

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 99-561V

Filed: 5 April 2007

* * * * *
JOYCE DIANNE KEENAN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.
* * * * *

PUBLISHED

Chemical Sensitivity & Reaction;
Significant Aggravation; Factors Unrelated

Clifford J. Shoemaker, Esq., Vienna, Virginia for Petitioner.
Heather L. Pearlman, Esq., U.S. Department of Justice, Washington, D.C., for Respondent.

AMENDED ENTITLEMENT RULING¹

ABELL, Special Master.

On 3 August 1999, Petitioner brought a petition under the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act” or “Act”),² for alleged vaccine-related injuries resulting from a Hepatitis B vaccination (“HBV”) administered on 30 August 1993.³ Specifically, Petitioner alleges that, as

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 ruling 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).

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 Hepatitis B was added to the Vaccine Injury Table in August 1997, and the Act provides for an eight-year "look-back" window for the years before a vaccine's addition to the Table, with the understanding that such petitions must be filed within two years of that addition. §16(b)(2). The filing of this petition on 3 August 1999 prevented the statute of limitations from running, but it was many years before Petitioner completed the evidentiary filing requirements set forth in §11(c).

a result of that vaccination, she suffered a respiratory illness including bronchospasm and asthma and an immunological dysfunction involving sensitivity to various chemicals.

I. FINDINGS OF FACT

The Vaccine Act authorizes a special masters to make Decisions on petitions which include findings of fact and conclusions of law. §12(d)(3)(A)(I). However, the Court may not find in favor of a petitioner based on her asseverations alone; rather, his 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 recorded facts and then to the expert medical opinions offered thereupon.

By law, the Petitioner can demonstrate entitlement to compensation either by offering proof that she suffered 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, in the alternative, that she "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 the Vaccine Injury Table." §11(c)(1)(C)(I) & §11(c)(1)(C)(ii)(I).

According to the language of the Vaccine Act,

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) the 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 for the petition to be timely filed has been met.

Here, the Petitioner is not arguing that she suffered a Table Injury.⁴ Rather, she is claiming that the Hepatitis B Vaccination caused in fact the injuries alleged.

The Federal Circuit has articulated a three part test regarding a petitioner's burden of proof under a cause-in-fact analysis: Petitioner must "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).

A. Fact Testimony and Medical Records

On 8 March 2005, this Court conducted an evidentiary hearing in the above-captioned case for the purpose of determining the facts upon which the Court and the experts may rely in rendering a decision on entitlement, after which, the Court set a briefing schedule. A ruling was rendered on 17 October 2005 as a result of that process and is incorporated herein by reference.

That factual ruling was summarized by the Court as follows:

Though hampered by a dearth of medical records, the Court finds Petitioner's story overall to be credible. The testimony of Mr. Keenan, who is a supervisory

⁴ Injuries listed on the Vaccine Injury Table in conjunction with Hepatitis B include:

A. Anaphylaxis or anaphylactic shock 0-4 hours

B. Any acute complication or sequela (including death) of above event

42 C.F.R. § 100.3 (VIII).

Anaphylaxis and anaphylactic shock are defined by the Qualifications and Aids to Interpretation ("QAI") that accompany the Vaccine Table as follows:

Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

42 C.F.R. § 100.3(6).

fireman as well as an emergency medical technician, was of particular help in putting together the pieces. The Court finds the following summary to be an accurate sketch of Petitioner's medical course post-vaccination:

- (1) Within ten hours of receiving HBV Petitioner suffered a rash accompanied with itching that was treated with Benadryl and a cold bath;
- (2) She passed out at work the next day, was hospitalized, treated and released;
- (3) Thereafter Petitioner progressively developed sensitivities to a variety of chemicals though no specific dates or intervals can be ascribed;
- (4) Petitioner experienced a particularly serious event in March 1995 connected with exposure to an oven cleaner; and
- (5) Eventually, Petitioner's condition – as respects her chemical sensitivities – improved.

Petitioner contends that her health took a dramatic turn for the worse following the Hepatitis B vaccination and then again following the March 1995 exposure to oven cleaner. The Court can find no record of a dramatic decline. Rather, the Court will accept that Petitioner progressively developed a sensitivity eventually to a legion of chemical and other items which caused her a great deal of physical and, over time, mental anxiety and which eventually improved but not without leaving a lasting impact on Petitioner's standard of living. Now whether that condition was caused by the HBV is another issue altogether.

Onset Ruling, 17 October 2005, at 6-7 (footnotes and citations omitted).

B. Medical Opinion

On 6 April 2006, the Court conducted a second hearing in the above-captioned case for the purpose of hearing from the medical experts on the issue of causation.

Petitioner presented an expert report as well as live testimony from Dr. Joseph A. Bellanti, who is a professor of pediatrics and microbiology and immunology at Georgetown University School of Medicine and has been for some forty-three years. Dr. Bellanti is board certified by the American Board of Pediatrics and by the American Board of Allergy and Immunology, a conjoint board of the American Board of Internal Medicine and the American Board of Pediatrics. His research efforts have largely been focused on studies of anti-microbial immunity. He has published some twenty score articles in addition to serving in an editorial and review capacity for several noteworthy journals. Entitlement Hearing Transcript, 6 April 2006, ("Tr.") at 5-6, 9; Petitioner's Exhibit ("Pet. Ex.") 26.

