

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-563V

January 15, 2013

Not to be Published

JESUS AGUAYO,

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Petitioner,

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v.

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Respondent.

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Martin J. Martinez, Napa, CA, for petitioner.

Ann D. Martin, Washington, DC, for respondent.

GBS over three months after
seasonal flu vaccine and over
two months after H₁N₁ flu
vaccine but within one week of
cold and diarrhea

MILLMAN, Special Master

DECISION¹

On September 4, 2012, petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa–10-34 (2006), alleging that trivalent

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

influenza vaccine, administered September 24, 2009, and H₁N₁ monovalent influenza vaccine administered October 28, 2009 (the petition states the year is 2010, but the vaccine records show it was 2009), caused him Guillain-Barré syndrome (GBS) whose onset was January 7, 2010.

Only trivalent influenza vaccine is included in the Vaccine Injury Table. H₁N₁ monovalent influenza vaccine is not included in the Vaccine Injury Table. 42 C.F.R. § 100.3. “Monovalent” means one strain of influenza virus. The H₁N₁ monovalent influenza virus vaccine was administered solely during the 2009-10 flu season. “Trivalent” means three strains of flu virus. Trivalent influenza vaccine can include H₁N₁ and other influenza viruses in the same vaccine, and, if it does, any reaction to it is covered under the Vaccine Act.

During the flu season from the end of 2009 through the spring of 2010, H₁N₁ virus was not included in the 2009-10 seasonal flu vaccine “because it was identified after manufacturers had started making the seasonal flu vaccine.” Centers for Disease Control and Prevention, “Questions and Answers. Vaccine against 2009 H₁N₁ Influenza Virus,” http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm (last visited Jan. 15, 2013). After the 2009-10 flu season, seasonal influenza vaccine did include the H₁N₁ viral strain.

Those individuals who allege a vaccine injury from H₁N₁ monovalent influenza vaccine administered during the 2009-10 flu season have recourse for compensation under the Countermeasures Injury Compensation Program (CICP) run by the Health Resources and Services Administration (HRSA). See: <http://www.hrsa.gov/gethealthcare/conditions/countermeasurescomp/cicpantiviralinfo.html> (last visited Jan. 15, 2013).

Starting in the 2010-11 flu season, when H₁N₁ virus was combined with the seasonal flu virus into one trivalent influenza vaccine, the Office of Special Masters has had subject matter

jurisdiction over allegations of adverse reaction to seasonal trivalent influenza vaccine which includes H₁N₁ virus strain. For allegations of adverse reaction to H₁N₁ monovalent virus vaccine administered in 2009, HRSA is the only avenue for compensation for adverse reactions to H₁N₁ monovalent influenza vaccine. Petitioner has filed for compensation under the CICP for H₁N₁.

In the instant action, the interval between the trivalent influenza vaccination administered September 24, 2009 and petitioner's onset of GBS on January 7, 2010 is three and one-half months. This is too long for causation. Prior to petitioner's onset of GBS on January 7, 2010, he had an upper respiratory infection on January 1, 2010 followed by a two-day diarrheal illness.

On September 28, 2012, the undersigned issued an order suspending the deadline of respondent's filing a Rule 4(c) Report and setting the initial Rule 4(b) Conference for January 3, 2013.

On December 14, 2012, the undersigned issued an Order to Show Cause why this case should not be dismissed based on the length of time between the seasonal flu vaccination and the onset of petitioner's GBS and the close interval of time between petitioner's upper respiratory infection and diarrheal illness and the onset of petitioner's GBS. The undersigned said that the basis for the Order to Show Cause would be discussed at the initial telephonic conference.

On January 3, 2013, the undersigned held a Rule 4(b) Conference with petitioner's and respondent's counsel. During this telephonic conference, the undersigned noted the three and one-half months between seasonal flu vaccination and the onset of petitioner's GBS and contrasted the one-week interval between petitioner's upper respiratory infection and diarrheal illness and the onset of petitioner's GBS, explaining the lack of subject matter jurisdiction the

undersigned has over the H₁N₁ flu vaccination. Petitioner's counsel asked for time to write his client about the weaknesses of the case in light of the undersigned's discussion.

On January 15, 2013, the undersigned held a status conference with petitioner's and respondent's counsel. Petitioner's counsel stated he wrote petitioner about the case and petitioner responded by letting his counsel make the decision about whether or not to proceed. Both counsel orally moved for a ruling on the record. Respondent asked that the undersigned reflect in her decision that respondent does not believe compensation is appropriate in this case. There has been no petitioner's expert report filed in this case in support of petitioner's allegation.

FACTS

Petitioner was born on February 18, 1958.

On September 24, 2009, he received the seasonal trivalent influenza vaccine. Med. recs. Ex. 4, at 1.

