In the United States Court of Federal Claims

No. 94-58V

(Filed Under Seal: February 9, 2006)[1]
(Reissued: February 24, 2006)

DORY ZATUCHNI, Executrix of the Estate of E. BARBARA SNYDER, deceased, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	National Vaccine Injury Compensation Program; Causation in Fact; Burden of Proof; Medical Evidence; Remand

Ronald Craig Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner.

Linda S. Renzi, with whom were *Peter D. Keisler,* Assistant Attorney General, *Timothy P. Garren,* Director, *Vincent J. Matanoski,* Acting Deputy Director, and *Gabrielle M. Fielding,* Assistant Director, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for Respondent.

OPINION AND ORDER

WHEELER, Judge.[2]

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[1] Pursuant to the Rule 18(b) of the Court's Vaccine Rules, each party is afforded 14 days from the date of filing to object to the public disclosure of any information furnished by that party. Neither party having filed such an objection, the Court today publishes this Opinion and Order without redaction.

[2] This case was transferred to Judge Thomas C. Wheeler on December 7, 2005, pursuant to Rule 40.1(b) of the Rules of the Court of Federal Claims.

Introduction

This case is before the Court for review of the Special Master's May 6, 2005 Decision denying E. Barbara Snyder's Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-1 et seq. (the "Vaccine Act"). The substituted Petitioner, Dory Zatuchni, is the legal representative of the estate of Barbara Snyder, appointed by the Register of Wills of New Castle County, Delaware on December 20, 2005. Barbara Snyder died in Delaware on April 28, 2005. At issue is whether Ms. Snyder's estate is entitled to compensation under the Vaccine Act for injuries allegedly caused by a measles, mumps, and rubella vaccination administered to Ms. Snyder in 1992.

For the reasons stated below, the Court concludes that the Special Master's Decision is not in accordance with law, particularly in light of the Federal Circuit's decision in Althen v. Sec'y of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005), issued after the Special Master's Decision in this case. The Special Master set the burden of proof bar too high for Petitioner, and not high enough for Respondent. The Court sets aside the Special Master's Decision, and issues its own findings of fact and conclusions of law on entitlement. 42 U.S.C. § 300aa-12(e)(2)(B). The Court remands to the Special Master for further proceedings to determine compensation, consistent with this opinion.

Factual Background[3]

Barbara Snyder was born on June 15, 1946.[4] The record before the Court does not indicate any unusual medical history for Ms. Snyder until February 10, 1992, when at the age of 45, she received a measles, mumps, and rubella ("MMR") vaccination.[5] (Petitioner's Exhibit 15 at 9 [hereinafter "Pet. Exh."]). At the time of her vaccination, Ms. Snyder worked for the Atlantic City Medical Center in New Jersey as a receptionist and registrar. Id. at 3, 7.

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[3] The facts included herein are from the Special Master's May 6, 2005 Decision, as supplemented by other evidence of record.

[4] Ms. Snyder's date of birth appears on her State of Delaware Death Certificate, as well as in other documentary evidence on file with the Court.

[5] Ms. Snyder's medical records indicate a tonsillectomy at age 17, and a "resection of an ovarian cyst in 1976." (Pet. Exh. 4 at 1; Pet. Exh. 3 at 2). In a 1992 Rheumatology Consultation with Dr. Ana M. Cilursu, Ms. Snyder was "completely negative for any prior history of arthritis or arthralgias, weight loss, anorexia, photosensitivity, oral ulcerations, gastrointestinal or genitourinary symptoms, or pulmonary problems." (Pet. Exh. 4 at 1; Pet. Exh. 6 at 2).

According to Ms. Snyder's sworn affidavit, dated November 10, 1992, her employer asked her in October 1991 to have an MMR vaccination because her pre-employment physical and blood work showed that she was not immune to rubella.[6] Id. at 8. Ms. Snyder initially told both her Employee Health Coordinator and one of the resident physicians at the Atlantic City Medical Center that she did not want the MMR vaccination because she "had been told by [her] mother that [she] had had a bad reaction to a vaccination as a child." Id. However, with both of her parents deceased, and without any memory of specific childhood vaccinations, or access to her early medical records, Ms. Snyder was unable to provide documentation of the reactions she had experienced or the vaccines she had received. Id. After further requests from the Atlantic City Medical Center, including a January 27, 1992 certified letter stating that she would "risk restriction from work without pay until immunized" (Pet. Exh. 2), Ms. Snyder relented. (Pet. Exh. 15 at 8). Even on the day she was to be vaccinated, when Ms. Snyder still did not want the MMR immunization, her manager told her that she "had to get the vaccine" or she "couldn't work at Atlantic City Medical Center because it was hospital policy." Id. Fearful of losing her job, Ms. Snyder reluctantly agreed to be vaccinated. The Employee Health Coordinator administered the MMR vaccination to her on February 10, 1992. Id. at 9.

According to Ms. Snyder's 1992 affidavit, within hours of receiving the MMR vaccination, she experienced "a thick itchy tongue and throat and sore, burning eyes." Id. She took Benadryl at the end of the day to help relieve these symptoms. Id. Within one week of receiving the MMR vaccine, Ms. Snyder broke out in a rash. Id. Within two weeks of receiving the MMR vaccine, she began experiencing swollen lymph nodes and diffuse achiness throughout her body, particularly in her hips, knees, and wrists. Id. at 10. She also began running a fever. Id.

