In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 01-700V

(Filed: March 14, 2012)

TO BE PUBLISHED[1]

SONIA SUAREZ,	*	
	*	Vaccine Act Entitlement;
Petitioner,	*	Causation-in-fact; Hepatitis B/
	*	Still's Disease Causation Issue.
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Clifford Shoemaker, Vienna, Virginia, for petitioner.
Althea Davis, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION

HASTINGS, ***Special Master***.

This is an action in which the petitioner, Sonia Suarez, seeks an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[2]), on account of an ongoing condition involving joint pain that she believes was caused by a hepatitis B vaccination. For the reasons set forth below, I conclude that the petitioner is not entitled to an award.

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[1]Because I have designated this document to be published, this document will be made available to the public unless petitioner files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." See 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b).

[2]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). I will also sometimes refer to the Act of Congress that created the Program as the "Vaccine Act."

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

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 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.[3] 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. 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)(1)(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)(1)(A); *see also Althen*, 418 F.3d at 1278; *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:

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[3] As will be detailed below, no Table Injury is alleged in this case.

> 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. 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 (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 instruction 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 (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.

II

FACTS AND PROCEDURAL HISTORY

A. Facts

Sonia Suarez ("Petitioner") was born on August 25, 1970. She received her first hepatitis B vaccination on July 24, 1998, and her second on August 24, 1998. (Ex. 14, p. 1.)[4] Her third and final hepatitis B vaccination was administered on January 29, 1999. (*Id.*)

On April 10, 1999, Petitioner sought treatment at the Buffalo General Hospital Emergency Department, with complaints of generalized aches, sore throat, and fever for the previous five days, accompanied by persistent vomiting and transient swelling of the face and neck. (Ex. 13, pp. 373-76.) An examination revealed a temperature of 100.7 degrees Fahrenheit, pharyngitis, mild dehydration, and elevated liver enzymes. She was diagnosed with a viral syndrome, possibly hepatitis. (Ex. 13, p. 375.)

Petitioner returned to the emergency department on April 11 and 12, with ongoing complaints of fever and vomiting. (Ex. 13, pp. 369-72.) On April 15 she was admitted to the Buffalo General Hospital by the emergency department staff, who noted her three previous E.R. visits, ongoing abdominal pain, and a temperature of 102º F. (Ex. 5, pp. 15-18.) The attending physician, Dr. Aston Williams, summarized her initial examination, and her extensive testing and treatments over the next twelve days in the hospital. He noted intermittent fevers; a papular rash over the abdomen, knees, and elbow areas; and redness at the back of her throat. (Ex. 5, pp. 5-8.) Ms. Suarez continued to experience fevers, hives, joint pain, and a rash during the hospitalization. During this hospitalization, Petitioner was examined by rheumatologist Dr. John Starr, who proposed a diagnosis of "Still's disease." (Ex. 5, p. 7; Ex. 17, pp. 43-44.) Upon her discharge from the hospital, her diagnoses were "Adult onset Still's disease" ("AOSD"), and a remote history of asthma. (Ex. 5, p. 5.)[5]

On May 7, 1999, Ms. Suarez returned to the Buffalo General Emergency Department, complaining of chest pain the previous night and a diffuse maculopapular rash on her trunk, hands, and feet. (Ex. 43, pp. 102-05.) She received further treatment for her persistent rashes at the Buffalo General Outpatient Dermatology Clinic on May 11, June 9, August 2, and September 30 of 1999. (Ex. 31, pp. 215-20.) During this time, Dr. Aston Williams continued to monitor her intermittent

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[4]Petitioner filed exhibits numbered 1 through 7 on September 6, 2002, and further consecutively-numbered exhibits on several occasions thereafter. Respondent filed Exhibit A on November 29, 2006, and further consecutively-lettered exhibits on several dates thereafter. "Ex." references will refer to those exhibits. "Tr." references will be to pages of the transcript of the evidentiary hearing held on November 17, 2010.

[5]As will be discussed below (p. 11), "Still's disease" is a condition that involves chronic arthritis in multiple joints.

pains in her low back, arms, legs, and hands. (Ex. 17, pp. 11-15.) Petitioner also received treatment at the Endocrine Clinic of Sheehan Memorial Hospital, from June through November 1999, for her complaints of joint pain and swelling. (Ex. 7, pp. 6-18.)

On December 22, 1999, Ms. Suarez had a medical evaluation performed by Dr. M. Jaffri, who documented limitations of range of motion in multiple joints. (Ex. 13, pp. 272-75.) Dr. Julian Ambrus examined her on December 23, 1999, and noted that Petitioner had experienced "a perplexing constellation of symptoms," which "argue against a diagnosis of Still's disease." (Ex. 13, p. 211.)

On February 26, 2000, Petitioner returned to the Buffalo General Hospital emergency department with complaints of body aches, stiffness, and sore throat. (Ex. 43, p. 120.) When she was examined by Dr. Corstiann Brass of the Buffalo Medical Group on March 1, he recorded a resurgence of her pain, widespread pruritic rashes, and swelling of the joints. His assessment was "possible collagen vascular disease." (Ex. 1, p. 13.) On March 3, 2000, she was admitted to the Buffalo General Hospital and was examined by multiple medical specialists during an extended hospitalization. Upon her discharge four weeks later, Dr. John Starr compared her current round of fevers, myalgias, arthralgias, and abdominal pain to the hospitalization of April 1999, when she was diagnosed with Still's disease. His primary diagnosis for Ms. Suarez' condition during the hospitalization of March 2000 was "Adult Still's." (Ex. 15, pp. 55-56.)

On July 10, 2000, Dr. Herman Mogavero, a dermatologist in the Buffalo Medical Group, examined Ms. Suarez, and wrote that her diagnosis was either "Adult Still's" or "primary vasculitis." (Ex. 1, pp. 9-10.) On August 1, 2000, Ms. Suarez was evaluated by a rheumatologist at the Cleveland Clinic, Dr. Sudhakar Sridharan, who noted that the diagnosis of her chronic illness "presents a perplexing problem." (Ex. 13, p. 15.) He noted that it was "possible that adult onset Still's disease" was Petitioner's diagnosis, but that there were "other possibilities," including "vasculitis." (*Id*.)

Petitioner continued to experience chronic joint pain, rashes, and other symptoms over the following years, and continued to seek treatment for those symptoms from a number of physicians.

On June 8, 2001, Ms. Suarez sought treatment from Dr. Vinay Reddy, a rheumatologist. He wrote that while she had been diagnosed with either Still's disease or "collagen vascular disease" in the past, he himself was "not too sure what the actual diagnosis is." (Ex. 1, pp. 223-24.)

In addition to joint and skin problems, Ms. Suarez began to manifest respiratory difficulties. Tests performed at Buffalo General Hospital in February of 2002, including a CT scan of the chest, revealed extensive mediastinal lymphadenopathy (*i.e.*, enlargment of a lymph node in her chest area) and nodules in her lungs. (Ex. 8, pp. 6, 8.) A pulmonary function analysis performed on March 1, 2002, revealed that her lung capacity was severely reduced, a condition characterized as "severe restrictive lung disease." (Ex. 1, pp. 196-97.)

On March 4, 2002, Ms. Suarez was evaluated by pulmonologist and sleep disorder specialist Dr. Taj Jiva. (Ex. 1, p. 27.) His report noted her history of asthma, arthritis, and generalized rashes, which were still ongoing. He opined that "her case has been perplexing to the clinician and diagnostician," but that her proper diagnosis was either "lymphoma or sarcoidosis." (*Id*. at 29.)

