IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

(Filed: July 7, 2006)

DO NOT PUBLISH

DIANE M. SOHN,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 99-0580V
	)	Entitlement
SECRETARY OF	)	
HEALTH AND HUMAN SERVICES,	)	
	)	
Respondent.	)	
	)	

DECISION[1]

Petitioner, Diane M. Sohn (Ms. Sohn), seeks compensation under the National Vaccine Injury Compensation Program (Program).[2] In an amended petition that she filed on July 9, 2004, Ms. Sohn alleged that she suffers a variety of conditions that are related to Hepatitis B vaccinations that she received on May 15, 1991, and on June 12, 1991. *See generally* Amended Petition for Vaccine Compensation (Am. Pet.). According to Ms. Sohn, she "has sought medical treatment more frequently, in that from the time of the vaccinations[,] she has had to go to see a doctor at least once a month." Am. Pet. ¶ 74.

Ms. Sohn pursues necessarily an actual causation theory. Thus, to prevail, Ms. Sohn must demonstrate by the preponderance of the evidence that (1) "but for" the administrations of her

---

[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.

Hepatitis B vaccines, she would not have sustained an injury, and (2) the administrations of her Hepatitis B vaccines were a "substantial factor in bringing about" an injury. *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The preponderance of the evidence standard requires the special master to believe that the existence of a fact is more likely than not. *See, e.g.*, *Thornton v. Secretary of HHS,* 35 Fed. Cl. 432, 440 (1996); *see also In re Winship,* 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring), *quoting* F. James, CIVIL PROCEDURE 250-51 (1965). Mere conjecture or speculation will not meet the preponderance of the evidence standard. *Snowbank Enter. v. United States,* 6 Cl. Ct. 476, 486 (1984); *Centmehaiey v. Secretary of HHS*, 32 Fed. Cl. 612 (1995), *aff'd*, 73 F.3d 381 (Fed. Cir. 1995).

The mere temporal relationship between a vaccination and an injury, and the absence of other obvious etiologies for the injury, are patently insufficient to prove legal cause. *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *see also Wagner v. Secretary of HHS*, No. 90-1109V, 1992 WL 144668 (Cl. Ct. Spec. Mstr. June 8, 1992). Rather, Ms. Sohn must present "a medical theory," supported by "[a] reliable medical or scientific explanation," establishing "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant*, 956 F.2d at 1148; *see also 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)). "The analysis undergirding" the medical or scientific explanation must "fall within the range of accepted standards governing" medical or scientific research. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). Ms. Sohn's medical or scientific explanation need not be "medically or scientifically certain." *Knudsen*, 35 F.3d at 549. But, Ms. Sohn's medical or scientific explanation must be "logical" and "probable," given "the circumstances of the particular case." *Knudsen*, 35 F.3d at 548-49.

According to the United States Court of Appeals for the Federal Circuit (Federal Circuit), "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the [injured party] child without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549. However, in most actual causation cases in the Program, petitioners are not able to adduce epidemiological evidence regarding a vaccination and an injury. As a result, some special masters have struggled over the years to articulate the proper method of analyzing actual causation cases that lack epidemiological evidence regarding a vaccination and an injury. *See e.g.*, *Stevens v. Secretary of HHS*, No. 99-0594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001); *see also Pafford v. Secretary of HHS*, 64 Fed. Cl. 19 (2005), *appeal docketed* No. 05-5105 (Fed. Cir. Apr. 12, 2005). The Federal Circuit iterated recently that the actual causation standard requires a petitioner to adduce "preponderant evidence" demonstrating: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also id.* at 1281 (Under the "court's well-established precedent," a petitioner must "provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes.").

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). Numerous cases construe § 300aa-13(a). The cases reason uniformly that "special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone." *Raley v. Secretary of HHS*, No. 91-0732V, 1998 WL 681467, *9 (Fed. Cl. Spec. Mstr. Aug. 31, 1998); *see also Camery v. Secretary of HHS*, 42 Fed. Cl. 381, 389 (1998).

Since April 2, 2004, the special master has monitored the development of Ms. Sohn's claim, directing the submission of medical records and of medical opinion. Now, Ms. Sohn moves "for a Judgment on the Record as it stands." Motion for Judgment on the Record (Motion), filed July 6, 2006, at 1. Ms. Sohn represents that she "cannot find an expert to support causation in" the case. *Id.* As a consequence, Ms. Sohn acknowledges that she cannot "prove causation." *Id.* Ms. Sohn understands that her Motion will result in an adverse ruling on entitlement. *See generally id.*

The special master has canvassed thoroughly the record as a whole. He determines that Ms. Sohn's medical records alone do not establish more likely than not that Ms. Sohn's Hepatitis B vaccinations caused actually an injury. And, as Ms. Sohn concedes, the special master determines that Ms. Sohn has not proffered a reliable medical opinion demonstrating that Ms. Sohn's Hepatitis B vaccinations caused actually an injury. *See* Motion at 1. Thus, in *granting* Ms. Sohn's Motion, the special master is constrained to conclude "on the Record as it stands" that Ms. Sohn is not entitled to Program compensation. Motion at 1.

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