On February 28, 1992, 18 days after receiving the MMR vaccine, Ms. Snyder visited Dr. Michele Anthony to inquire about a nicotine patch to help her quit smoking.[7] Id. During that visit, Ms. Snyder also reported that, since the vaccination, she had experienced the onset of a rash, slight fever, "thick throat," swollen lymph nodes, and joint pains. (Pet. Exh. 3 at 2). The rash was gone by the time of Dr. Anthony's February 28, 1992 examination, but Ms. Snyder still was experiencing pain in some joints, including her hips, knees, and wrists. (Pet. Exh. 3 at 2). Dr. Anthony recorded as one of her "impressions" during that visit "[a]cute

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[6] Rubella is a highly contagious disease also known as "German Measles" or "three-day measles." Dorland's Illustrated Medical Dictionary 1644 (30th Ed. 2003) [hereinafter "Dorland's"].

[7] Dr. Anthony was a member of the Faculty Practice Department at the Atlantic City Medical Center. (Pet. Exh. 15 at 10).

rubella [secondary] to vaccine," indicating that Ms. Snyder was suffering from acute rubella caused by the rubella portion of her MMR vaccine. Id. at 3.

Ms. Snyder returned to see Dr. Anthony on March 5 and March 10, 1992. (Pet. Exh. 15 at 10). On March 5, Dr. Anthony again recorded that Ms. Snyder suffered from "acute rubella syndrome [secondary] to vaccine given by Employee Health," and further noted that Ms. Snyder "is suffering from diffuse arthralgia."[8] (Pet. Exh. 3 at 6). Dr. Anthony ordered bed rest, and Ms. Snyder remained in bed from Thursday evening, March 5, through Monday, March 9, 1992. (Pet. Exh. 15 at 10).

According to Ms. Snyder's 1992 affidavit, despite the four days of bed rest, her condition worsened. Id. She now had severe pain upon motion in both wrists, both shoulders, both knees, and both ankles. Id. On March 10, 1992, following a further examination of Ms. Snyder, Dr. Anthony recorded in her notes that Ms. Snyder was reporting "increased arthralgia." (Pet. Exh. 3 at 8). Dr. Anthony found "synovial thickening"[9] and "bogginess" in Ms. Snyder's right wrist. Id. She recorded in the "Assessment" section of her medical report that Ms. Snyder "continues to have acute Rubella syndrome secondary to vaccination." Id. Dr. Anthony recommended continued bed rest and a "follow-up in one week's time." Id. She prescribed the anti-inflammatory drug Ansaid in doses of 100 mg every 4-6 hours. Id.; (Pet. Exh. 4 at 1).

On March 16, 1992, following further bed rest, Ms. Snyder visited Dr. Ana Cilursu, a rheumatologist recommended by Dr. Anthony. (Pet. Exh. 15 at 11; see supra note 5). After examining Ms. Snyder, and taking extensive notes, Dr. Cilursu recorded in the "Impressions" section of her report that Ms. Snyder suffers from "[p]ersistent arthralgias with recent subjective evidence of arthritis, most likely as a result of vaccination for rubella." (Pet. Exh. 4 at 1). Dr. Cilursu noted a "temporal association" between the vaccination and the joint pains, and concluded that "the classic symptoms make the diagnosis of post-vaccination reactive arthritis most likely in this case." Id. at 1-2. Dr. Cilursu also noted that "there was no evidence of acute synovitis, although the elbows were both tender." Id. at 1. Dr. Cilursu prescribed Relafen in a daily dose of 1,000 mg, and advised further bed rest with minimal exertion. Id. at 2.

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[8] "Arthralgia" means "joint pain." Dorland's at 149. "Diffuse arthralgia" means that the joint pain is not limited or localized, but is widely distributed. See id. at 517.

[9] "Synovial thickening" refers to thickening of the "synovia," a transparent fluid resembling the white of an egg, secreted by the synovial membrane, and contained in joint cavities. Dorland's at 1839.

Ms. Snyder returned to work on March 16-20, 1992, because she had used up her 40 hours of authorized leave, and was hopeful that the new medication prescribed by Dr. Cilursu would be effective. (Pet. Exh. 15 at 11). By Friday, March 20, 1992, Ms. Snyder still was in severe pain, and her right knee was swollen. Id. She returned to work on Monday, March 23, 1992, but because her conditions had worsened over the weekend, she saw Dr. Cilursu again that day. Id. Dr. Cilursu again noted that "there is no evidence of acute synovitis in either knee, although palpation along the joint line is somewhat tender." (Pet. Exh. 4 at 3). Dr. Cilursu increased the dosage of Relafen, and instructed Ms. Snyder to remain home from work for the remainder of the week. Id. Dr. Cilursu prepared a note for Ms. Snyder's employer stating that Ms. Snyder was suffering from "weight-bearing aggravated arthritis [secondary] to rubella vaccine," and prescribed "Bed Rest for next four working days." Id. at 3A.

Dr. Cilursu saw Ms. Snyder again on April 2, 1992. Dr. Cilursu noted the continued symptoms of arthralgia, low grade fevers, joint swelling, and systemic complaints of stiffness and fatigue. Id. at 7. Dr. Cilursu prescribed continued bed rest and the use of the Relafen medication. Id. Dr. Cilursu issued another note to Ms. Snyder's employer stating that Ms. Snyder is "still having significant migratory arthralgia, low grade fever, and fatigue," and that she was "not able to work at this time." Id. at 6.

Dr. Cilursu saw Ms. Snyder another time on April 8, 1992. Id. at 7. Dr. Cilursu noted that "today's history and physical examination corroborates a diagnosis of secondary fibromyalgia,"[10] and that "[t]he post-rubella vaccine induced arthritis may be entering a resolution phase." Id. Dr. Cilursu prepared another note to Ms. Snyder's employer stating that Ms. Snyder "should remain off duty pending repeat evaluation on Friday, 4/17." Id. at 8. Dr. Cilursu saw Ms. Snyder again on April 15 and May 7, 1992. (Pet. Exh. 15 at 12). By May 7, the pain in Ms. Snyder's right hip and knee was so severe that Dr. Cilursu injected the hip with Kenalog, Marcaine, and Lidocaine to help alleviate the pain. Id.; (Pet. Exh. 4 at 11).