Respondent proffered an expert report from Dr. Burton Zweiman who is a professor of medicine and neurology at the University of Pennsylvania Medical Center, where he has been since 1963, and where he presided for twenty-four years as chief of its allergy and immunology division. He is board certified by the American Board of Internal Medicine and the American Board of Allergy and Immunology. A prolific author, Dr. Zweiman has published more than 250 papers in addition to other material in the field of immunology. He has likewise been involved in research in several related areas. Tr. at 53. Respondent's Exhibit ("R. Ex.") B.

The Court notes that neither party raised any contention on voir dire as to the expertise or credibility of either of these gentlemen. And having heard from both of these experts on several occasions in the past, the Court understands that both are as well-versed in their fields as any two experts one could hope to obtain.

1. Dr. Bellanti

Dr. Bellanti posits that the vaccine at issue started a two-step chain reaction, which led to dysregulation of Petitioner's immune system, leaving her susceptible to heightened physiological reactions from certain triggering substances. According to his theory, Petitioner's immediate reaction could have arisen in response to elements in the vaccination administered other than the active vaccine agent. These other substances, which are part of the vaccination, could have elicited a reaction from Petitioner within the first several hours following vaccination, even though the hepatitis B agent would not have had such quick effect.

Dr. Bellanti's expert medical opinion is that Petitioner's adverse reaction to the hepatitis B itself could have later affected her physiology to the extent of "immune dysregulation," possibly by a mechanism such as "molecular mimicry." The former he described as a loss of proper or proportionate response from the body's immune system, often leading to over-reaction, and the latter he explained as a sort of biological 'mistaken identity', such that the body's immune response reacts against certain benign stimuli as it would normally against more noxious substances. Dr. Bellanti does not attribute these reactions to a pre-existing lung condition and other allergies. Instead, he views the vaccine's effects as distinct phenomena, separate or cumulative to the Petitioner's pre-existing conditions.

Dr. Bellanti acknowledged that his statements regarding Petitioner's pre-vaccinal state of relative good health are premised on her testimony, and not on any contemporaneous medical records, which are non-existent for the 13 years prior to vaccination. Tr. at 27. However, the testimony he relies on is consistent with the Court's findings of fact at the previous onset hearing.

According to Dr. Bellanti, environmental allergies are "a very common immunologically mediated disorder affecting the population. We do see a number of patients with that type of allergy." Tr. at 7-8. Certain individuals are genetically predisposed to respond to certain environmental stimulants. Tr. at 24-25. Dr. Bellanti indicates that the Petitioner had, prior to vaccination, demonstrated a history of allergies to environmental items allergens including polycillin,

phenobarbital, and bee stings, and had a history of sinus headaches. Tr. at 28. And, in fact, she habitually carried an epi-pen as a prophylactic measure against an anaphylactic reaction to one of those known dangers. In addition, her long-term smoking habit had probably resulted in chronic lung disease by the time of her vaccination, which can aggravate existing allergies. Tr. at 26.

However, for Dr. Bellanti, these pre-existing ailments do not explain the full array of Petitioner's current condition, or her immediate reaction to the vaccination. On reviewing the history of this case, Dr. Bellanti notes that the Petitioner "seemed to be in a fairly good state of health" prior to receiving the vaccination at issue. Tr. at 12. In his opinion:

[I]t seems this patient did have some degree of allergy to environmental allergens, bee stings and drugs. *But there was a profound increase in the frequency and severity of things that she became allergic to or hyper-sensitive to subsequent to the hepatitis B immunization.*

Tr. at 14 (emphasis added).

Dr. Bellanti's opinion is similar in reference to Petitioner's chronic obstructive pulmonary disease (COPD), which he agrees pre-existed the vaccination. Tr. at 37. For Dr. Bellanti, this disease is discernibly distinct from Petitioner's reaction to environmental stimuli following her hepatitis B vaccination. Tr. at 26. He believes that the condition of Petitioner's lungs "could have been aggravated by the changes that occurred after the immunization." Tr. at 37.

Dr. Bellanti opines that while smoking no doubt had some effect on her health, and may have resulted in a pre-existing condition of chronic obstructive pulmonary disease ("COPD"), he sees it as a separate issue from the acquisition of environmental allergies or sensitivities following the administration of the Hepatitis B vaccination. Tr. at 26-27, 37. He views the COPD as an irreversible lung-deteriorative disease, but reiterates that there is something superimposed upon that pre-existing condition, caused by the vaccination. Tr. at 51. Hence, the Petitioner's COPD could have been aggravated by the vaccination. Id. (emphasis added). So, while there may have been objective evidence of the COPD on medical examination, due to the nature of an immunotoxic insult, there would be no visible indicia of the superimposed condition caused by the vaccine. And yet that injury, caused by the Hepatitis B vaccine, would be juxtaposed with, or superimposed over, the COPD. Id.

As to the vaccine's active hepatitis B agent itself, Dr. Bellanti stated that it "can give rise to many autoimmune reactions," noting that these would be statistically rare, "but they do occur." Tr. at 15-16. The hepatitis B agent itself would not have caused the immediate reactions suffered by the Petitioner, admits Dr. Bellanti, but such reactions could have been precipitated as a toxic response. Tr. at 16. Dr. Bellanti noted that vaccinations contain other additives and adjuvants that might also bring about a reaction, "including the eccipients, the yeast components, the thimerosal," as well as "aluminum hydroxide used as an adjuvant," which is "a substance that can augment an immune

response." Tr. at 16.⁵ Therefore, the Petitioner could have suffered a reaction to one of those additives or adjuvants—additives or adjuvants that also combine to constitute the vaccine, and which reaction could therefore be characterized as a 'vaccine-related' reaction. Among those included additives, Dr. Bellanti acknowledges that the question of a reaction to thimerosal is "very controversial"; however, a reaction to the yeast included in the vaccine could have elicited an allergenic or potentially even a toxic response.

