In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 99-638V
May 8, 2007
To be Published

VERONICA PEUGH, Administratrix of the Estate of JUSTIN PEUGH,	*	
Petitioner,	*	
v.	*	Entitlement; hepatitis B vaccine caused axonal variant of GBS leading to hypertension and death or leading to pain and depression for which medications acting in synergy led to hypotension and death
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer, Sylvia Chin-Caplan, Boston, MA, for petitioner.
Alexis B. Babcock, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Former petitioner Justin Peugh filed a petition on August 4, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine

[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.

injured him. The case was assigned to Chief Special Master Gary Golkiewicz on August 4, 1999 and became part of the Chief Special Master's hepatitis B-demyelinating disease cases. The Chief Special Master reassigned the case to former Special Master Margaret M. Sweeney on May 7, 2003. For a general description of the Omnibus proceedings before the Chief Special Master and former Special Master Sweeney, see Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Former Special Master Sweeney held a hearing in the Omnibus proceeding on October 13, 14, and15, 2004, during which the parties presented evidence concerning the general issue of hepatitis B and demyelinating diseases and specifically four paradigm cases.

Justin Peugh died on July 26, 2005. On November 30, 2005, Justin Peugh's wife (now petitioner Veronica Peugh) filed the death certificate and autopsy report for Mr. Peugh. P. Exs. 36, 37.

On January 11, 2006, the Chief Special Master reassigned this case along with the other hepatitis B-demyelinating cases to the undersigned.

This case was picked as one of the four paradigm cases in the Omnibus proceeding to determine if hepatitis B vaccine can cause demyelinating disease, in this case, Guillain-Barre Syndrome (GBS). The issue in Stevens was whether hepatitis B vaccine can cause transverse myelitis (TM), and the undersigned ruled that it could and did in Stevens. Two of the paradigm cases concerned multiple sclerosis (MS) and chronic inflammatory demyelinating polyneuropathy (CIDP): Werderitsh v. Secretary of HHS, No. 99-319V, 2006 W: 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006) (MS), and Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (CIDP beginning as GBS). The undersigned ruled

in favor of petitioners in those cases as well. Approximately 65 cases were waiting for the undersigned's decision.

On April 21, 2006, the undersigned issued an Order in this case, ruling that hepatitis B vaccine caused Justin Peugh's GBS. However, because Justin Peugh died, petitioner had to present evidence causally associating his death to his vaccine injury. The undersigned held a hearing on this issue on January 30, 2007. Testifying for petitioner was Dr. Carlo Tornatore. Testifying for respondent was Dr. Gerald F. Winkler. Both doctors are neurologists.

FACTS

Mr. Peugh was born on February 21, 1974. He was in a car accident with whiplash on February 13, 1992 and hospitalized for two days. Med. recs. at Ex. 1, p. 12. His blood pressure on May 6, 1992 was 120/80. Med. recs. at Ex. 1, p. 6. Mr. Peugh fractured his lumbar spine at the L-1 level in a motor vehicle accident February 9, 1994 for which he was hospitalized for two days. Med. recs. at Ex. 1, p. 7. However, an x-ray of his lumbar spine did not show a fracture. Med. recs. at Ex. 1, p. 10. He had a bone scan on July 21, 1994 which appeared normal, according to Dr. Jerry B. Jennings. Med. recs. at Ex. 1, p. 8. Mr. Peugh received three hepatitis B vaccinations in either 1994 or 1995, with the dates conflicting. Med. recs. at Ex. 15.

Mr. Peugh received a fourth hepatitis B vaccination on April 3, 1998. Med. recs. at Ex. 2, p. 1. On April 11, 1998, eight days later, Mr. Peugh went to Titus Regional Medical Center Emergency Services with the complaint that he could not walk and his legs were numb. Med. recs. at Ex. 4, p. 1. His blood pressure was 140/99. Med. recs. at Ex. 4, p. 2. Dr. Kurt Pflieger wrote that Mr. Peugh, a nurse, was in bed at home and about 1:30 a.m. developed a dull aching pain in both calves following a radiation of this pain with inability to use his toes or to walk. He

could not bear weight on his legs. He had no recent injury, chills, or fever. He had no change in his bowel or bladder. He had no abdominal pain or specific back pain outside of diffuse dull achiness around the sacral region. He has had no other intercurrent illness. He had a friend of his pop his back two or three weeks previously because it was hurting. He has a long history of low back pain and has a cyst in his right upper back. Med. recs. at Ex. 4, p. 4. His neurological examination was normal to pinprick and light touch and he had slightly increased deep tendon reflexes at the knees. His Babinski was equivocal. Dr. Pflieger opined Mr. Peugh had acute paresis of bilateral lower extremities vs. herniated disk vs. mass lesion vs. CVA. Med. recs. at Ex. 4, p. 5. A lumbar spine x-ray showed reverse spondylolisthesis slippage posteriorly of L5 vertebral body in relationship to S1. This misalignment appeared chronic. Med. recs. at Ex. 4, p. 9. He was transferred on April 11, 1998 to Trinity/Mother Francis Health System. Med. recs. at Ex. 4, p. 6.

Dr. Ted Gould at the Emergency Room at Trinity/Mother Francis wrote on April 11, 1998 that Mr. Peugh had acute paresis of his lower extremities. Med. recs. at Ex. 5, p. 2. The history was that Mr. Peugh was well on April 10, 1998 and worked the night before. However, that morning, he began to experience weakness and numbness of his legs and was unable to stand and walk properly. He had some difficulty voiding and Dr. Pflieger thought he had essential cord compression. Mr. Peugh's blood pressure was within normal limits. Med. recs. at Ex. 5, p. 1.