On or about May 9, 1992, Ms. Snyder received a letter from Karen Smith of Scibal Insurance Group, advising Ms. Snyder of an appointment with Dr. David Sagransky for an examination and second opinion. (Pet. Exh. 15 at 13). Scibal Insurance Group was reviewing Ms. Snyder's worker's compensation claim. Id. at 12. One month later, on June 9, 1992, Dana Peabody of the Scibal Insurance Group notified Ms. Snyder that Dr. Sagransky would now serve as her primary physician, and that she was no longer a patient of Dr. Cilursu. Id. at 14. Ms. Snyder was not pleased with this development, as she wanted to stay with Dr. Cilursu, but Ms. Peabody told Ms. Snyder that she "had no choice" in the matter. Id.

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[10] "Fibromylagia" means "pain and stiffness in the muscles and joints that is either diffuse or has multiple trigger points." Dorland's at 697.

On May 28, 1992, Ms. Snyder lost her job with the Atlantic City Medical Center. Id. Referring to Ms. Snyder's absence from work since March 23, 1992, her manager explained that she "only had to hold [Ms. Snyder's] position open for two months." Id. Ms. Snyder had expected to return to gainful employment at the Atlantic City Medical Center once her injuries had abated. Id. Shortly thereafter, Ms. Snyder learned of a bookkeeping position at a company called Landsman Uniform. Id. Ms. Snyder agreed to work at Landsman for one week without pay, to see if she physically could handle the position, and the return to full-time work. Id. at 14. During the morning of June 11, 1992, on her first work day at Landsman, Ms. Snyder experienced severe pain in her knee and hip that radiated throughout her leg. Id. Her pain was so severe that she was unable to concentrate on her bookkeeping duties. Id. She did not return to Landsman the next day due to the severity of her pain. Id.

On June 15, 1992, the Scibal Insurance Group doctor, David Sagransky, M.D., examined Ms. Snyder. (Pet. Exh. 5; Pet. Exh. 15 at 14). On July 7, 1992, Dr. Sagransky prepared a detailed report summarizing the June 15, 1992 examination, a July 6, 1992 follow-up visit, and intervening phone calls from Ms. Snyder. (Pet. Exh. 5). Dr. Sagransky noted that Ms. Snyder was "quite anxious" and "extremely upset that I had informed the insurance company that she had found a new job as she apparently never got that job because she was unable to work." Id. at 2. Dr. Sagransky further found:

> It is my impression that Ms. Snyder did suffer a reaction to her MMR vaccine and may have had a rubella vaccine arthritis which is a well described entity. Her symptoms and examination at the present time, however, do not fit this diagnosis and she seems to fall more into the realm of fibromyalgia. In light of the extensive normal laboratory testing and normal physical examination, I feel that a great deal of her symptoms are also on the basis of anxiety.

Id. at 3. Dr. Sagransky concluded by finding, "[b]ased on my present physical examination, I see no reason why [Ms. Snyder] could not perform gainful employment." Id. As a result of Dr. Sagransky's conclusions, Ms. Snyder did not receive worker's compensation benefits. (Pet. Exh. 41 at 2).

Ms. Snyder returned to work at Landsman Uniform on June 16 and 17, 1992. By 12:00 Noon each day, her wrist became painful from writing, her knee was throbbing, and she experienced sharp pains in her ankle. (Pet. Exh. 15 at 15). The Darvocet prescribed by Dr. Sagransky provided no pain relief, made Ms. Snyder drowsy, and contributed to her inability to concentrate. Id. at 15-16. Ms. Snyder tried to work two more days, on June 18 and 19, 1992. On June 18, she was "miserable and uncomfortable all day," and by the time she left, she was "limping" and her "joints were throbbing." Id. at 16. On June 19, her pain and

discomfort worsened "to the point of distraction." Id. Her "head, body and joints throbbed," and she "was not able to bend her knee." Id. She remained in bed for the weekend attempting to recover from headaches and joint pain. Id. After another bad experience at work on June 22, 1992, Ms. Snyder concluded that, despite her desire to work for Landsman Uniform, her constant pain and condition prevented her from working full-time or part-time. Id.

Ms. Snyder visited another doctor, Mark Fisher, M.D., on July 27 and August 29, 1992. (Pet. Exh. 6; Pet. Exh. 15 at 18). Dr. Fisher was a Board certified internist and rheumatologist. (Pet. Exh. 15 at 18). In his detailed report, Dr. Fisher found as follows:

> . . . Ms. Snyder does have a fibromyalgia syndrome, Palindromic rheumatism, and post rubella arthralgias. The patient did not have any antecedent rheumatic or arthritic syndrome and it is my considered medical opinion that these have a high probability of all being directly attributable to her rubella vaccination. It is the usual pattern that such a disorder would usually dissipate within six to twelve months. However, in any individual patient the pattern can certainly be somewhat different. In any event, there is no other definable rheumatic syndrome at this time. The patient is certainly having ongoing symptoms as described above including multiple arthralgias, acute synovitis in joints associated with low grade fevers and fatigue.

(Pet. Exh. 6 at 2-3). Dr. Fisher concluded that "[t]his patient does remain disabled from her gainful employment due to her ongoing arthritic syndrome at this time." Id. at 3.

Other doctors examined Ms. Snyder in 1993 and thereafter. The following is a summary of those additional medical examinations, among others:

- Dr. Naheed Khan, a rehabilitation specialist, examined Ms. Snyder on March 12, 1993, and diagnosed "Post Rubella vaccination Arthralgia, Fibromyositis, Probable Carpal Tunnel Syndrome – Right and Left." (Pet. Exh. 8 at 3).