On March 20, 2002, a biopsy of tissue from a lymph node in Petitioner's chest area was taken, and then analyzed. (Ex. 34, pp. 1-4.) One of the results of that biopsy was that "noncaseating granulomas" were found. (*Id*. at 1, 3.) At that point, in light of the recent lung symptoms and the finding of noncaseating granulomas in the biopsy, the diagnostic thinking of some of Petitioner's physicians turned to "sarcoidosis"[6] as the likely diagnosis.

For example, once Dr. Jiva saw the biopsy finding of noncaseating granulomas, he then opined that Petitioner's case "strongly suggests the diagnosis of sarcoidosis." (Ex. 1, p. 219.) Similarly, soon after the biopsy results, Dr. Eugene Gosy, a specialist in neurology and pain management, wrote on April 12, 2002, that Petitioner's ongoing joint pain ("arthralgias") was "possibly due to sarcoidosis." (Ex. 48, p. 76.) And an expert in pulmonology, Dr. Alexander Gelfer, writing on December 19, 2003, concluded that Petitioner's entire symptom history was "highly suggestive of sarcoidosis." (Ex. 50, pp. 15-17.)

However, even after the biopsy results there were still some differences of opinion among Petitioner's treating physicians as to the appropriate diagnosis for Petitioner's chronic condition. For example, a pathologist who reviewed the biopsy results, Dr. Mohamed Zeid, wrote on May 16, 2002, that due to the noncaseating granuloma, "sarcoidosis" was one possible diagnosis, but there also existed the possibility of "an infectious process or immunologic disorder." (Ex. 34, p. 1.) Also, Dr. Julian Ambrus wrote on May 6, 2002, that the overall biopsy results "suggested a reactive etiology rather than sarcoidosis." (Ex. 13, p. 199.) And Dr. Aston Williams, who in 1999 had diagnosed AOSD, indicated on June 25, 2002, that he was no longer confident of that earlier diagnosis, writing that Petitioner's illness was "a perplexing and puzzling condition which is of unclear etiology." (Ex. 13, p. 198.)

Finally, from the medical records filed in this case, it appears that beginning in early 2003, Ms. Suarez sought treatment for her ongoing joint pain chiefly from Dr. Gosy, an expert in neurology and pain management. There are records of Dr. Gosy's treatment of her every two-to-three months from January to September of 2003, and from August of 2004 through August of 2007. (Ex. 38, pp. 7-49.) From reading the entire reports, especially the initial lines of each report, it appears that Dr. Gosy's view of the proper diagnosis for Petitioner's chronic joint pain began to focus on another diagnosis. That is, beginning in August of 2004, and uniformly thereafter, Dr. Gosy indicated that

[6]As will be discussed below (p. 11), sarcoidosis is a poorly understood chronic disorder that involves both joint pain and lymph node irregularities.

Petitioner's chronic joint pain was a product of "fibromyalgia," a common syndrome involving chronic pain in multiple joint and muscle areas.[7]

I found, in the records of this case, no medical records of treatment of Ms. Suarez after August of 2007. However, the records indicate that, at least up until that time, Petitioner, unfortunately, continued to suffer from chronic joint pain and some other symptoms. The records also indicate that her treating physicians have never been confident of the proper diagnosis of and cause of her chronic difficulties, finding her condition to be perplexing and unclear.

B. Procedural history

The petition was filed on December 19, 2001. Proceedings were delayed until 2008 at Petitioner's request, as Petitioner sought expert opinions to support her claim. After Petitioner filed her expert reports in 2006 and 2008, and respondent filed expert reports in response, status conferences were held by Special Master John Edwards and then Special Master Richard Abell, but no evidentiary hearing was conducted. On March 29, 2010, the case was reassigned to my docket, because of the retirement of Special Master Abell. After that reassignment, I scheduled an evidentiary hearing for November 17, 2010, and the hearing was held on that date. At that hearing, Petitioner relied on the testimony of two expert witnesses, as did respondent. At the conclusion of the hearing, petitioner's counsel requested that the parties file post-hearing briefs. The last of the post-hearing briefs was filed on April 29, 2011. At this time, the case is now ripe for a ruling concerning the issue of "entitlement," *i.e.*, whether Petitioner has demonstrated that she is entitled to a Program award.[8]

III

ISSUE TO BE DECIDED

In this case, Petitioner seeks a Program award, contending that her chronic arthritis and related symptoms were "caused-in-fact" by her hepatitis B vaccination received on January 29, 1999. After careful consideration, I conclude that Petitioner has *failed* to demonstrate causation.[9]

Petitioner's theory of the case may be briefly summarized as follows. Petitioner contends that most of her symptoms, described above at pp. 4-5, are symptoms of a condition known as

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[7]DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 703.

[8]Usually, I would be able to complete my evaluation of a causation issue in a much more prompt fashion. I apologize to Petitioner for the fact that, in this instance, I was delayed in reaching this ruling by the press of other business.

[9]Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

"adult-onset Still's disease," or "AOSD." She contends that her AOSD was caused by the hepatitis B vaccination that she received on January 29, 1999.

Respondent disagrees. Respondent contends that the Petitioner's symptoms, which Petitioner believes to be a product of AOSD, are more accurately characterized as the product of a different condition, known as "sarcoidosis." Respondent contends that the sarcoidosis is unrelated to Petitioner's hepatitis B vaccination. Further, respondent argues that even if Petitioner is found to suffer from AOSD, rather than sarcoidosis, nevertheless Petitioner has failed to demonstrate that either that the hepatitis B vaccine *can* cause AOSD in general, or that it *did* cause Petitioner's AOSD.

After carefully considering all of the evidence in the record, I must *reject* Petitioner's claim that her ongoing joint symptoms, or any other symptoms, were caused by her hepatitis B vaccination. There are two chief reasons for this ultimate conclusion. First, I find that Petitioner has failed to demonstrate that it is "more probable than not" that her condition is accurately described as AOSD. Instead, it seems more likely that Petitioner's condition falls within the category of sarcoidosis. And there is no evidence in the record that *sarcoidosis* can be caused by a hepatitis B vaccination.

Second, I conclude that even if Petitioner's condition *is* considered to be a case of AOSD, nevertheless Petitioner has not shown it "more probable than not" either that the hepatitis B vaccine *can* cause AOSD, or that it *did* cause Petitioner's AOSD.

I will discuss these two reasons separately in parts V and VI of this Decision, below. I will first note, however, that Petitioner would have to prevail on *both* of these issues in order to demonstrate that she has a vaccine-caused injury. If her argument fails on *either* point, she fails to demonstrate causation. Thus, my conclusions stated in parts V and VI below are separate, alternative reasons to deny Petitioner's claim. If my reasoning on either point is correct, Petitioner's case fails.[10]

IV

SUMMARY OF EXPERT WITNESSES' CREDENTIALS AND OPINIONS

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

[10]Accordingly, it is not strictly necessary that I discuss *both* issues, but I do so for the sake of completeness.

