In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 09-524V
Filed: September 23, 2014
(Not to be published)

CHARLOTTE JACUNSKI,	*	Vaccine Act Entitlement;
	*	Influenza Vaccine/Chronic
Petitioner,	*	Inflammatory Demyelinating
	*	Polyneuropathy ("CIDP");
v.	*	Significant Aggravation
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
	*	
	*	
Respondent.	*	
	*	

DECISION

HASTINGS, *Special Master*.

This is an action in which the Petitioner, Charlotte Jacunski, seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program[1]), on account of an ongoing neurological condition that she believes was aggravated by two influenza vaccinations. For the reasons set forth below, I conclude that Petitioner is not entitled to an award.

I

APPLICABLE STATUTORY SCHEME AND CASELAW

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showings that an

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. §300aa-10 *et seq*. (2006). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2006).

individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-lasting injury; and has received no previous award or settlement on account of the injury. Finally--and the key question in most cases under the Program--the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table" corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. §300aa-13(a)(1)(A); §300aa-11(c)(1)(C)(i); §300aa-14(a); §300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table.[2] In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. §300aa-13(a)(l)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. §300aa-13(a)(l)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

[2] No Table Injury is alleged in this case. Petitioner's theory in this case is that a vaccine "actually caused" a "significant aggravation" of a preexisting condition.

> If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (emphasis in original)(citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting the petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. *Id*. at 1279-80. The court also indicated that, in finding causation, a Program factfinder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by
Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Id*. at 1280.

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instructions for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program factfinders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of *expert testimony* and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert's* factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases. One of the factors listed in *Daubert* is whether the scientific theory "has been subjected to peer review and publication." 509 U.S. at 593. The Court noted that while publication does not "necessarily" correlate with reliability, since in some instances new theories will not yet have been published, nevertheless "submission to the scrutiny of the scientific community is a component of 'good science,'" so that the "fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity" of a theory. *Id*. at 593-94.

Here, Petitioner does not assert that her vaccinations *initially caused* her CIDP. Rather, she asserts that they caused a *significant aggravation* of her CIDP. (Ex. 10, p. 4) According to *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013), "The Vaccine Act created the National Vaccine

Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had *significantly aggravated'* a vaccine-related 'illness, disability, injury, or condition.'" *Id.* at 1355–56, *quoting* 42 U.S.C. § 300aa–11(c)(1)(C))(emphasis added.) In *Whitecotton v. HHS*, 81 F.3d 1099, 1103 (Fed. Cir. 1996), the U.S. Court of Appeals for the Federal Circuit stated that "the statutory requirements to make out a *prima facie* significant aggravation claim are analogous to those required to make out a *prima facie* initial onset claim." The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4).

The elements of an off-Table significant aggravation case are set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). There, the court combined the test from *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), which defines off-Table causation cases, with a test from *Whitecotton v. HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resultant test has six components, which are:

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

Loving, 86 Fed. Cl. at 144; *see also W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims").

II

PROCEDURAL HISTORY

On August 11, 2009, Petitioner filed a petition for compensation ("Petition") under the National Childhood Vaccine Injury Act of 1986, as amended, §§300aa-1 *et seq*. ("Vaccine Act" or "Act"). Petitioner alleged that influenza vaccinations administered on December 4, 2006, and November 16, 2007, "caused or triggered" her development of chronic inflammatory demyelinating polyneuropathy ("CIDP"). (*See* Petition ("Pet"), pp. 1-3.) The petition was initially assigned to Special Master Gary Golkiewicz.

On November 23, 2009, Respondent's counsel filed her "Rule 4(c) Report," asserting that Petitioner had failed to establish causation-in-fact by a preponderance of the evidence because the onset of Petitioner's CIDP occurred prior to her influenza vaccinations.

A fact hearing was held on November 1, 2010, concerning the onset of Petitioner's CIDP. Petitioner and witness Linda Heck testified. (*See* Transcript of Proceedings, November 1, 2010.)[3] On November 3, 2010, Special Master Golkiewicz filed an Order rejecting Petitioner's testimony "concerning the correctness of the information contained in the medical records." (Order, filed Nov. 1, 2010, p. 1.) He found that Petitioner's "memory was not sufficiently clear to be relied upon." (*Id*.) He directed the parties to file expert reports in support of their claims. However, the special master emphasized that all experts would be expected to pay particular attention to the information contained in the medical records, and to cite those records when discussing whether Petitioner's symptoms pre-dated her influenza vaccinations. (*Id*.) Special Master Golkiewicz also noted a lack of evidence that Petitioner suffered a "worsening" of her condition after her second vaccination, on November 16, 2007. He directed that any expert opinion that discussed aggravation of Petitioner's condition after that vaccination must "set forth, **in detail**, what facts are being relied upon for such worsening." (*Id*., p. 2.)(Emphasis in the original.)

The parties subsequently filed expert reports in support of their respective positions. Petitioner filed the expert report of Dr. Thomas Morgan, on August 29, 2011, which acknowledged Petitioner's "pre-existent CIDP," but argued that the two influenza vaccinations that she received had both "aggravated and made worse her underlying CIDP." (Ex. 10, p. 4.)[4] Respondent filed the expert report of Dr. Elijah Stommel, on April 25, 2012, which contended that there was "no evidence that the vaccines altered the course of Ms. Jacunski's CIDP." (Ex. A, p. 6.)

On May 9, 2012, the case was reassigned from Special Master Golkiewicz to the undersigned special master. By agreement of the parties, a second hearing was scheduled, to determine Petitioner's entitlement to compensation under the Vaccine Act. (*See* Order, filed June 7, 2012.) Pursuant to my Order, dated June 7, 2012, both parties filed their pre-hearing memoranda in September of 2012.

The second hearing was held on October 26, 2012, at which Dr. Morgan and Dr. Stommel testified. (*See* 2-Tr.) Petitioner filed her Post-Hearing Brief on March 29, 2013, and Respondent filed a Post-Hearing Brief on June 27, 2013. Petitioner filed a Reply on September 10, 2013.

III

[3] The record of this case includes transcripts for two hearings, which occurred on November 1, 2010, and October 26, 2012. I will refer to those transcripts as "1-Tr.," and "2-Tr.", respectively.

