules, wasn't he?

A Yes.

Q So wasn't there a significant worsening of symptoms after the Hepatitis B?

A Absolutely.

Tr. at 103-04.

This seems to contradict statements made by Dr. Brenner elsewhere in the hearing transcript, in which he explains his firm belief that Petitioner's post-vaccinal symptomatology is no worse than a normal vaccine reaction, and that those symptoms are unrelated to his long-term illness:

> In my opinion, it's unrelated, and I'll tell you why. This is one of the most common reported reactions to vaccinations, anyway, you know. I mean, in all of the vaccine studies, local, acute, reactions are foremost amongst the reacto-genic problems of vaccines. So these happen to everybody.

Tr. at 56.

II. FINDINGS OF FACT

Something happened to Mr. Williams the day of his vaccination. The issue is whether that something is related to the vaccination, in which case he may be eligible for compensation under this program, if the Court can find such to be manifest by a preponderance of the evidence.

A. Standards Governing Findings of Fact

It is axiomatic to say that the Petitioners bear the burden of proving, by a preponderance of the evidence – which this Court has likened to fifty percent and a feather – that a particular fact occurred. Put another way, it is required that a special master, "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 [special master] of the fact's existence." In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. Snowbank Enterprises v. United States, 6 Cl. Ct. 476, 486 (1984).

This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

Medical records are afforded substantial weight, as has been elucidated by this Court and by the Federal Circuit:

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

Cucuras v. Secretary of HHS, 993 F.2d 1525, 1528 (Fed. Cir.1993).

Medical records are more useful to the Court's analysis when considered in reference to what they include, rather than what they omit:

> [I]t must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992) (citations omitted), citing Clark v. Secretary of HHS, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

Just as contemporaneous medical records are afforded substantial, if not deferential weight, the treating doctors responsible for their composition are regarded likewise, because of their ability to observe a petitioner at important points or periods of the injury alleged. Accordingly, the Federal Circuit has ruled that "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.'" Cappizano v. Secretary of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006), quoting Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

B. Factual Analysis

There was a great deal of semantic fog clouding the hearing in this case. The experts often spoke cryptically or anecdotally, even hypothetically, about what could happen in another case, with different facts. They were regrettably short in explanation, long on arguments and hypotheses. Further, the questions posed by Counsel, even to the parties' own experts, did not address the elements of the evidentiary burdens borne by the parties. Consequently, there is a great deal that was left unclear about the facts of this case. Into this morass, the Court reluctantly plunges.

It seems clear to the Court that, despite being an overweight and unapologetic, long-term smoker with a history of hypertension and chronic skin ulcers haunting his lower back and extremities, Petitioner appears to have been in relative good health prior to the vaccination, having been physically capable of serving as a volunteer fire fighter, of participating with his sons in a lawn care business, and of being his wife's care-giver for nine years. Four hours after the vaccination there appeared the onset of what everyone seems to agree was a vaccine-related reaction, which included previously absent levels of debilitating pain. At some point in the course of Petitioner's condition, his symptoms were diagnosed as systemic Lupus, which led Petitioner to be adjudicated to be disabled, and he is unable to do those aforementioned activities. To be sure, the diagnosis of Lupus is primarily clinical and somewhat subjective as to presence and prevalence of arthralgias and myalgias. But there is no reason, derived from within the medical records extant, to justify suspicion that Petitioner was exaggerating his level of pain, discomfort and other issues related to his condition, including loss of balance and the inability even to write his own name. Likewise, most, if not all of the contemporaneous medical records note a temporally direct relationship between the vaccination and the onset of Petitioner's injury, with several doctors stating explicitly that they viewed the injuries as sequela to the vaccination.

The Court first addresses whether Petitioner has presented a reputable medical or scientific explanation that causally connects the Hepatitis B vaccination to the injury alleged. See Grant v. Secretary of HHS, 956 F.2d 1144, 1184 (Fed. Cir. 1992). Based on the testimony taken at trial, it appears that the expert witnesses on both sides agree theoretically that an immunologic reaction – specifically an antigen antibody complex – *can* cause a myriad of issues including quite plausibly a connective tissue disorder as was experienced by Petitioner. Petitioner's Expert noted "a number of reported cases of Lupus being initiated by Hepatitis B immunizations" which "were all published in very reputable journals, with a discussion of a plausible immunologic mechanism." Tr. at 10. Respondent's expert agreed that "the acute reaction that occurred about four hours post-vaccinal, in and of itself was sequela to the vaccination." Tr. at 44. But while this represents a reasonable medical theory in the abstract, the parties contest its application to the facts of this case.

