

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: November 28, 2007)

DO NOT PUBLISH

GLORIA LEE McNETT,)	
)	
Petitioner,)	
)	
v.)	No. 99-0684V
)	Decision on the Record;
SECRETARY OF)	Petitioner’s Burden of Proof;
HEALTH AND HUMAN SERVICES,)	Dismissal
)	
Respondent.)	
)	

DECISION¹

Petitioner, Gloria Lee McNett (Ms. McNett), seeks compensation under the National Vaccine Injury Compensation Program (Program).² In a second amended petition that she filed on November 1, 2006, Ms. McNett chronicles her medical maladies from January 1975 to June 1992. *See generally* Second Amended Petition (Second Am. Pet.) ¶¶ 7-18. According to Ms. McNett, all of her medical maladies between January 1975 and June 1992 resolved completely by December 1992. *See* Second Am. Pet. ¶ 6. Ms. McNett represents that she received Hepatitis B vaccinations on December 3, 1992, January 7, 1993, and June 1, 1993. *See* Second Am. Pet. ¶ 19. Then, Ms. McNett chronicles her medical maladies from early 1993 to April 2006. *See generally* Second Am. Pet. ¶¶ 22-100. Ms. McNett asserts that she is entitled to Program compensation because she “has sought medical treatment more frequently for her ailments, in that from the time of the

¹ As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, “the entire decision” will be available to the public. *Id.*

² The statutory provisions governing the Vaccine Program are found in 42 U.S.C. §§ 300aa-10 *et seq.* For convenience, further reference will be to the relevant section of 42 U.S.C.

vaccinations[,] she has had to go to see a doctor at least once a month, usually more.” Second Am. Pet. ¶ 101. Ms. McNett advances that her “injuries were in fact caused by” her Hepatitis B vaccinations. Second Am. Pet. ¶ 103.

PROCEDURAL BACKGROUND

Beginning in April 2004, this special master monitored the factual and medical development of Ms. McNett’s claim. *See, e.g., McNett v. Secretary of HHS*, No. 99-0684V, Order of the Chief Special Master (Fed. Cl. Spec. Mstr. Apr. 2, 2004); *McNett v. Secretary of HHS*, No. 99-0684V, Order of the Special Master (Fed. Cl. Spec. Mstr. Apr. 20, 2004). Over the years, Ms. McNett filed additional exhibits, *see, e.g.,* Notice of Filing Documents, Exhibits 18-20, filed May 21, 2004; Notice of Filing Documents, Exhibits 21-22, filed June 25, 2004; Notice of Filing Documents, Exhibit 23, filed May 24, 2005; Notice of Filing Documents, Exhibit 24, filed June 3, 2005; Status Report, Exhibits 25-29, filed April 24, 2006; Notice of Filing Documents, Exhibits 30-31, filed September 14, 2006; Notice of Filing Documents, Exhibit 32, filed October 4, 2006; Notice of Filing Documents, Exhibit 33, filed January 3, 2007; Notice of Filing Documents, Exhibit 34, filed June 18, 2007; an amended petition, *see* Amended Petition for Vaccine Compensation, filed June 1, 2004; multiple status reports addressing her progress in the investigation of her case, *see, e.g.,* Status Report, filed January 20, 2006; Status Report, filed April 24, 2006; Status Report, filed June 23, 2006; Status Report, filed July 17, 2006; and a second amended petition. *See* Second Am. Pet. In addition, Ms. McNett participated in numerous informal status conferences regarding her prosecution of the case.

Increasingly dissatisfied that Ms. McNett had failed to express in her pleadings a substantive basis for attributing “a broad array of seemingly unrelated medical complaints to vaccination,” *McNett v. Secretary of HHS*, No. 99-0684V, Order of the Special Master (Fed. Cl. Spec. Mstr. Nov. 21, 2006), and in an effort to advance the case, this special master directed Ms. McNett to “identify any” disputed “factual issues” that were crucial to her theory of the case. *McNett v. Secretary of HHS*, No. 99-0684V, Order of the Special Master (Fed. Cl. Spec. Mstr. Oct. 12, 2006); *see also* Status Report, filed July 17, 2006, at 1 (requesting “that a fact hearing be scheduled to obtain a ruling concerning the facts of the Petitioner’s claim before the case is referred to an expert for a report”). According to Ms. McNett:

Basically[,] the issues for factual resolution are what symptoms Petitioner had after receiving her three Hepatitis B vaccinations, when in fact the Petitioner’s symptoms began after her vaccinations, and the issue of what role if any did the illness the Petitioner had before her vaccinations play, as the Petitioner contends that she recovered from any illness she had before the vaccination [and] that these illnesses did not play a part in the symptoms the Petitioner had subsequent to the Hepatitis B vaccinations.

