In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 06-834V
July 23, 2008
To be Published

LESLI RIDGWAY and MICHAEL RIDGWAY, Individually and next friends of MAX RIDGWAY, a minor,	*	
Petitioner,	*	
v.	*	Entitlement; significant aggravation of preexisting influenza A virus, causing encephalopathy and sequelae
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mark L. Krueger, Baraboo, WI, for petitioners.
Althea W. Davis, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioners filed a petition on December 7, 2006, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that DPaT, HiB, inactivated polio, and Prevnar

[1] 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 clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. 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.

vaccines administered on December 8, 2003 at 11:45 a.m. to Max Ridgway (hereinafter, "Max") caused a Table encephalopathy. At the time he was vaccinated, Max had a cough and was diagnosed with an upper respiratory infection (URI), although he was later diagnosed with influenza A. His siblings had the flu at the time as well. Later in the afternoon, Max had a high fever. He was hospitalized on December 9, 2003 and ultimately diagnosed with pneumoccocal meningitis, sepsis, strep pneumonia, shock, and pulmonary dysfunction.

The undersigned and the parties had a telephonic status conference on January 19, 2007 during which the undersigned discussed the issues of a Table encephalopathy and whether the vaccinations and the influenza A virus were all substantial factors in causing Max's illness.

On January 22, 2007, the undersigned filed an Order directing respondent to file a Rule 4(c) Report by March 7, 2007 addressing whether respondent agreed that Max sustained an on-Table injury and whether respondent was willing to concede liability or, in the alternative, to consider engaging in a litigative risk settlement. The undersigned asked the parties to review the following cases: Capizzano v. Secretary of HHS, 440 F.3d 1274 (Fed. Cir. 2006); Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005); and Knudsen v. Secretary of HHS, 35 F.3d 543 (Fed. Cir. 1994), all describing petitioners' burden in proving causation in fact. The undersigned also asked the parties to review the following cases: Shyface v. Secretary of HHS, 165 F.3d 1344 (Fed. Cir. 1999) (baby with early stage E. coli infection received whole cell DPT and developed high fever from both infection and vaccine, causing his death; petitioners prevailed because vaccine was a substantial factor); Nash v. Secretary of HHS, No. 00-149V, 2002 WL 1906501 (Fed. Cl. Spec. Mstr. June 27, 2002) (child with pneumococcal infection received whole cell DPT; infection worsened and he had pneumococcal meningitis; undersigned

ruled for petitioner on basis that vaccine was a substantial factor); and Herkert v. Secretary of HHS, No. 97-518V, 2000 WL 141263 (Fed. Cl. Spec. Mstr. Jan. 19, 2000) (child with cytomegalovirus infection received acellular DPT and developed transverse myelitis; undersigned ruled for petitioner on basis that vaccine was a substantial factor).

On March 7, 2007, respondent made an oral motion to suspend the filing of respondent's Rule 4(c) Report pending settlement negotiations. Petitioners did not object. The undersigned issued an Order dated March 7, 2007 granting respondent's motion and suspended the filing of the Rule 4(c) Report.

The parties and the undersigned had status conferences on March 26, 2007, May 30, 2007, July 9, 2007, September 10, 2007, November 29, 2007, January 8, 2008, January 31, 2008, and March 14, 2008, having each hired life care planners who analyzed the case and conducted site visits, but they failed to settle.

On April 28, 2008, respondent filed a Rule 4(c) Report recounting the facts in this case and concluded that, although respondent does not consider this case appropriate for compensation, "respondent chooses not to expend funds to obtain an expert opinion in this case." Rule 4(c) Report, p. 5. Respondent requested the undersigned rule on the record.

On May 6, 2008, the parties and the undersigned had another status conference and petitioners' counsel stated he would file an expert report.

On May 7, 2008, the undersigned issued an Order giving petitioners until June 6, 2008 to file an expert report.

On June 6, 2008, petitioners faxed an expert report from Dr. Marcel Kinsbourne, a pediatric neurologist, with an attached medical article. Petitioners moved that the undersigned

file the expert report and article by her leave, which the undersigned did by Order dated June 9, 2008, ordering respondent to file an expert report in response to Dr. Kinsbourne's report by July 18, 2008.

On June 11, 2008, petitioners filed as Ex. L another medical article to which Dr. Kinsbourne referred in his expert medical report.