Both parties note the issue presented by the specific facts in this case: Petitioner's reaction began very shortly after receiving his first administration of the Hepatitis B vaccine, and it seems to be common knowledge in immunological circles that any serious reaction to the Hepatitis B vaccine would have to occur after a secondary or tertiary challenge by the vaccine, not immediately following the first shot. The experts agree that, in general, this sort of antigen antibody complex disorder takes

a week or more before the first symptoms become manifest, and that such injuries typically occur after the second or third administration of Hepatitis B vaccine. In this particular case, Petitioner alleges that his symptoms began four hours after the first administration of the Hepatitis B vaccine.[20] Petitioner's expert assumed that Petitioner must have already had Hepatitis B antibodies present in his system before the vaccination, thereby allowing for a near-immediate onset of Petitioner's condition. This contention is neither supported nor excluded by the medical records extant.

Secondly, then, Petitioner's medical records are replete with numerous doctors who either treated or evaluated him, and concluded, some against their pecuniary interests perhaps, that his medical issues were causally linked to the vaccination. Dr. Jones with the Canby Medical Clinic is the first treating physician to relate the vaccine to the Petitioner's condition, and she maintained throughout his course of treatment that Petitioner's injuries were due to an "ongoing problems as a result of his reaction to hepatitis B and ensuing systemic lupus that he had because of it." Her colleague, Dr. Musselman unwaveringly reiterated that assessment. Pet. Ex. 4 at 3.

Thereafter, Dr. Musselman sent Petitioner to hospital where he could be evaluated by a rheumatologist. The hospital admission notes indicate "probable adverse reaction to hepatitis b vaccine." Pet. Ex. 9 at 7.

Thereafter, in conjunction with a claim for workers' compensation (Petitioner was required to get the Hepatitis B shot in conjunction with his role as a volunteer firefighter), Mr. Williams was evaluated by several doctors.

The first, Dr. Downs, says that Petitioner's "musculoskeletal disability secondary to his arthralgias and myalgias is reasonably medically probable have been an adverse reaction to the hepatitis B vaccine." Pet. Ex. 7 at 17 (emphasis added). Dr. Downs then added, after viewing more of Petitioner's medical records, "This is a very unusual reaction if it is related to the hepatitis B vaccine and frankly the best opinion that I can render is that it is possible that Mr. Williams' autoimmune disorder was triggered by the vaccine. It is based upon the history presented by Mr. Williams given the onset of symptoms being associated directly with a vaccine that industrial causation of his autoimmune disorder may be reasonable. However, I would suggest that a more expert opinion may come through a sophisticated rheumatologist or immunologist." Pet. Ex. 7 at 6. After a thorough review of Petitioner's records however, he indicated, "The information provided in these records tends to support Mr. Williams' arthralgias and myalgias being secondary to an adverse reaction to the hepatitis B vaccine." Pet. Ex.7 at 2. After viewing a complete sampling of Petitioner's medical records at that time, Dr. Downs was convinced that Petitioner's injury was vaccine-related.

[20] Of course, Petitioner has stated that he had a prior administration of the Hepatitis B vaccine many years ago pursuant to a sojourn in the Republic of South Vietnam, a claim uncorroborated by any medical records or tests. It is the Court's understanding that there was no vaccination for Hepatitis B at that time, although this Special Master did receive a gamma-globulin injection for Hepatitis, presumably Hepatitis A, at that time, and perhaps Petitioner did as well.

Dr. Nagy, a board certified immunologist, also evaluated Petitioner at the behest of the insurance company. He concluded that, despite a conflict in the medical literature:

> In my opinion, the immunization with hepatitis B which was given to the claimant in the left upper arm on 5/14/02 [sic] either initiated de novo a lupus-like syndrome, or exacerbated an undiagnosed connective tissue disorder. In either case, this is an occupational-related illness. The most persuasive aspect of the history is the fact that within hours of the immunization he developed an obvious immunologic response manifested by local swelling/erythema which progressed to the illness as defined over the ensuing four months.

Pet. Ex. 8 at 10.

A third doctor who evaluated Petitioner concerning the workers' compensation claim at the behest of the insurance company, Dr. Adam Duhan with the Evaluation Resource Group, states "Certainly, as reported by numerous treating physicians, taking the Hepatitis B vaccine triggered his Lupus." Pet. Ex. 13 at 67.