A. Petitioner's experts

1. Dr. Andrew J. White

Dr . Andrew J. White received a Bachelor of Arts degree from Brandeis University in 1986, and a Master of Science degree in organic chemistry from the University of Chicago in 1989. He graduated from the University of Texas Southwestern Medical School in 1994 with a degree in medicine. From 1994 through 1997, Dr. White served as an intern, then a resident at the St. Louis Children's Hospital. He also trained in a fellowship for pediatric immunology and rheumatology at the Washington University School of Medicine from 1997 through 2000. He is board-certified in pediatrics and pediatric rheumatology. Dr. White was an instructor in pediatrics from 2000 to 2001, and co-director of the Pediatric Residency Program from 2001 to 2002, at the Washington University School of Medicine. At the same school, he became the Director of the Pediatrics Residency Program and Assistant Director of Pediatrics in 2002, positions that he continues to hold. In 2004, he became the Director of Pediatric Rheumatology/Immunology at the Washington University School of Medicine, a position that he also continues to hold. He is also the Director of Rheumatology at Shriner's Hospital in St. Louis. Dr. White's resume lists seven peer-reviewed publications. (Ex. 20, pp. 4-5; Tr. 4-6.)

2. Dr. John J. Shane

Dr. John J. Shane received a Bachelor of Arts degree from Lehigh University and his medical degree from Hahnemann University College of Medicine. He served an internship at Wilkes-Barre General Hospital in 1961-62, and a residency at Hahnemann Hospital from 1962 to 1966. He is board certified in Pathologic Anatomy and Clinical Pathology. From 1966 through 1974, he was a Clinical Assistant Professor in Pathology at Hahnemann Medical College. Concurrently, Dr. Shane served as the Chief of Pathology and Director of Laboratory Medicine, at St. Agnes Hospital in Phildelphia. From 1974 through 1988, he was a Clinical Associate Professor in Pathology at Thomas Jefferson University Hospital. He was also Chairman of the Department of Pathology at Lehigh Valley Hospital Center from 1974 through 2000. He served as a Clinical Professor in Pathology at Hahnemann University from 1986 to 1996. Dr. Shane retired from his hospital-based chairmanship and clinical practice in 2000. Since then, he has maintained a full-time practice as a pathologist in a private office in Allentown, Pennsylvania. He has published fifteen medical articles. (Ex. 51, pp. 1-3; Tr. 42-4 and 61-2.)

3. Summary of opinions of Petitioner's experts

Both Dr. White and Dr. Shane testified that the proper diagnosis of Petitioner's ongoing condition is AOSD, rather than sarcoidosis. Dr. White also indicated the opinion that Petitioner's AOSD was caused by her hepatitis B vaccination of January 29, 1999.

B. Respondent's experts

1. Dr. Carlos Rosé

Dr. Rosé received his medical degree from the University of Buenos Aires (Argentina) School of Medicine in 1977. After performing his military service at the Central Military Hospital of Buenos Aires, he trained in Internal Medicine at the University of Buenos Aires Hospital José de San Martín, where he served as Chief Resident in 1982-83. From 1983 to 1985, he performed a fellowship in rheumatology at the National Institute of Rehabilitation in Buenos Aires, and specialized in rheumatology as a staff physician at the Central Military Hospital, and the Spanish Hospital, in 1985 and 1986, respectively. During those years, he also served as an instructor of Internal Medicine at the University of Buenos Aires School of Medicine. From 1987 to 1988, Dr. Rosé performed an internship in pediatrics at the Medical Center of Delaware. From there, he served in two fellowships in pediatric rheumatology, at the Children's Hospital of Philadelphia (1988-89) and the Alfred I. DuPont Institute in Delaware (1989-91). In addition to a medical license in Delaware, Dr. Rosé is board-certified in both pediatrics and pediatric rheumatology. He has also been an instructor of pediatrics at the University of Pennsylvania School of Medicine, and a professor of pediatrics at the Thomas Jefferson Medical College. Since 1994, he has been the head of pediatric rheumatology at Thomas Jefferson University, and maintains his clinical practice at the Dupont Children's Hospital in Delaware. He has published more than 50 professional articles, book chapters and monographs within his area of specialty, and delivered more than 100 lectures for the American College of Rheumatology and other professional organizations. (Ex. B, pp. 1-6: Tr. 107-10.)

2. Dr. Nadine S. Aguilera

Dr. Nadine S. Aguilera received a Bachelor of Science at the University of California, Davis, in 1982. She earned her medical degree at the Uniformed Services University of Health Sciences in 1987. Her specialization in pathology commenced as a pathology resident at the Geisinger Medical Center, from 1987 to 1992, where she also served as Chief Resident from 1991 to 1992. Dr. Aguilera further specialized in hematopathology (focusing primarily on lymph nodes, bone marrow and the spleen) during a fellowship at the University of Pittsburgh, from 1992 to 1993. She then became a staff pathologist at the Armed Forces Institute of Pathology, in the Department of Hematopathology. Dr. Aguilera served as Assistant Chairman of that department from 1994 to 2005, at which time she was appointed Chairman, a position that she still holds. She has board certification in Pathology, with a special certification in Hematology. Between 1995 and the present, Dr. Aguilera was a pathology instructor at the Uniformed Services University of the Health Sciences. Concurrently, she was a teacher in the Hematopathology fellowship program of the Armed Forces Institute of Pathology, where she served as fellowship director from 2005 to 2007. Within her field of expertise, she has published more than 80 professional abstracts, presentations, and papers. (Ex. K, pp. 2-3; Tr. 90-94.)

3. Summary of opinions of Respondent's experts

Dr. Rosé stated the opinion that the appropriate diagnosis of Petitioner's chronic condition is sarcoidosis, rather than AOSD. He also stated that even if Petitioner's condition were considered to be AOSD, there still is no good evidence for the theory that AOSD *can* be caused by the hepatitis B vaccine, or that such vaccine *did* cause Petitioner's condition of AOSD.

Dr. Aguilera's opinion, on the other hand, was limited in its scope. She testified that a certain finding in the biopsy of Petitioner's lymph node, the finding of noncaseating granulomas, was a finding *always* made in cases of sarcoidosis, but was a finding *never before* associated with AOSD. She also stated disagreement with Dr. Shane's assertion that certain other features of Petitioner's biopsy were more indicative of AOSD than sarcoidosis.

V

THE DIAGNOSIS OF "SARCOIDOSIS" SEEMS MORE LIKELY THAN THAT OF "ADULT-ONSET STILL'S DISEASE" (AOSD)

The question of the proper diagnosis for Petitioner's ongoing illness is a complicated one, and the answer is certainly *not* crystal clear. A number of Petitioner's medical records, especially in the early days of her illness, do indicate a diagnosis of AOSD. After an important finding was made in a biopsy of her lymph node tissue in 2002, however, some physicians diagnosed sarcoidosis rather than AOSD. And still other physicians' notations as to her diagnosis have offered other diagnoses, or indicated uncertainty as to the proper diagnosis. While the issue is not free from doubt, I conclude that Petitioner has *failed* to demonstrate that it is "more probable than not" that petitioner has AOSD. To the contrary, the balance of evidence indicates that it is at least somewhat more likely that sarcoidosis is the accurate diagnosis.

A. General discussion of issue of AOSD vs. sarcoidosis

"Adult-onset Still's disease," or "AOSD," is a fairly rare type of chronic arthritis, which is thought to be a type of "autoimmune" condition, in which the body's immune system mistakenly attacks the body's own tissue instead of a foreign agent that has invaded the body. (Tr. 7-9, 14-17.) (There is also a juvenile-onset form of Still's disease, which is also known as "juvenile rheumatoid arthritis." Tr. 7.) In general, the cause of AOSD is unknown. (Tr. 10, 14.)

Sarcoidosis, on other hand, is a very different type of chronic system disorder, also rare, involving irregularities of the lymph nodes and other symptoms, including joint pain. (Ex. L, p. 1224.) In general, the causation of sarcoidosis is also not understood, but there is no indication that it is an autoimmune disorder. (*Id*.)