[4] Both parties have filed numerous documents in this case. Petitioner filed Exhibits 1-3 in October of 2009, and Exhibits 4-12 on several dates thereafter. I will refer to those exhibits as Ex. 1, Ex. 2, etc. Respondent filed Exhibits A and B on April 25, 2012. I will refer to those exhibits as Ex. A and Ex. B. Respondent also filed medical articles as attachments to Exhibit A, numbered 1 through 17. I will refer to these items as Ex. A-1, A-2, etc.

FACTS

Petitioner was born on February 6, 1955. (Ex. 1, p. 1.) She received an adult influenza vaccination at fifty-one years of age, on December 4, 2006, and another about one year later, on November 16, 2007. (Ex. 3, p. 1.) Prior to those influenza vaccinations, Petitioner had a past history of irritable bowel syndrome, uterine fibroids, and a cystocele. (Ex. 1, pp. 63, 65.) More importantly, Petitioner had previously experienced some *neurological* symptoms--namely, weakness in her lower extremities--which began in August or September 2006 after Petitioner returned from a trip to Germany. (Ex. 1, pp. 47, 51, 53; Ex. 6, p. 3; Ex. 10, p. 4; Ex. A, pp. 2, 6; 2-Tr., pp. 31, 123.) Around September 2006, Petitioner started having trouble getting upstairs, especially when the steps were steeper. This problem "gradually became worse." (Ex. 1, p. 47.) These neurological symptoms, tragically, turned out to be the first symptoms of Petitioner's eventual diagnosis of "CIDP"--*i.e.*, "chronic inflammatory demyelinating polyneuropathy."

On December 4, 2006, Petitioner sought treatment at the Henry Ford Medical Center in Novi, Michigan ("Ford Center"), primarily because she had a sensation of burning when urinating, and her urine was cloudy. (Ex. 1, p. 65.) Petitioner also reported a rash on her neck and a feeling of weakness in her thigh region. (*Id*.) Dr. Steven Fried examined Petitioner and observed normal gait, normal strength in the legs, and "1+" reflexes, which he characterized as "diminished." (*Id*.) Dr. Fried's "assessment" stated that that Petitioner suffered from a urinary tract infection (UTI) and dermatitis, while he attributed her subjective leg weakness to a change in her exercise regimen. (*Id*.) Dr. Fried recommended imaging of the spine or an electromyogram ("EMG") if her symptoms persisted. (*Id*.) At this visit, Petitioner received her first influenza vaccination. (*Id*; Ex. 3, p. 1.)

Four days later, on December 8, 2006, Petitioner first saw a chiropractor, Stephen Tepper, to seek treatment for discomfort in her hands and legs. He recorded her history of constant numbness, tingling, stiffness, and weakness of both hands and both legs, which had started about August 1, 2006, and became "progressively worse." (Ex. 6, p. 3.) She made subsequent visits to the chiropractor in December 2006 and January 2007. (Ex. 6, pp. 9-15.) On December 13 and 15 of 2006, Dr. Tepper noted that her condition was "improving favorably," and "showing progress." (Ex. 6, pp. 9-10.)

On December 19, 2006, Petitioner returned to the Henry Ford Medical Center to receive her complete yearly physical examination. (Ex. 1, p. 63.) During this visit she reported her recent treatment by a chiropractor for leg weakness, and that she had noticed *improvement* in her symptoms since that visit. (*Id*.)[5] Her treating provider, Dr. Mudita Malhotra, indicated that Petitioner "will notify us if symptoms worsen at any time." (*Id*.) Dr. Malhotra's examination revealed a normal gait, normal motor strength in both legs, and bilateral deep tendon reflexes of 2+ (normal). (*Id*.)

[5]Dr. Malhota's notes on December 19, 2006, state: "She was evaluated in the office early December for UTI, which has completely resolved. She also complained of subjective leg weakness secondary to change in exercise regimen at that time. Has been following up with chiropractor for the same and has noticed improvement in symptoms." (Ex. 1, p. 63.)

Petitioner received chiropractic manipulation and/or moist heat treatments from Dr. Tepper during a total of seven appointments in December 2006, and three more in early January 2007. (Ex. 6, pp. 3-15.) On January 9, 2007, her chiropractor noted that "there is relative improvement in the patient's symptomology." (Ex. 6, p. 15.) Petitioner did not receive any further chiropractic treatment for eleven months thereafter. (*Id*.)

The records do not indicate that Petitioner sought any other medical evaluation of leg weakness or problems with her hands throughout most of 2007. On February 17, 2007, Petitioner received a "screening colonoscopy." (Ex. 2, p. 56.) At that time, she was described as a 51 year old female "who does not have significant medical problems." (*Id*.)

Petitioner returned to her general practitioner nine months later on November 16, 2007, with a complaint of numbness in her legs, and that her legs felt "heavy." (Ex. 1, p. 55.) Dr. Malhotra indicated: "[Petitioner] comes in today with [a] one-year history of progressive worsening of leg symptoms including numbness as well as 'weakness.' Symptoms are worse in the left leg as compared to right." (*Id*.) Petitioner informed Dr. Malhotra that she could not lift herself up from a chair or from a squatting position without help, and that she experienced difficulty climbing up stairs without the use of handrail support. (*Id*.) She also reported a worsening of her symptoms in the winter and "less intense" symptoms during the summer months. (*Id*.)

Petitioner's physical examination at that time was normal. (*Id*.) Dr. Malhotra observed normal gait, reflexes at 2+ bilaterally, and "good" bilateral motor strength in petitioner's arms and lower legs. (*Id*.) However, Petitioner had "subjective weakness" when asked to raise herself up from a sitting position in a chair. (*Id*.) Dr. Malhotra's assessment was bilateral leg numbness and weakness. (*Id*.) He ordered laboratory studies and referred Petitioner to a rheumatology specialist. (*Id*.) Petitioner also received her *second* influenza vaccination on November 16, 2007. (Ex. 1, p. 56; Ex. 3, p. 1.)

Three weeks after the visit to Dr. Malhotra, on December 7, 2007, Petitioner resumed her chiropractic treatments by Dr. Tepper. (Ex. 6, p. 15.) During that December, she received a total of eight such treatments, and four more in the beginning of January 2008. (*Id*., pp. 15-23.) She indicated that the severity of her pain was quite low, usually at the "zero" level. (*Id*.) Although at some of these visits Dr. Tepper recorded "no change" in the patient's condition (Ex. 6, pp. 15-23), at three visits he noted some progress or improvement. (*Id*., pp. 16, 17, 19).