Therefore, while the medical providers, including the treating physicians Doctors Armisen, Jones, and Peters, are hardly unanimous in ascribing Petitioner's condition to the Hepatitis B vaccination, that conclusion does find repetition throughout the medical records. As the Federal Circuit has repeated on more than one occasion, "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.'" Cappizano v. Secretary of HHS, 440 F.3d at 1326, quoting Althen v, Secretary of HHS, 418 F.3d at 1280.

In this particular case, of the extensive literature filed by both parties, only a very few articles were actually referenced at hearing and in the post-hearing briefs. Those articles with few exceptions go to the theory whereby the second or third administration of Hepatitis B vaccination has been temporally, if not causally, linked to connective tissue disorders like Lupus with onset two to three weeks after vaccination. Petitioner notes that one letter to the editor, not subject to peer review, indicated a case where such had developed two to three weeks after the first administration of Hepatitis B. Pet. Ex. 32. In accordance with § 13(b)(1), the Court has reviewed the literature proffered.

Furthermore, while Dr. Brenner believed the musculoskeletal pain is unrelated to the Lupus and/or the vaccination, Tr. at 48, the following exchange, quoted previously, is particularly instructive:

A He already had Lupus.

Q Now he has Lupus?

A No, he had Lupus then. That's my point.

Q Yes, but he was asymptomatic, aside from the nodules, wasn't he?

A Yes.

Q So wasn't there a significant worsening of symptoms after the Hepatitis B?

A Absolutely.

Tr. at 103-04. So, according to Dr. Brenner, was there a significant worsening of symptoms following the vaccination? "Absolutely." Tr. at 104.

Respondent seems to say that Petitioner had a pre-existing though latent condition, that emerged in stronger force and severity after the vaccination at issue. The Court considers this position along with the opinions of his treating and evaluating physicians, three of whom went out of their way to opine in favor of causation, even against the potential pecuniary interest arising from their employment by the insurance company embroiled in Petitioner's workers' compensation claim. It is that group of treating physicians (which includes Dr. Nagy), who "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,'" Capizzano, 440 F.3d at 1317 (quoting Althen, 418 F.3d at 1280), and who associated the onset of his deteriorating condition with the acute vaccine-related reaction four hours post vaccination, a reaction that Dr. Brenner agrees was sequela to the vaccination, Tr. at 44, but for which he does not "understand the mechanism" of how "an acute reaction, which is probably allergic mediated, then, in and of itself, led to chronic muscular/skeletal pain." Says Brenner, "I don't have an explanation for that, because I don't understand the mechanism. It doesn't make sense." Tr. at 43-44.

The obstacles to Petitioner's theory on the issue of "did it"[21] causation are threefold: (1) The quickness of response following the vaccination, which was Petitioner's first Hepatitis B vaccination, contrasted to what both experts accept as an appropriate temporal relationship; (2) The dearth of evidence to support Dr. Nagy's theory that Petitioner had already encountered Hepatitis B; and (3) Whether that immediate response was related to Petitioner's long-term illness.

As stated above, Respondent's expert noted that experiencing an acute reaction within four hours of vaccination is "probably the most common reaction" (Tr. at 43), and conceded that "the acute reaction that occurred about four hours post-vaccinal, in and of itself was sequela to the vaccination" (Tr. at 44). However, the issue remains that "Immune complex problems like Lupus require time for the development of some antibody; and we don't have any evidence of antibody, having developed de novo, as a result of vaccination." Tr. at 41.

In reality, this first issue is only problematic if the Court finds to a preponderance of the evidence that Petitioner had not already been exposed to Hepatitis B, the second of the three issues

[21] See Pafford v. Secretary of HHS, No. 01-0165V, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), aff'd, 64 Fed. Cl. 19, 2005 U.S. Claims LEXIS 31 (2005), aff'd 451 F.3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in Althen and Shyface"), rehearing and rehearing *en banc* denied, 2006 U.S. App. LEXIS 28907, cert. den., 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

raised above. If the Court accepts that Petitioner already had an encounter with Hepatitis B prior to the vaccination on 15 May 2002, both experts have stipulated that a vaccine-related injury could occur that would resemble closely the condition(s) experienced by Petitioner. If the Court does not accept as true such a previous encounter, then even Petitioner's expert agrees that Petitioner's injuries would not likely then be vaccine-related. As that is the case, the Court moves to the underlying, foundational issue of fact on this point, whether Hepatitis B had been introduced to Petitioner before 15 May 2002.