Status Report, filed November 2, 2006, ¶ 5. This special master discussed Ms. McNett's November 2, 2006 status report during a status conference on November 21, 2006. This special master informed Ms. McNett that unless Ms. McNett were successful in obtaining a favorable medical expert's opinion based upon Ms. McNett's assumptions of fact, a fact hearing would be futile. Moreover, this special master informed Ms. McNett that aspects of her proposed factual issues—the characterization of her condition preceding her Hepatitis B vaccinations and the effect of any conditions preceding her Hepatitis B vaccinations on her current condition—presented really medical issues that only a medical expert could address. Therefore, this special master instructed Ms. McNett to retain “an appropriate medical expert,” who would guide Ms. McNett in necessary “additional development.” *McNett v. Secretary of HHS*, No. 99-0684V, Order of the Special Master at 1 (Fed. Cl. Spec. Mstr. Nov. 21, 2006).³

Ms. McNett pursued a medical opinion from various sources. *See, e.g.*, Status Report, filed February 2, 2007. Indeed, in March 2007, Ms. McNett represented that she had retained a medical expert who anticipated rendering an opinion by April 16, 2007. *See* Status Report, filed March 16, 2007; *see also* Motion for Enlargement of Time, filed April 16, 2007, at 1 (expert required 30 additional days “to complete his expert report”). However, Ms. McNett never proffered the medical expert's opinion. Instead, on June 20, 2007, Ms. McNett filed a motion for judgment on the record. *See generally* Motion for Judgment on the Record (Motion), filed June 20, 2007. Citing *Althen v. Secretary of HHS*, 418 F.3d 1274 (Fed. Cir. 2005), Ms. McNett maintains “that the record supports a prima facie case of Rheumatological problems, Chronic Fatigue Syndrome, and auto-immune disease from three Hepatitis B vaccinations.” Motion at 1.

Respondent contests Ms. McNett's Motion. *See generally* Respondent's Response to Petitioner's Motion for Judgment on the Record (Response), filed July 26, 2007. Respondent contends that Ms. McNett's medical records alone do not establish Ms. McNett's case. *See* Response at 1, 4-9. And, respondent notes that Ms. McNett has not submitted a medical expert's opinion associating Ms. McNett's vague, diverse conditions with Ms. McNett's Hepatitis B vaccinations. *See* Response at 3, 6-8.

THE LEGAL STANDARD

The United States Court of Appeals for the Federal Circuit (Federal Circuit) endorses the Restatement (Second) of Torts as a “uniform approach” to resolving actual causation issues in Program cases. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). Thus, to

³ Ms. McNett had enlisted previously the assistance of “Dr. Greenspan.” Status Report, filed January 20, 2006, at 1. Mark Greenspan, M.D., is a retired physician who is also an attorney. Ms. McNett represented that Dr. Greenspan was attempting “to find an expert to see the Petitioner and evaluate her and her records.” *Id.* In addition, Ms. McNett had enlisted previously the assistance of “Dr. Hammond,” her primary care physician. *Id.* Ms. McNett represented that she was “working with Dr. Hammond (Exhibit 13) to obtain further support for his opinion.” *Id.*

prevail, Ms. McNett must demonstrate by the preponderance of the evidence that (1) “but for” the administration of a vaccine listed on the Vaccine Injury Table (Table), she would not have been injured, and (2) a vaccine listed on the Table was “a ‘substantial factor’ in bringing about” her injury. *Id.* at 1352, citing Restatement (Second) of Torts § 431. The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. JAMES, CIVIL PROCEDURE 250-51 (1965)). Mere conjecture or speculation will not meet the preponderance of evidence standard. *See Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612, 624 (1995), *aff’d*, 73 F.3d 381 (1995).

The simple temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove actual causation. *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148-50 (Fed. Cir. 1992). Rather, long-standing, well-established Federal Circuit precedent instructs that Ms. McNett establishes a *prima facie* actual causation case by adducing “preponderant evidence” of: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278; *see also Capizzano v. Secretary of HHS*, 440 F.3d 1317 (Fed. Cir. 2006); *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994), citing *Jay v. Secretary of HHS*, 998 F.2d 979, 984 (Fed. Cir. 1993); *Grant*, 956 F.2d at 1148. The “*prima facie* case” is “a party’s production of enough evidence to allow the fact-finder to infer the fact at issue and rule in the party’s favor.” BLACK’S LAW DICTIONARY 1228 (8th ed. 2004).