On July 18, 2008, respondent filed a Response to June 9, 2008 Order, stating that respondent "hereby notifies the court that he will not be submitting an expert report and renews his request that the court rule on the issue of entitlement based on the record."

Since the undersigned is ruling in favor of petitioners on the issue of entitlement, the hearing set for Wednesday, September 10, 2008, at 10:00 a.m., will concern damages.

FACTS

Max was born on June 3, 2003. P. Ex. A.

On December 8, 2003, at the age of six months, Max went to his pediatrician's office for symptoms of a URI and saw Pediatric Nurse Practitioner (PNP) C. Johnson. P. Ex. D, p. 12. Max was alert and active. He had "slight dullness" of his left ear with clear nasal discharge. Otherwise, he was well. Max received DPaT, HiB, IPV, and Prevnar vaccines. *Id.*

On December 9, 2003, one day later, Max was taken by ambulance to Cook Children's Medical Center. His mother gave a history to Dr. Larr E. Easterling that Max awoke on December 8, 2003 with a moist cough. In the afternoon after the vaccinations, he had decreased appetite, "slept hard," and had a temperature of 102.7º. P. Ex. G, p. 19. Max's respiratory status worsened and he began to have retractions. Overnight, his breathing pattern worsened and his retractions increased. He went to Dr. James Wheeler's office the morning of December 9, 2003

and was taken to the hospital from there. The ambulance record for December 9, 2003 notes that Max had difficulty breathing and had a croupy cough. P. Ex. H, p. 14. In the ER, his condition did not improve and he developed high-pitched, noisy breathing (stridor). His oxygen saturation level decreased and Max was intubated. Prior to intubation, Max became pale. Tests showed he had influenza A. Max was transferred to the PICU and sedated due to intubation. P. Ex. H, pp. 29, 35-37. After 36 hours, Max was extubated and taken off mechanical ventilation. P. Ex. H, p. 92.

On December 11, 2003, Max continued to have intermittent low grade fevers. P. Ex. H., p. 97. He was slightly agitated upon examination. P. Ex. H, p. 96. He continued to have occasional stridor, moderate retractions, and 98-100% oxygen requirement per face mask. *Id.*

On December 13, 2003, before being transferred from the PICU, he developed respiratory distress and a fever, and became unresponsive. P. Ex. H, p. 137. He had difficulty maintaining blood pressure. He was reintubated. Max was diagnosed with pneumoccocal meningitis and sepsis. P. Ex. H, pp. 199-205.

On December 14, 2003, a lumbar puncture of his cerebrospinal fluid showed a protein level of 280. P. Ex. G, p. 19. Max had increased intracranial pressure as manifested by bulging fontanel and abnormal pupil reaction. P. Ex. H, p. 191. He had cardiovascular instability. *Id.* He had gram-positive cocci in his cerebrospinal fluid as well as in his blood. P. Ex. H, p. 192.

Dr. Lynne M. Eger, an infectious diseases consultant, noted on December 14, 2003 that, on December 13, 2003, Max had neurologic deterioration with roving eye movements and decreased mental status. P. Ex. H, p. 199.

On December 16, 2003, Max presented with status epilepticus. An EEG showed diffuse biphasic slowing consistent with either postictal condition or encephalopathy. P. Ex. H, p. 281. He was extubated on December 20, 2003. An EEG on that date showed diffuse slowing consistent with severe encephalopathy. P. Ex. H, pp. 403-05. On physical examination, Max's pupils were very sluggish to light if reactive at all. P. Ex. H, p. 291. He was on 55% oxygen. P. Ex. H, p. 292.

On December 17, 2003, a CT scan of the head showed marked interval change with development of abnormal density throughout the cerebral peduncies, basal ganglia, frontal lobes, and parietal lobes. These findings suggested a diffuse ischemic process. P. Ex. H, p. 310.

On December 20, 2003, an EEG showed diffuse slowing in a generalized manner. The background was abnormally slow and poorly reactive to tactile stimuli. Dr. Jose Aceves' conclusion was that the EEG indicated global central nervous system (CNS) dysfunction compatible with a severe encephalopathy. P. Ex. H, p. 403.

On December 21, 2003, Max was noted to have a weak cry and a cough. P. Ex. H, p. 404.