Dr. Susan D. Rountree, a neurologist, wrote the history and physical examination on April 11, 1998. Med. recs. at Ex. 5, p. 3. An MRI of his cervical, thoracic, and lumbar area was basically unremarkable. There were no compressive lesions to account for his descending paralysis. He had a tick bite about four weeks previously at the level of his left waist with no

rash afterwards. He had an upper respiratory infection in January. His blood pressure was 143/93. He had stocking-glove loss to pinprick at midcalf level with paresthesias to the inguinal area. Ankle jerks were absent. Med. recs. at Ex. 5, p. 3. Dr. Rountree's impression was ascending paralysis, probable acute inflammatory demyelinating polyneuropathy or GBS. Med. recs. at Ex. 5, p. 4.

Dr. Charles Gordon, a neurosurgeon, wrote a consulting report on April 11, 1998. Mr. Peugh had a motor vehicle accident several years prior with small thoracic compression fracture. Two weeks prior, he had chiropractic manipulation. Otherwise, he had no previous spinal problems. Med. recs. at Ex. 5, p. 5. Mr. Peugh's blood pressure was 143/93. He was slightly anxious. He had diffuse weakness in both legs. Plain films revealed an old compression fracture at T12 which appeared to be mild. MRI revealed a small T6-T7 disc in the spine. (Med. recs. at Ex. 5, p. 11.) It did not compress the spinal cord. No compressive lesion was seen on the lumbar spine MRI. Dr. Gordon concluded that Mr. Peugh appeared to have some sort of ascending paralysis, possibly GBS. Med. recs. at Ex. 5, p. 5.

Mr. Peugh was discharged from the hospital on April 20, 1998. Dr. Rountree wrote the discharge summary. His diagnosis was acute inflammatory demyelinating polyneuropathy, GBS, and postvaccinal hepatitis B. Med. recs. at Ex. 5, p. 7. A lumbar puncture revealed increased protein at 64. Med. recs. at Ex. 5, p. 8. He was administered human immunoglobulin and improved. Med. recs. at Ex. 5, p. 7. His blood pressure was 130/100. *Id.*

On April 20, 1998, Mr. Peugh was transferred to Columbia Medical Center of McKinney for rehabilitation under the care of Dr. Eduardo G. Acosta. Med. recs. at Ex. 6, p. 1. Mr. Peugh was allowed to go back to work on light duty on May 11, 1998. Med. recs. at Ex. 6, p. 4. From

May 4, 1998 to July 3, 1998, Mr. Peugh had 19 physical therapy visits at Columbia Medical Center of McKinney. Med. recs. at Ex. 6, p. 268. He gained strength and endurance. His major complaint was tingling in the right foot along the lateral border, continued decreased sensation in the lower extremities, and weakness in the lower extremity muscles. *Id.* He used a single tip cane. He was being discharged to Phase II physical therapy as an outpatient. Med. recs. at Ex. 6, p. 270.

On May 13, 1998, Mr. Peugh saw Dr. Rountree. He had a history of progressive numbness and weakness. Initially, he was thought to have a spinal cord lesion or a clonus lesion because he lost bladder-bowel function and could not dorsiflex his legs. However, MRI screens were negative and cerebrospinal fluid (CSF) studies showed minimally elevated protein of 64. A presumptive diagnosis of GBS was made. Electromyography and nerve conduction studies were performed on May 13, 1998 showing a great deal of axonal injury into the L5 through S2 nerve roots with no proximal L2 or L3 involvement. Also, he had a predominantly motor pattern with a normal sural nerve. Med. recs. at Ex. 3, p. 1.

Mr. Peugh's knee jerks were 2/2, but his ankle jerks were absent. He had a dense saddle loss of sensation. He did not have foot drop. Dr. Rountree's impression was that he had an axonal variant of GBS, predominantly caudal involvement of the nerve roots. *Id.* Dr. Rountree commented that Mr. Peugh's GBS occurred after hepatitis B vaccination which has been associated with a GBS-like illness. Med. recs. at Ex. 3, p. 2.

On May 26, 1998, Mr. Peugh saw Dr. Paul Flavill, a neurologist, who noted that his TM was improving. Med. recs. at Ex. 7, p. 7. The aching pain in his legs resolved in three days. Mr. Peugh developed urinary and fecal incontinence while hospitalized at Tyler. He never had any

problems with strength or function in his arms. By history, he has had a couple of motor vehicle accidents, the last four years previously, but no severe injuries. Med. recs. at Ex. 7, p. 19. Dr Plavill thought that with the initial pain and the bowel and bladder dysfunction that, in addition to the demyelinating syndrome, Mr. Peugh might have had an episode of myelitis. Mr. Peugh had restarted hepatitis B vaccination. The possibility of post-vaccination myelitis was certainly present. Med. recs. at Ex. 7, p. 20.

On May 27, 1998, Dr. Rountree wrote to Mr. Peugh that she agreed with Dr. Flavill that Mr. Peugh probably did have TM since the nerve conduction studies they performed did not show demyelination. She stated that both TM and GBS are listed in the Physicians Desk Reference (PDR) as potential complications of hepatitis B vaccination. Med. recs. at Ex. 3, p. 4.