The centerpiece of a *prima facie* actual causation case is the “medical theory.” In a petitioner’s *prima facie* actual causation case, the “medical theory” is the “reliable medical or scientific explanation” buttressing the proposition that a vaccine listed on the Table can cause a particular injury. *Grant*, 956 F.2d at 1148. Thus, the medical theory must consist of “more than subjective belief.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993); *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (An “expert’s bald assurance of validity is not enough.”). Instead, the medical theory must be grounded “in the methods and procedures of” medicine or science. *Daubert*, 509 U.S. at 590; *see also Daubert*, 43 F.3d at 1317 (“[T]he analysis undergirding” the medical theory must fall “within the range of accepted standards governing” medical or scientific research.). Nevertheless, the medical theory need not be “medically or scientifically certain.” *Knudsen*, 35 F.3d at 549. The medical theory need only be “logical” and “probable,” given “the circumstances of the particular case.” *Id.* at 548-49.

Congress prohibited special masters from awarding compensation “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 300aa-13(a)(1). In *Capizzano*, the Federal Circuit described “medical records” as “favored” evidence, positing that “treating physicians are likely to be in the best position to determine whether ““a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.”” 440 F.3d at 1326, citing *Althen*, 418 F.3d at 1280, and § 300aa-13(a)(1). Indeed, the statute enacting the Program

commands a special master to “consider. . . any diagnosis, conclusion, [or] medical judgment. . . which is contained in the record regarding the nature, [or] causation. . . of the petitioner’s illness, disability, injury, [or] condition” and “the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” § 300aa-13(b)(1). *Yet, the statute enacting the Program provides specifically that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master.” Id.* Thus, Congress intended obviously special masters to plumb the reliability of statements regarding causation in a petitioner’s medical records, abrogating any common law or administrative “treating physician” rule—a principle according great deference to a treating physician’s opinion. *See, e.g., BLACK’S LAW DICTIONARY* 1507 (7th ed. 1999).

DISCUSSION

A petitioner bears at least two burdens in a Program proceeding: the burden of production and the burden of persuasion. The statute governing the Program requires initially a petitioner to submit with a petition particular items supporting the claim to compensation. *See* § 300aa-11(c). Then, the statute governing the Program requires a petitioner to *demonstrate* “by a preponderance of the evidence the matters” contained “in the petition.” § 300aa-13(a)(1)(A).

By proffering medical records and other documents, Ms. McNett has met at least in part her burden of production. *See* § 300aa-11(c). As mandated by the statute enacting the Program, this special master has canvassed thoroughly Ms. McNett’s medical records and other documents. *See* § 300aa-13(b)(1). This special master recognizes certainly that a number of Ms. McNett’s medical records and other documents mention Ms. McNett’s Hepatitis B vaccinations. For instance, in September 1993, Ms. McNett informed Nicholas R. Straniero, M.D. (Dr. Straniero), a physician associated with Midwest Arthritis Center, that “she noted aching through her fingers, shoulders, neck and knees” approximately “a week after she” received a “second” Hepatitis B vaccination in early 1993. Petitioner’s exhibit (Pet. ex.) 28 at 1. According to Ms. McNett, the symptoms “seemed to subside.” *Id.* However, Ms. McNett informed Dr. Straniero that she had experienced “increased joint pain, generalized swelling and weight gain ever since” she received a “third” Hepatitis B vaccination “in June 1993.” *Id.* Upon examining Ms. McNett, Dr. Straniero could not “document any signs of an inflammatory process.” *Id.* at 3. Instead, Dr. Staniero determined that Ms. McNett exhibited only “fairly generalized arthralgias.” *Id.* Moreover, Dr. Staniero did not offer any medical conclusion relating Ms. McNett’s Hepatitis B vaccinations to Ms. McNett’s condition. *See generally id.* at 1-3.