On December 22, 2003, a brain MRI was done which showed developing significant cerebral atrophy bilaterally probably related to diffuse cerebritis. There were multiple foci of abnormal, T-2 signal scattered through the central white matter and within the brainstem, some of which likely represented old infarcts. There was focal abnormal T-2 signal scattered through the basal ganglia bilaterally. There was interval development of moderate-sized, extra axial fluid collections bilaterally, left greater than right. P. Ex. H, p. 444.

A neurology consultation on December 22, 2003 noted that the foci seen on brain MRI probably represented ischemia secondary to small vessel clogging from meningitis, but could also represent ADEM (acute disseminated encephalomyelitis) from influenza A. P. Ex. H, p. 450.

On December 23, 2003, Max was noted to be irritable when awake and cried to noxious stimuli. He did some bicycling of his legs and fisting of his hands. He did not purposely move. His pupils were unequal with his right pupil significantly larger than his left. His left pupil was briskly reactive but his right was very sluggishly reactive. P. Ex. H, p. 453.

On December 23, 2003, Max was noted to have right upper lobe infiltrate with fever, leading to a possible diagnosis of a new pneumonia. P. Ex. H, p. 471.

On December 28, 2003, a neurologist noted that Max's abnormal MRI showed likely ADEM rather than strokes. P. Ex. H, p. 573.

On December 29, 2003, Dr. Alan A. Normal performed an ophthalmologic consultation, finding anisocoria, with the right pupil larger than the left, and exotropia, the latter probably due to injury to the occipital and/or parietal areas controlling motor fusion, commonly seen in patients with severe closed head injuries and/or infections. P. Ex. H, p. 592.

On December 31, 2003, Max had another brain MRI. P. Ex. H, p. 611. He had moderately large left extra-axial fluid collection, slightly increased in size from the December 22, 2003 MRI and increased mass effect on the left cerebral hemisphere. The ventricles and sulci were prominent, consistent with cerebral atrophy from the sequela of recent infection. *Id.* Max might also have petechial-type micro-hemorrhages in the gray-white junction bilaterally. P. Ex. H, p. 612.

On January 8, 2004, Max had a percutaneous endoscopic gastrostomy performed to help with his oral intake. P. Ex. H, p. 748. He had profound neurologic impairment. *Id.*

On January 9, 2004, Max had a head CT scan done which showed a developing hypodensity adjacent to the left frontal horn compatible with a small focal ischemic insult. P. Ex. H, p. 765.

On January 14, 2004, Max was discharged from the hospital. P. Ex. H, p. 827.

On June 4, 2004, Max received MMR and Varivax vaccines at his 12-month well-baby visit. P. Ex. H, p. 883.

On July 19, 2005, Max had a physical therapy initial evaluation by Andrea Dye. P. Ex., pp. 1418, 1421. She noted that right after his six-month vaccinations, Max developed a very high fever and flu-like symptoms. *Id.* at 1418. He was on a ventilator for three weeks with significant swelling of the brain, multiple strokes, and bilateral hearing loss. He had a cochlear implant in his left ear and wore a hearing aid in his right ear. *Id.* His neurologist Dr. McLaughlin told Ms. Dye that Max's last brain MRI showed that the left frontal lobe sustained the worst damage and the rest of the brain had slight atrophy. *Id.* Max was recently discharged from physical therapy and decreased occupational therapy to one time every three months. He had speech therapy once a week and audiovisual therapy once a week. Max had left-sided weakness and foot drop. *Id.* Max's gross motor scores were poor for his age compared to his peers. *Id.* at 1421.

Other Submitted Materal

On August 8, 2007, petitioners filed a life care plan (Ex. K) written by Dan M. Bagwell, RN, and Dr. Alex Willingham, who is president of Rehabilitation Professional Consultants, Inc.

The authors note in the plan that Max's clinical presentation is consistent with a diagnosis of encephalopathy and associated cerebral palsy which he developed after complications following vaccinations with subsequent meningitis. Other presenting medical conditions associated with his encephalopathy and cerebral palsy are global developmental delay, seizure disorder, profound hearing impairment, and strabismus. P. Ex. K, p. 12.