On August 12, 1998, Mr. Peugh saw Dr. Timothy J. Brinkman. Mr. Peugh had a history of TM, including some paralysis of the lower extremities. His blood pressure was 120/74. Med. recs. at Ex. 8, p. 1.

On October 7, 1998, Dr. Flavill wrote a note that Mr. Peugh had TM which developed in April 1998 and was not physically able to resume his full-time working duties. Med. recs. at Ex. 7, p. 21.

On November 3, 1998, Dr. Flavill noted Mr. Peugh's TM continued to improve. Med. recs. at Ex. 7, p. 10. Also on November 3, 1998, Mr. Peugh saw Dr. Brinkman. His blood pressure was 124/84. Med. recs. at Ex. 8, p. 1.

On November 4, 1998, Mr. Peugh saw Dr. Vivian Abrams, a podiatric surgeon, for ingrown toenails that she stated came from poor shoe fitting with the AFOs. Med. recs. at Ex. 8, p. 3.

On March 18, 1999, Mr. Peugh saw Dr. Brinkman. His blood pressure was 110/84. He had some bladder spasm which Dr. Flavill agreed was spasm. Med. recs. at Ex. 8, p. 2.

On July 14, 1999, Mr. Peugh saw Dr. Brinkman. His blood pressure was 140/88. He had pain with urination and continued to have bladder spasm. *Id.*

Dr. Brinkman recommended Mr. Peugh see Dr. Michael B. Gross, a urologist, whom he saw on July 28, 1999. Med. recs. at Ex. 8, p. 8. On August 10, 1999, Mr. Peugh underwent a urodynamics test. His family history was remarkable for hypertension and coronary artery disease. Med. recs. at Ex. 9, p. 6. Besides having urinary problems, Mr. Peugh had problems with constipation. His blood pressure was 144/92. Med. recs. at Ex. 9, p. 7.

On August 18, 1999, Mr. Peugh saw Dr. Gross for follow-up of voiding symptoms with a history of GBS. Med. recs. at Ex. 9, p. 1.

On August 25, 1999, Mr. Peugh saw Dr. Brinkman. His blood pressure was 140/84. He had a urologic procedure and subsequently developed urosepsis and was hospitalized for five days. He had gained some weight due to deconditioning. Med. recs. at Ex. 8, p. 11; Ex. 13, p. 10. His blood pressure was 168/99. Med. recs. at Ex. 13, p. 10.

Mr. Peugh saw Dr. Richard C. Hinton, a neurologist, on September 1, 1999. Med. recs. at Ex. 8, pp. 1, 2. Cerebrovascular accidents and transient ischemic attacks ran in Mr. Peugh's family. Mr. Peugh's last MRI of his spine was in June 1998 and was said to be normal. In rehabilitation, the attending physician thought Mr. Peugh had more of a myelitis than GBS. He was hospitalized recently for cystitis and the pain in his legs returned for a short period of time but resolved with treatment of the cystitis. Mr. Peugh's blood pressure was 128/98. Med. recs. at Ex. 8, p. 2. Dr. Hinton's impression was this was most likely a GBS-like polyradiculopathy

rather than a myelitis or conus infarct. Mr. Peugh clearly has a peripheral problem, confirmed by the normal MRIs. He might have cauda equina involvement with heavy involvement of his sacral roots. His blood pressure was 128/98. Med. recs. at Ex, 8, p. 14.

Mr. Peugh saw Dr. Brinkman on September 7, 1999. Mr. Peugh's blood pressure was 140/74. He was there to have skin tags removed and a wart treated. He was not sleeping as well. He was unable to walk 200 feet due to the TM. Med. recs. at Ex. 25, p. 18.

On September 21, 1999, Mr. Peugh saw Dr. Mitchell Sorsby. His blood pressure was 138/90. He weighed 246 pounds. His triglycerides were 572. Mr. Peugh had hyperlipidemia and adrenal obesity. Med. recs. at Ex. 12, p. 1.

On September 22, 1999, Mr. Peugh saw Dr. Gross. His blood pressure was 150/102. He was 5'7" and weighed 240 pounds. His voiding symptoms had almost complete resolved on medication. Med. recs. at Ex. 9, p. 4.

On January 13, 2000, Mr. Peugh saw Dr. Brinkman. He had hypertriglyceridemia on blood tests done in October 1999. Dr. Sorsby recommended a weight-loss regimen. His blood pressure was 142/90. Med. recs. at Ex. 25, p. 16.

On February 29, 2000, Mr. Peugh went to Baylor Medical Center Emergency Department, complaining of pain radiating to both legs and fever. This started the day before. His blood pressure was 136/91. He weighed 240 pounds and was 5 foot 7 inches tall. Med. recs. at Ex. 26, p. 94.

On March 21, 2000, Mr. Peugh saw Dr. Rajiv Joseph, a neurologist. Med. recs. at Ex. 14, p. 1. Mr. Peugh had an isolated foot drop most likely secondary to L5 radiculopathy. *Id.*

On March 27, 2000, Mr. Peugh had an MRI of his lumbar spine which showed multilevel degenerative disc disease with no evidence of central spinal canal stenosis, disc herniation, or neural impingement. He had mild L4-L5 and L5-S1 degenerative facet arthropathy. Med. recs. at Ex. 24, pp. 24, 25.