The particular yeast that's used in the preparation of hepatitis B is called bakers yeast, *saccharomyces cerevisiae*. There could be up to five percent contamination in the preparation. And they ingest yeast. They can develop a rash, respiratory symptoms. If it's very severe they presumably could even have an anaphylactic shock.

Tr. at 31. Moreover, Mrs. Keenan did exhibit certain of these symptoms.

Dr. Bellanti discussed an article by DeStefano et al., on "Childhood Vaccination and Risk of Asthma" (2002) in which no connection is found between brewers yeast and asthma; however, that same article indicates "that HIB and hepatitis B vaccines were associated with 18 and 20 percent increases in asthma risk, respectively." R. Ex. F at 502. However, it is important to distinguish that the authors noted an associated increased risk for asthma and not an associated increase in asthma. Tr. at 35.

Dr. Bellanti postulates that the immediate reaction encountered by the Petitioner eventually resulted in a dysregulation of her immune system such that she then encountered difficulties when exposed to other antigens, accomplished through a process known as molecular mimicry. According to Bellanti, such dysregulating action has been encountered with the Hepatitis B vaccine affecting the central nervous system, raising the spectre of demyelinating conditions via a theory of "molecular mimicry."

Dr. Bellanti explains that, with molecular mimicry, the body's immune system errs by "recogniz[ing] certain foreign constituents in a way that cross-reacts with their own body constituents so that the immune system is doing something that it shouldn't be doing -- that is, reacting with itself." Tr. at 20. This is not the same as an autoimmune response, however. In this instance, a person does not experience an auto-immune type reaction, but a hypersensitivity-type reaction to foreignness and to increasing reactions to foreign substances. Id.

Under this analysis, Petitioner's condition would not follow an autoimmune pattern wherein the body "wars within its members," but would instead show itself in excessive reaction to external stimuli, out of normal proportion for a typical reaction to such stimuli. Dr. Bellanti does not only

⁵ If the Petitioner did indeed suffer a reaction to one of those additives or adjuvants, such reaction could thereby be characterized as a 'vaccine-related' reaction. See Leroy v. Secretary of HHS, No. 02-392V, 2002 WL 31730680 (Fed. Cl. Sp. Mstr. Oct. 11, 2002) (ruling that the term 'vaccine' strongly implies the inclusion of additional additive ingredients); 21 C.F.R. § 610.15(a).

believe that such a reaction *could* have occurred to someone in Petitioner's position; in this case, he believes that indeed it *did* occur in Petitioner's case. Essentially, he explained his theory as follows:

Immune dysregulation refers to an effect on the cells and the cell products that are responding to environmental antigens or foreignness. We know that the immune system is a very intricate system of cells that recognize foreignness. And they recognize them at different levels. The antigen-presenting cells, the T-cells, the B-cells, these cells all talk to one another. We know that after hepatitis B there is, if you look at the immune system as a system in balance within these components, the balance is kind of tilted after you receive the hepatitis B in some individuals -- and this appears to be genetically controlled -- that allows them now to react differently to things that they had been exposed to previously. *That's what I think is going on in this patient.*

Tr. at 17-18 (emphasis added).

On further clarification, Dr. Bellanti indicated that his opinion is that Mrs. Keenan's initial reaction within ten hours post-vaccination and the dysregulation of her immune system resulting in her heightened sensitivity to various environmental allergens are two separate issues. Consider the following exchange on cross examination:

Question: Dr. Bellanti, I think you testified that the reaction Ms. Keenan suffered both the night of the hepatitis B vaccine when she manifested a rash and was treated with Benadryl and all that, and the following day when she passed out at work, I believe you said that is not necessarily linked to her immune dysregulation. Did I get that right?

Answer: That's what I said, yes. I think those would be -- the immune dysregulation was responsible for subsequent things. The immediate reaction is more likely due to toxic reactions of elements in the vaccine that we spoke about, the adjuvant, the thimerosal, or the small amounts of yeast.

Question: So those reactions were transient reactions separate and apart from the things that happened later?

Answer: That's my opinion, yes.

Tr. at 39.

Dr. Bellanti maintains that the theory of molecular mimicry and the field of immunotoxicology are well within the scientific mainstream. Within the study of immunotoxicology, a patient may experience a reaction to an environmental chemical, as opposed to an allergen, that produces the same symptomatology of immunodeficiency without the clinical indicia. According to Dr. Bellanti:

there are a number of studies in animals and the human that speak to the point of toxic substances giving rise to immunologic reaction that don't follow the usual reactions, such as allergy. And it's probably the release of certain of these chemical substances that our immune system makes, these cytokines, the inflammatory mediators such as the IL-6, TNF-alpha. *There are studies that support that certain environmental agents can give rise to immunotoxic reactions.*

Tr. at 22 (emphasis added).

Dr. Bellanti references an NIEHS paper (Goth, et al., "Uncoupling of ATP-mediated Calcium Signaling and Dysregulated IL-6 Secretion in Dendritic Cells by Nanomolar Thimerosal," Pet. Ex. 59) from March 2006, which indicates that ethyl mercury in a mouse model system can give rise to immunotoxic reactions. Tr. at 22. And thimerosal is neurotoxic. *Id.* However, again, Dr. Bellanti is careful to indicate that the theory of mercury toxicity, particularly with regards to mercury fillings or dental amalgams, is one that is "sort of out of the ballpark." Tr. at 33. However, "going out on a limb," Dr. Bellanti does think it is biologically plausible, as demonstrated in a paper by Nicoletti, "Long Term Effects of Vaccination on Potential Performance" in 22 *Vaccine* 3877 (2004), that vaccinations affecting the immune system can likewise affect the cognitive system as well.