It is important to note that, as Dr. White and Dr. Rosé agree, both AOSD and sarcoidosis have a number of common symptoms, including chronic pain in multiple joints, from which Petitioner has suffered. (Tr. 27-28, 132-33.) Both conditions can involve fevers, rash, arthritis, and

lymph node abnormalities. (Tr. 28.) It is not uncommon for the two conditions to be mistaken for one another (Ex. C, p. 1; Tr. 132-33, 156), and it is a "tricky" business for a physician to diagnose one condition over the other (Tr. 27). Thus, it is not wholly surprising that a review of the records of Petitioner's medical treatment for her chronic condition contains some notations of AOSD as a diagnosis, some notations of sarcoidosis as a diagnosis, and other notations indicating other diagnoses or a physician's uncertainty about the diagnosis.

However, the most important factor in Petitioner's diagnosis is that in March of 2002, at the Buffalo General Hospital, a tissue biopsy was taken from one of Petitioner's lymph nodes, and the analysis of that tissue indicated an important finding: the existence of features called "noncaseating granulomas." (Ex. 34, pp. 1, 3.) The existence of such noncaseating granulomas is, as all of the experts acknowledged, a defining characteristic of sarcoidosis; in fact, without the existence of such granulomas, a diagnosis of sarcoidosis cannot be made. (*E.g.*, Ex. M, p. 2; Tr. 35, 112-113.) This finding of noncaseating granulomas in Petitioner's biopsy is the factor that ultimately persuades me that it is more likely that Petitioner suffers from sarcoidosis than that she suffers from AOSD.

To be sure, the finding of noncaseating granulomas in Petitioner's lymph node does not *conclusively* establish that she has sarcoidosis, because such granulomas *can* exist in disorders besides sarcoidosis. But the striking factor here is that while such granulomas *always* exist in sarcoidosis, there is no persuasive evidence in the record of this case that such granulomas have *ever* been found in a case of AOSD. (Ex. M, p. 2; Tr. 112-13.)

Petitioner's experts did acknowledge that Petitioner's biopsy contained noncaseating granulomas (Tr. 34), and that such granulomas are a crucial factor in a diagnosis of sarcoidosis (Tr. 31, 34-35, 58). But both experts argued that nevertheless other factors in the case point to a diagnosis of AOSD rather than sarcoidosis. I have carefully considered the arguments made by Petitioner's experts in this regard, but ultimately found those arguments to be unpersuasive.

First, Dr. White testified that certain factors caused him to choose AOSD as a more likely diagnosis than sarcoidosis. (Tr. 28-29.) Specifically, he pointed to these factors: Petitioner's high white blood cell count (Tr. 28); her elevated "ferritin" level (Tr. 28); the presence of a "pericardial effusion" on a CT scan (Tr. 28); a normal "angiotensin converting enzyme" ("ACE") level (Tr. 29); and a normal "serum calcium" level (Tr. 29).

Dr. Shane also pointed to certain factors in the analysis of Petitioner's biopsy that he found to be more indicative of AOSD than sarcoidosis. Specifically, he pointed to "eosinophilic infiltration," "nuclear fragmentation debris," "prominent reactive immunoblastic proliferation," and "paracortical hyperplasia." (Ex. 36, p. 2; Tr. 58.)

Respondent's experts refuted these assertions in part. For example, in response to Dr. Shane's reliance on "eosinophilic infiltration" of Petitioner's biopsy, Dr. Aguilera stated that she observed only "scattered" eosinophils, not a "heavy" concentration. (Tr. 100.)

Further, Dr. Aguilera commented on Dr. Shane's hearing testimony that several specific factors (listed above) prompted him to conclude that AOSD is a more likely diagnosis than sarcoidosis. Dr. Aguilera disagreed with Dr. Shane. (Tr. 104-05.) She testified that the findings described by Dr. Shane were "nonspecific," *not* generally indicative of AOSD more so than sarcoidosis. (*Id*.) And this testimony of Dr. Aguilera is of some persuasive value, because of Dr. Aguilera's specific experience as a pathologist. That is, while Dr. Shane does have an impressive breadth of general experience as a pathologist, Dr. Aguilera's experience is much more *particularly* relevant to this specific issue. While Dr. Shane has no pathologic subspecialty certification (Tr. 63), Dr. Aguilera has certification in the subspecialty of hematopathology, which deals specifically with the analysis of tissue from lymph nodes, bone marrow, and the spleen (Tr. 91-92). Dr. Aguilera has reviewed thousands of lymph node biopsies, several thousand of those in sarcoidosis patients. (Tr. 94.)

However, for whatever reason, Dr. Aguilera was not asked to describe *specifically why* she disagreed with Dr. Shane on this point. While Dr. Shane and Dr. White pointed to *specific* factors in Petitioner's medical records that they believe to be more indicative of AOSD than sarcoidosis, Dr. Aguilera did *not* analyze each of those specific factors individually, to refute Dr. Shane's and Dr. White's reliance on those factors. Dr. Aguilera did, as noted above, specifically indicate disagreement with Dr. Shane's reliance upon eosinophilic infiltration. (Tr. 100.) But otherwise, Dr. Aguilera merely stated her *general* disagreement with Dr. Shane's analysis. (Tr. 104-05.) Thus, while Dr. Aguilera has superb credentials to opine concerning this issue, her failure to be more specific severely reduces the value of her testimony.

In addition, respondent's other expert, Dr. Rosé, did forthrightly admit that there *is* at least some validity to Dr. White's testimony concerning *certain* of the factors in Petitioner's case that Dr. White found to be more suggestive of AOSD than sarcoidosis. That is, Dr. Rosé acknowledged that Petitioner's elevated ferritin level and elevated platelet level were more suggestive of AOSD than sarcoidosis. (Tr. 156-57.) And Dr. Rosé further acknowledged that the fact that Petitioner had an elevated white blood cell count might also be more indicative of AOSD than sarcoidosis. (Tr. 157.)

Thus, the testimony of Drs. White and Shane, about certain factors in petitioner's case that may be more suggestive of AOSD than sarcoidosis, does provide some evidence supporting a diagnosis of AOSD in petitioner's case. However, the evidence to the contrary is substantially stronger.

First, Dr. Rosé did point to an *additional* factor, besides the existence of the noncaseating granulomas, that in his view is strongly suggestive of sarcoidosis rather than AOSD. Dr. Rosé noted that Petitioner has experienced parotitis, which, he testified, is very characteristic of sarcoidosis, but is *not* a part of AOSD. (Tr. 119, 150.)

More importantly, Dr. Rosé convincingly explained the *overwhelming importance* of the finding of noncaseating granulomas. Dr. Rosé stressed that in the ordinary practice of treating a patient with symptoms such as those of Petitioner, finding noncaseating granulomas in a lymph node

biopsy would ordinarily be such an important factor that it would not only strongly point to a diagnosis of sarcoidosis, but would essentially *rule out* a diagnosis of AOSD. The presence of such granulomas is by definition a *defining* aspect of sarcoidosis, but they are not present in AOSD. (Tr. 35, 112-13, 135.) Dr. Rosé further explained that AOSD is by definition a "diagnosis of exclusion," meaning that a physician will diagnose AOSD only after ruling out other possible conditions that could be causing the patient's symptoms. (Tr. 112-13, 132.) According to Dr. Rosé, when a physician familiar with AOSD and similar conditions considers the possibility of AOSD as a diagnosis, if noncaseating granulomas are found in lymph node tissue, that physician will *automatically eliminate AOSD* from the list of potential diagnoses, since such granulomas point to sarcoidosis or other non-AOSD conditions. (Tr. 115-16, 126, 132.) I find this testimony of Dr. Rosé to be very powerful evidence in this case because of Dr. Rosé's great experience relevant to this particular issue. Dr. Rosé has *very* extensive experience in diagnosing and treating both Still's disease and sarcoidosis (Tr. 110-11), has written a number of medical textbook chapters on sarcoidosis (Tr. 130), has written an international registry on pediatric sarcoidosis (*id*.), and consults internationally on sarcoidosis issues because of his expertise in that area (Tr. 111-12, 130).