On December 18, 2007, Petitioner presented to the Ford Center for a rheumatology evaluation by Dr. Michael Lubetsky. (Ex. 1, pp. 51-52.) Petitioner reported that,

> [S]he has been having [a] numb feeling with weakness in the arms and legs [since] last September. She actually had the same thing happen just in her thighs last year. It lasted for 3 months. She went to a chiropractor and it resolved. This year, it's not only in the thighs, this numb feeling, but also all the way down her legs to her feet. She will notice a fluttering or possible twitching or fasciculations in the muscles.

(Ex. 1, p. 51.) Petitioner reported a tingling sensation in her fingers, numbness in her forearms, and weakness in her hands. (*Id*.) She also had trouble raising her legs to climb stairs. (*Id*.) Petitioner's physical examination was normal except for absent reflexes throughout. (*Id*.) Dr. Lubetsky did not think that "this is an inflammatory myopathy because of the fasciculations and the paresthesias and numbness." (*Id*.) Rather, Dr. Lubetsky suspected that Petitioner had a neurologic disease, and referred her to neurology. (*Id*., p. 52.)

Later on that same day, December 18, 2007, neurologist Dr. Howard Feit examined Petitioner. (Ex. 1, pp. 53-54.) Petitioner informed Dr. Feit that "about 2 years ago" she lost power in her legs and could not get up out of a chair. (*Id*., p. 53.) She indicated that she saw a chiropractor, and her symptoms improved but did not go away completely. (*Id*.) Petitioner reported that in September 2007 she had experienced "a marked loss of power, which has persisted since then." (*Id*.) The examination on December 18, 2007 showed mild weakness at 4/5 of the arms and hands symmetrically, 4/5 strength in the legs, absent reflexes throughout, and intact sensation despite a subjective sense of numbness. (Ex. 1, pp. 53-54.) Dr. Feit's initial impression was "either a myopathic or neuromuscular junction process." (*Id*.)

On December 26, 2007, medical personnel at the Ford Center performed further studies on Petitioner. (*See* Ex. 1, p. 114.)

Dr. Feit referred Petitioner to the neurology clinic at the Henry Ford Medical Center, where, on January 14, 2008, she was examined by two doctors, Daniel S. Newman and Ximena Arcilalondono, for "possible CIDP." (Ex. 1, p. 47.) They recorded Petitioner's recollection that her problems had started two years previously, in September 2006,[6] when she started having trouble getting up stairs. (*Id*.) One year later, around September of 2007, her leg symptoms worsened--"she noticed that she was walking with shorter steps…" and "[h]er legs felt like there were heavy weights in them." (*Id*.) She also felt "flutters" in her legs, like "when they were really tired," and began to have problems carrying loads of clothing or doing things with both hands. (*Id*.) Upon performing a physical examination, these doctors could not detect any reflexes in her ankles and arms, and reflexes were only 1+ in her knees. (*Id*.) She had a few areas of decreased sensation in the arms and legs. (*Id*.) Based on the entirety of Petitioner's symptoms and laboratory studies, on January 14, 2008, Drs. Newman and Arcilalondono diagnosed Petitioner with "slowly progressive" CIDP, and they advised treatment with intravenous immunoglobulin ("IVIG"). (*Id*., pp. 48-49.)

On April 1, 2008, Petitioner saw Dr. Newman for a follow-up visit. (Ex. 2, p. 16.) Dr. Newman noted that since last seeing Petitioner, she had received two courses of IVIG treatment. (*Id*.) He indicated that Petitioner "has done extremely well on IVIG and her strength is now normal." (*Id*.) After detailed testing, Dr. Newman observed normal bulk, tone, and strength in all of Petitioner's extremities. (*Id*.) His diagnosis remained CIDP, and he prescribed continued IVIG therapy at tapered doses. (*Id*.)

[6] Petitioner referred to the onset of her "weakness" in September 2006, "after coming back from a trip to Germany." (Ex. 1, p. 47.) This "trip to Germany" often served to mark the specific time of when her symptoms appeared.

Dr. Newman again examined Petitioner on September 29, 2008. (Ex. 2, p. 9.) Petitioner's physical examination was normal with hypoactive reflexes. (*Id*.) Dr. Newman indicated that Petitioner had received IVIG therapy every seven weeks since April. (*Id*.) He noted that Petitioner had subjectively normal strength with no numbness or tingling and was walking two miles a day on a treadmill. (Id.) Dr. Newman prescribed IVIG every eight weeks and recommended a follow-up in six months. (*Id*.) It appears that Petitioner received IVIG treatments through April 28, 2009. (*See, e.g.*, Ex. 2, p. 24; Ex. 1, pp. 3-43.)

IV

ISSUE TO BE DECIDED

Petitioner seeks a Program award, contending that her CIDP and related symptoms were significantly aggravated by the influenza vaccinations she received on December 4, 2006, and November 16, 2007. After careful consideration, I conclude that Petitioner has *failed* to demonstrate that her influenza vaccinations caused a significant aggravation of her CIDP.

Petitioner's theory of the case may be briefly summarized as follows. Petitioner contends that each of the two influenza vaccinations that she received caused an immediate aggravation of her CIDP symptoms. (Ex. 10, p. 4.) Further, Petitioner asserts that these aggravations "were caused by a post vaccinial [sic] immune mediated mechanism known as rechallange [sic] based on the immune concept of molecular mimicry" (Ex. 10, p. 5; *see also* Pet. Pre-Hearing Memorandum, filed Sept. 21, 2012, pp. 3-4.)

Respondent disagrees. Respondent's expert witness asserts that the first symptoms of Petitioner's CIDP first appeared "around August of 2006," and that there was no indication of "deterioration after the first flu vaccination." (Ex. A, pp. 6-7) Further, her CIDP took a significant turn for the worse only once, in September 2007, which was long after her *first* influenza vaccination and well prior to her *second* influenza vaccination. (Resp. Post-Hearing Brief, filed June 17, 2013, pp. 10-11.) Finally, Respondent contends that there is no reliable scientific evidence that supports Petitioner's theory that the influenza vaccine *can* aggravate CIDP via molecular mimicry. (Ex. A, pp. 6-7.)

After carefully considering all of the evidence in the record, I must reject Petitioner's claim that her CIDP was aggravated by her influenza vaccines, for two reasons. First, while Petitioner's expert, Dr. Morgan, based his causation opinion on an assumption that Petitioner experienced two separate exacerbations, one immediately after each vaccination, that factual assumption is *contradicted* by Petitioner's medical records. The only significant exacerbation of Petitioner's CIDP symptoms actually occurred long *after* her first influenza vaccination, and well *before* she received her second influenza vaccination. Second, Dr. Morgan failed to provide any significant support for his theory that the influenza vaccine *can* cause an aggravation of CIDP.