On March 31, 2000, Mr. Peugh had an EMG and nerve conduction studies which Dr. Joseph interpreted as showing bilateral L5-S1 radiculopathy, severe on both sides, worse on the right, with chronic denervation. Med. recs. at Ex. 24, p. 17. Dr. Joseph was concerned about lumbar polyradiculopathy. *Id.*

On May 8, 2000, Mr. Peugh saw Dr. Joseph. Mr. Peugh's blood pressure was 150/106. His heart sounds were normal. EMG of the lower limbs showed chronic bilateral L5-S1 radiculopathy, worse on the right. MRI of the LS spine showed mild L4-L5 and L5-S1 degenerative disease. MRI of the thoracic spine showed a small disc bulge at T5-T6. Med. recs. at Ex. 14, p. 2. Dr. Joseph advised Mr. Peugh to see Dr. Brinkman for his hypertension. *Id.*

On August 29, 2000, Mr. Peugh saw Dr. Joseph. Mr. Peugh's blood pressure was 130/84. An MRI of the brain was unremarkable except for a prominent pituitary fossa. MRI of the cervical spine was also unremarkable. Med. recs. at Ex. 14, p. 3.

On September 5, 2000, Mr. Peugh saw Dr. Brinkman. He had hyperprolactinemia, chronic leg pains, and neuralgia. His blood pressure was 134/84. Med. recs. at Ex. 25, p. 12.

On September 14, 2000, Mr. Peugh had an MRI of his brain which showed a pituitary tumor in the left portion of his pituitary gland. Med. recs. at Ex. 24, p. 12. On September 22, 2000, Mr. Peugh saw Dr. Joseph. He had a pituitary adenoma. Med. recs. at Ex. 25, p. 4.

On September 20, 2000, Mr. Peugh saw Dr. Sorsby. His blood pressure was 150/90. His weight was 271 pounds, which was 25 pounds higher than one year before. Med. recs. at Ex. 27, p. 52.

On September 25, 2000, Mr. Peugh saw Dr. Brinkman for an old sebaceous cyst. His blood pressure was 150/88. He weighed 271 pounds. Med. recs. at Ex. 25, p. 11.

On October 20, 2000, Mr. Peugh saw Dr. Ayaz H. Malik for a pituitary neoplasm. Med. recs. at Ex. 27, pp. 6, 7. Both grandparents had heart disease and hypertension, and his mother had hypertension. Med. recs. at Ex. 27, p. 8.

On November 2, 2000, Mr. Peugh saw Dr. J. Robert Wyatt about his pituitary adenoma. He had significant weight gain. Med. recs. at Ex. 27, p. 58.

On November 14, 2000, Mr. Peugh was admitted to Baylor Medical Center for a transsphenoidal hypophysectomy for a prolactin-secreting adenoma and evidence of hypopituitarism. Med. recs. at Ex. 26, p. 5. Mr. Peugh's blood pressure on November 14, 2000 was 127/70. Med. recs. at Ex. 26, p. 22. It was also 150/83 on November 14, 2000 at 6:10 a.m. Med. recs. at Ex. 26, p. 23. After the operation on November 14, 2000, Mr. Peugh's blood pressure was 155/83 (at 1:54 p.m.), 150/84 (at 2:00 p.m.), 151/87 (at 2:10 p.m.), 163/89 (at 2:25 p.m.), and 159/86 (at 2:40 p.m.). Med. recs. at Ex. 26, p. 25. He was discharged on November 16, 2000. Med. recs. at Ex. 26, p. 9.

On January 11, 2001, Mr. Peugh saw Dr. Brinkman for a referral for new orthotics. His pituitary adenoma had been removed in December. His blood pressure was 134/78. Med. recs. at Ex. 25, p. 8.

On January 30, 2001, Mr. Peugh saw Dr. David M. Feinstein. Med. recs. at Ex. 30, p. 3. Mr. Peugh weighed 272 pounds. His blood pressure was 160/90. Med. recs. at Ex. 30, p. 5.

On June 26, 2001, Mr. Peugh saw Dr. Brinkman with a lot of nausea and vomiting. It happened occasionally two to three hours after he had eaten. His blood pressure was 138/78. Med. recs. at Ex. 25, p. 7.

On July 23, 2001, Mr. Peugh saw Dr. Brian C. Procter for periodic gastrointestinal upset and reflux. His blood pressure was 130/86 and he weighed 238 pounds. Med. recs. at Ex. 21, p. 23.

On August 17, 2001, Mr. Peugh had Dr. Procter remove warts, keratosis, and a skin tag. Med. recs. at Ex. 21, p. 18. His blood pressure was 136/84. Med recs. at Ex. 21, p. 21.

On January 18, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 148/60. Med. recs. at Ex. 21, p. 17. He had chronic neuralgia and depression. *Id.*

On March 28, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 142/88. Med. recs. at Ex. 21, p. 16.

On June 5, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 152/84. Med. recs. at Ex. 21, p. 14.

On June 13, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 152/94. Med. recs. at Ex. 21, p. 13.

On October 11, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 128/84. Med. recs. at Ex. 21, p. 12. He had nightly left shoulder and back pain intermittently for two weeks. *Id.* He weighed 214 pounds and was five foot seven and one-half inches tall. *Id.*

On October 25, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 124/78. He had left foot pain. Med. recs. at Ex. 21, p. 11.

On October 28, 2002, Mr. Peugh saw Dr. Abrams. Med. recs. at Ex. 22, p. 3. He had a possible lipoma of his left heel. He admitted a family history of arthritis, cancer, diabetes, foot problems, heart attack, and hypertension. *Id.*

On November 27, 2002, Mr. Peugh saw Dr. Procter. His blood pressure was 120/88. Med. recs. at Ex. 21, p. 10.

