OFFICE OF SPECIAL MASTERS

No. 03-0620V

(Filed: June 30, 2006)

ADELA QUINTANA DE BAZAN Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	UNPUBLISHED Tetanus, ADEM, Causation in Fact, Factor Unrelated

Peter G. Lomhoff, Esq., Oakland, California, for Petitioner.
Heather L. Pearlman, Esq., U.S. Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING[1]

The above captioned case is on remand from the United States Court of Federal Claims solely on the question of "whether respondent can show by a preponderance of the evidence that petitioner's illness was the result of some other cause than Ms. De Bazan's Td vaccination." De Bazan v. Secretary of HHS, No. 03-620V, 2006 WL 1388417 (Fed. Cl. May 15, 2006) (hereinafter "De Bazan II").

Discussion

According to the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2], a

[1] Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this decision 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" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq*. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

petitioner may prevail under the Vaccine Injury in one of two ways. First, a petitioner may show that an injury recognized by the Vaccine Injury Table, 42 C.F.R. § 100.3, ("Vaccine Table" or "Table") occurred within the statutorily prescribed time period. § 11(c)(1)(C)(i). If a petitioner demonstrates such an injury by a preponderance of the evidence, she is entitled to a presumption of causation. § 13(a)(1)(A). If a petitioner qualifies under this presumption, she will be said to have suffered a "Table Injury." The burden would then shift to the Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B). Second, if a petitioner fails to satisfy the requirements under the Act for demonstrating a Table Injury, she may yet prevail by proving by preponderant evidence that the vaccination in question, more likely than not, caused the alleged injury. §§ 11(c)(1)(C)(ii)(I) and (II). This causation-in-fact standard, according to the Federal Circuit, requires that petitioner demonstrate by preponderant evidence:

(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). Once again, if a petitioner is successful in that showing, thereby establishing a prima facie case, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B). The statutory presumption of causation afforded to the Petitioner, supra, may be affirmatively defeated if a preponderance of the evidence indicates that the condition was caused by a factor unrelated to the vaccine. §13(a)(1)(B). The Vaccine Act states that, for petitioners to receive compensation under the act, the special master must find:

> that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

Section 13(a)(1)(B).

Furthermore, § 13(a)(2) further explains that the term"factors unrelated to the administration of the vaccine"

> (A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and
> (B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

According to the Federal Circuit, "[T]he standards that apply to a petition's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact." Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (Fed. Cir. 1994). Hence, Respondent must prove the existence of the factor unrelated alleged and that this alleged condition actually caused Mrs. De Bazan's injuries. To satisfy this burden, Respondent must prove a "logical sequence of cause and effect." Strother v. Secretary of HHS, 18 Cl.Ct 816, 818

(1989), decision foll. remand, 21 Cl.Ct. 365, 370-73 (1990), aff'd without opinion, 950 F.2d 731 (Fed. Cir. 1991). This sequence "must be supported by a sound and reliable or scientific explanation." Knudsen at 548 (citing Daubert v. Merrell Dow Pharm., Inc., 113 S.Ct. 2786 (1993)). Moreover, by statutory mandate, in this particular case Respondent may be required to affirmatively show that the alleged factor unrelated was the agent "principally responsible for causing" Mrs. De Bazan's injuries. §13(a)(2).

On 25 April 2006, the Court of Federal Claims convened a hearing concerning Petitioner's Motion for Review and, as a result, held that Mrs. De Bazan "has established a prima facie case that her Td vaccination on April 19, 2000 was the cause-in-fact of her injuries." De Bazan II, 2006 WL 1388417. Therefore, "The government should be allowed to put forward a full rebuttal case and should be provided with an opportunity to prove by a preponderance that petitioner's illness was caused by some factor other than the vaccination, in accord with 42 U.S.C. § 300aa-13(a)(1)(B). Because the court is remanding this case to the special master for disposition, see infra, the special master should receive additional evidence from respondent and petitioner on the issue of alternative causation." Id.[3]

In this Court's bench ruling on the factual question of the timing of Onset, it was noted that "during the medical visit when the vaccine was administered, Mrs. Bazan presented with a sore throat, swelling in the left of her neck, and nasal discharge. Petitioner's Exhibit ('Pet. Ex.') 16 at 56. At that time, the Court made 'no finding as to what the foregoing facts signify, if anything, but merely notes their inclusion in the medical records.'" De Bazan v. Secretary of HHS, No. 03-620V, slip op. at *2 (Fed. Cl. Spec. Mstr. Feb. 7, 2006) (hereinafter "De Bazan I").

On further consideration in the Entitlement Decision of 7 February 2006, this Court held the following:

> [T]he Court cannot say whether the symptoms present at the 19 April 2000 health care visit were indicative of an underlying viral or bacterial infection. Such is certainly suggested by the medical records; however, the Court cannot draw such a conclusion by a preponderance of the evidence. In fact, the Court takes particular note of a letter from the treating physician who writes, "I feel confident in stating that she did not appear to have any viral or bacterial infection when I evaluated her." Pet. Ex. 37. Had the treating physician noted a bacterial or viral infection, presumably Mrs. Bazan would have been treated accordingly. Instead, her physician attributed these symptoms to and treated them as allergies or rhinitis. Is it possible that her symptoms were caused by an underlying, precipitant but mild (or asymptomatic) viral or bacterial infection? Certainly. The Court is particularly suspicious given Mrs. Bazan's history of colds and other sinus issues. See, Onset Hearing Transcript at 77-78. All things considered, however, the Court cannot say there is preponderant evidence of a viral or bacterial infection in the medical records.

Id. (emphasis added).

---

[3] It is unclear what effect, if any, will result from the Federal Circuit's recent holding in Pafford v. Secretary of HHS, 2006 WL 1679714 (Fed. Cir. June 20, 2006). Regardless, this Court is confined to the limited directive of the remand in the above captioned case.

Based on the above finding and on the apparent lack of any other potential alternative causes patent on the face of the medical records, on 26 May 2006, the Court conducted a telephonic status conference in this matter, at which time Respondent was provided the opportunity to present additional evidence as to a factor unrelated. See, Order, 31 May 2006.

Respondent later declined this opportunity. Hence, it is unnecessary to collect additional evidence from Petitioner on the matter.[4]

Therefore, the Court has no alternative but to hold that Respondent has failed to "show by a preponderance of the evidence that petitioner's illness was the result of some other cause" than the tetanus vaccination in question. De Bazan II, 2006 WL 1388417.

Conclusion

In accordance with the Decision on remand that Petitioner has demonstrated a prima facie case, coupled with Respondent's failure to show a "factor unrelated," **the Court finds that Petitioner is entitled to Program compensation**.

The parties shall contact the Court post haste to set further proceedings in this case on the topic of damages. The Petitioner should engage the services of a life care planner if such has not already transpired, and the parties are strongly encouraged to begin discussions amongst themselves in light of the Court's long standing policy recommending amicable settlement.

IT IS SO ORDERED.

Richard B. Abell
Special Master

[4] Petitioner offered to file with this chambers the additional evidence presented before the Court of Federal Claims on review. De Bazan II, 2006 WL 1388417, n. 5. Given Respondent's declination to present additional evidence, Petitioner's offer was declined.