Dr. Bellanti explained that laypersons often conflate symptoms such as those experienced by the Petitioner through descriptive use of the word "allergic," which medically refers to an IgE reaction. In contrast to allergies, the immunotoxic reaction which Dr. Bellanti discussed responds to an environmental or chemical stimulus to which the person may have a biological sensitivity. However, at present, there are no objective diagnostic tests available as there are for IgE allergic responses. Tr. at 45. Consequently, persons with such a condition may not present symptoms which are measurable through current clinical diagnostics: "At the present time we don't have the very fine objective tools like IgE skin tests or in vitro tests. But there is research being done that hopefully will provide these diagnostic parameters in the near future." Tr. at 45.

Despite the current lack of objectively-measurable phenomena, Dr. Bellanti commended the theory of molecular mimicry as "generally well[-]respected and well[-]held." Tr. at 21. He relies in a "general way" on Dr. Terr's article *Environmental Sensitivity* (2003), R. Ex. E, starting at 313, referencing the molecular mimicry theory as well as the immunotoxic initiation of immune dysregulation. However, he does acknowledge, as does the author that "[a] number of major medical organizations have taken the position that environmental sensitivity is not a recognized clinical syndrome and that its concepts are unscientific and lack validation" which includes, as Dr. Bellanti lists "the American Academy of Allergy and Immunology Board of Directors, the United Nations, the American Academy of Allergy and Clinical Immunology Executive Committee; the Council of Scientific Affairs; Clinical Ecology; and the Journal of the American Medical Association." Tr. at 41; R. Ex. E at 312. The author likewise acknowledges such reactions are most often attributed to a "psychosocial condition." *Id.*

However, Dr. Bellanti is not cowed by this indictment, and maintains that immunotoxic reactions often involve subjective reactions to environmental stimuli that cannot currently be measured via objective, clinical means. In these types of cases, "Symptoms are wide-ranging and suggesting [sic] illness in multiple organ systems even though objective examinations fail to reveal any structural or functional abnormalities." Tr. at 41. When questioned on cross-examination, Dr. Bellanti stipulated that the Petitioner did not present "any structural or functional abnormalities," but he quickly added that "she did show subjective symptomatology that was triggered by environmental chemicals." And while significant elements in the medical establishment remain wary of this analysis, Dr. Bellanti stated that there exist sources in medical literature "that establish biologic plausibility," even if this theory has not been tracked in a study of a large population sample. Tr. at 44.

Dr. Bellanti believes that such "biologic plausibility" is sufficient to satisfy the preponderance standard on the question of whether the vaccine *could* cause the injury alleged by the Petitioner. He described his conclusion of a medical theory of causation as based upon established "biologic plausibility and timing" that is appropriate to fit that theory. Tr. at 45.

Dr. Bellanti acknowledged that the IOM report referenced in Respondent's Expert report as Reference 7 indicates a lack of statistically relevant evidence between the Hepatitis B vaccine and immune dysregulation. However, that report, says Dr. Bellanti, was looking for "large epidemiologic studies", not the admittedly rare event forwarded by Petitioner's theory. And while there is perhaps sparse epidemiological support for such in the populations studied, that is not to say that such instances do not rarely occur to individuals.⁶ Instead, according to Dr. Bellanti, "There's no question that these things occur rarely. But when they occur in an individual it is 100 percent for that individual. These are admittedly rare events. The autoimmune diseases, the adverse effects of vaccines are extremely rare, fortunately." Tr. at 38.

2. Dr. Zweiman

Dr. Zweiman's explanation of Petitioner's condition, as a preliminary matter, likewise denies its singularity as such, viewing the data instead as two distinct phenomena: on one hand, he categorizes the Petitioner's immediate sensitivity response reactions as a flushing disorder of a speculative, and thoroughly non-allergenic, origin; on the other hand, he observes most of Petitioners overall continuing presentation as eclipsed by pre-existing conditions that find their root in broad lifestyle patterns, such as cigarette use. Accordingly, once the Petitioner's indications are attributed between these two groupings, Dr. Zweiman sees nothing left to categorize further.

⁶Epidemiology is the science concerned with the study of the factors determining and influencing the frequency and distribution of disease, injury, and other health-related events and the causes in a defined human population for the purpose of establishing programs to prevent and control their development and spread." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 626 (emphasis added).

Testifying on behalf of Respondent, Dr. Burton Zweiman acknowledges that the incident experienced ten hours post-vaccination with the rash and what-not could have been related to the vaccination, and that the ensuing loss of consciousness the following morning, though further out in time, is not beyond the realm of possibility.

Question: As you know from the medical records, Ms. Keenan the night of her vaccination had an event where she had some what is described as rashes and was given Benadryl and a cold bath. Do you believe that was related to the hepatitis B vaccination?

Answer: I wasn't there at the time so I cannot say with certainty whether it was or not. The temporal sequence would suggest that, assuming the individual had not been exposed to anything else that might have induced the reaction such as this.

Question: So it's possible that that was a reaction?

Answer: Yes.

Tr. at 57-58. But while Dr. Zweiman allows that the "temporal sequence would suggest" that the immediate reaction was related to the vaccination, he was reluctant to attribute the complications, such as losing consciousness the following day at work, to the vaccination. Id. Even so, he does not rule out the possibility of such a connection.