Dr. Aguilera, while less forceful in her testimony than Dr. Rosé, also found the existence of the noncaseating granulomas to be a crucial finding pointing to sarcoidosis rather than AOSD. She stated that, in light of the granulomas, she *disagreed* with Dr. Shane's testimony that the findings in Petitioner's lymph node tissue were consistent with AOSD. (Ex. M, p. 1.) She added that "[n]oncaseating granulomas are not described or typically seen in" AOSD. (Ex. M, p. 2.)

Dr. White and Dr. Shane did try to minimize the importance of the finding of the noncaseating granulomas in Petitioner's biopsy, but I found those attempts to be unpersuasive. For example, Dr. White criticized the diagnosis of Dr. Rosé as being based upon the granulomas alone (Ex. 37), but Dr. Rosé explained that his diagnosis is based upon a *combination* of the granulomas plus the clinical symptoms compatible with sarcoidosis (Tr. 152).

Dr. Shane, on the other hand, attempted to assert that noncaseating granulomas *have* been found in cases of AOSD. During the evidentiary hearing, Dr. Shane referred to an article to which he had not referred in his expert report, and which petitioner had not filed prior to the evidentiary hearing. (Tr. 68.) That article was published by a team of Korean researchers, Jeon and colleagues, in 2004.[11] Dr. Shane claimed that the Jeon article "support[s] a finding of noncaseating granulomas in Still's disease." (Tr. 68, lines 9-17.) However, my review of the article does *not* support Dr. Shane's assertion. The article describes 13 biopsies of lymph nodes in AOSD patients. However, I found *no* mention of noncaseating granulomas in any of the biopsies. Dr. Rosé and

[11]That article was filed after the hearing, as Petitioner's Ex. 54, on November 18, 2010. Y.K. Jeon et al, *Spectrum of lymph node pathology in adult onset Still's disease; analysis of 12 patients with one follow up biopsy*, 57 J. CLINICAL PATHOLOGY 1052 (2004). Because Petitioner relied at hearing on an article not previously submitted, I permitted the respondent to file supplemental post-hearing reports from respondent's experts, commenting on the article. Two such expert reports were filed on December 10, 2010: Ex. M authored by Dr. Aguilera, and Ex. N authored by Dr. Rosé.

Dr. Aguilera both studied the Jeon article as well, and they too found no mention of noncaseating granulomas. (Exs. M, N.)[12]

Further, Dr. White's attempt at the hearing to argue around the existence of the noncaseating granulomas was weak. Dr. White acknowledged that AOSD is a diagnosis of exclusion, and that to sustain such a diagnosis the physician must "rule out" sarcoidosis, among other potential causes. (Tr. 30.) But Dr. White never explained how he could "rule out" sarcoidosis in this case, especially in light of the biopsy showing the existence of noncaseating granulomas, which granulomas, he admitted, are the "hallmark" feature of sarcoidosis. (Tr. 35.) Dr. White also admitted that "there is no evidence that such granulomas do exist in AOSD patients. (Tr. 36, lines 9-11.)[13]

B. Medical record notations

In *Capizzano v. HHS*, the U.S. Court of Appeals for the Federal Circuit stressed that "medical records and medical opinion testimony are favored in vaccine cases, *as treating physicians are likely to be in the best position to determine* whether 'a logical sequence of cause and effect shows that the vaccination was the reason for the injury.'" 440 F. 3d 1317, 1326 (Fed. Cir. 2006) (emphasis added, citation omitted). Similarly, in several recent cases, judges of this court have, in resolving the Vaccine Act causation issues, relied heavily upon the statements of treating physicians contained in the vaccinee's medical records. *See, e.g., Zatuchni v. HHS*, 69 Fed. Cl. 612, 623 (2006); *Kelley v. HHS*, 68 Fed. Cl. 84, 100 (2005).

Accordingly, in this case I have carefully reviewed the medical records of Petitioner's treatment, in order to see whether those records shed any substantial light upon the issue of the proper diagnosis of her condition, in the form of statements by her treating physicians. The short answer is that the medical records do *not* support the Petitioner's argument in this regard.

As noted above, the records of Peittioner's treatment, over a period of several years, have included diagnoses of AOSD and of sarcoidosis, and other diagnoses as well. In the final analysis of all of the medical record notations, as a whole they do *not* point strongly to *either* AOSD or sarcoidosis, and are certainly not dispositive of that issue. I conclude that, taken as a whole, these notations are *not* inconsistent with my ultimate conclusion that sarcoidosis is the more likely diagnosis. More importantly, these notations as a whole *fail* to offer substantial support to Petitioner's argument that *AOSD* is, "more probably than not," an accurate diagnosis.

In analyzing the medical records as to diagnoses, it is logical to analyze the three- year period from 1999 to March 2002, *prior* to the discovery of noncaseating granulomas in Petitioner's lymph

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[12]After respondent filed Exs. M and N, petitioner did not seek to respond to those two analyses of the Jeon article.

[13]Dr. Rosé stressed that if there had ever been a published report of noncaseating granulomas in AOSD, such a report would have immediately become well-known by rheumatologists. (Ex. N, p. 1.)

node biopsy, separately from the records of the subsequent *post-biopsy* period. It is certainly true that in the medical records made during the *pre-biopsy* period, the diagnosis of AOSD does appear several times in the medical records. For example, during her first inpatient hospitalization for the condition, in April of 1999, rheumatologist Dr. John Starr included "Still's disease" as one possible diagnosis (Ex. 17, p. 44), and then petitioner received a discharge diagnosis of AOSD from Dr. Aston Williams (Ex. 5, p. 5). And one year later, when petitioner was again hospitalized for several weeks, Dr. Starr again wrote that his primary diagnosis for Petitioner was "Adult Still's." (Ex. 15, pp. 55-56.)

But it is also true that, even during that pre-biopsy period of Petitioner's chronic illness, other doctors were not as confident in the AOSD diagnosis. Two physicians wrote that AOSD was a *possible* diagnosis. Specifically, on August 1, 2000, a rheumatologist, Dr. Sudhakar Sridharan, wrote that it was "possible that adult onset Still's disease" was Petitioner's diagnosis, but that there were "[o]ther possibilities," including "vasculitis." (Ex. 13, p. 15.) Similarly, on July 10, 2000, Dr. Herman Mogavero, a dermatologist, wrote that Petitioner's diagnosis was *either* "Adult Still's" or "primary vasculitis." (Ex. 1, pp. 9-10.)

Further, during those early years, yet other treating physicians wrote notations indicating active *disagreement* with AOSD as a diagnosis. Specifically, Dr. Julian Ambrus, an associate professor of medicine in the division of Allergy/Immunology and Rheumatology at the State University of New York at Buffalo, wrote on December 23, 1999, that Petitioner had experienced a "perplexing constellation of symptoms," which "argue against a diagnosis of Still's disease." (Ex. 13, p. 211.) Similarly, on June 8, 2001, Dr. Vinay Reddy, a rheumatologist, wrote that while Petitioner had been diagnosed with either Still's disease or "collagen vascular disease" in the past, he himself was simply "not too sure what the actual diagnosis is." (Ex. 1, pp. 223-24.)

