

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 07-0005V

Filed: 28 April 2008

* * * * *
WILMA FAGIO *
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Petitioner, *
*
v. *
*
SECRETARY OF HEALTH AND *
HUMAN SERVICES, *
*
Respondent. *
* * * * *

UNPUBLISHED DECISION¹

Thomas Scott Carnes, Esq., Carnes & Carnes, Virginia Beach, Virginia, for Petitioner;
Michael Patrick Milmoie, Esq., U. S. Department of Justice, Washington, D.C., for Respondent.

**RULING ON ENTITLEMENT
BASED UPON THE WRITTEN RECORD**

ABELL, Special Master:

On 5 January 2007, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),² alleging that she ("Wilma") suffered from on-Table brachial neuritis and/or axillary neuropathy, and that such was related to the administration of a trivalent flu vaccine to Wilma on 16 October 2002. Petition (Pet.) at 1. As an

¹ This opinion constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Therefore, unless a motion for review of this decision is filed within 30 days after the time given herein to Petitioners to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioners are 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 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.

alleged vaccine-related injury, Petitioner demanded compensation for unreimbursable expenses for past or future treatment, pain and suffering, and attorney's fees and costs. This Court is invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

I. PROCEDURAL HISTORY

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. See Petitioner's Exhibits ("Pet. Ex.") 3-9. Petitioner filed the written medical opinions of two doctors. Pet. Ex. 1 and 11. Respondent filed its Report, pursuant to Rule 4(c), on 16 April 2007, denying compensation. After sincere attempts to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 7 December 2007 for a ruling on the written record, and the Court granted that motion on even date.

II. FACTUAL RECORD

On 29 October 2002, almost two weeks after she had received the influenza vaccine, Petitioner Wilma Fagio reported to the Monroe Family Medical Center that ever since vaccination she had suffered pain in her arm and discomfort in moving her shoulder and neck. Pet. Ex. 3 at 1-2. The treating doctor concluded that the condition was bursitis, and conjectured without affirmative conclusion that it was "triggered" by the vaccination she had recently received. Petitioner returned to the doctor's office on 12 December 2002 for left shoulder tenderness, which was diagnosed as "localized myofascitis" suspected of being caused by irritation from a foreign body introduced by the vaccine injection, and which the doctor assumed would resolve on its own through the passage of time. Pet. Ex. 3 at 3. Nevertheless, on 8 July 2003, Petitioner once again returned because of continued shoulder pain, but this time was diagnosed with "an impingement syndrome." Pet. Ex. 3 at 4. Although at that time Petitioner voiced her belief that her painful condition was causally linked to the influenza vaccination, the treating doctor concluded that the flu shot had nothing to do with it. *Id.*

Petitioner suffered injuries from diverse sources such as vehicular collisions and overuse, but treating doctors ruled out vaccine causation in lieu of "typical rotator cuff bursitis." Pet. Ex. 3 at 8. When Petitioner's condition was evaluated by Dr. Chock Tsering, prior to filing the Petition, he assessed that she probably suffered from "causalgia over the left deltoid," but that there was "no object[ive] neurological deficit." Pet. Ex. 6. Moreover, Dr. Tsering noted that nerve conduction studies and EMG of the shoulder area manifested results that were "completely normal" and that Petitioner was "not likely to have any significant disability from the condition." *Id.* With the filing of the Petition, Petitioner filed an affidavit from neurologist Chock Tsering, M.D., a diplomate of the American Board of Neurology and Psychiatry. The entirety of his medical opinion is that:

Based upon the patient's history and the electromyographic studies, it is my opinion to a reasonable degree of medical certainty that Ms. Fagio suffers from causalgia, i.e.,

brachial neuritis or axillary neuropathy which was most likely brought on by the trivalent influenza vaccine injection she received on [29 October 2002].

Pet. Ex. 1.

Petitioner also filed the medical opinion of Ryan S. Conrad, M.D., but did not file a curriculum vitae in accompaniment. Pet. Ex. 11. Dr. Conrad made no ultimate conclusion regarding Petitioner's condition or the cause thereof, due to admitted limitations in his experience and expertise. *Id.* at 3-4. He did dispute Dr. Tsering's mention of "brachial plexitis" [*sic*], as he (Dr. Conrad) believes that condition would be evident in EMG scan results. *Id.* at 3. Dr. Conrad declined to opine that Petitioner's condition was vaccine-related, and the diagnosis he most affirmatively adopts is "complex regional pain syndrome." *Id.* at 4.

III. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccine which Petitioner alleges to have caused her condition was the trivalent flu vaccine, listed under category XIV on the Vaccine Table, a category with no coordinate injury assigned. 42 C.F.R. § 100.3(a). Essentially, this relegates all claims for such a vaccine to an "actual causation" theory of relief. Consequently, Petitioner's claim for on-Table brachial neuritis fails, and Petitioner must then prove that the vaccine actually caused the injury(ies) alleged.

Under the statute, the Court cannot grant a petitioner Program compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not seem to support the petitioner's claim, a medical opinion must be offered in support. The medical expert opinion reports filed by Petitioner, however, did not support the claims of the Petition to a preponderance of the evidence, because they did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

[A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] 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.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioner filed the reports of Doctor Tsering and Doctor Conrad. Neither doctor attempted to proffer, let alone explain, a "medical theory causally connecting the vaccination [to] the injury." Certainly absent was a detailed analysis of the Record to indicate a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Dr. Tsering offered a mere statement of conclusion, with no explanation whatsoever, and Dr. Conrad declined to opine in support of the Petition altogether. As such, Petitioner has not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion. There has not been demonstrated to the Court a "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Q.E.D. See Althen, supra*.

In short, Petitioner has not met the burden of proof set forth in the Act.³ Petitioner has presented none of the evidence required by the Act in the form of corroborative medical records, and failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

IV. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

Richard B. Abell
Special Master

³ See *Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating “[t]he requirement that [a] petitioner[‘s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone”); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) (“The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.”).