Dr. Zweiman believes Mrs. Keenan's symptoms in her clinical course following vaccination are best be described as a flushing disorder or a "dilation of the superficial blood vessels in the skin" that can cause an individual's face to turn red, to feel hot or perhaps to itch. Tr. at 60. But, while these symptoms involve reactions to certain chemical or environmental challenges, they do not appear to be allergenic, and a blue ribbon panel from the premier medical society in this field, the Academy of Allergy, Asthma and Immunology, whose report had been previously referenced by Dr. Bellanti, concurs. Id. at 61. Nevertheless, Dr. Zweiman agreed with Dr. Bellanti that immunotoxic disorders are not related to an IgE mediated reaction or, in other words, the typical allergic reaction. And, according to Dr. Zweiman, it is possible that one such immunotoxic disorder could also disturb the respiration of someone like Mrs. Keenan with advanced COPD.

However, that's quite different than somebody claiming that they have flushing, itching, loss of cognitive function, memory loss, et cetera, due to exposure to these chemicals. This has been claimed by those who describe the so-called multiple chemical sensitivity syndrome or the idiopathic environmental exposure imbalance that you heard about earlier in this hearing. Individuals who have this have subjective symptoms. They do not have symptoms focused just on the respiratory tract as one would expect with somebody who had COPD who was then exposed to an irritant.

Id. at 62.

Dr. Zweiman concurs with the "number of major medical organizations [who] have taken the

position that environmental sensitivity is not a recognized clinical syndrome and that its concepts are unscientific and lack validation," as noted in the article supra. Id. To his mind:

It's very difficult to study this disorder because there are no objective manifestations and no objective ways of measuring such responses. I can only say that I have heard -- I have not seen instances, especially when blind challenges have been carried out. It's been very difficult to document this sort of responsiveness. But again, as I said, it's very difficult to study.

Id. at 64. While he has evaluated individuals who claim to have a chemical sensitivity condition (he does not refer to it as a "syndrome"), there is no real "treatment" other than to advise them to avoid the substances that give rise to their perceived issues. In his medical field, "Whether or not this is a defined entity with an organic cause, that appears to be where the question is." Id. at 101-02. And for him, while he is not saying that such is "all in their head," rather "the question mark comes up is whether or not these are significant causes of reactions, manifest by subjective clinical manifestations without objective evidence of disease." Tr. at 103-04.

Moreover, Dr. Zweiman is not aware of a link between hepatitis B and dysregulation of the immune system. Though he is not an epidemiologist, Dr. Zweiman notes in particular, "One would think of the millions of doses of that vaccine that have been administered and the exposures that were postulated to cause this reaction that one would see it." Id. at 66. And, therefore, a question is raised in his mind as to statistical coincidence.

Dr. Zweiman also criticizes the Petitioner's reliance on molecular mimicry as a plausible theory connecting this vaccination with the injury alleged. According to a 2002 IOM report:

The Committee concludes that there is weak evidence for bystander activation, alone or in concert with molecular mimicry as a mechanism by which multiple immunizations under the U.S. infant immunization schedule could possibly influence an individual's risk of autoimmunity.

R. Ex. J (Institute of Medicine, Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders, National Academy Press 2002).

From Dr. Zweiman's perspective, Mrs. Keenan was essentially suffering from two unrelated medical issues, the first being the flushing disorder that involved the rash with the itching and whatnot. He believes this condition warrants further investigation as "the etiology of those episodes is still not defined." The second condition is her respiratory disorder which Dr. Zweiman feels is in no way related to the Hepatitis B vaccination but was secondary to the COPD due to decades of smoking. Tr. at 71.

On cross examination, Dr. Zweiman did admit that irritants, which are not truly categorized as allergenic, and which do not cause an immune reaction, can trigger asthma.

Irritant is not an antigen, by definition. It's a non-specific trigger. It -- the so-called irritant receptors, it probably triggers them, but it's not an antigen. It's not an immune reaction. It can trigger asthma; it can trigger episodes of COPD, which I think happened in this lady.

Tr. at 93. Dr. Zweiman conceded that being injected with yeast would be different from merely ingesting it in bread, but noted that, statistically, "it very hard to find people who reacted to yeast as part of hepatitis immunization," adding, "if these occur they're extremely rare events." Tr. at 94.

Dr. Zweiman believes Mrs. Keenan suffers from COPD and bronchospasm:

If one gives such individuals corticosteroids and there is a significant transient improvement in their symptoms they are related to bronchospasm. The reason why this is not done as chronic therapy is that the adverse effects of using systemic corticosteroids are such that they outweigh the modest[,] moderate improvement that one can achieve by such therapy.

Tr. at 98.

In fact, the Court raised its own concern as to the effects steroids may have played in Mrs. Keenan's cognitive issues:

THE COURT: The discussion about prednisone, were her cognitive problems related to the prednisone?

THE WITNESS: Conceivably. Again I don't know exactly how much she got and the timing in relation to the cognitive steroids. One of the physicians did posit the possibility that she may have corticosteroid psychosis. These are generally seen in people who receive sizable doses of steroids, corticosteroids like prednisone for a longer period of time. But there are variabilities.

Tr. at 99-100.

C. Findings of Fact

The following findings are in addition to those already incorporated by reference in the 17 October 2005 Onset Ruling.

First, the Court reiterates that Petitioner bears 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).

It is worth noting that the Court received Dr. Bellanti's testimony with credibility, and appreciated his discussion of theories circulating in the medical field, as well as his candor regarding their overall prominence and acceptance in the medical literature. The Court is inclined to accept the theory he offered in support of Petitioner's claim, unless such theory could be adequately discounted by Respondent.

