

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-819V

Filed: May 30, 2012

JESSICA MURA,

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Special Master Zane

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Petitioner,

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Ruling on the record; trivalent (flu)

v.

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vaccine; acute disseminated

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encephalomyelitis (“ADEM”)

SECRETARY OF HEALTH
AND HUMAN SERVICES

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Respondent.

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Corey J. Hogan (John DeFazio), Hogan, Willig, Amherst, New York, for Petitioner.
Linda S. Renzi, United States Dep’t of Justice, Washington, D.C., for Respondent.

UNPUBLISHED RULING FINDING ENTITLEMENT TO COMPENSATION¹

This matter is before the undersigned on Respondent’s Motion for Ruling on the Record. Petitioner, Jessica Mura (hereinafter “Ms. Mura”), filed a petition for compensation under the National Childhood Vaccine Injury Act² (“Vaccine Act” or “Act”), as amended, 42 U.S.C. §

¹ Because this ruling contains a reasoned explanation for the special master's action in this case, the special master intends to post it 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). 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 clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document’s disclosure. As such should either party wish to have certain information redacted from the final posted ruling, they should file a motion within 14 days. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. § 300aa-10 through § 300aa-34 (2006).

300aa-1, *et seq.*, alleging that a trivalent influenza (“flu”) vaccination she received in November 2006, caused her to suffer from acute disseminated encephalomyelitis (“ADEM”).³ Petition, ¶ 8. Ms. Mura submitted a medical expert’s report in which the expert opined that, to a reasonable degree of medical certainty, Petitioner’s ADEM was caused by an influenza vaccination she received on November 22, 2006. Petitioner’s Ex. 46. In the motion for a ruling, Respondent explains that she has decided not to expend additional resources defending this case and asks for a ruling on the record. *See* Respondent’s Motion for Ruling at 8. As explained below, a review of the record as a whole indicates that Respondent’s Motion for Ruling on the Record should be and, thus, is granted. The record establishes that Petitioner is entitled to compensation.

BACKGROUND

The background relating to this matter was discussed in detail in the undersigned’s previous Ruling Regarding Finding of Fact issued in September 2011, incorporated herein. As such, only a brief summary shall be included in this ruling. Ms. Mura, a healthy 21-year old Emergency Medical Technician, received an influenza vaccination in November 2006. Four days after the vaccination, she began to experience various symptoms and was eventually diagnosed as having acute disseminated encephalomyelitis (“ADEM”). Her ADEM caused Ms. Mura significant injuries, including paraplegia and respiratory failure. Ms. Mura continues to suffer from conditions caused by her ADEM.

Following the filing of Ms. Mura’s petition, two material fact disputes arose. The first was a dispute as to the date Ms. Mura received the flu vaccine. To address this issue, the previously assigned Special Master held a fact hearing in July 2010, and subsequently determined that Ms. Mura had received the flu vaccine on November 22, 2006, four days prior to the onset of her symptoms and her admission to the hospital. *See* July 20, 2010 Order.⁴

The second factual dispute related to whether Ms. Mura had suffered from a respiratory infection, viral gastroenteritis or other viral-type syndrome, in the ten to fourteen day prior to her hospitalization. This fact dispute was a material issue in that Respondent’s expert’s opinion was

³ The Institute of Medicine defines acute disseminated encephalomyelitis or ADEM as an acute inflammation of the brain and spinal cord with variable symptoms that are thought to be an allergic or immune response following infectious disease or vaccination. Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality*, 2012, Appendix A; *see also* *Dorland’s Medical Dictionary*, www.dorlands.com, (Acute Disseminated Encephalomyelitis or ADEM is an acute or sub-acute encephalomyelitis or myelitis characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination; it occurs most often after an acute viral infection, especially measles, but may occur without a recognizable antecedent. It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Symptoms include fever, headache, and vomiting; sometimes tremor, seizures, paralysis, and lethargy progressing to coma that can be fatal. Many survivors have residual neurologic deficits); *see generally* Pira, et al., *Acute Disseminated Encephalomyelitis (ADEM): Two Paediatrics Case Reports*, Petitioner’s Ex. 26 at 1.

⁴ This matter was reassigned to the undersigned Special Master on March 15, 2011.

based on the premise that such prior viral-type illness had occurred. Based on a review of the record as a whole and in consideration of the parties' submissions on the issue, including Ms. Mura's numerous references to an absence of any notations in the medical records of any prior illness, the undersigned found that Ms. Mura had not suffered from any such viral illness immediately prior to her hospitalization. *See* Sept. 6, 2011 Ruling Regarding Finding of Fact at 8; *see also* Appendix A to Ruling Regarding Finding of Fact.

Following this finding, Respondent filed the subject Motion. In the motion, Respondent stated that "[w]hile respondent believes that petitioner has failed to provide preponderant evidence supporting her allegation or to establish a logical cause and effect relationship between the vaccine and the alleged injury, DVIC has determined that no further resources should be spent defending this case." Respondent's Motion for Ruling on the Record at 8. Thus, Respondent requested a ruling on the existing record. *Id.* at 8-9.