- Dr. Sunil Singh, certified in neurology and internal medicine, evaluated Ms. Snyder on October 6, 1993. Among his recorded impressions were post-MMR vaccine "polyarthralgia." (Pet. Exh. 11 at 1).

- Dr. Stephen J. Hefferen, a neurologist, concluded after a November 15, 1993 examination of Ms. Snyder that "[t]his patient has probable post MMR syndrome as manifest by fibromylagias, polyarthropathy and polyneuropathy." (Pet. Exh. 14 at 3).

- Dr. Aubrey Tingle, a professor and Assistant Dean on the Faculty of Medicine, University of British Columbia, reviewed Ms. Snyder's medical file and reported to her in a November 29, 1993 letter that:

> My medical opinion of your history is that you have developed a typical course for rubella vaccine-associated arthropathy together with secondary fibromyalgia or fibrositis. These syndromes frequently co-exist and we have followed more than 20 women with this clinical history.
>
> Of particular importance in your history is the fact that you received the vaccine at age 45 years which is associated with a much higher risk of adverse rubella vaccine reactions. It is further my opinion that your medical history is particularly well documented and clearly outlines your clinical course to date.
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> * * *
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> . . . I want you to know that I am prepared to express the medical opinion that there is a strong probability that rubella vaccine is directly responsible for your medical history of recurrent arthralgias, fatigue, fibrositis and associated clinical findings. (Pet. Exh. 21).

- Dr. Arthur G. Nahas, certified in sports medicine, examined Ms. Snyder on December 9, 1993, December 22, 1993, and January 28, 1994. Dr. Nahas found as a "provisional diagnosis that Ms. Snyder was experiencing "[p]ost adverse reaction to MMR vaccine," and "[p]robable fibromylagia/fibromyositis syndrome." (Pet. Exh. 17 at 1). After the later visits, Dr. Nahas concluded that "[t]he prognosis for this patient is poor." He observed that patients with adverse reactions to MMR vaccines "will tend to improve within the first two years," but that "[t]here have been cases as long as six to seven years." Id. at 3. He found that Ms. Snyder's symptoms were "worsening and not improving." Id.

- Dr. Stanley Rogers began treating Ms. Snyder on May 12, 1994, and thereafter twice monthly to adjust her medications. In a November 10, 1995 report, Dr. Rogers observed that Ms. Snyder has "[p]ost-MMR Arthropathy with a chronic Fibromyalgia Syndrome." (Pet. Exh. 20, tab 9 at 1). He concluded that "[h]er prognosis is extremely poor," that "[s]he is non-rehabilitative, unequivocally," and that "this vaccine has completely destroyed her." Id. at 2.

- Dr. Susan M. Keith began caring for Ms. Snyder in 1996 upon Ms. Snyder's relocation to Delaware. In an October 24, 1996 report following a physical examination, Dr. Keith observed that Ms. Snyder suffers from "[p]olyneuropathy secondary to adverse reaction to MMR vaccine." (Pet. Exh. 31 at 8). In a follow-up report, dated December 17, 1996, Dr. Keith recorded that Ms. Snyder's prognosis was "[c]hronic pain management with fibromylagia secondary to adverse reaction to MMR. This is an exceedingly difficult problem." Id. at 12.

- Other physicians who treated Ms. Snyder in 1996-1997, such as Dr. Russell Labowitz (Pet. Exh. 31 at 32), and Dr. Marshall Williams (Id. at 24), simply were unsure of the causes of Ms. Snyder's joint pains and fibromyalgia. Dr. Labowitz, however, reported that "[t]he patient has carried the diagnosis of a post-Rubella viremia, chronic" and that "[t]he physical examination was quite consistent with fibromyalgia." Id. at 33.

The record does not indicate that Ms. Snyder ever returned to work after attempting to fill the bookkeeping position at Landsman Uniform in June 1992. Her condition steadily deteriorated in later years due to continued severe joint pains and fibromyalgia. She eventually moved to a one-bedroom, handicapped accessible apartment in Claymont, Delaware, near her sister's residence. (Pet. Exh. 41 at 2). She was unable to ambulate without a walker or cane, and she used a motorized scooter when leaving her building. Id. at 3. A nurse's aid assisted Ms. Snyder with bathing, cooking, laundry and errands. Id. She led a "home bound" existence except for monthly doctor's appointments. Id. Her weight dropped from a normal 107-110 pounds to approximately 72-75 pounds until corrected with medication. Id.; Pet. Exh. 39 at 136.

Barbara Snyder died on April 28, 2005 at age 58. (Pet. Exh. 45). The State of Delaware Certificate of Death indicates that one of the causes of Ms. Snyder's death was "post-rubella vaccination syndrome." Id.

History of Proceedings

Barbara Snyder filed her petition at this Court on January 31, 1994. Her case became one of many at the Court where a petitioner alleged that a rubella vaccine caused chronic joint pain or arthritis. In reviewing Ms. Snyder's petition, Respondent conceded in its May 2, 1994 report that "Ms. Snyder has demonstrated her eligibility for a finding that the rubella vaccine in fact caused her condition." (Respondent's May 2, 1994 Report at 2). Respondent further observed:

> While Ms. Snyder['s] medical records indicate that she suffers from fibromyalgia, it appears that this diagnosis in this particular case

> was incidental to her presumed post-rubella vaccination polyarthropathy. For instance, Ms. Snyder's records do not indicate that she suffered from any pre-vaccination stressors which serve as indicators of fibromyalgia.