On February 14, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 148/90. Med. recs. at Ex. 21, p. 9.

On April 8, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 136/88. Med. recs. at Ex. 21, p. 8. He had malaise and myalgia. *Id.*

On April 15, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 140/80. Med. recs. at Ex. 21, p. 7. He had chronic neuralgia, peripheral neuropathy, gastroesophageal reflux, and depression. *Id.*

On August 15, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 128/92. Med. recs at Ex. 21, p. 5. He had insomnia, back pain, and depression. *Id.*

On September 4, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 140/84. Med. recs. at Ex. 21, p. 4. He had muscle spasms up his back and left shoulder. *Id.*

Also on September 4, 2003, Mr. Peugh saw Dr. Joseph, with chronic feet weakness and lumbar polyradiculopathy. He wore bilateral AFO braces to ambulate. He had chronic low back pain and foot pain. He slept poorly. His left arm was painful. His blood pressure was 140/98.

Med. recs. at Ex. 24, p. 1. Dr. Joseph suspected the lumbar polyradiculopathy was secondary to GBS. *Id.*

On October 22, 2003, Mr. Peugh saw Dr. Procter. His blood pressure was 158/98. Med. recs. at Ex. 21, p. 3. He had a left foot recurrent abscess and urinary retention. *Id.*

On January 23, 2004, Mr. Peugh saw Dr. Procter. His blood pressure was 114/78. Med. recs. at Ex. 34, p. 3.

On January 29, 2004, Mr. Peugh saw Dr. Procter. His blood pressure was 140/58. Med. recs. at Ex. 34, p. 2.

On June 10, 2004, Mr. Peugh saw Dr. Procter. Med. recs. at Ex. 47, p. 1. His blood pressure was 124/68 and he weighed 210 pounds. *Id.* He had an increase in bladder spasms and urge incontinence. His peripheral neuropathy was worse. *Id.*

On November 18, 2004, Mr. Peugh saw Dr. Procter. Med. recs. at Ex. 47, p. 2. His bladder was still bothering him and his blood pressure was up and down. *Id.* His blood pressure was 154/108. Med. recs. at Ex. 47, p. 3. He was not overweight. Dr. Procter diagnosed Mr. Peugh was essential hypertension and chronic major depression. Med. recs. at Ex. 47, pp. 3-4.

On January 26, 2005, Mr. Peugh saw Dr. Procter. Med. recs. at Ex. 47, p. 10. He had an achy sore throat, headache, low fever, and almost fainted twice. *Id.* His blood pressure was 92/50. Med. recs. at Ex. 47, p. 11.

On March 20, 2005, Mr. Peugh went to the Presbyterian Hospital of Winnsboro Emergency Department at 1:25 a.m. with ascending paralysis from his feet. Med. recs. at Ex. 43, p. 2. He was transferred to East Texas Medical Center (ETMC). Med. recs. at Ex. 44, p. 263. His blood pressure on March 20, 2005 was 119/86. Med. recs. at Ex. 44, p. 256.

The history and physical Dr. Robert L. Boyne, a neurologist, wrote on March 20, 2005 included blood pressure of 130/80. Med. recs. at Ex. 44, p. 165. It was unclear if Mr. Peugh were experiencing an exacerbation of old symptoms because he fell asleep in an odd position or if his TM had returned. Med. recs. at Ex. 44, p. 166.

On March 20, 2005, Dr. Kurt S. Reuland interpreted an MRI of Mr. Peugh's thoracic spine as having spondylosis with small disc protrusions at multiple levels but no significant canal or foraminal stenosis. Med. recs. at Ex. 44, p. 186.

On March 21, 2005, Dr. Reuland interpreted an MRI of Mr. Peugh's lumbar spine as showing disc degeneration with mild disc protrusion at L1-L2, but no canal or foraminal stenosis. Otherwise, the lumbar spine was normal. Med. recs. at Ex. 44, p. 188.

On March 21, 2005, Dr. Reuland interpreted an MRI of Mr. Peugh's head as negative except for mild sinusitis. Med. recs. at Ex. 44, p. 187.

On March 24, 2005, his blood pressure was 140/74 at 8:00 a.m. and 161/96 at noon. Med. recs. at Ex. 44, p. 224. Also on that day, his blood pressure was 157/69 and 161/96. Med. recs. at Ex. 44, p. 179. He was discharged on March 24, 2005. Med. recs. at Ex. 44, p. 267. Dr. Boyne noted on the discharge summary that Mr. Peugh's strength, sensation, pain, and gait improved in the hospital. Med. recs. at Ex. 44, p. 162.