V

SUMMARY OF EXPERT WITNESSES' CREDENTIALS AND OPINIONS

In this case, each side presented the expert reports and hearing testimony of one medical expert. At this point, I will briefly summarize both the credentials and the opinions of these expert witnesses.

A. Petitioner's expert

1. Dr. Morgan's qualifications

Dr. Morgan received a B.A. in history and a B.S. in chemistry from St. Louis University in 1966. (Ex. 11, p. 1; 2-Tr., p. 10.) Dr. Morgan received his medical degree from Meharry Medical College in 1970. (Ex. 11, p. 1; 2-Tr., p. 10.) From 1970-1975, Dr. Morgan served first as an internal medicine intern at the Brown University School of Medicine, and then as a resident in neurology at the Boston University School of Medicine. (Ex 11, p. 2; 2-Tr., p. 10.) Concurrent with his duties as a resident, he served as a Teacher Fellow in Neurology at the Boston University School of Medicine. Thereafter, Dr. Morgan was a Clinical Instructor in Neurology at the same medical school until 1978. (Ex. 11, p. 3.) Between 1978 and the present, he served as Assistant Professor in the Department of Clinical Neuroscience at Brown University School of Medicine. (Ex. 11, p. 3; 2-Tr., p. 13.)

Dr. Morgan is licensed to practice medicine in Rhode Island. He is board-certified in psychiatry and neurology, and has been certified as a medical examiner by the American Board of Medical Examiners, since 1996. (Ex. 11, pp. 2-3; 2-Tr., p. 15.) He has also been a member of the medical staff of Rhode Island Hospital since 1975, and a senior member of the medical staff at Kent County Hospital since 1996. Between 1996 and 1998, Dr. Morgan participated as a researcher in ten clinical research trials for a variety of pharmaceutical products. He has published seven medical journal articles. (Ex. 11, pp. 4-5.)

2. Summary of opinion of Petitioner's expert

Dr. Morgan asserts that Petitioner's pre-existing CIDP "was aggravated by the first flu vaccination on 12/04/06," and that her "second flu immunization on 11/16/07, again, aggravated and made worse her underlying CIDP." (Ex. 10, p. 4; see also 2-Tr., p. 38.) Dr. Morgan opined that Petitioner's influenza vaccines exacerbated her CIDP "by a post vaccinial [sic] immune mediated mechanism known as rechallange [sic] based on the immune concept of molecular mimicry." (Ex. 10, p. 5; *see also* 2-Tr., p. 57.)

According to Dr. Morgan, molecular mimicry occurs when the immune system mistakes the myelin in a person's peripheral nervous system for an "antigen"--*i.e.*, an invading agent. The immune system then mistakenly attacks the myelin, which can cause or exacerbate CIDP. (Ex. 10, p. 5; 2-Tr., pp. 56-60.) In Petitioner's case, according to Dr. Morgan, her "preexisting CIDP was activated by exposures to flu immunization antigens that cross reacted with the myelin of

her peripheral nerves," which caused a "recurrence and worsening of her CIDP." (Ex. 10, p. 5.) Further, Dr. Morgan asserted that the time of onset of her recurrences of CIDP after each of the two influenza immunizations, and the aggravation of Ms. Jacunski's CIDP "is appropriate for post vaccinial [sic] immune mediated reaction." (*Id*.)

B. Respondent's expert

1. Dr. Stommel's qualifications

Dr. Elijah Stommel received a B.A. in Music from Bowdoin College in 1977. (Ex. B, p. 1; 2-Tr., pp. 110-11.) In 1984, Dr. Stommel received a Ph.D. in Physiology from the Boston University School of Medicine, where he also received his degree as a medical doctor, four years later in 1987. (Ex. B, p. 1; 2-Tr., p. 111.)

Dr. Stommel served as a medical intern at St. Elizabeth's Hospital in Boston, Massachusetts, from 1987-1988, and as a resident in neurology from 1988-1990 at the Dartmouth-Hitchcock Medical Center, where he also served as Chief Resident in neurology from 1990-1991. (Ex. B, p. 1.) Dr. Stommel is licensed to practice medicine in Massachusetts, New Hampshire, and Vermont. (*Id.*, pp. 1-2.) He is board-certified in electrodiagnostic medicine, psychiatry, and neurology. (*Id.*; 2-Tr., pp. 111-12.)

Dr. Stommel commenced his academic career as an Instructor in Medicine at the Dartmouth Medical School from 1990-1991, then advanced to Assistant Professor of Medicine and served in that capacity from 1991 to June 2001. (Ex. B, p. 2.) Since 2001, he has served as an Associate Professor of Medicine at the Dartmouth Medical School. (Ex. B, p. 2; 2-Tr., pp. 112-14.) In his clinical practice, Dr. Stommel has been the Staff Neurologist at the Hitchcock Clinic in New Hampshire, since 1991. Concurrently, he served as a Consultant Neurologist at several medical centers in New Hampshire and Vermont. (Ex. B, p. 2.) In 1999, he founded the Neurology Neuromuscular Clinic at Dartmouth-Hitchcock Medical Center, where he continues to practice and train medical residents. (Ex. B. p. 4.)

Dr. Stommel's extensive involvement with research and clinical trials has focused on neurological issues, particularly the investigation of amyotrophic lateral sclerosis. (Ex. B, pp. 8-10.) He has authored eight chapters in a variety of medical texts, and published more than sixty medical journal articles and abstracts. (*Id*., pp. 10-17.)

2. Summary of opinion of Respondent's expert

Dr. Stommel disagreed with Dr. Morgan that either of Petitioner's influenza vaccinations caused an aggravation of her CIDP. In his view, the onset of her CIDP symptoms probably occurred on or about August 1, 2006 (Ex. A, p. 6), that is, four months before her first flu vaccination. Then, "her CIDP just continued to worsen in a progressive manner as it would naturally." (*Id*.) Further, he opined that there is no "reliable evidence for a deterioration after the first flu vaccination, in any time frame that could be mechanistically linked in temporal fashion." (Ex. A, pp. 7-8; 2-Tr., pp. 124, 126.)