Ms. Mura responded to Respondent's Motion for Ruling on the Record. Ms. Mura referenced her medical expert's report and argued that she had "met her prima facie burden to establish entitlement to compensation under the National Childhood Vaccine Injury Act, based upon her expert's opinions/report, medical records, affidavits, and medical literature in this case." Petitioner's Response at 4. Respondent did not file a reply. This issue is now ready for ruling.

DISCUSSION

To be awarded compensation under the Vaccine Act, a petitioner must prove either: 1) that she suffered a "table injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question, which creates a presumption that the injury was caused by the vaccination, or 2) that her medical problems were caused by the vaccine(s) at issue. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). A petitioner may not be awarded compensation based on the petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. *Id.*

On the issue of a table injury, Ms. Mura may not take advantage of any presumption because the Table does not compensate for an association between the vaccination at issue here, the flu vaccination, and her alleged injuries. 42 C.F.R. § 100.3(a). Further, Ms. Mura has not alleged that she suffered from a "table injury," and there is no evidence that any "table injury" occurred. As a result, Ms. Mura cannot be deemed entitled to compensation on that basis.

Because Ms. Mura cannot prevail based on a showing that she has a "table injury," Ms. Mura bears the burden of proving that the vaccination caused the injury for which she seeks compensation. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Ms. Mura must demonstrate that the vaccination was a substantial factor in causing her injuries. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010). To do this, Ms. Mura "must 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.” *Moberly*, 592 F.3d at 1322, *quoting Althen*, 418 F.3d at 1278. As explained below, a review of the record as a whole demonstrates that Ms. Mura has satisfied this burden and demonstrates by preponderant evidence that the flu vaccination caused her to suffer from ADEM.

As an initial matter, the parties agree that Ms. Mura suffers from ADEM. *See* Petitioner’s Ex. 46 at 5, 15, and Respondent’s Ex. A at 2. Because the parties agree that Ms. Mura suffers from ADEM, the issue is whether, based on the record, Ms. Mura has demonstrated by preponderant evidence that the vaccination caused her to suffer from ADEM. In other words, has Ms. Mura has presented sufficient evidence to show a medical theory causally connecting the vaccination and her injuries, a logical sequence of cause and effect between the vaccination and her injuries, and an appropriate temporal association between the vaccination and her injuries. *See Althen*, 418 F.3d at 1278.

A. *Althen* Prong 1.

First, as to the medical theory presented by Ms. Mura, Petitioner’s expert, Dr. Kinsbourne, stated that “ADEM is an immune-mediated demyelinating disorder of the central nervous system, which commonly presents acutely, with multifocal neurological findings, including motor deficits, and lowered level of consciousness, ‘that occurs a few days or weeks following vaccine administration or virus-like disease.’” Petitioner’s Ex. 46 at 5-6. Dr. Kinsbourne further opined that molecular mimicry is “clearly a medically reasonable and reliable mechanism of injury in immune mediated neurological illnesses, and was so in the case of Jessica Mura.” Petitioner’s Ex. 46 at 4-5, 12-13. Dr. Kinsbourne also referenced medical literature that supported the conclusion that vaccination is a recognized cause of ADEM. *Id.*

Respondent’s expert, Dr. Ward, did not disagree that Petitioner’s expert had presented a medical theory causally connecting the vaccine to the injury. Dr. Ward admitted that there have been case reports of ADEM occurring after viral illnesses and after vaccination. Respondent’s Ex. A at 2. Dr. Ward also acknowledged that the potential mechanisms of how this could occur, i.e., how the vaccine could cause the injuries, are described in Respondent’s references and in Petitioner’s expert report. *Id.* The evidence provides a reliable a medical theory causally connecting the vaccination with Ms. Mura’s injuries.

B. *Althen* Prong 2.

Second, with respect to the logical sequence of cause and effect prong, Petitioner’s expert, Dr. Kinsbourne, stated that the influenza vaccination caused an autoimmune reaction in Ms. Mura’s body and against her brain which manifested as ADEM. Petitioner’s Ex. A at 14-15. In support of his opinion, Dr. Kinsbourne referred to the affidavit of one of Ms. Mura’s treating physicians, Dr. Updegraff, Petitioner’s Ex. 13, who stated that at the outset of Ms. Mura’s hospitalization, Dr. Updegraff’s initial assessment was that Ms. Mura’s ascending paralysis was related possibly to her receipt of the flu vaccination. Petitioner’s Ex. 13, ¶ 13. Dr. Updegraff, one of Ms. Mura’s treating physicians, noted that prior to her hospitalization, Ms. Mura was healthy and free of any neurologic or life threatening disease. Petitioner’s Ex. 13, ¶ 14.