The Court takes very seriously Dr. Nagy's testimony that "Hepatitis B is epidemic in Southeast Asia [and is] also epidemic in certain parts of Los Angeles and New York, where [Petitioner] spent a good part of his life," such that the Court "can presume" that Petitioner had Hepatitis. Tr. at 27.

Also, the very fact itself, that Petitioner reacted so strongly to a vaccine which Respondent has characterized as weak, supports the contention that this was a rechallenge reaction, not an initial reaction. Despite the way Respondent's expert described his condition in the first hours and days after vaccination as "localized", the facts are clear that the uncontrovertedly vaccine-related reaction was systemic, and affected Petitioner all across his body.

These facts and circumstances lend credence to the conclusion that Petitioner's biological relationship with Hepatitis B preexisted the vaccination at issue, as they amount to circumstantial evidence of the same. The sticking point, however, is that Petitioner was tested, and retested, for Hepatitis antibodies, the presence of which would verify to a doctor that Petitioner was reacting physiologically with the Hepatitis B antigen. These tests came back negative; i.e., antibodies were not found in Petitioner when they were sought by medical testing.

The Court notes that this absence is not fatal. It is worth noting that the absence of Hepatitis B antibodies in the sample taken from Petitioner does not perforce equate with an absence of such antibodies in trace amounts in Petitioner's system. Moreover, to say that those antibodies were absent in Petitioner at the time of testing is likewise not equivalent to saying that Petitioner has never possessed such antibodies. As Dr. Nagy, a reputable immunologist and Petitioner's treating, examining doctor indicated, antibodies are commonly, even typically, consumed, along with the antibody-antigen complexes, which are destroyed by the body's natural defense mechanisms. Tr. at 17-18.

Of especial note, Dr. Brenner admitted that this theoretical possibility cannot be denied; he noted that a negative finding in the tests performed does not necessarily negate the existence of Hepatitis antibodies within Petitioner, and that positive test results would not be necessary for the Court to find Dr. Nagy's proposed mechanism at work in this case. Tr. at 61. Immediately after that admission, however, Dr. Brenner derided Dr. Nagy's theory nonetheless, on the basis that he had "never heard of it," had "never seen it happen," and had "never heard of it happening." Id. However, that alone does not quash Petitioner's theory. By Dr. Brenner's own testimony (as well as his *curriculum vitae*) the Court is made aware that, even though he is board-certified in

immunology, his experience lies almost wholly in rheumatology: "[M]y practice is and always has been exclusively rheumatology." Tr. at 38. It is not unreasonable that he would perceive Petitioner's illness first and foremost through that lens, and it does not make him any less of an expert medical professional if indeed that is the case.

Furthermore, the tests which Petitioner underwent to determine whether he possessed Hepatitis B antibodies were not themselves conclusive, and should not be understood to exclude the possibility of their presence within him. Therefore, even though Respondent's expert said, "Mr. Williams had no evidence [borne out in the medical records] of response to the vaccine; by which I mean, on multiple determinations, soon after vaccination, and as late at 2004, he showed no evidence of Hepatitis B antibody," (Tr. at 40), he also testified that "Unfortunately, the very best test for core antigen wasn't done, and it wasn't done because nobody considered the possibility that he had underlying Hepatitis B" (Tr. at 44-45). This is quite relevant because, as Respondent's expert noted, "when people have chronic Hepatitis B, the really bad actor turns out not to be surface antigen. The really bad actor in chronic Hepatitis B turns out to be core antigen." Tr. at 60.

All in all, the Court believes that Petitioner has convincingly proven to a preponderance that Petitioner's physiology had been challenged in the past, such that his response mechanism was primed to respond sharply, violently, and certainly quickly, almost immediately after the vaccination on 15 May 2002. Therefore, the Court accepts this to be true.

The last hurdle facing Petitioner's case in chief is in many ways the most central issue to proving that the injury, or the extent of the injuries suffered, was vaccine-related. As noted above, Respondent has apparently conceded that *at least* the acute reaction, which overcame Petitioner those few short hours after administration of the Hepatitis vaccine, was related to the vaccine. The issue then becomes differentiating between the acute reaction and the long-term illness afflicting Petitioner's connective tissues. Certainly, Respondent has not offered any alternative theories of causation which would otherwise explain the course of Petitioner's condition:

> [T]he question becomes, you know, why would an acute reaction, which is probably allergic mediated, then, in and of itself, lead to chronic muscular/skeletal pain? I don't have an explanation for that, because I don't understand the mechanism. It doesn't make sense.

Tr. at 43-44.