And, again during the pre-biopsy period of Petitioner's illness, other physicians recorded diagnoses that failed to mention AOSD at all. On August 27, 1999, Dr. Joseph Torre noted that Petitioner was suffering from "rheumatoid arthritis" of "uncertain etiology." (Ex. 7, pp. 11-12.) And on March 1, 2000, Dr. Corstiaan Brass listed his assessment of Petitioner's condition as "possible collagen vascular disease." (Ex. 1, pp. 13-14.)

Thus, even prior to the discovery of noncaseating granulomas in Petitioner's lymph node biopsy in March of 2002, there were differences among the treating physicians about whether AOSD was a likely diagnosis, or even a possible diagnosis. But around March of 2002, when that biopsy was analyzed and Petitioner also began to have lung symptoms, the diagnoses of Petitioner turned in a *different* direction, toward the new diagnosis of sarcoidosis.

For example, on March 4, 2002, even before the lymph node had been biopsied, Petitioner was examined by Dr. Taj Jiva, an expert in pulmonology and sleep disorders. (Ex. 1, p. 27.) After reviewing her three-year history, Dr. Jiva opined that her diagnosis was either "lymphoma or sarcoidosis." (*Id*. at 29.) Then, once Dr. Jiva saw the biopsy finding of noncaseating granulomas, Dr. Jiva opined that her case "strongly suggests the diagnosis of sarcoidosis." (Ex. 1, p. 219.)

Similarly, soon after the biopsy results, Dr. Eugene Gosy, a specialist in neurology and pain management, wrote on April 12, 2002, that Petitioner's ongoing joint pain ("arthralgias") was "possibly due to sarcoidosis." (Ex. 48, p. 76.) And an expert in pulmonology, Dr. Alexander Gelfer, writing on December 19, 2003, concluded that Petitioner's entire symptom history was "highly suggestive of sarcoidosis." (Ex. 50, pp. 15-17.)

To be sure, even after the biopsy results there were still some differences of opinion among Ms. Suarez' treating physicians as to the appropriate diagnosis for Petitioner's chronic condition. For example, a pathologist who reviewed the biopsy results, Dr. Mohamed Zeid, wrote on May 16, 2002, that due to the noncaseating granulomas, sarcoidosis was one possible diagnosis, but there also existed the possibility of "an infectious process or immunologic disorder." (Ex. 34, p. 1.) Also, after the biopsy Dr. Julian Ambrus wrote on May 6, 2002, that the overall biopsy results "suggested a reactive etiology rather than sarcoidosis." (Ex. 13, p. 199.) And Dr. Aston Williams, who in 1999 had diagnosed AOSD, indicated on June 25, 2002, that he was no longer confident of that earlier diagnosis, writing that Petitioner's illness was "a perplexing and puzzling condition which is of unclear etiology." (Ex. 13, p. 198.)

Finally, from the medical records filed in this case, it appears that beginning in early 2003, Ms. Suarez sought treatment for her ongoing joint pain chiefly from Dr. Gosy, the expert in neurology and pain management. There are records of Dr. Gosy's treatment of Petitioner every two-to-three months from January to September of 2003, and from August of 2004 through August of 2007.[14] (Ex. 38, pp. 7-49.)

As noted above, on April 12, 2002, after viewing the biopsy results, Dr. Gosy wrote that Petitioner's joint pain ("arthralgias") was "possibly due to sarcoidosis." (Ex. 48, p. 76.) Also, in the records of those visits between October of 2004 through 2007, Dr. Gosy's reports always contain, near the bottom of the page, a notation of "Medical Problems" that includes "Rheumatoid Arthritis," among other conditions. However, from reading Dr. Gosy's entire reports, especially the initial lines of each report, it appears that Dr. Gosy's view of the proper diagnosis for Petitioner's chronic joint pain changed. Dr. Gosy *never* used the words "AOSD" or "Still's disease," and he never used "sarcoidosis" after his April 2002 report. Instead, beginning in August of 2004, and uniformly thereafter, Dr. Gosy indicated that Petitioner's chronic joint pain is a product of "fibromyalgia." (Ex. 48, pp. 7-38.) Fibromyalgia syndrome is a phenomenon which was not discussed by any of the experts in this case, but is a very common syndrome involving chronic pain in multiple joint and muscle areas.[15] The syndrome has been discussed in many Vaccine Act decisions, which illustrate that the cause of fibromyalgia syndrome is not yet understood by medical scientists. See *e.g.*, *Gard-Valdez v. HHS*, 1998 WL 458369, at *4, *14-15 (Fed.Cl.Spec.Mstr. July 20, 1998); *Roy v. HHS*, 1996 WL 445383, at *3-4 (Fed.Cl.Spec.Mstr. July 24, 1996); *Awad v. HHS*, 1995 WL 366013, at *5 (Fed.Cl.Spec.Mstr. June 5, 1995). Those cases also make it clear that fibromyalgia syndrome is unrelated to either AOSD or sarcoidosis. Accordingly, Dr. Gosy's continuing conclusion, after years

[14]The filed medical records do not document treatment after August of 2007.

[15]DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 703.

of treatment of Petitioner, that Petitioner's chronic joint pain stems from *fibromyalgia syndrome*, constitutes additional evidence *against* a conclusion that Petitioner suffers from chronic AOSD, as she contends.

Finally, Dr. Rosé noted that some insight into the conclusions of Petitioner's treating physicians can be gained by analyzing their *actual treatment* of Petitioner's condition. He explained that if Petitioner's treating physicians had actually believed that her condition was AOSD, rather than sarcoidosis, subsequent to the finding of the noncaseating granulomas, then they likely would have treated her with a drug called "methotrexate." (Tr. 134.) But the records do not indicate use of that drug, offering additional support for the conclusion that AOSD is not the appropriate diagnosis. (*Id*.) Petitioner's experts did not attempt to refute that observation of Dr. Rosé.

C. Summary

In sum, in addressing this issue I have carefully considered *both* the testimony of the expert witnesses and the notations of Petitioner's treating physicians in her medical records. As explained in detail at pp. 11-15 above, on an overall basis I found the testimony of Respondent's experts to be somewhat more persuasive than that of the Petitioner's experts. To be sure, Petitioner's experts supplied persuasive testimony that *some* aspects of the biopsy analysis tended more toward AOSD than sarcoidosis. (See p. 12 above.) However, that testimony was outweighed by the overwhelming importance of the finding of noncaseating granulomas, which points so strongly to sarcoidosis rather than AOSD as the likely diagnosis. (See pp. 13-15 above.)

Next, concerning the physicians' notations in the medical records, again the overall evidence tips against Petitioner. While during the three-year *pre-biopsy* period of Petitioner's illness AOSD was the most prominent diagnosis, in the period *after* Petitioner's lymph node biopsy in March of 2002, the weight of the treaters' diagnoses was more in favor of sarcoidosis than AOSD.