On April 1, 2005, Mr. Peugh saw Dr. Procter. Med. recs. at Ex. 47, p. 21. His blood pressure was 108/60. Med. recs. at Ex. 47, p. 22. Mr. Peugh felt tired and had pharyngitis, acute TM, chronic major depression, and generalized anxiety disorder. *Id.*

On April 7, 2005, Mr. Peugh saw Dr. Charles T. Dickson, Jr., a urologist. Med. recs. at Ex. 46, p. 6. Dr. Dickson strongly suspected Mr. Peugh had a neurogenic bladder. *Id.*

On April 25, 2005, Mr. Peugh saw Dr. Dickson. Med. recs. at Ex. 45, p. 60. He had neurogenic bladder with the exact type unclear. *Id.*

On April 27, 2005, Mr. Peugh saw Dr. Boyne. Med. recs. at Ex. 45, p. 77. In March, Mr. Peugh had significant weakness in his distal lower extremities. Dr. Boyne thought he had probable TM of the conus with residual distal lower extremity weakness greater than proximal, right distal lower extremity sensory deficits, and significant bowel and bladder dysfunction with the use of intermittent catheterization. *Id.*

On June 8, 2005, he had a 36-hour history of increased temperatures with increased lower extremity numbness. Med. recs. at Ex. 44, p. 6. Also on June 8, 2005, Mr. Peugh had an MRI of his thoracic spine. Dr. Stephen Armstrong found no definite acute abnormality. Med. recs. at Ex. 45, p. 18. He was admitted to ETMC because of TM exacerbation. Med. recs. at Ex. 45, p. 80.

Mr. Peugh had a fall on the floor. Med. recs. at Ex. 44, p. 95. An MRI of the thoracic spine was normal to Dr. Stephen Armstrong. Med. recs. at Ex. 33, p. 64. He was discharged on June 11, 2005. Med. recs. at Ex. 45, p. 90. Mr. Peugh's blood pressure was 145/85, 132/79, 143/93, 139/69, 129/76, 163/107, 137/77, 150/77, 130/51, 117/66, 150/74, 153/92, and 148/89 from June 9 - 11, 2005. Med. recs. at Ex. 44, p. 54. On June 12 and 13, 2005, his blood pressure was 164/98, 177/99, 159/97, 159/81, 166/103, 167/99, and 166/92. Med. recs. at Ex. 44, p. 52. Dr. Paul J. Lim noted blood pressure of 129/76 on June 9, 2005, and 117/66 on June 10, 2005. Med. recs. at Ex. 44, pp. 41, 42. Dr. Alexandra Kisson-Detweiner noted blood pressure of 153/92 on June 11, 2005. Med. recs. at Ex. 44, p. 39. Dr. Lim noted blood pressure of 166/92 on June 13. 2005. Med. recs. at Ex. 44, p. 29.

Dr. Lim wrote an internal medicine consultation on June 9, 2005. Med. recs. at Ex. 44, pp. 11-15. Mr. Peugh had a recent viral infection. Med. recs. at Ex. 44, p. 11. He had low extremity weakness due to exacerbation of TM. Med. recs. at Ex. 44, p. 13. Mr. Peugh's blood pressure was 132/79. *Id.* He had a chronic neurogenic bladder. Med. recs. at Ex. 44, p. 15.

On June 15, 2005, Mr. Peugh went to Hopkins County Memorial Hospital with pneumonia. Med. recs. at Ex. 48, p. 3. Dr. Darren J. Arnecke found a blood pressure of 118/64. Med. recs. at Ex. 48, p. 4. Dr. Arnecke diagnosed Mr. Peugh with TM with significant neurologic deficit, including bowel and bladder compromise and weakness. *Id.*

Mr. Peugh was discharged on June 17, 2005. Med. recs. at Ex. 48, p. 6.

On July 1, 2005, Mr. Peugh saw Dr. Procter. Med. recs. at Ex. 47, p. 47. His blood pressure was 152/84 and he weighed 219 pounds. Med. recs. at Ex. 47, p. 28. He had generalized osteoarthritis, acute TM, and GBS. *Id.* However, the review of symptoms showed Mr. Peugh had normal sensory and motor examination, his deep tendon reflexes were normal, and he had normal gait and stance. *Id.*

On July 11, 2005, Mr. Peugh saw Dr. Stella Hecker, an endocrinologist. Med. recs. at Ex. 45, pp. 40-44. He had muscle atrophy of the lower extremities and pan hypopituitarism. Med. recs. at Ex. 45, p. 43. His blood pressure was 112/64 and he weighed 216 pounds. *Id.*

Mr. Peugh died on July 26, 2005. The death certificate gives as the immediate cause of death hypertensive cardiovascular disease. Other conditions listed which, however, did not result in the underlying cause of death were transverse myelitis and chronic pain. P. Ex. 36.

The autopsy states that Mr. Peugh's heart showed concentric left ventricular hypertrophy. P. Ex. 37, p. 2. The conclusion of Dr. Amy Gruszecki, Medical Examiner, was that Mr. Peugh

died as a result of hypertensive cardiovascular disease. Multiple drugs were detected in postmortem blood in near-therapeutic levels. Dr. Gruszecki stated that the role of these drugs in contributing to Mr. Peugh's death was unclear. P. Ex. 37, p. 5.

TESTIMONY

At the Omnibus proceeding, held in 2004 before Mr. Peugh's death, Dr. Carlo Tornatore, a neurologist, testified for petitioner that Mr. Peugh's case reminded him of the Sindern case report[2] because the 36-year-old man in that case report developed an inflammatory polyradiculoneuropathy similar to GBS nine days after receiving his fourth hepatitis B vaccine and his illness included inflammation of his spinal cord. Mr. Peugh, at the age of 24, received his fourth hepatitis B vaccination and, eight days later, also had a GBS-like illness which included inflammation of his spinal cord. Tr. at 532.

Dr. Tornatore said that typically the spinal cord is not involved in GBS. People who have the natural infection of hepatitis B can get GBS. Tr. at 533. The same protein that is in the vaccine is in the wild virus and can cause GBS, referring to the Sindern case report.[3] *Id.* Dr.