Dr. Kinsbourne also discussed Ms. Mura's medical records. He noted that the records indicated that Ms. Mura's illness progressed from a demyelinating disorder that began four days after she received the vaccination and progressed from her distal extremities to her spinal cord and brain. This disorder made Ms. Mura comatose, quadriplegic, incontinent of urine and feces, and she required mechanical ventilation, rendering her intellectually handicapped and subject to severe whole body neurogenic pain. Significantly, Dr. Kinsbourne, relying on the medical literature that describes numerous viral agents and bacteria as well as vaccinations as relating to ADEM, *see* Petitioner's Ex. 29, noted that the medical records did not indicate any other intervening factors or any other prior illnesses that could have caused Ms. Mura's ADEM. Petitioner's Ex. 46 at 14. Thus, he concluded Ms. Mura's ADEM was caused by the vaccination.

Respondent's expert, Dr. Ward, disagreed with Dr. Kinsbourne's opinion regarding the logical sequence of cause and effect prong. Dr. Ward's disagreement as to cause was based on his reliance that Ms. Mura had experienced a "viral illness occurring 10-14 days before the onset of her symptoms." *Id.* Dr. Ward concluded that it was this prior viral illness "[that] was the trigger for her illness and she happened to receive an influenza vaccination subsequent to that time." *Id.* Dr. Ward's conclusion that Ms. Mura had a prior viral illness was based on a single reference in a doctor's notes regarding Ms. Mura's prior medical history recorded nearly two weeks after her admission to the hospital at a time when Ms. Mura was unresponsive and comatose. That notation was inconsistent with the numerous other references in the records that Ms. Mura had no prior viral infection, notations made by doctors who had personally interviewed Ms. Mura at the time of her admission when she was alert.

As set forth in the Ruling Regarding Finding of Fact of September 2011, referenced above, the undersigned found that the record as a whole demonstrated that in the ten days to two weeks prior to Ms. Mura's admission to the hospital on November 26, 2006, Ms. Mura "did not suffer a respiratory infection, viral gastroenteritis, or other viral type syndrome." *See* Ruling Regarding Finding of Fact at 8. Because the facts as found are that Ms. Mura had not suffered from any viral-type syndrome prior to hospitalization, Dr. Ward's opinion, which relies on a fact inconsistent with the undersigned's finding and the evidence in the record, does not have a sufficient basis in fact and, thus, is insufficient upon which to rely. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict"); *Perreira v. Sec'y of Health & Human Servs.*, 33 F.3d 1375, 1376 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it"); *see generally* FRE Rule 702 (an expert may testify as to an opinion only where the testimony is based on sufficient facts); *Colon v. Abbott Laboratories*, 397 F. Supp.2d 405, 417 (E.D.N.Y. 2005) (rejecting opinion testimony where facts did not support it). By stating that Respondent does not intend to contest this matter further in her Motion for Ruling on the Record, Respondent implicitly acknowledges the lack of support for her expert's conclusions. Because the facts upon which Respondent's expert bases his conclusions regarding logical sequence and effect are unsupported, his opinion is not as reliable as the opinions of Petitioner's expert and treating physician. Moreover, Petitioner's expert's report and her treating physician's affidavit provide sufficient evidence to demonstrate by preponderant evidence a logical sequence of cause and effect between the vaccination Ms. Mura received and her development of ADEM.

C. Althen Prong 3.

Finally, with respect to the temporal association prong, it was four days from the date Ms. Mura received the vaccine on November 22, 2006, to the onset of her symptoms and her hospitalization on November 26, 2006. Dr. Kinsbourne stated in his report that “[t]he temporal interval of four days between the influenza vaccination and the onset of Jessica’s ADEM is consistent with medical literature as to temporal intervals between provocative events and the onset of ADEM.” Petitioner’s Ex. 46 at 13. Respondent’s expert, Dr. Ward, did not directly dispute that four days may be an appropriate time interval. Respondent’s Ex. A. Although Dr. Ward stated that it would be unusual for a case of ADEM to begin within 72 hours of vaccination, he noted that there were case reports to that effect, in essence, acknowledging that the longer period of four days was an appropriate time interval. Respondent’s Ex. A at 2. There is no dispute between the parties’ experts that the four days was an acceptable medical time interval between the vaccination and the onset of Ms. Mura’s illness. The evidence is sufficient to establish an acceptable temporal association between the vaccination and Ms. Mura’s illness.

CONCLUSION

Based on the foregoing, in consideration of the record as a whole, the undersigned finds that Petitioner, Ms. Mura, has established by preponderant evidence that she is entitled to compensation. Accordingly, the undersigned **finds that Petitioner is entitled to compensation.** A damages order shall be issued separately. The parties are hereby directed to contact undersigned’s judicial assistant, Lori Lewis, at (202) 357-6339, within **10 days of this order** to schedule a status conference to address future proceedings.

IT IS SO ORDERED.

/s/ Daria J. Zane
Daria J. Zane
Special Master