On October 28, 2009, petitioner received H₁N₁ monovalent influenza vaccine. Id.

On January 7, 2010, petitioner went to Eden Medical Center and gave a history to Dr. David C. Bonovich that he awoke that day with left leg weakness and right lower extremity weakness. He told Dr. Bonovich that, on January 1, 2010, he had an upper respiratory infection followed by a two-day diarrheal illness. Med. recs. Ex. 1, at 9.

DISCUSSION

The United States is sovereign and no one may sue it without the sovereign's waiver of immunity. United States v. Sherwood, 312 U.S. 584, 586 (1941). When Congress waives sovereign immunity, courts strictly construe that waiver. Library of Congress v. Shaw, 478 U.S. 310 (1986); Edgar v. Sec'y of HHS, 29 Fed. Cl. 339, 345 (1993); McGowan v. Sec'y of HHS, 31 Fed. Cl. 734, 740 (1994); Patton v. Sec'y of HHS, 28 Fed. Cl. 532, 535 (1993); Jessup v. Sec'y

of HHS, 26 Cl. Ct. 350, 352-53 (1992) (implied expansion of waiver of sovereign immunity was beyond the authority of the court). A court may not expand on the waiver of sovereign immunity explicitly stated in the statute. Broughton Lumber Co. v. Yeutter, 939 F.2d 1547, 1550 (Fed. Cir. 1991).

On April 12, 2005, HRSA included trivalent influenza vaccine on the Vaccine Injury Table, effective July 1, 2005. 70 Fed. Reg. 19,092. For the most recent version of the Vaccine Injury Table, see 76 Fed. Reg. 36,367 (June 22, 2011) (codified at 42 C.F.R. § 100.3(a)). H₁N₁ vaccine administered as a monovalent vaccine in the 2009-10 flu season was not included in the seasonal trivalent influenza vaccine, and therefore not included within the jurisdiction of the Office of Special Masters until the following flu season, i.e., 2010-11. Congress enacted the CICP to compensate adverse reactions to H₁N₁ vaccine in the flu season of 2009-10.

The undersigned has no subject matter jurisdiction in the instant action over whether or not the H₁N₁ monovalent vaccine caused petitioner's GBS two and one-quarter months later.

As for the September 24, 2009 seasonal trivalent influenza vaccination, the undersigned has subject matter jurisdiction over the question whether or not it caused petitioner's GBS three and one-half months later. The undersigned has never gone beyond a two-month interval in holding that a vaccination caused a demyelinating illness. In Corder v. Secretary of Health & Human Services, No. 08-228, 2011 WL 2469736 (Fed. Cl. Spec. Mstr. May 31, 2011), the undersigned dismissed a case in which petitioner alleged that influenza vaccine caused her GBS four months later. The reason for the dismissal was that the onset interval was too long.

In the instant action, petitioner had an upper respiratory infection and a diarrheal illness one week before onset of his GBS, which are far more likely to be the cause of his GBS. On

January 7, 2010, Dr. Bonovich at Eden Medical Center diagnosed petitioner with GBS by evaluating petitioner's symptoms over six to seven hours that day with gradual weakness progressing toward near paralysis of petitioner's lower extremities "as well as his prodrome of an upper respiratory illness and a diarrheal illness." Med. recs. Ex. 1, at 11. "Prodrome" means a "precursor" to an illness. Dorland's Illustrated Medical Dictionary, 1522 (32nd ed. 2012). In other words, the rapidity of the symptoms, the type of symptoms, and the prior upper respiratory illness and diarrhea suggested to Dr. Bonovich that petitioner had GBS due to his recent upper respiratory infection and diarrheal illness.

To satisfy his burden of proving causation in fact, petitioner must prove 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. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for seasonal trivalent influenza vaccine, he would not have had GBS, but also that the vaccine was a substantial factor in causing his GBS. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the instant action, petitioner has not provided an expert report stating that his trivalent flu vaccination caused GBS three and one-half months later, ignoring whether or not H₁N₁ vaccine two and one-quarter months before the GBS, and his upper respiratory infection and diarrheal illness one week before the GBS were instead the cause.

Based on the extended time interval between trivalent flu vaccination and the onset of petitioner's GBS, petitioner has not satisfied the third prong of Althen which requires the interval between vaccination and illness to connote causality. Because petitioner has not satisfied the third prong of Althen, he also has not satisfied the second prong of Althen which requires petitioner to prove that trivalent flu vaccine caused GBS in his particular case.

Petitioner has failed to make a prima facie case of causation in fact, and this petition must be and hereby is **DISMISSED**.

CONCLUSION

Petitioner's petition is dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

January 15, 2013
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.