Dr. Stommel also asserted that there is no reliable evidence that the influenza vaccine *can* cause CIDP via molecular mimicry. Likewise, Dr. Stommel opined that there is no reliable evidence to support Dr. Morgan's theory of "rechallenge." (Ex. A, pp. 7-8; 2-Tr., pp. 127-32.)

VI

DR. MORGAN'S OPINION IS BASED ON A FLAWED ASSUMPTION AS TO THE HISTORY OF PETITIONER'S CONDITION

Dr. Morgan's causation opinion is predicated on his belief that Petitioner suffered two distinct aggravations of her CIDP symptoms, one soon after each of her influenza vaccinations. (*See* Ex. 10, p. 4; 2-Tr., pp. 33, 35-38, 49.) The record demonstrates, however, that Petitioner did *not* suffer aggravations of her CIDP symptoms soon after either of her influenza vaccinations. The record, rather, demonstrates that the only significant worsening of Petitioner's CIDP symptoms occurred around September of 2007, long *after* her first vaccination in December of 2006, but well *before* her second influenza vaccination in in November of 2007.

A. First alleged "exacerbation"

Petitioner received her first influenza vaccination on December 4, 2006.[7] In the ensuing weeks, Petitioner's neurological condition did *not* worsen. In fact, it *improved*. Petitioner visited Dr. Tepper, the chiropractor, ten times between December 2006 and January 2007. (Ex. 6, pp. 9-15.) Petitioner did not report that her condition had worsened at any of those visits. On December 15, 2006, Dr. Tepper documented that Petitioner's "condition is showing progress." (Ex. 6, p. 10.) Likewise, on December 19, 2006, Dr. Tepper noted "measurable improvement" (*id*., p. 12), and on January 9, 2007, Dr. Tepper noted further improvement (*id*., p. 15).

Similarly, Petitioner's treating physician, Dr. Malhotra, performed a "[c]omplete physical exam" on December 19, 2006, and noted that Petitioner recently had "noticed improvement in symptoms." (Ex. 1, p. 64.)

Simply stated, there is no indication in the medical record that Petitioner's symptoms worsened in the weeks after her influenza vaccination on December 4, 2006. Rather, the record indicates that Petitioner's symptoms either remained the same or *improved* during that time period.

To be sure, Dr. Morgan urged repeatedly that Petitioner suffered a sharp downturn after her flu vaccination of December 4, 2006. (Ex. 10, p. 4; 2-Tr., pp. 33, 47, 76.) But, as set forth above, the overall medical records make it clear that Dr. Morgan was *mistaken* in that

[7] The two experts agree that Petitioner suffers from CIDP, and that she suffered her *first* symptoms of her CIDP about August or September of 2006, after a trip to Germany. (*E.g.*, Ex. 10, p. 4; 2-Tr., pp. 37, 115, 123.)

assumption. Dr. Malhotra's record from December 19, 2006, along with the overall chiropractor records of December 2006/January 2007, make it clear that Petitioner was actually *improving* in the weeks after the vaccination of December 4, 2006. (Ex. 1, p. 63; Ex. 63, pp. 1-15.)

In this regard, Dr. Morgan seemed to rely heavily on a single chiropractor record of December 8, 2006, four days after the vaccination in question. (*E.g.*, 2-Tr., pp. 47, 76.) But this reliance was misplaced. The December 8 record does *not* indicate a sudden worsening of the symptoms that Petitioner had *already reported* to Dr. Fried on December 4. (Ex. 1, p. 65.) The December 8 record, rather, was simply the *first time* that Petitioner saw the chiropractor, Dr. Tepper, and Dr. Tepper was recording essentially the same symptoms that Petitioner had *already* reported to Dr. Fried on December 4. (*Compare* Ex. 1, p. 65, *with* Ex. 6, p. 3.) Note that on December 8 Dr. Tepper wrote that Petitioner's symptoms had been "progressively worse" since August 1, 2006, *not* that such symptoms had significantly worsened in the prior four days.[8]

Moreover, in this regard I have not ignored the testimony that Petitioner and her friend presented during the *first* evidentiary hearing in this case, held before Special Master Golkiewicz on November 1, 2010. To be sure, the oral testimony at that hearing indicated sharp downturns in Petitioner's neurological condition after each of her two influenza vaccinations. However, Special Master Golkiewicz issued an Order on November 3, 2010, concluding that while Petitioner was doing her best to accurately recall the events of years before, he found it "perfectly evident that [Petitioner's] memory was not sufficiently clear to be relied upon." (Order, p. 1.) Instead, Special Master Golkiewicz found the medical records to provide a *much more accurate* history of Petitioner's symptoms. (*Id.*) I have reviewed both the transcript of the first hearing, and the medical records, and I concur completely with Special Master Golkiewicz. I rely on the medical records for the history of Petitioner's symptoms.

In short, I conclude that Petitioner did *not* suffer an exacerbation of her CIDP symptoms soon after her first influenza vaccination.

B. Second alleged exacerbation

Next, Dr. Morgan assumed that a *second* sharp worsening of Petitioner's neurological symptoms occurred after Petitioner's second influenza vaccination. But again, Dr. Morgan's assumption was wrong. The medical records simply do not show a sudden worsening of Petitioner's symptoms after the flu vaccination of November 16, 2007. The records, instead, show that on November 16, 2007, Petitioner was already reporting a *progressive* worsening of her symptoms over the preceding year. (Ex. 1, p. 55.)

Also, the chiropractor's records again *contradict* Dr. Morgan's assumption about the period soon after November 16, 2007. Those records show that the chiropractor, Dr. Tepper, saw Petitioner a number of times in December of 2007. (Ex. 6, pp.15-23.) Those records not

[8] On cross-examination, Dr. Morgan himself admitted that Dr. Tepper's records did *not* document an exarcerbation after the first influenza vaccination. (2-Tr., p. 78.)

only fail to show an exacerbation of symptoms, but instead show *progress* or *improvement*. (Ex. 6, p. 16 (12-8-07) ("progressing favorably"); Ex. 6, p. 17 (12-10-07) ("improvement"); Ex. 6, p. 19 (12-17-07) ("progress").)

Further, on December 18, 2007, Petitioner saw two different physicians. (Ex. 1, pp. 51-52, 53-54.) Neither physician described a sudden increase in Petitioner's neurological symptoms since the November 16 vaccination. (*Id*.) To the contrary, *both* physicians wrote that the exacerbation of Petitioner's neurological symptoms took place in *September* of 2007, *not* after the November vaccination. (Ex. 1, pp. 51, 53.) Then, again, on January 14, 2008, Petitioner once more reported the same worsening in *September 2007*. (Ex. 1, p. 47.)