One aspect borne out in the medical records, although not much discussed at the hearing, is that there was no break in symptomatology between the acute reaction and the chronic illness. Debilitating joint pain came out of nowhere after the vaccination, and it came to stay. The medical records do not even hint that Petitioner suffered any such pain prior to the vaccination, much less the overwhelming, disabling pain which became a mainstay of Petitioner's existence afterward. Respondent's attempts to rebut or even to dispute this obvious point are received as less than convincing: "The only reason that we see high grade inflammation following vaccination and not before vaccination is because nobody looked before vaccination." Tr. at 47. Actually, the only evidently plausible reason why the medical records evidence painful "high grade inflammation" after

the vaccination and not beforehand is because Petitioner had not gone to the hospital complaining of unbearable pain or immobilizing swelling, and did not mention any preexisting symptoms of this sort when he did. One can assume that if the pain was incrementally progressive prior to hospitalization, that would be reflected in the history taken at presentation. Respondent's expert ignored these otherwise glaring aspect of the medical records at many points during the hearing:

> In my opinion, it's unrelated, and I'll tell you why. This is one of the most common reported reactions to vaccinations, anyway, you know. I mean, in all of the vaccine studies, local, acute, reactions are foremost amongst the reacto-genic problems of vaccines. So these happen to everybody.

Tr. at 56.

On the contrary, speaking as a long-time participant in the Vaccine Compensation Program and as a personal subject of previous vaccinations, what happened to Petitioner *does not* happen to everybody. Furthermore, the medical records note that Petitioner's reaction to the vaccination was local only when it initiated; it soon spread over much of his body. In contrast, Petitioner's expert testified that Petitioner's symptoms which persisted over the first three weeks following vaccination, which included some swelling, a rash, arthralgia(s), a fever, weight loss, and fatigue, were directly related to the reaction: "That was part of this inflammatory process." Tr. at 106-107. These symptoms, persisting weeks after vaccination, are not part of the normal reaction that happens to everyone receiving this vaccine, which Respondent's expert elsewhere referred to as a "weak" vaccine. Tr. at 41.

Moreover, none of Petitioner's treating doctors noted suspicion as to whether the symptoms expressed by Petitioner were idiosyncratic or subjective to him, as Respondent's expert argued:

> THE COURT: Is his condition today significantly worse than what it was prior to the vaccination?
>
> THE WITNESS: I don't know; subjectively, perhaps -- objectively, no. I mean, objectively, the chances are overwhelming.

Tr. at 47. The Court accepts the statements and notations of Petitioner's treating physicians and specialists over Dr. Brenner, who seemed to base this aspect of his testimony on a preconceived epidemiology of averages, rather than Petitioner's course of symptoms and treatment. As such, the Court finds that Petitioner did not suffer from these severe symptoms prior to vaccination, but experienced disability and debility after the vaccination as the result of pain in his joints and muscles. Also, as a result of his treatment, the Court finds that he has suffered muscle atrophy and damage, due to the steroids that have been a central pharmacological treatment for those symptoms.

The Court here pauses to remark upon this point, that no evidence was ever proffered by either party to support the suggestion that Petitioner's health would have followed the same course if he had never received the Hepatitis B vaccine at issue. Though the medical opinions in this case may cavil about how much of his immune response is attributable to the vaccination, no serious dispute exists that the vaccination affected Petitioner's health condition to notable extent.

Building out from this realization, it soon becomes apparent that there is no distinguishable marker to delineate between the concededly vaccine-related "initial reaction" and the long-term disability that continued to affect Petitioner. Instead, observation reveals an unbroken continuum of symptoms that have transmogrified somewhat in subtle particulars, but which show no evidence of a radical shift in symptomatology: If the Court ascribed the initial reaction to the vaccine, but decided that, at some later time, Petitioner's condition was more affected by another underlying injury, and tried to transcribe a limit betwixt the twain, the Court would not be able to differentiate between a distinct vaccine-related injury, and an underlying long-term illness which remained asymptomatic before the vaccination and ran concurrently with the symptoms of the initial reaction to the vaccine. The medical records bespeak one continuum of a condition, beginning with acute onset immediately following administration of the Hepatitis B vaccine, and extending over the course of months and years, unabated.