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[2] "Inflammatory polyradiculoneuropathy with spinal cord involvement and let[h]al outcome after hepatitis B vaccination," by E. Sindern, et al., 186 *J Neurological Sci* 81-85 (2001). P. Ex. 23, p. 37. The authors state that a causal relationship between the recombinant hepatitis B vaccination and the inflammatory polyradiculoneuropathy appears strongly supported by the close temporal relationship between vaccination and onset of symptoms, the strong increase of hepatitis B surface antibodies within three weeks after vaccination, and the immune-mediated nature of this manifestation. Other etiologies were excluded. P. Ex. 23, p. 41.

[3] Sindern and his co-authors mention this point as well in their case report, describing the deposition of immune complexes consisting of hepatitis B surface antigen, anti-hepatitis B surface antigen, and complement, which participate in the pathogenesis of arthritis, uveitis, glomerulonephritis, and GBS after the hepatitis B viral infection. They analogized the process from the wild virus to the effect of the hepatitis B vaccine, i.e., it may also induce the formation of soluble antigen-antibody complexes, initiating clinical disease. P. Ex. 23, p. 41.

Tornatore stated the temporal relationship made sense in terms of causation. *Id.* Based on the temporal relationship, biological plausibility, and the Sindern case report, he viewed Mr. Peugh's hepatitis B vaccination as the cause of his GBS with spinal cord inflammation. Tr. at 534. Attempts were made to rule out other etiologies for Mr. Peugh's GBS. *Id.* Mr. Peugh would not have developed GBS if it had not been for the hepatitis B vaccination. Tr. at 535.

Mr. Peugh's GBS was axonal which is severe, and those with the axonal form of GBS do not recover nearly as well because the nerve itself is lost as opposed to just losing the myelin or insulation. Tr. at 537.

Dr. Thomas P. Leist, a neurologist, testified for respondent. Tr. at 704. Mr. Peugh had a history of low back injury and he reached a full presentation within a very short period of time after his friend did a chiropractor movement on him. Tr. at 709. He did not have real ascension of symptoms. His elevated protein in the cerebrospinal fluid was only slightly above normal. *Id.* Dr. Leist thinks that Mr. Peugh had an anterior spinal cord infarct rather than GBS. Tr. at 710. It was a symmetrical injury predominantly in the anterior spinal cord. Tr. at 710-11. Mr. Peugh's maximum presence was within hours rather than within several days as one would expect in GBS. Tr. at 711. The electromyography findings indicated that Mr. Peugh had a motor neuron disease affecting areas of the spinal cord. Tr. at 712. Mr. Peugh had two motor vehicle accidents, previous sports injuries, and a friend cracked his neck leading Dr. Leist to conclude that Mr. Peugh had an anterior cord infarct. Tr. at 714-15. He is not comfortable with a diagnosis of GBS. Mr. Peugh had a central nervous system problem, not a peripheral nervous system problem. Tr. at 715. Dr. Leist analogized Mr. Peugh's problem to a stroke in his spine. Tr. at 717.

Dr. Leist admitted on cross-examination that there is an axonal variant of GBS. Tr. at 718. Dr. Leist disagreed with Mr. Peugh's discharge diagnosis that he had acute inflammatory demyelinating polyneuropathy, GBS, due to post-vaccinal hepatitis B. Tr. at 720. Dr. Rountree, a neurologist, wrote that Mr. Peugh had an axonal variant of GBS with involvement of the nerve roots, and Dr. Leist disagreed with her diagnosis. Tr. at 722. The EMG Dr. Rountree did showed axonal loss in the L5/S1 or S2 area. Tr. at 723. In severe cases of GBS, one can have axonal degeneration in addition to segmental demyelination. Tr. at 754.

On rebuttal, Dr. Tornatore testified that the MRI done on Mr. Peugh dated May 21, 1998, several weeks after hospitalization, showed there was no obvious abnormality to the conus or the cauda equina of the spinal cord, which is the very area to which Dr. Leist referred in opining that Mr. Peugh had a spinal cord infarct. Tr. at 815-16. This MRI clearly demonstrated that this part of the spinal cord was normal and there was no evidence for a spinal cord infarction. Tr. at 816. Mr. Peugh's EMG results were typical of someone with GBS and would never be seen in someone with spinal cord injury. *Id.*

Dr. Tornatore stated that Mr. Peugh had demyelination of the peripheral nerve which one would never see in spinal cord infarction. Tr. at 817. The MRI would have shown some areas of high signal if Mr. Peugh had a bona fide infarct to his spinal cord. *Id.*

On January 30, 2007, the undersigned held a hearing on whether Mr. Peugh's vaccine injury led to his death. (Citations to this transcript are not citations to the Omnibus transcript.) Dr. Carlo Tornatore testified for petitioner. Tr. at 5. He is an associate professor of neurology and is board-certified in neurology. Tr. at 6. He is the director of the MS Clinic and the related autoimmune disorders clinic at Georgetown. Tr. at 6. Dr. Tornatore has seen patients with GBS,

transverse myelitis, and other autoimmune disorders. Tr. at 6,7. He has also published articles regarding demyelinating disorders and viral-mediated disorders. Tr. at 6.