In sum, I conclude that the medical records indicate that the *only* time Petitioner's symptoms sharply worsened was around September of 2007, two months *before* her influenza vaccination of November 2007.

C. Summary

The record establishes that, in formulating his opinion, Dr. Morgan assumed *plainly incorrect* facts concerning when Petitioner allegedly suffered exacerbations of her CIDP symptoms. The record demonstrates that Petitioner did *not* suffer an exacerbation of her CIDP symptoms shortly after her influenza vaccination of December 4, 2006, as Dr. Morgan assumed, nor did she suffer an exacerbation of her CIDP symptoms shortly after her influenza vaccination of November 16, 2007. Thus Petitioner's causation theory must fail for this reason alone--because Dr. Morgan relied upon a *clearly mistaken* assumption concerning the history of Petitioner's symptoms.

VII

ADDITIONAL REASONS TO CREDIT DR. STOMMEL'S TESTIMONY OVER THAT OF DR. MORGAN

As noted above, Dr. Morgan's causation opinion could be readily dismissed simply because he based it on clearly flawed assumptions as to the timing of Petitioner's CIDP symptoms, as described in Section VI. However, I will also briefly discuss several *additional* reasons to discount Dr. Morgan's causation opinion.

A. Dr. Stommel's testimony was more persuasive in general.

In general, Dr. Stommel's presentation was substantially more persuasive than that of Dr. Morgan, whose opinion was plagued by a lack of evidentiary support for his causation theory.

Most importantly, Dr. Morgan simply failed to put forth any coherent presentation of *evidence or reasoning* to support his causation conclusion. As explained above, Dr. Morgan

opined that Petitioner's CIDP was exacerbated both by her first influenza vaccination in December of 2006 and her second influenza vaccination in November of 2007. But Dr. Morgan failed to offer any coherent evidence for the proposition that the influenza vaccination is even *capable* of exacerbating CIDP. Dr. Morgan failed to point to any medical articles or other actual evidence demonstrating that influenza inoculations can do so. (2-Tr., p. 60.) He failed to persuasively explain *by what mechanism* influenza vaccinations could exacerbate CIDP.

Indeed, Dr. Morgan even *acknowledged himself* that he knows of no medical literature indicating that the influenza vaccine can cause CIDP--and he does not believe that any such literature exists. (2-Tr., p. 60.)

And Dr. Stommel, on the other hand, was persuasive in pointing out the lack of any scientific support for Dr. Morgan's speculations. He maintained that Dr. Morgan's theory of the case was *not* persuasive, and that Petitioner's two vaccinations in question likely did not influence the course of Petitioner's CIDP in any way. (Ex. A, p. 6; 2-Tr., pp. 124, 134-35.)

B. Dr. Morgan's presentation concerning "molecular mimicry" was not persuasive.

To support his causation theory, Dr. Morgan suggested that perhaps the influenza vaccines caused Petitioner's alleged exacerbations by a mechanism known as "molecular mimicry." (*E.g.*, 2-Tr., p. 50.) CIDP is thought to be an autoimmune disease, meaning that the patient's own immune system is erroneously attacking the patient's own tissue, mistaking that tissue for an invasive agent. (Ex. A, p. 3; 2-Tr., pp. 50, 127-128.) Dr. Morgan's expert report argues that Petitioner's preexistent CIDP could be activated "by exposures to flu immunization antigens that cross reacted with the myelin of her peripheral nerves to cause recurrence and worsening her CIDP." (Ex. 10, p. 5; s*ee also* 2-Tr., p. 50 -- "there's a cross reactivity of the antigen that gets destructive and attacks her own system.") Thus, Dr. Morgan appears to suggest that an antigen[9] within the influenza vaccine erroneously prompted Petitioner's immune system to attack her own tissues, thereby exacerbating her CIDP.

But, Dr. Morgan failed to offer any *evidence* or even any *explanation* to support this vague suggestion. In his expert report and his testimony, Dr. Morgan introduced the concept of an antigen that is part of the influenza vaccine, which may have caused a harmful response. (*See* Ex. 10, p. 5; 2-Tr., p. 50.) However, when pressed for more details, he had no idea what particular antigen within the vaccine might have caused the alleged molecular mimicry effect. (2-Tr., p. 59.) Indeed, he acknowledged that he knows of no evidence to support the idea that a flu vaccine can cause CIDP via molecular mimicry -- "it's a theory" was the best he could offer. (2-Tr., p. 57.)

Dr. Stommel, on the other hand, indicated that he saw *no merit* to Dr. Morgan's "molecular mimicry" suggestions. (Ex. A, p. 5; 2-Tr., pp. 127-31.) He testified that there is no

[9] Antigen – "any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is with specific antibodies or specifically sensitized T- lymphocytes or both." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (31st ed. 2007), p. 104.)

evidence that modern day influenza vaccines "have any homology" with the parts of the nervous system attacked by the immune system in CIDP--in other words, that there is no similarity between vaccine components and neuronal or myelin structures that would prompt such an erroneous immune system attack. (Ex. A, p. 4.) He reiterated that testimony at the hearing--that he knows of no similarity between the proteins in the flu vaccine and the myelin proteins that are attacked in CIDP. (2-Tr., pp. 129-30.) He testified that no medical researcher has ever shown that the influenza vaccine *could* cause molecular mimicry resulting in an aggravation of CIDP. (2-Tr., p. 130.) He acknowledged that some in the medical community have hypothesized that CIDP might be caused through a process of molecular mimicry by "*something*" in the environment (*Id*., line 24), but explained that there is no evidence that the *influenza vaccine* could be the trigger of CIDP exacerbation (2-Tr., pp. 129-30, 131).

Viewing the overall record, I find no merit in Dr. Morgan's "molecular mimicry" theory in this case.

C. Dr. Morgan's "challenge/rechallenge" theory was not persuasive.

Dr. Morgan also asserted that Petitioner's case is an example of the "challenge/ rechallenge" theory, which supports a conclusion that Petitioner's CIDP was vaccine-caused. (*E.g.*, 2-Tr., pp. 49, 57; Ex. 10, p. 5.) After closely studying the record of this case, I firmly conclude that the "challenge/rechallenge" concept does *not* apply to this case.