Respondent's expert apparently agrees that the reaction suffered by Mrs. Keenan soon after the vaccination, which involved an itchy rash with red spots and which was treated by benadryl and a cold bath, was related to the vaccine. Tr. at 57-58. At least as far as the initial reaction is concerned, the question of "can it" is answered in the affirmative, even from Respondent's own admissions.

Not surprisingly, Respondent's contention on this point comes down to the question of "did it"— was Petitioner's loss of consciousness and subsequent increase in sensitivity to certain environmental factors a result of the vaccination in this particular case? Petitioner presented a credible explanation that Respondent's expert concedes is possible. The Court has no reason to doubt this explanation, and Respondent did not cast doubts of a substantial nature. In contrast, Respondent asserts that these phenomena were not the fruit of Petitioner's vaccination, yet Respondent has not proffered a complete explanation for the noted difference in Petitioner's condition after the initial reaction to the vaccine. Respondent's expert noted a couple of possible explanations, but did not commit to any firm explanation in light of the sparse medical record in this case. Tr. at 58-59. Based on a plain reading of the testimony given by Respondent's expert, causation of the injury as vaccine-related seems at least as likely as other hypothetical possibilities, if not more so. In light of these considerations, the Court finds that the initial reaction which occurred ten hours post-vaccination, while not rising to the level of a Table Injury anaphylaxis, was more likely than not related to the hepatitis B vaccination administered on 30 August 1993.

The Court's analysis follows a similar course in considering the persistent aspects of Petitioner's condition, which she alleges to be vaccine-related. On the whole, the Court was persuaded not only by Petitioner's offered fact witnesses, but also by her testifying medical expert, Dr. Bellanti. Though the Court may not henceforward view all hypersensitivity conditions as results of immune dysregulation through vaccine-induced molecular mimicry, in this particular (and factually peculiar) case, that seems to be the best explanation of the confluence of phenomena attending Petitioner's overall condition. Petitioner has proffered a medical theory which logically connects the vaccine administered to the condition complained of by Petitioner, and which explains Petitioner's injury in this case.

This case is not the first instance of a petitioner before this Court explaining causation by a theoretical mechanism of molecular mimicry. In Scott v. Secretary of HHS, No. 03-2211V, 2006 WL 2559776 (Fed. Cl. Spec. Mstr. Aug. 21, 2006), Special Master Vowell summarized the theory,

stating that sometimes, "in the immunization process, in certain genetically susceptible persons, something goes awry," causing certain immune agents (e.g., lymphocytes) to produce antibodies in a defensive response that can cause adverse consequences with other components in the body. Id. at 24; see also Stevens v. Secretary of HHS, No. 99-0594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (stating that "[w]ith molecular mimicry, when the foreign protein or a piece of it looks very much like a self-antigen, one can produce T-cells that react against the self body proteins, noting that T-cells, unfortunately, are "not as specific as once thought and a wide variety of triggers can set them off"). In the Scott case, after weighing the evidence presented therein, the Special Master concluded that the molecular mimicry theory "provided a sufficient basis to establish the first prong of the Althen test, a biologically plausible mechanism." Scott at 25. Nor is this the first appearance of a theory linking molecular mimicry to immune dysregulation. In Mulvaney v. Secretary of HHS, No. 05-0556, 2006 WL 2438454 (Fed. Cl. Spec. Mstr. July 26, 2006), a successful petitioner's expert argued that "molecular mimicry or [another mechanism] leads to immune system dysregulation, which transiently allows otherwise forbidden autoaggression against cross-reactive [] antigens" within the injured person's body. Id. at 8.

Moreover, in Birdsell v. Secretary of HHS, No. 04-1755V, 2006 WL 1663297 (Fed. Cl. Spec. Mstr. May 30, 2006), a case, like this one, wherein the petitioner sought compensation for a hepatitis B vaccination, the special master considered testimony from Respondent's expert, which distinguished "an alloimmune or molecular mimicry process" from "an autoimmune process," much as Petitioner's expert did in this case. Likewise, Dr. Bellanti's theory of molecular mimicry as a mechanism of inflammatory response that leads to a hypersensitivity reaction has already served as a basis for a special master's finding for compensation, in the case of Casey v. Secretary of HHS, No. 97-0612, 2005 WL 3597263 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). In that case, the special master found that the petitioner had met the required elements of the Althen test, and proceeded to state, "Respondent's expert did not dispute the theoretical possibility of causation, but did contend that such a reaction would occur very rarely," to which the Court answered, "It is precisely because individuals experience adverse reactions to safe vaccines on rare occasions that Congress created the Vaccine Program." Id. at 26.

Conversely, the Court also finds that Respondent's theory did not offer a satisfactory explanation of Petitioner's condition in all its respects. As found by the Court at the hearing on the issue of onset, "Petitioner progressively developed sensitivities to a variety of chemicals" after her vaccination, and Respondent's evidence does not address these acute occurrences other than to attribute them as symptoms of a chronic, degenerative condition that would normally follow a slow, almost static course in its typical case. Without an explanation for these specific reactions to certain chemicals, the Court finds that Respondent's theory is not persuasive under the facts of this case, either as a disputation to Petitioner's case in chief, or as a theory of alternate causation by factors unrelated in response.