In the final analysis, weighing all of the evidence together, I conclude that Petitioner has *failed* to carry *her burden* of demonstrating that it is probable that AOSD is her accurate diagnosis. Of the two diagnoses argued at the hearing, sarcoidosis seems somewhat more likely than AOSD. But from *both* the expert testimony and the physician's notations it is also evident that the accurate diagnosis of Petitioner's chronic joint pain condition is simply *unclear*. Sarcoidosis seems more likely than AOSD, but, it is also quite possible that neither diagnosis is accurate.[16] The important point is that Petitioner has certainly failed to carry *her burden* of demonstrating that AOSD is the proper diagnosis.[17]

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[16]At one point, Dr. Shane may have suggested that Petitioner might be suffering from *both* AOSD and sarcoidosis. However, I found Dr. Rosé to be persuasive in arguing that that would be extremely unlikely. (Ex. A, p. 2; Ex. C, pp. 1, 3-4; Tr. 129.)

[17]It is a straightforward matter of logic that if, as in this case, a petitioner's expert bases a causation opinion upon the assumption that the petitioner's injury falls within a certain diagnosis,
(continued...)

VI

THERE IS NO PERSUASIVE EVIDENCE THAT THE HEPATITIS B VACCINE *CAN* CAUSE AOSD, OR THAT IT *DID* CAUSE AOSD IN PETITIONER

As explained above, the first prong of Petitioner's causation theory in this case is that her condition is properly characterized as AOSD. Having rejected that argument for the reasons set forth above, I could end my analysis here. However, for the sake of completeness I will analyze the second prong of Petitioner's argument: the assertion that Petitioner's hepatitis B vaccination of January 29, 1999, caused her (purported) AOSD. My conclusion is that, even if one were to *assume* that Petitioner's condition is accurately diagnosed as AOSD, there is no persuasive evidence in the record either that the hepatitis B vaccine *can* cause AOSD in general, or that her hepatitis B vaccination *did* cause the Petitioner's disorder in this case.

A. General discussion

Petitioner's causation theory in this regard was put forward entirely through the opinion of Dr. White.[18] Dr. White explained that AOSD is an example of an autoimmune disease, in which the human body's immune system mistakenly attacks the body's own tissue instead of attacking a foreign agent that has invaded the body. In the case of AOSD, the part of the body being attacked is the lining of the joints. Dr. White theorizes that in Petitioner's case, while the intent of the hepatitis B vaccination is to prompt the immune system to attack the *hepatitis B virus* if that virus invades the body, to the Petitioner's immune system the joint tissue "looks like" the hepatitis B virus, so the immune system attacks the joint tissue. (Ex. 20, p. 1; Tr. 14-20.) According to Dr. White, this is an example of a phenomenon known as "molecular mimicry;" in other words, the molecular structure of the joint tissue inadvertently "mimics"--*i.e.*, "looks like"--the hepatitis B virus, thereby drawing the attack of Petitioner's immune system. (Tr. 19-20, 23.)

Dr. Rosé, however, strongly disagreed with the contention that Dr. White's theory is plausible. Dr. Rosé argued that Dr. White's theory is unsupported by any substantial evidence. Dr. Rosé noted that Dr. White does not suggest what part of the joint tissue is involved, or what part of the immune system is involved. (Ex. A, p. 2.) Nor did Dr. White offer any explanation as to why any component of the hepatitis B vaccine would "look" similar to any of the joint tissues. (Ex. A,

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[17](...continued)
then if the petitioner fails to demonstrate that his or her injury *does* fall within that diagnosis, the petitioner's causation theory automatically fails. It is also noteworthy that this logic has been endorsed by the U.S. Court of Appeals for the Federal Circuit in *Broekelschen v. HHS*, 618 F. 3d 1339, 1346 (Fed. Cir. 2010).

I also note that Petitioner offered no evidence that the hepatitis B vaccine can cause *sarcoidosis*.

[18]Dr. Shane opined only that Peittioner's condition is accurately characterized as AOSD. Dr. Shane did *not* offer an opinion as to whether petitioner's alleged AOSD was vaccine-caused.

pp. 2-3, 7.) Dr. Rosé noted that it has never been demonstrated that *any* environmental factor can cause AOSD, much less that the hepatitis B vaccine can do so. (Ex. A, p. 2.) Dr. Rosé simply sees no evidence whatsoever that the hepatitis B vaccine is capable of causing AOSD, or has ever caused it in any individual. (Tr. 126-27.)

After reviewing the entire record of this case, I too, like Dr. Rosé, simply do not see any substantial evidence that the hepatitis B vaccine *can* cause AOSD in general. It appears to me that this causation theory is simply a matter of *pure speculation* by Dr. White.

Indeed, some aspects of Dr. White's *own testimony* support the idea that his causation theory is pure speculation. In his expert report, Dr. White summarizes the causation theory extremely briefly, in paragraphs 6 and 7 of Ex. 20 (pp. 1-2), without substantial explanation. In both paragraphs, he simply states that "the theory of causation is" and then summarizes the theory. He never states *that he himself believes* that the theory is probable, or even plausible.

Similarly, in his hearing testimony, Dr. White was never asked whether he *believed* the theory to be probable, nor did he volunteer such a positive opinion. (Tr. 5-22.) To the contrary, Dr. White acknowledged that his causation theory is "hypothetical," and is "not proven." (Tr. 24.) The best that he could say is that the theory is "plausible." (*Id*.) He acknowledged that medical science really has "no idea what causes" AOSD. (Tr. 14.) Then he explained that since medical science has no idea what causes AOSD, "then we could hypothesize that almost anything" could cause AOSD. (*Id*.) In other words, in effect Dr. White admitted that his own theory amounts to a *wild guess*--since we have no idea what causes the condition, his guess that the hepatitis B vaccine might cause it is as good as any other theory. This is hardly a statement of Dr. White's confidence in his own theory that would prompt me to find that theory to be "more probable than not."

Dr. White also admitted that there does not exist any evidence of "homology" between the hepatitis B vaccine and the joint lining ("synovium")--meaning no evidence that the two would "look alike" to the Petitioner's immune system. (Tr. 23.)

Later, when asked why Petitioner's *third* hepatitis B vaccination might have caused her to suffer AOSD, when neither of the first two hepatitis B vaccinations did so, Dr. White admitted that that is "a very good question." (Tr. 40.) Dr. White, however, did not have a good *answer* to the question. Dr. White merely offered a two-sentence answer that was less than clear (Tr. 40, lines 14-20), admitted that he had "no evidence to back up" that answer (Tr. 40, line 13), and acknowledged that "that's kind of the best response that I have for that" question (Tr. 40, lines 20-21).

Dr. White did try to support his causation theory by citing some medical literature, at Ex. 20, p. 2, paragraphs 7(d) and 7(e). In his expert report, Dr. White described those articles as demonstrating that "arthritis has been demonstrated to occur after Hepatitis B vaccination." (*Id*. at para. 7(e).) Dr. White cited eleven articles (*id*. at paras. 7(d) and 7(e)), and Petitioner filed copies of ten of those eleven articles into the record as Exs. 21-30 (filed on October 18, December 13, and December 14, 2006).

Dr. White himself, however, did *not* rely upon any of those articles during his hearing testimony in this case. (*See* Tr. 4-40.) And petitioner's counsel did *not* cite any of those articles in

either of his two post-hearing briefs. That absence of any discussion of the articles by petitioner's expert or counsel seems to indicate that neither Dr. White nor petitioner's counsel find that those articles constitute strong evidence for a causal connection between the hepatitis B vaccine and AOSD. In fact, the only substantive commentary on those articles came from respondent's expert Dr. Rosé, who analyzed each article and found them all to be *devoid* of substantial evidence of a causal connection between the hepatitis B vaccine and AOSD. (Ex. A, pp. 4-7; Tr. 128-30.)