To be sure, if a *true* instance of "challenge/rechallenge" occurs, that can indeed be powerful evidence of causation. As Dr. Morgan explained, "challenge/rechallenge" refers to a situation where a person has a clinical reaction to a particular stimulus (*i.e.* - administration of a vaccine or drug), and then suffers increased symptoms after an additional exposure to that same stimulus (*i.e.* - a second administration of a vaccine or drug). (2-Tr., p. 57.) For example, in one Vaccine Act case, *Capizzano v. HHS*, 2004 WL 1399178 (Fed. Cl. Sp. Mstr. 2004), *rev'd on other grounds* 440 F.3d 1317 (Fed. Cir. 2006), the special master stated that the "challenge/rechallenge cases are such strong proof of causality that it is unnecessary to determine the mechanism of cause -- it [causation] is understood to be occurring." 2004 WL 1399178 at *15-16.

Unfortunately for Petitioner, however, the actual facts of *Petitioner's* case clearly do *not* fit the challenge/rechallenge scenario.

In this case, as explained above, and contrary to Dr. Morgan's assumption, Petitioner clearly did *not* suffer an exacerbation of her CIDP after her first influenza vaccination in December of 2006, *nor* did she suffer a second rapid onset of symptoms after her second influenza vaccination in November of 2007. Rather, as discussed above, the record of this case makes it clear that Petitioner, unfortunately, was already experiencing the initial symptoms of her CIDP during the months *prior* to her first influenza examination. To be sure, there is no doubt that Petitioner's disorder *did* significantly worsen one year later, around September of 2007. But the medical records do *not* point to any rapid worsening her symptoms after *either* of the vaccinations in question.

Accordingly, I do *not* find that Petitioner's case fits the "challenge/rechallenge" scenario. Dr. Stommel reached the same conclusion. (2-Tr. 132.) The challenge/rechallenge argument is not persuasive in this case.

D. Petitioner's symptom history followed a typical course for CIDP.

Another factor leading me to credit Dr. Stommel over Dr. Morgan is the testimony concerning the *typical* course of CIDP. CIDP can often follow a "relapsing/remitting" course, in which symptoms often stay the same for a period of time, then get suddenly worse at various times for no discernible reason, while sometimes gradually worsening over time. (Ex. A, pp. 2-3; 2-Tr., pp. 116, 123, 123, 126, 144.) Dr. Stommel opined that Petitioner's condition was a typical relapsing/remitting form of CIDP, and that her vaccinations have had no effect on the course of her CIDP. (2-Tr., pp. 123, 126, 139-40.)

Dr. Morgan himself acknowledged that the natural course of CIDP is often a relapsing/remitting course. (2-Tr., pp. 70-72, 96, 100, 106.)

My conclusion from the overall record is that Petitioner, unfortunately, suffers from a typical form of relapsing/remitting CIDP, and that her vaccinations have had *no effect* on the course of her disease.

E. The IOM committee report also is consistent with my conclusion.

Another factor in this case is the existence of a recent report of the prestigious Institute of Medicine, regarding the possible adverse effects of vaccines, which specifically addressed the issue of whether influenza vaccines can affect CIDP. (Ex. A, p. 6.) The IOM committee found that the available evidence was *insufficient* to determine whether an association exists between influenza vaccines and CIDP. (Ex. A, pp. 6-7.)[10]

Dr. Morgan acknowledged that this conclusion of the IOM committee did not support his theory. (2-Tr., p. 58.)

Of course, this IOM committee conclusion is of very slight importance in this case, since the committee did not find enough evidence to conclude *either way* as to whether the flu vaccine can affect CIDP. But since the Petitioner bears the burden of proof to demonstrate causation, this IOM committee conclusion could be said to add very slight additional weight against Petitioner's causation case.

F. Summary concerning causation issue

[10] *See* Ex. A-14, Kathleen Stratton, *et al*., Institute of Medicine, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY (The National Academies Press, pre-publication ed. 2011), excerpt of pp. 281-82, entitled *Chronic Inflammatory Disseminated Polyneuropathy* (concluding that "The evidence is inadequate to accept or reject a causal relationship between influenza vaccine and CIDP.")

In short, I find Dr. Morgan's causation argument to be wholly unpersuasive, and I find the contrary testimony of Dr. Stommel to be persuasive.

VIII

PETITIONER'S CASE FAILS THE TESTS REQUIRED BY *ALTHEN* AND *LOVING*

In this part of my Decision, I will explain how this case fits specifically within the interpretive standards set forth in the *Althen* and *Loving* decisions. The short answer is that I find that Petitioner's case clearly does *not* satisfy the standards presented in either *Althen* or *Loving*.

The U.S. Court of Appeals for the Federal Circuit declared in *Althen* that it is a Petitioner's burden

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278 (emphasis in original)(citations omitted). There can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." (§ 300aa-13(a)(l)(A).) The overall evidence here shows that the onset of Petitioner's CIDP occurred in August 2006, more than three months before her first influenza vaccination, so it is clear that the influenza vaccines that she received were not the initial cause of her preexisting CIDP. However, in this case, Petitioner does not assert that her influenza vaccinations *initially caused* her CIDP. Rather, the injury that she alleges is that her influenza vaccinations caused a *significant aggravation* of her CIDP. (Ex. 10, p. 4.)

A. Analysis of a "significant aggravation" issue is guided by the ruling in Loving.

The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4).

The elements of an off-Table significant aggravation case were set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). The Federal Circuit Court of Appeals acknowledged that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims," in *W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Thus, the Federal Circuit Court of Appeals, which sets binding precedent for decisions by the Office of Special Masters, endorsed the use of a six-part test for significant aggravation, which was first elaborated in

Loving. A petitioner must prove by preponderant evidence that a vaccination caused significant aggravation by showing:

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

W.C. v. HHS, 704 F.3d at 1357 (Fed. Cir. 2013).

The standard elaborated in *Loving*, and affirmed in *W.C. v. HHS*, combines elements from previous Federal Circuit decisions. *W.C. v. HHS*, 704 F.3d at 1537 ("The *Loving* test combines the first three *Whitecotton* factors, which establish significant aggravation, with the *Althen* factors, which establish causation.") Since the last three elements of a *Loving* test include the entirety of the *Althen* test, with insignificant wording modifications, the analysis of those three elements would be the same using either standard.

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test (that is, prongs 4 and 5 of the *Loving* test). Initially, it was not absolutely clear how the two prongs differed from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between the "vaccination" and "the aggravation." However, a number of Program opinions concerning *Althen* have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the particular vaccination received by the specific vaccinee *did* cause the vaccinee's own injury. (*See, e.g. Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002).) Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. (*See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008).)