Even though the initial reaction and the subsequent immune dysregulation were distinguished into two separate issues by the Petitioner's expert, it is consistent with such expert's theory that both were related to the same vaccine. Respondent's issue with Petitioner's theory of immune

dysregulation did not squarely confront Petitioner's opinion that the hepatitis B agent could interact with a person's immune response, but instead addressed the lack of an objective, clinical diagnostic test by which such effect could be discerned. It is important to note, however, that this Court's decision need not be predicated on evidence amounting to medically-verifiable certainty, as the science surrounding this area of medicine is not settled, but still retains open questions for further study. As with many of the injuries alleged in petitions brought before this Program, the condition claimed by Petitioner is, by every account, rare. However, this case comes before the Court within "a field bereft of complete and direct proof of how vaccines affect the human body." Althen, 418 F.3d at 1280. It is enough to say that in this case, the Court is satisfied with the explanation given by Petitioner's expert witness regarding whether the vaccine's various components *can* cause the conditions, and is persuaded, based on the evidence given in this case, that it *did* cause the injurious condition alleged by the Petitioner in this case.

The Court does not take lightly its role in weighing the testimony and medical theories raised in this case. It is true that Dr. Zweiman, testifying for the Respondent, remained critical of immunotoxic disorders, given the inability of technology at present to discern any objective clinical indicia; however he did not dismiss the condition or disorder as entirely beyond the pale. Even though some of the theories discussed in this case were outside the mainstream, and perhaps, as Dr. Zweiman alleges, out of this world, there is apparent recognition of Petitioner's sensitivity to certain substances as a matter of fact in this case. As Dr. Zweiman agreed, it cannot simply be that these things are 'all in [Petitioner's] head.' Nevertheless, the condition presented by Petitioner's theory is statistically rare, has not yet been observed in broad studies of population samples, is somewhat under-developed in scientific study, and presents with typically subjective symptoms, as yet without objective clinical markers that can be used to diagnose or even to treat the condition. Coupled with the testimony of Dr. Bellanti in this case, the Court finds that it may be faced here with one of the rarest occurrences of a vaccine-related injury, one that might find no significant statistical traces in epidemiological data. It may be that, as medical science progresses, there will eventually be found some way to plot this condition through a diagnostic test administered in a controlled clinical setting. But until that time, the Court is loathe to say that Mrs. Keenan's claim is without merit.

Respondent has maintained that most of Petitioner's condition, potentially all of it, is attributable to preexisting conditions, some of them chronic in nature. However, as the records demonstrate, Mrs. Keenan underwent a battery of tests, and no sufficient explanation emerged to completely explain away all of her symptoms. Respondent asserted that the respiratory issues were completely attributable to her years of smoking. And the Court finds, more likely than not, that the pulmonary experts who evaluated her were right to note certain lung issues related to COPD. It is clear that Petitioner's pulmonary condition is not entirely attributable as an effect of the vaccination; yet it is likewise clear that such condition may not be entirely attributable to the COPD, either. Her overall clinical picture is not completely overshadowed by that singular explanation. At that point, Dr. Bellanti's discussion of a vaccine-related hyper-sensitivity that was superimposed over the COPD begins to provide the missing element. Accordingly, the Court finds that Petitioner's adverse reaction to the hepatitis B vaccine was a vaccine-related injury that, at least, significantly aggravated other conditions experienced by the Petitioner.

Certainly, as the Court heard at the Entitlement Hearing, Petitioner's treating physician, Dr. Allen, looked long and hard for an etiology, but was unable to find one, and sincerely believed there existed a direct sequence of cause and effect between the vaccination, the initial reaction, and Mrs. Keenan's subsequent course of events, in which she grew steadily worse for a number of years before gradually improving. Now, granted, much of that testimony is taken *cum grano salis*, because the Court did not hear directly from Dr. Allen, and because the medical records proffered in this case are so sparse. But regardless, the Court convened in Jacksonville, Florida, heard the testimony of Mrs. Keenan and her husband, and had occasion to observe their comportment, demeanor and presentation firsthand. Based upon that examination, the Court concluded that, where her medical records fell short of telling the story, she, and particularly her husband, were able to fill in the gaps in a clear and cogent manner.

On the other hand, Respondent did *not* convince the Court to a preponderance of the evidence offered that Petitioner's condition(s) could be subsumed within the 'factors unrelated' that Respondent proposed. Even when taking into account the pre-existing conditions referenced by Respondent, the Court was left to contemplate significant unexplained phenomena within Petitioner's clinical picture that remained. Respondent vigorously asserted how Petitioner's initial reaction was not technically to be classified as "allergic", but failed to explain away its proximate temporal occurrence as a consequence of some other (unrelated) cause. Similarly, as has been noted, Respondent attempted to subsume all of Petitioner's clinical indicia under the generalized rubric of the COPD. That attempt posed a problem, in that there were certain aspects which Petitioner presented that did not strictly comport with that diagnosis. To the extent Respondent addressed these more complex aspects, such attention appeared as shaving corners off of the square peg, so as to retrofit the clinical picture into the round hole of COPD, an approach too procrustean for the Court's comfort or credence. That is not to say that Respondent did not capably present its argument as a cogent theory, but only to manifest the Court's unenviable task of weighing the factual evidence for the purpose of finding the facts in this particular case. Accordingly, this Court finds that Respondent did not convince the Court to a preponderance of the evidence that Petitioner's condition was caused by a factor unrelated to the vaccination at issue.

II. CONCLUSIONS OF LAW

Referring back to the Althen standard, set forth supra, and applying it to the facts presented before the Court, Petitioner bears the burden of proving, from the evidence presented, that Petitioner's vaccination was connected to her injury, via a medical theory which follows a logical sequence to convince this Court of a causal relationship between the two. Based upon the factual findings of the earlier Onset Hearing, it is beyond argument that the third Althen factor has been satisfied; namely, that the ten-hour difference between vaccination and injury in this case establishes a proximate temporal relationship between vaccination and injury that coincides with Petitioner's theory of causation. Therefore, what remains to be addressed is whether Petitioner has established a medical theory causally connecting the vaccination and the injury, one which connects by a logical sequence of cause and effect to implicate the vaccination as the reason for the injury. This may be described in simple terms of a "can it" prong and a "did it" prong; that is, under a credible medical theory, can

the vaccine at issue cause the condition complained of by Petitioner, and was that process at work in this case, such that the vaccine did actually cause Petitioner's injury.