I, too, have examined those ten articles filed by Petitioner, and, like Dr. Rosé, I do not find any substantial support in those articles for the proposition that the hepatitis B vaccine can cause AOSD. None of the articles documented even one case in which *AOSD* developed after hepatitis B vaccination. Some of the articles such as Ex. 23, did discuss a very few cases of *rheumatoid arthritis* that were seen after hepatitis B vaccination. However, no cases of *AOSD* were reported, and, as Dr. Rosé explained, that handful of case reports was too small to constitute any significant evidence that even *rheumatoid arthritis*[19] can be caused by the hepatitis B vaccine. (Ex. A, pp. 4-5; Tr. 142-43.) I conclude that the ten articles do *not* constitute significant evidence that the hepatitis B vaccine can cause *AOSD*.[20]

B. Analysis of medical record notations concerning causation

As noted above (p. 15), the case law dictates that a special master should give due consideration to any notations in the medical records by a vaccinee's *treating physicians*, to see whether such notations shed any light on the "causation" issue. Accordingly, in this case I have scrutinized the few notations in this regard in the medical records, but they do not offer any substantial evidence concerning the issue of what *caused* Petitioner's chronic joint pain condition.

Petitioner, in her post-hearing briefs, points to only one physician notation in the medical records concerning what *caused* Petitioner's chronic condition. (Petitioner's Post-Hearing Brief, p. 3.) That was a notation by a Dr. James Conway, who was consulted concerning Petitioner's case on March 13, 2000, and wrote that the "only possible precipitating factor was having received the hepatitis B virus in late 1998." (Ex. 15, pp. 65-66.) But this notation hardly supplies any substantial support to Petitioner's contention that her hepatitis B vaccination of January 29, 1999, caused her chronic joint pain. (This is so even if I assume, as I do, that Dr. Conway meant the "hepatitis B *vaccine*," rather than the "hepatitis B *virus*," and meant the January 1999 vaccination rather than a 1998 vaccination.)

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[19]Further, Dr. White himself admitted that it would be "a bit of a stretch" to apply articles dealing with rheumatoid arthritis to AOSD, since AOSD is a clinically-different disease. (Tr. 33-34.)

[20]I note that in his expert report, Dr. White did *list* an eleventh article, entitled *Adult-onset Still's disease after hepatitis A and B vaccination*. (Ex. 20, p. 2.) But petitioner never filed a copy or translation of such article, which apparently was published in French. (*Id*.) Neither Dr. White in his report or hearing testimony, or petitioner's counsel in his briefs, discussed that article in any way. To the contrary, Dr. White specifically stated at the hearing that he did not think that any of the articles that he cited in his report contained any reports of *AOSD* after hepatitis B vaccination. (Tr. 32.) Accordingly, I draw no inferences from, and attach no evidentiary weight to, the mere mention of this article in Dr. White's report.

First, the context makes it appear that Dr. Conway was referring to Petitioner's *initial*, *acute* episode of rash and pain in April 1999, not to her *chronic* condition, as having been "precipitated" by the vaccine. Second, even if he was referring to Petitioner's chronic condition, we still know neither what Dr. Conway's medical specialty is, nor *why* he believed that there might be a causal connection.

I have also reviewed the medical records myself to see if any *other* physician's notations might shed light on Petitioner's contention that the hepatitis B vaccination caused her chronic joint condition. Again, I find no substantial support for Petitioner's claim. I do note that in one record, Dr. Eugene Gosy speculated, in a note written on August 5, 2003, that Petitioner's chronic joint pain ("arthalgias") was "possibly due to hepatitis vaccine." (Ex. 38, pp. 43-43.) But in his note of his very next visit with Petitioner, on September 16, 2003, Dr. Gosy wrote unequivocally that the "connection between the hepatitis B vaccine and her fibromyalgia [chronic joint pain] is spurious." (Ex. 38, pp. 44-45.)

In sum, I have not found *any* physician's notations in the medical records that would afford any substantial support to Petitioner's contention that the hepatitis B vaccination caused Petitioner's chronic joint condition, regardless of what is the most accurate diagnosis for that condition.

C. Summary

In sum, for all the reasons cited above, I find that Petitioner has failed to supply any substantial evidence for the proposition that the hepatitis B vaccine can cause AOSD. Petitioner has certainly fallen *far short* of demonstrating that it is "more probable than not" that the hepatitis B vaccine can cause AOSD. Accordingly, even if one *assumes* that Petitioner has suffered from AOSD, Petitioner has nevertheless failed to demonstrate that it is "more probable than not" that her hepatitis B vaccination of January 1999 *did* cause her condition of AOSD.

VII

PETITIONER'S CASE FAILS THE *ALTHEN* TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated 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. 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 1274, 1278 (Fed. Cir. 2005) (citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioner's "causation-in-fact" theory in this

case. In this part of my Decision, then, I will briefly explain how that analysis fits *specifically* within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioner's theory in this case clearly does not satisfy either of the first two parts of the *Althen* test.

A. Application of Althen Prongs 1 and 2 to this case

One interpretative issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury," and "(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ 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 injury." However, a number of Program opinions 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). And, most importantly, the *Federal Circuit itself* 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.

A few decisions of judges and special masters have discussed issues with respect to the *precise* interpretation of Prongs 1 and 2 of *Althen*. *E.g.*, *Doe 11*, 83 Fed. Cl. at 173-74; *Scott v. HHS*, 2006 WL 2559776, at *18 (Fed. Cl. Spec. Mstr. Aug. 21, 2006); *Nussman v. HHS*, 2008 WL 449656, at *12-13 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd*, 83 Fed. Cl. 111 (2008); *Fields v. HHS*, 2008 WL 2222141, at *7 n.5 (Fed. Cl. Spec. Mstr. May 14, 2008). However, it is *not* necessary, in this case, to delve into any such potential interpretative issues, since under any reasonable interpretation of *Althen*, the petitioner's causation evidence put forward in this case could *not* satisfy either of the first two prongs of the *Althen* test.

That is, as set forth in detail above, I have concluded that Petitioner has fallen far short of demonstrating either that the hepatitis B vaccine *can* contribute, in *general*, to the causation of AOSD, or that Petitioner's hepatitis vaccination of January 29, 1999, *did* cause Petitioner's chronic

joint pain. Thus, petitioner's causation arguments in this case would fail under *any* interpretation of *Althen's* Prongs 1 and 2.

Moreover, 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)(1)(A).) And, whatever is the precise meaning of Prongs 1 and 2 of *Althen*, in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that the hepatitis B vaccine contributed to the causation of any of Petitioner's chronic health issues.

B. Application of Prong 3 of the Althen test to this case

Since I have concluded that Petitioner has failed to satisfy either of the *first two* prongs of *Althen*, I need not determine whether Petitioner's case satisfies the *third* prong.

C. This is not a close case

As noted above, 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. The first of the two issues discussed above, concerning what is the *proper diagnosis* for Petitioner's chronic condition (see part V above), is, to be sure, *somewhat* of a close case, upon which reasonable minds could differ. However, the second issue, concerning whether the petitioner has demonstrated that it is "more probable than not" that Petitioner's hepatitis B vaccination *caused* her chronic condition, is *far* from a close case. I found the evidence on that issue to be quite one-sided, for the reasons explained at part VI above.

VIII

CONCLUSION

The record of this case demonstrates plainly that Sonia Suarez has been through a very painful 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.[21]

/s/ George L. Hastings, Jr.

George L. Hastings, Jr.
Special Master

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