Most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. (*Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006).) Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen*, a petitioner must demonstrate that the *type* of vaccination in question can cause the *type* of condition in question; and under Prong 2 of *Althen*, that petitioner must then demonstrate that

the *particular* vaccination did cause the *particular* condition of the vaccinee in question. If these conclusions are applied to the analogous elements in the *Loving* test, then under Prong 4 of *Loving* a petitioner must demonstrate that the *type* of vaccination in question *can cause* the *type* of significant aggravation in question; while Prong 5 of *Loving* would require that the Petitioner also demonstrate that the particular vaccination *did cause* the significant aggravation.

B. Analysis of this case, under the six-part Loving/Althen test.

In this Section, I will discuss whether Petitioner has satisfied the six-part *Loving* test to establish the existence of a vaccine-related significant aggravation of a pre-existing condition.

1. What was Petitioner's condition prior to the administration of the vaccine?

Petitioner's expert witness, Dr. Morgan, opined in his report that, based on the medical records, "Ms. Jacunski developed her first symptom of CIDP in August of 2006 characterized by mild weakness of her lower extremity with abnormal sensations," and "these symptoms waxed and waned through the early fall of 2006." (Ex. 10, p. 4.) Respondent's expert, Dr. Stommel, stated, "I would agree with Dr. Morgan's assessment that Ms. Jacunski developed her first symptom of CIDP around August of 2006." (Ex. A, p. 6.) Thus, the experts representing both parties agree that Petitioner's CIDP was a pre-existing condition when she received her first flu vaccination on December 4, 2006.

2. What is Petitioner's current condition?

As discussed previously, in Section VI, I have concluded that Petitioner, in the weeks that followed both of the influenza vaccinations she received, did *not* exhibit any significant "change for the worse in a preexisting condition which result[ed] in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4). However, clearly Petitioner's condition got progressively worse during 2007. It also seems that since Petitioner's CIDP appears to be a condition that gradually worsens over time, then her current condition is, more likely than not, significantly worse than it was prior to either her December 2006 vaccination or her November 2007 vaccination. Therefore, it appears that Petitioner's case fulfills Prong 2 of the six-part Loving test.

3. Petitioner's current condition after her vaccinations technically is a "significant aggravation."

As noted in paragraph VIII(B)(2) of this Decision, immediately above, it appears that Petitioner's *current* condition is significantly worse than it was prior to either of the vaccinations in question. Therefore, under *Loving*, it appears that Petitioner's current condition does amount to a "significant aggravation" of her preexisting CIDP (although for the reasons set forth above and below, there is no reason to think that the "significant aggravation" was *vaccine-caused*).

4. Petitioner has failed to establish Prong 4 of Loving / Prong 1 of Althen.

As discussed above, Prongs 4, 5 and 6 of the *Loving* test are, in effect, the same as Prongs 1, 2, and 3 of the *Althen* standard. Under Prong 4 of *Loving,* and Prong 1 of *Althen*, a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause a significant worsening of the *type* of preexisting condition in question. In this case, however, the Petitioner has wholly *failed* to show that influenza vaccinations *can* exacerbate a preexisting CIDP.

Here, as described in Sections VII(B) and VII(C) above, Petitioner seems to rely on "molecular mimicry" and "challenge-rechallenge" theories to establish that influenza vaccinations are capable of aggravating CIDP. For the reasons described in Sections VII(B) and VII(C), however, Petitioner's reliance on those theories was clearly insufficient to meet Petitioner's burden of demonstrating a plausible medical theory. Petitioner plainly failed to establish that influenza vaccinations can aggravate a preexisting CIDP, so Petitioner has failed to satisfy Prong 4 of *Loving* / Prong 1 of *Althen* in this case.

5. Petitioner has failed to establish Prong 5 of Loving / Prong 2 of Althen.

Under Prong 5 of *Loving* / Prong 2 of Althen the Petitioner must "prove by preponderant evidence" that Petitioner's vaccinations *did* aggravate her *own* CIDP--*i.e.,* she must demonstrate "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." *W.C. v HHS*, 704 F.3d at1357. However, Petitioner has completely failed to make such a showing.

That is, for the reasons described in detail above, I find that Petitioner has failed to establish (1) that the Petitioner's CIDP was aggravated soon after *either* of her influenza vaccinations; (2) that "molecular mimicry" aggravated her CIDP; or (3) that her case fits a "challenge/ rechallenge" scenario. Therefore, I find that Petitioner plainly has failed to meet her burden under the fifth prong of *Loving* and the second prong of *Althen*.

6. Petitioner has failed to establish Prong 6 of Loving / Prong 3 of Althen.

Finally, under Prong 6 of *Loving*, a petitioner must demonstrate "a proximate temporal relationship between the vaccination and the significant aggravation." *W.C. v. HHS,* 704 F.3d at 1357. The Federal Circuit has further clarified that the analogous *Althen* Prong 3 requires "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation in fact." *DeBazan v. HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Since I have found that Petitioner has failed to meet her burden of proof concerning Prongs 4 and 5 of *Loving*, I need not necessarily reach the question of whether she has also failed to meet her burden under the final prong. But in the interest of completeness, I find that Petitioner has also failed to establish Prong 6. For the reasons explained at Section VI above, I find that Petitioner's expert relied upon a *flawed* assumption of fact concerning the *history* of Petitioner's CIDP symptoms. Moreover, just as Dr. Morgan was totally unpersuasive in arguing that there is any reason to think that influenza vaccinations even *can* aggravate CIDP, so he also

failed to offer any persuasive evidence as to *when* the first symptoms of such an allegedly vaccine-related aggravation might appear.

C. This is not a close case.

In *Althen*, the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (418 F.3d at 1280.) Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I find that Petitioner has failed to satisfy Prongs 4, 5, and 6 of the *Loving* test. She has not only failed to demonstrate any vaccine-related significant aggravation of her CIDP; she has also failed to find adequate support in the record for the medical theories that she advanced. This is simply not a close case at all.

IX

CONCLUSION

The record of this case demonstrates plainly that Petitioner has been through an unfortunate medical ordeal. She is certainly deserving of great sympathy. Congress, however, designed the Program to compensate only the individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or "causation-in-fact" evidence, to a listed vaccine. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that Petitioner in this case is *not* entitled to a Program award.[11]

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

[11] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.