Petitioners filed the expert report of Dr. Marcel Kinsbourne. He states that at the time Max received his vaccinations, Max had an ongoing but controlled viral infection. Max reacted to his vaccinations with fever and respiratory stridor. He was diagnosed with croup associated with influenza virus infection. The croup led to intubation, which led to pneumothorax, pneumococcal sepsis, and pneumococcal meningitis caused by either multiple strokes or the influenza/croup-caused ADEM. P. 2 of Dr. Kinsbourne's report (no exhibit number was given to this report).

Dr. Kinsbourne states that Max's two siblings had influenza-like symptoms at the time of his vaccinations and presumably caused his influenza infection, but Max's illness was immensely more severe, leaving him spastic, developmentally delayed, deaf, and epileptic. *Id.* Dr. Kinsbourne discusses the production of chemokines and cytokines in influenza A virus which cause the symptoms but also help resolve the illness. P. 3 of Dr. Kinsbourne's report. However, vaccines also release proinflammatory cytokines in order to produce a robust and protective adaptive immune response to the antigens in the vaccines. These vaccines amplified Max's cytokine response to the influenza A virus, increasing its severity, aggravating the clinical presentation of the influenza A virus symptoms. *Id.*

Dr. Kinsbourne concludes that Max's six-month vaccinations significantly aggravated his medical condition, resulting in Max's encephalopathy and multiple permanent neurological impairments. But for the vaccinations, Dr. Kinsbourne states, Max would not have experienced the sequence of events that left him permanently neurologically handicapped. Dr. Kinsbourne's opinion is based on causation in fact, rather than on a Table encephalopathy, since the onset of Max's encephalopathy was five days after his vaccination date. (A Table encephalopathy after DPT, whether whole cell or acellular, must occur within three days of vaccination.) *Id.*

Dr. Kinsbourne's discussion of the role of chemokines and cytokines in influenza A virus is discussed at p. 531 of the article attached to his report: "Detrimental Contribution of the Toll-Like Receptor (TLR)3 to Influenza A Virus-Induced Acute Pneumonia," by R. Le Goffic, et al., 2 *PloS Pathog* 6:e53 (June 2006) (pp. 526-35).

Petitioners filed as Ex. L Dr. Kinsbourne's second reference in his report: "Adverse Consequences of Immunostimulation" by Rafael Ponce, 5 *J of Immunotoxicology* 33-41 (2008), which also discusses the role of chemokines and cytokines in immune stimulation.

DISCUSSION

Although the undersigned thought that an analysis of substantial factor as in Shyface would be appropriate, petitioners have preferred through their expert Dr. Kinsbourne to prove causation in fact on the theory of significant aggravation, i.e., the vaccinations Max received significantly aggravated his preexisting influenza A virus, causing vastly more serious consequences.

The Vaccine Act, 42 U.S.C. § 300aa-33(4) defines "significant aggravation" as follows:

> The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

Dr. Kinsbourne states in his report that the effect of the production of cytokines and chemokines from the vaccines, added to the production of cytokines and chemokines from the influenza A virus which Max had at the time he received the vaccines, resulted in a significant aggravation of his preexisting flu virus, causing catastrophic illness. But for these vaccinations, Dr. Kinsbourne said, Max would not have had the serious sequelae of his flu infection.

Dr. Kinsbourne's opinion is consistent with the analyses in Shyface, Nash, and Herkert, cited and described above, in which the children harbored a preexisting infection that the vaccinations, by affecting their immune systems by lessening their ability to fight the infection and increasing their illness, caused injury. These cases were decided using the substantial factor analysis. The undersigned sees no difference in result using the significant aggravation analysis here.

To satisfy their burden of proving causation in fact, petitioners 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. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary 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[.]"

Petitioners herein have shown a biologically plausible medical theory, a logical sequence of cause and effect, and a medically appropriate time interval between vaccinations and significant aggravation of Max's preexisting illness. Respondent has opted not to present any evidence to challenge petitioners' allegations and expert report.

Petitioners have proven a prima facie case of causation in fact significant aggravation and, without Max's having received his six-month vaccinations, his preexisting flu infection would not have resulted in the severe illness he had post-vaccination and the sequelae therefrom.

CONCLUSION

Petitioners have prevailed on the issue of entitlement. We will proceed to a hearing on damages unless the parties have settled before September 10, 2008.

IT IS SO ORDERED.

_____ _____

DATE

Laura D. Millman
Special Master