Id. at 2 n.1. Respondent recommended that "further proceedings be scheduled to determine the type and amount of compensation which [sic] should be awarded in this case." Id. at 4. Toward that end, Respondent requested Petitioner to submit "[e]vidence regarding the type, level, and cost of Ms. Snyder's current care from doctor's [sic], therapists, or other health care providers." Id. Respondent did not contend that Ms. Snyder's fibromyalgia was unrelated to her MMR vaccination, and did not request that she separately identify the medical costs relating to different symptoms or causes.

More than two years later, on August 19, 1996, Respondent withdrew its agreement that Ms. Snyder satisfied the criteria for recovery under the Vaccine Act, and asserted that the fibromyalgia could not have been attributable to the MMR vaccination. (Respondent's August 19, 1996 Status Report at 1).

Following Respondent's change of position, Ms. Snyder's claim languished for years. Ms. Snyder and her counsel[11] filed 23 status reports between 1997 and 2001 describing their efforts to distinguish between vaccine-related and non-vaccine-related expenses, and their attempts to arrange for medical evidence and testimony. The parties tried to settle the claim, but were unsuccessful.

Separately, in dealing with the many cases in the early 1990s alleging that rubella vaccinations caused chronic arthropathy,[12] Special Master Hastings had undertaken a general inquiry into whether such a causal relationship in fact existed. (Spec. Mstr. Dec. at 8-9 n.9). The intent of the Special Master's Office was to apply the general information and conclusions from that general inquiry to help resolve each of the many individual cases. Id. at 8. Special Master Hastings initiated a series of meetings involving counsel for most petitioners and Respondent, and in November 1992, conducted a three-day evidentiary hearing in which six medical experts, three selected by petitioners' counsel and three by Respondent, testified concerning the general causation issue. Id. at 9. One of the petitioners' experts was

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[11] Boyd McDowell III originally represented Ms. Snyder when her petition was filed in this Court. In early 2002, Mr. McDowell left the practice of law. For approximately one year, between February 2002 and February 2003, Ms. Snyder represented herself. On March 5, 2003, present counsel, Ronald C. Homer, entered his appearance on behalf of Ms. Snyder.

[12] The term "arthropathy" encompasses any joint disease, including arthralgia (joint pain) and arthritis (joint swelling). Dorland's at 156.

Dr. Aubrey Tingle, from the University of British Columbia, who also issued a report in Ms. Snyder's behalf. (Spec. Mstr. Dec. at 24 n.27; Pet. Exh. 21).

On January 11, 1993, Special Master Hastings issued an opinion finding it was "more probable than not" that the rubella vaccine causes some cases of chronic arthropathy. Ahern et al. v. Secretary of HHS, 1993 WL 179430 (Fed. Cl. Spec. Mstr. Jan. 11, 1993). A copy of that opinion later became part of the record in this case. (Spec. Mstr. Order, Feb. 16, 1994). In Ahern, the Special Master identified six criteria, all of which must be satisfied to entitle a petitioner to a Vaccine Act award:

1. The petitioner received a rubella vaccination at a time when he or she was age 18 or older;

2. The petitioner had a history, for at least three years prior to the vaccination, free of any persistent or recurring polyarticular joint symptoms;

3. The petitioner had developed an antibody response to the rubella virus;

4. The petitioner experienced the onset of polyarticular arthropic symptoms between one and six weeks after the vaccination;

5. Polyarticular arthropic symptoms continued for at least six months after the onset, or if symptoms remitted after the acute stage, polyarticular arthropatic symptoms recurred within one year of such remission; and

6. There is an absence of another good explanation for the arthropathy; the petitioner has not received a confirmed diagnosis of rheumatoid arthritis, nor a diagnosis of any of a series of other specific conditions listed in the Ahern Order, at *10.

See id. at *13. Respondent addressed criteria one through five in concluding in May 1994 that Ms. Snyder had demonstrated that the rubella vaccine in fact caused her condition. Respondent did not address criterion six. (See Respondent's May 2, 1994 Report).

In 2001 and 2002, Special Master Hastings conducted a further general causation inquiry, due to the availability of more recent medical studies since the 1993 Ahern Opinion. He held another evidentiary hearing at which six expert witnesses testified. (Spec. Mstr. Dec. at 12). On December 13, 2002, Special Master Hastings issued a document entitled "Analysis of Recent Evidence Concerning General Rubella/Arthropathy Causation Issue." These findings were published as Snyder et al. v. Secretary of HHS, 2002 WL 3196572 (Fed. Cl.

Spec. Mstr. Dec. 13, 2002 [hereinafter "Snyder I"]). Id. A copy of the 2002 Analysis became part of the record in this case. In considering the more recent evidence, the Special Master made two modifications to the 1993 criteria. Under the revised criteria: (1) the petitioner must have received a rubella vaccination after puberty, not after age 18; and (2) the onset of polyarticular symptoms must have occurred between seven and 21 days after vaccination, not between one and six weeks after vaccination. In all other respects, the 1993 criteria remained the same. Id.

After the Special Master issued Snyder I on December 13, 2002, the parties in 2003 attempted to settle their dispute, but again reached an impasse. On March 8, 2004, with the case more than a decade old, Petitioner filed a motion asking the Special Master for judgment on the existing record. In that motion, Petitioner's counsel indicated that Ms. Snyder would not present an expert report or expert testimony specific to her case. Instead of ruling on the pleadings, the Special Master afforded Respondent an opportunity to present expert testimony. Respondent filed the expert report of Dr. Alan Brenner on June 15, 2004. The Special Master conducted a hearing on September 28, 2004 in Boston, Massachusetts to receive the expert testimony of Dr. Brenner.