Dr. Nagy described this progression as "a cascade of events, which just didn't stop." Tr. at 23. Dr. Brenner concedes that the acute onset of symptoms was vaccine-related, but argues that the Court should pay slight heed to that onset in the grander view of Petitioner's condition. Tr. at 44-45. However, this rationale does not offer reliable distinguishing indicia to differentiate the acute onset of symptoms from the now chronic condition affecting Petitioner. The Court finds it impossible, given the factual record extant, to offer a point of delineation, and Respondent surely does not offer one. Taken altogether as a whole, Dr. Brenner's testimony adds details and corroboration to the warp and woof of the theory which Dr. Nagy travailed to weave, leaving the Court more persuaded by Petitioner's theory as a result.

Moving on, the Court next addresses a factual issue that was the subject of much dispute at the hearing: whether Petitioner suffered from Lupus prior to the vaccination at issue. Respondent's expert expressed his belief that Lupus had been clinically manifest in Petitioner "for a very long time," and potentially as early as 1971. Tr. at 46-47. Petitioner's expert was indignant that anyone could base a diagnosis of Lupus merely on a prior history of hypertension and unidentified, inflammatory skin nodules that disappeared with the steroid treatment. Tr. at 29. While either or both of these clinical symptoms may often attend patients suffering from Lupus, they are general, corroborative indicia at best; neither is a specific indicator for Lupus.

The Court finds that Petitioner's condition was markedly worsened after the vaccination, based upon ample evidence in the medical records noted above, regardless of whether that was due to the initiation or aggravation of the connective tissue disorder experienced by Petitioner. Therefore the question of whether Petitioner *actually* had textbook Lupus before his vaccination *vel non* is not particularly relevant for the Court's purposes here. The Court's objective is not to diagnose Petitioner, and is certainly not to wager a timeline for that diagnosis. For off-table injuries, diagnostic labels are valuable for convenience and semantic ease at most. The Court's conclusion on the issue of causation regards whether an alleged injury is vaccine-related, vis-à-vis how or when such injury is categorically classified.

Taken together, the facts in this case are persuasively compelling, and indicate that the vaccination initiated an inflammatory response and reaction within Petitioner. The initial reaction changed gradually, but without interruption into a debilitating condition that left Petitioner seriously disabled in comparison to his pre-vaccinal state. Whether the vaccination was the impetus for a brand new connective tissue disorder such as Lupus, or whether it seriously aggravated a preexisting but very mild case of Lupus that had existed since 1971 or time immemorial, the important facts of this case do not change. The Court finds that Petitioner's injury is, in fact, vaccine-related, because Petitioner's most debilitating injuries would not have afflicted Petitioner but for the administration of the vaccine, and because the chain of causation from the vaccine to the immediate reaction, and then continuing on to the long-term disability, was direct and not interrupted or remote. Indeed, the vaccine was a substantial cause for Petitioner's injury.

III. CONCLUSIONS OF LAW

A. Legal Standards

In legal terms, "Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole -

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." §13(a)(1).

Concerning §11(c)(1) and certain other preliminary requirements, it is undisputed that (1) Petitioner is a valid legal representative; (2) the vaccine at issue is set forth in the Vaccine Injury Table; (3) the vaccine was administered in the United States; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. §§ 300aa-11(b) and (c). Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

The dispute rather is whether petitioner can demonstrate that he received an injury recognized by the Vaccine Injury Table, 42 C.F.R. § 100.3, ("Vaccine Table" or "Table") within the statutorily prescribed time period or that he "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A)." § 11(c)(1)(C)(I) & (ii)(I).

In this particular case, the Petitioner is not claiming a "Table Injury."[22] Therefore, he must demonstrate by preponderant evidence that the vaccination in question, more likely than not, actually caused the alleged injury. Id. If the Petitioner is successful in showing a *prima facie* case, the burden then shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed Cir. 1994).

In actual causation cases before the Vaccine Program, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See 11(c)(1)(C)(ii)(I) & (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); see also Strother, 21 Cl. Ct. at 370. Additionally, merely showing an absence of an alternative cause of injury does not meet petitioner's burden of proof. Grant, 956 F.2d at 1149. That being said, where several potential causes present themselves, a petitioner need not show that the vaccination was the sole cause of the injury but may demonstrate that it was a "substantial factor" in causing the alleged injury which would not have occurred "but for" the vaccine. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999).

However, the Federal Circuit recently amplified its causation-in-fact analysis as follows:

> [Petitioners'] burden is to show by preponderant evidence that the vaccination brought about [the] 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.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

According to the court in Althen, the Vaccine Act anticipates that Petitioners may use circumstantial evidence to prove their claim. A bright line test, like the one criticized in Althen, which required that petitioners provide medical literature in order to prevail, "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Id. at 1280. But see, Knudsen, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden) and Hines v. Secretary of HHS, 21 Cl. Ct. 634, 646

[22] Table injuries for Hepatitis B include "Anaphylaxis or anaphylactic shock" within zero to four hours of vaccination and "Any acute complication or sequela (including death) of above event." 42 C.F.R. § 100.3 (VIII).