Then, in January 1999, Ms. McNett completed a Vaccine Adverse Events Reporting System form. *See* Pet. ex. 32 at 2. Ms. McNett identified the date of her “adverse event onset” as “[‘]92.” Pet. ex. 32 at 2. Ms. McNett indicated that “3 weeks” after vaccination, she “ached” and “hurt.” *Id.* Ms. McNett described her pain as “so bad” that she “cried” and “could not roll over or get out of bed.” *Id.* Ms. McNett stated that although her physicians had tested her “for lupus, arthritis [and] M[ultiple]S[clerosis],” they provided “no [diagnosis]” for her condition. *Id.* Ms. McNett asserted

that she had become “tired” and “weak.” *Id.* In addition, Ms. McNett asserted that her hands were “becoming deformed.” *Id.*

While evaluating Ms. McNett for “chest congestion,” headache and “joint pain” in March 1999—nearly six years after Ms. McNett’s Hepatitis B vaccinations, but just five months before Ms. McNett filed her Program petition—Dr. Hammond registered an impression of “auto-immune response to hep[atitis] B vac[cine].” Pet. ex. 7 at 38. Dr. Hammond provided no rationale for the impression. *See id.* While evaluating Ms. McNett for “chronic sinusitis” and “muscle spasms” in May 1999, Dr. Hammond repeated an impression of “[questionable] reaction to hep[atitis] B vaccinations.” Pet. ex. 7 at 37. Again, Dr. Hammond provided no rationale for the impression. *See id.* In a general August 25, 1999 letter recommending reimbursement for “nutritional [sic] supplements” intended to “enhance” Ms. McNett’s “immune system,” Dr. Hammond stated that Ms. McNett “had a several year history of generalized arthralgias, myalgias, recurrent respiratory infections, weight gain, [and] profound fatigue that appears historically to be caused or contributed to by an auto-immune response to hepatitis B vaccines.” Pet. ex. 13 at 1. As before, Dr. Hammond offered no rationale for his statement. *See id.*

In September 1999, Dr. Hammond referred Ms. McNett to William F. Hanavan, M.D. (Dr. Hanavan), for a consultation regarding “[a]ltered bowel habit” and a “possible lactose intolerance.” Pet. ex. 10 at 10. Ms. McNett recounted that in 1993, “she had a ‘reaction to hepatitis B’” that rendered her constantly “sick and tired.” *Id.* Ms. McNett elaborated that she suffered “frequent sinus infections, hair loss, nervousness, confusion and a rapid weight gain,” as well as “joint pains and muscle spasms,” affecting her activity level. *Id.* Dr. Hanavan suspected “irritable bowel syndrome” with possible “elements of reflux.” *Id.* at 11. Dr. Hanavan did not relate Ms. McNett’s condition to Ms. McNett’s Hepatitis B vaccinations. *See id.*

In July 2000, Mark A. Noffsinger, M.D., evaluated Ms. McNett for resolving “pain” in “her right knee.” Pet. ex. 6 at 12. Dr. Noffsinger noted that Ms. McNett “mentioned that she has had a problem with REACTION TO HEPATITIS B VACCINE” that Dr. Hammond managed. Pet. ex. 6 at 11-12 (emphasis in original). As a consequence, Ms. McNett told Dr. Noffsinger that she was “limited in her” ability to tolerate “anti-inflammatories.” *Id.* at 11.

In October 2000, Dr. Hammond referred Ms. McNett to Roland R. Springgate, M.D. (Dr. Springgate), a physician associated with Rheumatology, P.C., for a consultation regarding “aching and pain in the joints and muscles” that had persisted “about ten years.” Pet. ex. 29 at 15. Dr. Springgate commented that Ms. McNett believed that “she was allergic” to Hepatitis B vaccine. *Id.* at 16. According to Dr. Springgate, Ms. McNett attributed “all of [her] problems” to her Hepatitis B vaccinations. *Id.*; *see also id.* at 15. Upon examining Ms. McNett, Dr. Springgate observed “[g]ood range of motion,” without “swelling in any specifics [sic] joints,” throughout Ms. McNett’s musculoskeletal system. *Id.* at 16. Dr. Springgate obtained “laboratories.” *Id.* Dr. Springgate planned to “discuss options” with Ms. McNett. *Id.* But, Dr. Springgate did not suggest that Ms. McNett’s presentation was associated with Ms. McNett’s Hepatitis B vaccinations. *See id.*

In October 2001, Ms. McNett underwent outpatient “arthroscopy” of her “left knee.” Pet. ex. 6 at 7. Following the surgery, Dr. Noffsinger diagnosed “[t]orn medial meniscus, chondromalacia, medial femoral condyle patella, and synovitis.” *Id.* When Dr. Noffsinger examined Ms. McNett “six weeks post her left knee arthroscopy,” Ms. McNett informed Dr. Noffsinger that she was “applying for disability from work due to her knee problems, her hepatitis B, and” other “general problems.” Pet. ex. 6 at 5.