Dr. Brenner had never met or examined Ms. Snyder, but testified from his review of Ms. Snyder's medical records on file with the Court. (Transcript of Sept. 28, 2004 Hearing at 85 [hereinafter "Tr."]). Dr. Brenner also had testified for the Government in the 2002 hearing before the Special Master, and he disagreed with some of the criteria that the Special Master adopted in Snyder I. (Tr. at 47). In essence, Dr. Brenner disagreed with the diagnosis of most of the doctors who examined Ms. Snyder, asserting instead that her fibromyalgia, whatever its cause, was not attributable to the 1992 MMR vaccination. (See, e.g., Tr. 61-80).

Following the receipt of the parties' post-trial briefs, the Special Master issued his May 6, 2005 Decision, denying Ms. Snyder's petition for compensation.

Special Master's Decision

In reviewing the evidence in this case, the Special Master considered not only the specific evidence applicable to Ms. Snyder, but also the evidence, including expert testimony, admitted in the 1993 and 2002 general causation decisions in Ahern, supra, and Snyder I, supra, (the "Omnibus Proceedings"). (Spec. Mstr. Dec. at 13-15). In applying the six criteria from the Omnibus Proceedings, the Special Master found that Ms. Snyder met criteria one through five, but failed under criterion six, that "[t]here is an absence of another good explanation for the arthropathy." Id. at 17-20. In referring to Snyder I, the Special Master observed that, even if a petitioner met all six criteria, he would not *automatically* conclude that the petitioner's chronic joint pain was vaccine caused. Id. at 15. Rather, he said that he

must also find an absence of "particular circumstances of the case that cast doubt on a causal relationship." Id. (citing Snyder I at *20).

The Special Master found that the existence of Ms. Snyder's fibromyalgia syndrome ("FMS") constituted an alternative explanation for Ms. Snyder's joint pain, even though the cause of FMS is seldom, if ever, identified. Id. at 19. The Special Master further noted that FMS is a very common syndrome, afflicting perhaps 2-4 percent of the population, and that Ms. Snyder "is simply one of the *very many* unfortunate people who develop FMS for no known reason." Id. In the Special Master's analysis, only an "explanation," not a "cause," is necessary to cast doubt on the theory of a causal connection between the vaccine and the chronic arthropathy. Id. While the cause of FMS remains unknown, Respondent's expert, Dr. Brenner, acknowledged at the hearing that stress plays an important role in the development of FMS. (Tr. 56, 86). Dr. Brenner also agreed that a chronic medical condition can cause stress. (Tr. 56).

Discussion

This Court has jurisdiction under the Vaccine Act to review the Special Master's Decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(1)-(2). In reviewing the Special Master's Decision, the Court is empowered to: (1) uphold the findings of fact and conclusions of law and sustain the Decision; (2) set aside any findings of fact and conclusions of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . ."; or (3) "remand the petition to the special master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(A)-(C); Althen v. Sec'y of Health and Human Services, 418 F.3d 1274, 1277-78 (Fed. Cir. 2005). Thus, the Special Master's decision may be set aside only if the findings of fact are arbitrary and capricious, the legal conclusions are not in accordance with law, or the discretionary rulings constitute an abuse of discretion. Turner v. Sec'y of Health and Human Services, 268 F.3d 1334, 1337 (Fed. Cir. 2001); Munn v. Sec'y of Health and Human Services, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). While the Court may not simply substitute its judgment for that of the Special Master, when the Special Master misinterprets or misapplies the applicable law, the Court must set aside that decision unless the error would not affect the outcome. Carter v. Sec'y of Health and Human Services, 21 Cl. Ct. 651, 653 (1990) (citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971)); Davis v. Sec'y of Health and Human Services, 54 Fed. Cl. 230, 233 (2002).

Under the Vaccine Act, a petitioner may pursue compensation through one of two statutory avenues. First, a petitioner may allege a "table injury." The Vaccine Act includes a Vaccine Injury Table identifying various injuries associated with specified vaccines which, if suffered within a specified time period after the vaccination, entitle the petitioner to a legal

presumption that the vaccine caused the injuries. See 42 U.S.C. § 300aa-14(a). Once such a presumption attaches, the burden shifts to the Respondent to prove by a preponderance of the evidence that the injuries were caused by some other unrelated factor. The second route to recovery requires the petitioner to prove affirmatively a causal link between the vaccine and the alleged injuries. Therefore, if a petitioner cannot show a table injury, she may nevertheless receive compensation if she can prove by a preponderance of the evidence that her injuries were in fact caused by the vaccine. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I), -13(a)(1); Althen, 418 F.3d at 1278; Munn, 970 F.2d at 865. These claims are known as "off-table" injuries.

In the instant case, Ms. Snyder presented her claim as an off-table injury. While the Secretary of Health and Human Services amended the Vaccine Injury Table in March 1995 to add "chronic arthritis" as an injury presumptively caused by rubella vaccines, 60 Fed. Reg. 7678 (1995), the "chronic arthralgia" Ms. Snyder suffered is not the same as "chronic arthritis," and specifically was excepted from the Vaccine Injury Table in this 1995 amendment. Thus, Ms. Snyder must prove by a preponderance of the evidence that the vaccination caused her injuries. Althen, 418 F.3d at 1278, citing Shyface v. Sec'y of Health and Human Services, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999). As the Federal Circuit recently explained in Althen:

> Concisely stated, [petitioner'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.

418 F.3d at 1278; see generally, 42 U.S.C. § 300aa-13(a).

The preponderance of the evidence standard for off-table cases also stems largely from Shyface, 165 F.3d 1344, where the Federal Circuit adopted the Restatement approach to establishing causation. Restatement (Second) of Torts § 430-432 (1965). In that case, the Federal Circuit concluded that a petitioner satisfies the preponderance standard by showing the injury would not have occurred "but-for" the vaccination, and that the vaccination was a "substantial factor" contributing to the injury. Shyface, 165 F.3d at 1352-53. A petitioner therefore need not show that a vaccination was the "only" or "predominant" cause of injury, but merely that the vaccination was a "substantial factor" in causing the injury. Id. (discussing the Restatement generally, and recognizing that causation may lie even where "concurrent forces . . . bring about a single harm.").