(1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991). In other words, even where a medical theory involves "a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Althen, 418 F.3d at 1280.

Concerning the framework iterated in Althen, the Federal Circuit recently held that the prongs may overlap. Capizzano v. HHS, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), aff'd, 63 Fed. Cl. 227 (2004) (Merow, J.), rev'd, No. 05-5049, slip op. at 14 (Fed. Cir. Mar. 9, 2006). Specifically, the Federal Circuit in Capizzano collapsed the second and third prongs for treating physicians who utilize temporal relationship to demonstrate a cause and effect relationship. According to Capizzano, 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.'" Id. (quoting Althen, 418 F.3d at 1280); see also Zatuchni v. Secretary of HHS, 69 Fed. Cl. 612, 624 (2006). Nevertheless, the Vaccine Act explicitly notes that the opinion or diagnosis of a treating physician is not binding on the Court but rather must be viewed in light of "the entire record and the course of the injury." §13(b)(1).

As to the third prong in Althen, the Federal Circuit more recently indicated that, even when a Vaccine can cause a particular injury, and particularly where there is more than one potential trigger, the petitioner must still demonstrate an appropriate temporal relationship between the vaccination and the injury alleged. Pafford v. Secretary of HHS, 2006 WL 1679714, slip op. at 4 (Fed. Cir. June 20, 2006).

Ultimately, however, there is "no hard and fast rule for what specific, individual elements of proof a petitioner must present in order to establish a prima facie case of causation-in-fact; the rule is really one of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time." Pafford v. Secretary of HHS, 64 Fed. Cl. 19, *31 (2005), aff'd, Pafford v. Secretary of HHS, 2006 WL 1679714, slip op. (Fed. Cir. June 20, 2006) (emphasis in original) (citing Knudsen, 35 F.3d at 548 ("Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.")).

Moreover, as the Court of Federal Claims opined:

> Indeed, one can imagine a hypothetical case where a completely healthy individual receives a vaccine and suffers some condition shortly thereafter. The Special Master may conclude that, based on the entirety of facts--including the petitioner's relative health prior to the vaccine--the petitioner has satisfied his burden of proof. This might be the case if there is an absence of alternative causes apparent in the record or the biologic mechanism that petitioner demonstrates is particularly compelling.

Pafford v. Secretary of HHS, 64 Fed. Cl. at *31.

The Vaccine Act also specifies that a Petitioner need not prove a vaccine caused an injury in isolation, but is entitled to compensation if a vaccination is shown to have "significantly

aggravated, any [preexisting or contemporaneous] illness, disability, injury, or condition." §11(c)(1)(C)(ii)(I). Section 33(4) of the Vaccine Act defines the term "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."

> The legislative history further elucidates the meaning of "significant aggravation":
>
> The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (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).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6356-57 (emphasis added).

In Whitecotton v Secretary of HHS, 81 F.3d 1099 (Fed. Cir. 1996) the Court of Appeals for the Federal Circuit announced its test for significant aggravation claims. Id. at 1107. For evaluating whether a petitioner has made out a prima facie significant aggravation claim under the Act, the special master must:

> (1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, . . . (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute.[23]

According to the Federal Circuit in Whitecotton, when it comes to significant aggravation, one of the primary questions is whether "the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination" within the meaning of the Vaccine Act. Whitecotton v Secretary of HHS, 81 F.3d 1099, 1107 (Fed.Cir. 1996). The Act, of course, defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." §33(4).

As aforementioned, when and if a Petitioner demonstrates a prima facie case of actual causation, the burden of proof then shifts to Respondent to show that the claimant's injuries are "due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed. Cir. 1994).

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[23] The Whitecotton decision includes a fourth prong, inapplicable to the present case, that requires the special master to "(4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table." 81 F.3d at 1107.

B. Legal Analysis

Petitioner argues that he "must only show by a preponderance of the evidence that a vaccine, rather than something else, likely caused the injury." Petitioner's Reply to Respondent's Post Hearing Brief at 14. The application of this reasoning is that, because there is no more likely cause identified in the medical records, the vaccine can be said to have been a direct cause of the injury suffered, or to have aggravated an erstwhile injury. However, Petitioner misapprehends his burden of proof, which is to show that the vaccine more likely than not was a cause the injury alleged. A prima facie case of causation-in-fact may be shown by affirmatively meeting the three prongs articulated in Althen and is not met simply by showing an absence of a more likely etiology. Grant, 956 F.2d at 1149.