Dr. Springgate continued to monitor Ms. McNett, as well, concluding eventually that Ms. McNett exhibited osteoarthritis, particularly in her knees. *See, e.g.*, Pet. ex. 29 at 9-14. On November 12, 2001, Dr. Springgate’s colleagues, Robert A. Roschmann, M.D. (Dr. Roschmann), and Steven J. Cowing, PA-C (Mr. Cowing), examined Ms. McNett. *See* Pet. ex. 29 at 5-8. Neither Dr. Roschmann nor Mr. Cowing had “previously encountered” Ms. McNett. Pet. ex. 29 at 5. Dr. Roschmann and Mr. Cowing reflected that Ms. McNett recounted “a multitude of symptoms which all began, in her opinion, with a hepatitis B vaccine series.” *Id.* Ms. McNett listed “global arthralgias/myalgias” and “intermittent extreme fatigue” and frequent illnesses among her “symptoms.” *Id.* Ms. McNett elaborated that the vaccines “adversely affected her immune system.” *Id.* However, Dr. Roschmann and Mr. Cowing were “unclear as to how [Ms. McNett’s] immune system ha[d] been affected.” *Id.* In February 2002, Dr. Roschmann and Mr. Cowing iterated that Ms. McNett was “adamantly convinced that all of her symptoms are due to the previous history of apparent reaction to a Hepatitis B vaccine.” Pet. ex. 29 at 3.

For the most part, Ms. McNett’s medical records and other documents contain simply Ms. McNett’s subjective statements correlating Ms. McNett’s Hepatitis B vaccinations to Ms. McNett’s myriad medical complaints. Just one of Ms. McNett’s numerous treating physicians—Dr. Hammond, Ms. McNett’s primary care physician—has postulated that Ms. McNett’s constellation of symptoms is linked to a “[questionable] reaction to hep[atitis] B vaccinations,” Pet. ex. 7 at 37, possibly an “auto-immune response.” *Id.* at 38; *see also* Pet. ex. 13 at 1. Yet, nowhere in his records does Dr. Hammond explain any basis for his conclusion. Ms. McNett attempted apparently, without success, to obtain from Dr. Hammond a fuller, medical analysis of his conclusion. *See, e.g.*, Status Report, filed January 20, 2006. Thus, this special master cannot judge adequately the reliability of Dr. Hammond’s conclusion. Moreover, Dr. Hammond referred Ms. McNett to many specialists, several of whom knew obviously that Ms. McNett implicated her Hepatitis B vaccinations in the development of her medical problems. *See, e.g.*, Pet. ex. 6 at 11-12; Pet. ex. 10 at 10-11; Pet. ex. 28 at 1-3; Pet. ex. 29. Yet, none credited seemingly Ms. McNett’s subjective statements, or endorsed seemingly Dr. Hammond’s conclusion.

This special master determines that as a whole, Ms. McNett’s medical records and other documents fail woefully to evince either “a medical theory causally connecting” Ms. McNett’s Hepatitis B vaccinations and Ms. McNett’s condition, or “a logical sequence of cause and effect showing that” Ms. McNett’s Hepatitis B vaccinations “are the reason for” Ms. McNett’s condition. *Althen*, 418 F.3d at 1278. Therefore, Ms. McNett requires unquestionably a medical expert’s opinion to establish her claim. *See* § 300aa-13(a). Yet, Ms. McNett must concede that she has not advanced a medical expert’s opinion during protracted proceedings.

In her Motion, Ms. McNett cites correctly the legal standard governing her case. *See, e.g.*, Motion at 13. And, Ms. McNett cites many examples of evidence that “is not required” to prevail in a Program claim under *Althen*. Motion at 14 (emphasis in original). Yet, Ms. McNett provides no analysis of the application of the legal standard governing her case to her evidence. Ms. McNett cannot expect surely this special master to divine the intricacies of complex factual, medical and legal issues in the case absent Ms. McNett’s presentation of an explanation of Ms. McNett’s evidence in the context of legal precedents. Therefore, this special master determines that Ms. McNett has not met at all her burden of persuasion. *See* § 300aa-13(a)(1)(A).

This special master rules that Ms. McNett has not demonstrated by the preponderance of the evidence that she is entitled to Program compensation. In the absence of a motion for review filed under RCFC Appendix B, the clerk of court shall enter judgment dismissing the petition.

s/John F. Edwards
John F. Edwards
Special Master