That is not the end of the matter. In addition to factual findings, decisions issued by this Court must also include conclusions of law. §12(d)(3)(A)(I). And, therefore, the Court must assess the foregoing factual findings under the rubric of the law as it presently stands in order to determine whether the Petitioner has proved entitlement to compensation.

Under the Vaccine Act, a petitioner is not required to prove his case by medical certainty, but only by a preponderance of the evidence, which this Court just described as 50% and a feather. Neither is a petitioner required to submit direct proof in order to prevail. Nor is she required to submit certain types of evidence. Such a bright line test "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." Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005); 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 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991). Instead, as has been noted by the Court of Federal Claims, ultimately 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, 451 F.3d 1352, 1355-56 (Fed. Cir. 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, the Court of Federal Claims recently ruled:

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. 19, *31 (2005).

As acknowledged supra, under the Vaccine Act, the Court may not hold that Petitioner is entitled to compensation based on her own asseverations, lacking substantiation by medical records or medical opinion. However, in this instance, the medical records themselves are quite sparse. Notwithstanding, Dr. Bellanti did offer his medical opinion which augmented what the Court understands to be the opinion of Petitioner's treating physician, Dr. Allen, who took a personal

interest in her case and did not dismiss her subjective complaints as those of a lunatic or delusional individual.

Moreover, the Federal Circuit has indicated that it is not improper for a treating physician to rely on a temporal relationship in articulating a sequence of cause and effect; instead, "[t]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect shows that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1317 (quoting Althen, 418 F.3d at 1280). Therefore the Court affords proper weight to Dr. Allen's contribution in this case.

The requirement that Petitioner prove causation runs to conditions that arise as a result of a vaccination, as well as to those that are significantly aggravated by the vaccination:

If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation....[H]owever, the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine....[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.

Shyface v. Secretary of HHS, 165 F.3d 1344, 1351 (Fed. Cir.1999); see also Zatuchni v. Secretary of HHS, No. 94-58V, 2006 WL 1499982, at *5 (Fed. Cl. Spec. Mstr. May 10, 2006) (holding that, although smoking was the primary cause of a decedent's death from COPD, her vaccine-induced fibromyalgia was a substantial factor in causing her death because it prevented her from exercising, and held that petitioner was entitled to the \$250,000 death award).

In Capizzano, 440 F.3d at 1325, the Federal Circuit reiterated "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen" Additionally, it is useful to note particularly well in this case that close calls are typically to be resolved in favor of petitioners. Capizzano, supra, at 1327; Althen, supra, at 1280. See generally Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir.1994).

As to the second prong, a special master looks for a medical explanation of a logical sequence of cause and effect (Althen, supra, 418 F.3d at 1278; Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). At this point, the divergence between the parties' experts comes into relief. In discussing the merits of Petitioner's theory of recovery, one study discussed by the experts seemed to disparage Petitioner's theory inasmuch as it did not evidence itself as a statistically relevant result in a larger study of a population sample. Epidemiological support is not necessary to show causation, and, notably, the Federal Circuit in Knudsen ruled for the petitioners in that case even though epidemiological evidence directly opposed their proffered theory of causation resulting from a vaccine. 35 F.3d at 550. Respondent's argument that Petitioner's condition was not the subject or result of broad population group studies is offset by

Petitioner's admission that such a condition is certainly very rare and would not likely show statistical relevance in a study of a population sample. Instead of undermining Petitioner's claim, this admission renders consistent the experts' divergences on the question of "did it" in this case. The Court was persuaded by Petitioner on this point.

The Court rules that Petitioner has met her burden under Althen by offering a plausible medical theory that logically connects the vaccination to the injury alleged within an appropriate proximate temporal relationship. The same standard of proof obtains even if the Court were to consider certain aspects of Petitioner's condition as a significant aggravation of the COPD or a completely independent illness. In the preceding discussion, the Court accepted Petitioner's evidence of causation, which included expert medical testimony and incorporated scientific studies that have addressed the scientific issues in this case. Based upon that evidence, the Court is convinced that Petitioner has met her burden of proof that the vaccine was "a substantial factor in bringing about the harm" experienced by the Petitioner. See Shyface at 1352.

Hence, the burden of proof 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); Whitcotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed Cir. 1994). This Respondent has not accomplished. While Dr. Zweiman attempted to poke many holes in Petitioner's theory, it continued to hold water. Though Mrs. Keenan had pulmonary issues incident to long-term smoking, the Court finds that her several conditions, especially her respiratory reactions to certain chemicals, may not all of a piece be attributed solely or primarily thereto. As the Federal Circuit has noted, the Respondent at this stage of the case "must prove that the 'factors unrelated' were 'principally responsible' for causing [Petitioner's] injury," Shyface v. Secretary of HHS, 165 F.3d at 1349-50 (citing § 300aa-13(a)(2)), but the Respondent has not persuaded the Court to a preponderance that such is the case here.

III. CONCLUSION

Accordingly, Petitioner is entitled to compensation in this case, and the Court now turns its focus to the postliminary issue of ascertaining the damages caused by the vaccine-related injury, in order to award compensation accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master