Upon establishing causation under the preponderance of the evidence standard, Althen holds that a petitioner 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." 418 F.3d at 1278 (citing Knudsen v. Sec'y of Health and Human Services, 35 F.3d 543, 547 (Fed. Cir. 1994)). However, in attempting to show "factors unrelated to the vaccine," the Vaccine Act expressly prohibits Respondent from relying upon any "idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition[.]" 42 U.S.C. § 300aa-13(a)(2)(A). A condition is "idiopathic" where there is no known cause. Wagner v. Sec'y of Health and Human Services, 37 Fed. Cl. 134, 139 (1997).

In Wagner, the Government asserted that the petitioner's injury resulted from a condition known as "Sjogren's Syndrome," an immunological disorder with no known cause. Id. at 138. Judge Bruggink of this Court ruled that the Special Master erred by requiring the petitioner to disprove that "Sjogren's Syndrome" was the cause of her condition. The Court observed:

> Placing that burden on the petitioner would require the petitioner to affirmatively prove that an infinite number of potential causes were not at work causing the injuries suffered. There is no foreseeable end to the burden that would be placed on the petitioners under such a statutory interpretation. The statutory language and the purpose of the Vaccine Act do not anticipate or support such a construction.
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> If the alternative cause here had not been idiopathic, the procedure followed may have been harmless. However, placing the burden on petitioner in this case forced her to disprove the causal effects of a condition – Sjogren's Syndrome – that the Government could not rely on as a defense. The Vaccine Act does not permit such a barrier to recovery.

Id. at 139. The Court concluded that "alternative factors of causation should be both offered and proven by the Government, and are subject to the statutorily imposed limitations on such evidence." Id. Here, the Special Master's May 6, 2005 Decision did not properly apply the Vaccine Act's burden of proof to either party.

Petitioner met her burden to show a prima facie case for recovery upon satisfying the first five criteria from the Omnibus Proceedings. On the evidence presented, the Special Master found that: (1) Ms. Snyder received a rubella vaccination at age 45, well past the age

of puberty; (2) Ms. Snyder did not have any persistent or recurring polyarticular joint symptoms prior to the rubella vaccination; (3) after receiving the rubella vaccination, Ms. Snyder developed an antibody response to the rubella virus; (4) Ms. Snyder experienced the onset of polyarticular joint symptoms between seven and 21 days after the vaccination; and (5) Ms. Snyder's polyarticular joint symptoms continued for at least six months after the onset. (Spec. Mstr. Dec. at 16-17). At that point, the burden should have shifted to Respondent to show by a preponderance of the evidence that Ms. Snyder's condition was not caused by the rubella vaccine, but was instead attributable to an unrelated, identifiable cause.

The Special Master, however, took an impermissibly different route that made Petitioner's burden more difficult than it should have been, and Respondent's burden easier than it should have been.

First, the Special Master erred in finding that Respondent need only offer "an explanation" that "casts doubt on a causal relationship" between the injury and the vaccine. (Spec. Mstr. Dec. at 15). This statement is not in keeping with the correct legal standard. By requiring Respondent only to offer an "explanation" that "casts doubt," – a phrase used at least four times in the Special Master's Decision (e.g., at 7, 12, 15, 19) – the Special Master applied a burden of proof to Petitioner's claim that approached the "beyond reasonable doubt" standard. The Special Master seemingly sought medical certainty where only preponderant evidence was required. See Bunting v. Sec'y of Health and Human Services, 931 F.2d 867, 872-73 (Fed. Cir. 1991) (standard of proof required by the Vaccine Act is simple preponderance of evidence, not scientific certainty); Tinnerholm v. Parke Davis & Co., 285 F.Supp. 432, 440 (S.D.N.Y. 1968), aff'd, 411 F.2d 48 (2d Cir. 1969) ("[i]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the Court meet the standards of the laboratorian.").

Second, by finding that Ms. Snyder's condition was attributable to FMS, a muscular illness of unknown cause, the Special Master allowed Respondent to avoid liability simply by suggesting an explanation that something other than the rubella vaccine was responsible for Ms. Snyder's post-February 1992 injuries and poor health.[13] The Special Master did not put Respondent to the test of showing by a preponderance of the evidence that something other than the rubella vaccine caused Petitioner's injuries. In easing Respondent's burden, and considering the unexplained illness offered by the Government, the Special Master ignored

[13] The Special Master's departure from the proper standard is exemplified by the following statement from his Decision: "if there exists another reasonable explanation for the chronic pain, *even if that explanation does not rise to the level of a 'cause' in the medical sense*, then that factor diminishes our confidence that there exists a causal relationship between the vaccination and the chronic pain." (Spec. Mstr. Dec. at 19) (emphasis added).

the Vaccine Act's express proscription of "any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition." 42 U.S.C. § 300aa-13(a)(2)(A); see also Wagner, 37 Fed. Cl. at 139; Knudsen, 35 F.3d at 547 ("lack of medical technology or understanding that prejudices the government's ability to prove alternate causation cannot be a basis for a rule to ease the government's burden of proof.").

The idiopathic nature of FMS is evident in the Decision of the Special Master, who characterized it as:

> . . . a *very common syndrome,* in which patients very often do report pain in multiple joint areas. And in many if not most cases of FMS, no cause for the syndrome is ever identified.