Petitioner further argues that "in a field bereft of complete and direct proof of how vaccines affect the human body," he may prove his claim via circumstantial evidence. See Althen, 418 F.3d 1274, 1280. Quite so. It is possible that circumstantial evidence may, on the whole, add up to a preponderance. However, the weight accorded that evidence is the demesne of this bench. As the court in Althen recognized that, given the relative rarity of vaccine-related injuries, a Petitioner ought not be required to present certain types of evidence like epidemiological studies, pathological markers, medical literature and the like, which may or may not exist. Hence, while petitioners may be limited in the type or quality of evidence available, they may yet proffer a quantum of circumstantial evidence including, but certainly not limited to, the opinions of treating doctors, expert opinions, and supportive medical or scientific literature, that – taken as a whole – adds up to preponderant evidence.

Petitioner argues that requiring him to prove the vaccine in question caused the injury alleged, or to prove certain factual suppositions on which his expert's theory is based, is equivalent to requiring proof of a biological mechanism, and according to the Federal Circuit,"[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (1994). However, Petitioner is not being required by this Court to propose or prove that a specific biological mechanism can and did cause Petitioner's injury, but he is required by the applicable law binding on this Court to proffer a plausible medical theory that causally connects the vaccine with the injury alleged.

According to the findings articulated *supra*, Petitioner was asymptomatic prior to the vaccination and afterwards the records document a cascade of medical issues the treatment of which led eventually to a clinical diagnosis of a connective tissue disorder and from which Petitioner has been saddled with a disability. Prior to the vaccine, the Petitioner was physically active as a volunteer firefighter, lawn maintenance provider, and long-time caretaker of his spouse. Afterwards, he could hardly scribe his own name.

Applying the rule for significant aggravation outlined in Whitecotton, *supra*, it appears that, (1) Petitioner's condition prior to administration of the vaccine was asymptomatic, or at least functional to support himself and aid his immediate family members; (2) currently, Petitioner is capable of much less activity and suffers a diminished ability; and (3) this development is certainly a change for the worse for Petitioner, and the results are easily categorized as an increase in disability (he was not significantly disabled before the vaccination) and pain (his primary symptom), and was accompanied by substantial deterioration of health. As such it is accurate to say that Petitioner's condition has been significantly aggravated.

Moreover, Petitioner's condition was significantly aggravated as a result of and/or by the vaccine. This is so because Petitioner has explained a medical theory that logically connects a chain of causation from the vaccination to the injury with the vaccination as a substantial cause or reason for the injury, and part of that explanation provides a basis to show that the temporal relationship between the two (which is certainly proximate) is appropriate within the matrix of medical science in its current form.

The Court has found *supra* that Petitioner's explanation is logically plausible, and that, more likely than not, the mechanism proposed was actually at work in Petitioner's case. Inasmuch as the Court found Petitioner's proffered explanation of a prior exposure to Hepatitis B to be credible, then even Respondent's expert can agree (albeit reluctantly) that the time between the vaccination and the onset of symptoms, and the course followed by Petitioner's condition thereafter, is medically and scientifically plausible, even likely. Moreover, Petitioner's theory is supported by the majority of Petitioner's treating doctors, whose opinions this Court is bound by precedent to hold in deferential stead, and, *a fortiori*, said theory has been proffered by one such treating doctor. The Court, appropriately, affords these accounts and opinions substantial and persuasive weight.

Consequently, Petitioner has met the standard of proof required by the Vaccine Act, as explained in the Althen case, and should therefore prevail on the issue of entitlement, on the theory that the vaccination at issue significantly aggravated Petitioner's condition. Directly applying the logic employed by the Federal Circuit's hypothetical situation cited above from Pafford, it is even more resoundingly clear that Petitioner prevails, given his relative good health before the vaccination and the overnight development of serious, systemic ailments affecting many aspects of his body. In contradistinction, Respondent has neither proffered nor proved that a factor unrelated caused the injury alleged, nor that a factor unrelated overwhelmed the vaccine to render it an insubstantial, or remote, cause of the injury. The Court therefore rules that Petitioner is entitled to compensation from the Vaccine Program.

CONCLUSION

The Court **RULES** that Petitioner is entitled to Program compensation.

IT IS SO ORDERED.

Richard B. Abell
Special Master