(Spec. Mstr. Dec. at 19). Elsewhere, the Special Master noted generally that "no particular physical cause for [FMS] pain . . . is identified." Id. at 18. Distinguishing the "cause" of an injury from an "explanation" of its symptoms, the Special Master concluded it was "very possible" that Petitioner "is simply one of the *very many* unfortunate people who develop FMS for no known reason." Id. at 19. The Special Master's conclusion that the cause(s) of FMS are unknown should have precluded him from finding for Respondent, because Respondent did not show by a preponderance of the evidence that Petitioner's injury was in fact caused by factors unrelated to the vaccine. See Althen, 418 F.3d at 1278.

Notwithstanding the Special Master's conclusion that the causes of FMS are unknown, the entire evidentiary record here does in fact indicate a causal link connecting the vaccination, the arthralgia, and the FMS. The record contains the analyses of many qualified physicians who examined Ms. Snyder, or who offered expert opinions based upon a review of her medical history. At least four of these physicians found a relationship between the rubella vaccine and Ms. Snyder's fibromyalgia. For example, Dr. Aubrey Tingle, who testified as an expert in both of the Omnibus Proceedings, diagnosed "post-rubella vaccine-associated arthropathy with associated secondary fibromyalgia." (Pet. Exh. 21 at 4). Dr. Stanley Rogers observed that Ms. Snyder had "[p]ost-MMR Arthropathy with a chronic Fibromyalgia Syndrome." (Pet. Exh. 20 at tab 9). Dr. Susan Keith found that Ms. Snyder's prognosis was "[c]hronic pain management with fibromylagia secondary to adverse reaction to MMR. This is an exceedingly difficult problem." (Pet. Exh. 31 at 12). Dr. Stephen Hefferen diagnosed Ms. Snyder with "probable post MMR syndrome as manifest by fibromylagias, polyarthropathy and polyneuropathy." (Pet. Exh. 14 at 3). The Special Master also could have relied upon Respondent's May 2, 1994 report that Ms. Snyder's fibromyalgia "in this particular case" was incidental to her presumed post-rubella vaccination polyarthropathy. (Respondent's May 2, 1994 report at 2 n.1).

Furthermore, even Respondent's expert, Dr. Brenner, who steadfastly maintained that FMS could not have been related to a rubella vaccination, acknowledged that stress plays an important role in FMS, and that a chronic medical condition can cause stress. (Tr. 56, 86). The fact that Ms. Snyder was under considerable stress following the February 10, 1992 MMR vaccine is readily apparent from the record. As a single, middle-aged, working woman, Ms. Snyder's ability to support herself became severely jeopardized when she could no longer work. The strong temporal relationship among (1) the MMR vaccination, (2) the stress of unemployment, (3) the stress of a chronic medical condition, and (4) the onset of fibromyalgia after severe joint pain, is difficult to deny. Seemingly, none of these follow-on conditions would have existed in the absence of the MMR vaccination. On the factual record presented, the Special Master could have found that a preponderance of the evidence supported a causal relationship between the MMR vaccine and the FMS.

Finally, some mention should be made of the September 28, 2004 hearing where only one witness testified. The Special Master gave considerable weight to the fact that Respondent's expert, Dr. Brenner, was the only witness to provide oral testimony, and that none of the doctors who examined Ms. Snyder provided oral testimony. (Spec. Mstr. Dec. at 22, 24, 26, 27). While certainly the testimony of others in a live hearing may have been useful, cases brought under the Vaccine Act are subject to relaxed evidentiary standards. As the Federal Circuit has observed, "[t]he Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen, 35 F.3d at 549. The statutory mandate is that the rules shall "provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,"and "include flexible and informal standards of admissibility of evidence[.]" 42 U.S.C. § 300aa-12(d)(2)(A)-(B). With regard to hearings, the Vaccine Act states that parties shall have the opportunity "to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings[.]" 42 U.S.C. § 300aa-12(d)(2)(D). Likewise, the Vaccine Rules of the Court expressly provide that hearings are not mandatory. RCFC Appendix B, Rule 8(d). The Special Master "may decide a case on the basis of written filings without an evidentiary hearing." Id.

Here, the documentary evidence submitted on Petitioner's behalf was especially thorough and compelling, consisting of the medical records of the many physicians who examined Ms. Snyder, or who reviewed the history of Ms. Snyder's symptoms and provided their medical opinion. Ms. Snyder's 1992 affidavit (Pet. Exh. 15), submitted for her worker's compensation claim, was much closer in time to the relevant events and presumably much more probative than her testimony would have been in 2004, 12 years after the fact. Even without the live testimony of Ms. Snyder's examining doctors, the evidence was more than ample to warrant the Special Master's conclusion that Ms. Snyder met her burden of proof. The legal flaw in the Special Master's approach, however, was in holding Petitioner to a greater burden than was required, and in not holding Respondent to its burden of showing by

a preponderance of the evidence that the injuries were caused by identifiable factors unrelated to the vaccine.

Conclusion

For the foregoing reasons, the Court sets aside the Special Master's May 6, 2005 Decision, and remands the petition to the Special Master for a determination of compensation, including reasonable attorneys' fees and costs. If the Petitioner asserts on remand that Ms. Snyder's death was caused by the vaccine, the Special Master shall receive evidence to determine whether the February 10, 1992 MMR vaccination was a "substantial factor" contributing to Ms. Snyder's death. Shyface, 165 F.3d at 1352-53. The remand proceedings shall be completed within 90 days from the date of this Opinion. 42 U.S.C. § 300aa-12(e); RCFC Appendix B, Rule 28. The Clerk shall not disclose this decision publicly for 14 days. RCFC Appendix B, Rule 18(b)(2).

IT IS SO ORDERED.

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THOMAS C. WHEELER
Judge