According to Dr. Tornatore, Justin's immediate cause of death was hypertensive cardiovascular disease. Tr. at 7. The autopsy report concludes the same. Tr. at 10. Dr. Tornatore noted from reviewing the autopsy report that there were no signs of a heart attack, no clot in the heart, no coronary artery disease, and no problems with the kidneys that would have contributed to cardiovascular problems. Tr. at 9-10. Instead, Dr. Tornatore attributed Justin's hypertension to his problems with GBS over the course of seven years. Tr. at 11. Specifically, Dr. Tornatore believes that the GBS caused an autonomic problem which resulted in a change in Justin's blood pressure or heart rate and Justin's ultimate death. Tr. at 40.

Prior to his hepatitis vaccination, Justin's blood pressure was relatively normal although a little bit on the high side. Tr. at 12. After the onset of symptoms of GBS, Justin's blood pressure became elevated. Tr. at 13-14. Dr. Tornatore attributes Justin's high blood pressure and heart rate to an autonomic insufficiency typical of somebody who has GBS. Tr. at 15-16. He cited petitioner's Exhibit 53, Gareth Parry's chapter of GBS[4] which states that GBS can cause autonomic changes that affect the blood pressure and heart rate which in turn can result in death. Tr. at 18. Additionally, because the bladder is mediated by the autonomic nervous system, Justin's urinary problems showed that Justin was left with residual damage to the autonomic nervous system. Tr. at 19. Finally, Justin had sensory and motor loss due to the GBS resulting in decreased mobility which in turn affected cardiovascular tone. Tr. at 20.

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[4] *Guillain-Barre Syndrome* (1993), Tab A, p. 15, Table 2-4.

Dr. Tornatore testified that the two hospital admissions prior to Justin's death show that his death was caused by hypertension resulting from his GBS. In March 2005, Justin was admitted to the hospital to be treated for a relapse of his GBS. Tr. at 22. He had another relapse on June 9, 2005 and was again admitted to the hospital. *Id*. According to the medical records, during the March visit, Justin's blood pressure and heart rate were fluctuating tremendously. Tr. at 22-23. Dr. Tornatore testified that this was a sign of autonomic instability. Tr. at 26. The medical record also states that, "the patient was left with a nonfunctioning bladder and possible megacolon." Tr. at 24. According to Dr. Tornatore, the nonfunctioning bladder and megacolon show that there was significant autonomic involvement because the colon and the bladder are controlled by the autonomic nervous system. *Id*. Both the bladder and colon problems were sequela of his axonal variant of GBS. Tr. at 24-25. Further signs of autonomic instability were that Justin's blood pressure and heart rate fluctuated a great deal during the June hospitalization. Tr. at 26.

Dr. Tornatore testified that Justin was on a number of medications that can affect the heart rate. These were Levbid, Ditropan, and Elavil. Tr. at 28. These have direct effects on the autonomic nervous system and can make the heart race. *Id*. They can also cause hypertension and hypotension, depending on the person. Tr. at 29. These medications were given to treat Justin's bladder problems and his depression, which were caused by the GBS, which was caused by the vaccine. Tr. at 29-31.

A chapter by Dr. Barry Arnason in *Peripheral Neuropathy*, 3d ed. (1993), P Ex. 53, Tab B, p. 1464, on acute inflammatory demyelinating polyradiculoneuropathy (AIDP) states that "the impairment of autonomic function in GBS or AIDP was temporary, returning to normal levels

over 3 to 18 months." Tr. at 31, 32. Thus, respondent's expert Dr. Winkler concluded that GBS "cannot be implicated in the death of a patient over seven years after the acute illness." Tr. at 32. In response, Dr. Tornatore explained that Justin's case was not typical in that he had multiple relapses. Significantly, Justin had ongoing bladder problems and megacolon which revealed that he had ongoing autonomic issues. Tr. at 32.

Respondent's expert Dr. Winkler also stated in his report that there were other factors that could have contributed to Justin's autonomic problems, specifically panhypopituitarism following surgery for Justin's tumor of the pituitary gland. Tr. at 33. Dr. Tornatore testified that Justin's labile blood pressure and heart rate were not caused by panhypopituitarism because the pituitary gland is endocrine-related, not nervous system-related. Tr. at 33, 34. Additionally panhypopituitarism does not cause problems with bladder and megacolon. Tr. at 34.

In response to Dr. Winkler's assertion that Justin's depression and anxiety were related to his family history, Dr. Tornatore testified that regardless of family history, Justin's physical disabilities contributed to his depression. *Id*. In fact, Justin saw several psychiatrists and counselors who stated that his depression was a reaction to his GBS and physical disabilities. Tr. at 34-35.

Dr. Tornatore also addressed whether Justin's death was associated with his obesity. Tr. at 36. Admittedly, Justin was obese, but his obesity was not the primary cause of his death. *Id*. Further, while Justin was heavy to begin with, his weight increased dramatically, partly due to inactivity secondary to his disability. *Id*.

Finally, Dr. Tornatore testified that the medications Justin was taking could have contributed to causing his blood pressure to fluctuate. Tr. at 36. All of the drugs he was taking,

with very few exceptions, were being used to treat sequelae of the GBS. Tr. at 37. The drugs contributed to the death because he was taking them to treat symptoms of GBS. *Id*.

Dr. Gerald Winkler testified for respondent. Dr. Winkler is a neurologist who is board-certified in neurology. Tr. at 43-44. He has taken care of patients with GBS. Tr. at 44. He is an assistant clinical professor of neurology at Harvard Medical School. *Id*. Dr. Winkler reviewed the medical records and Dr. Tornatore's opinion and related medical literature. *Id*.

Dr. Winkler testified that Justin had a tumor of the pituitary gland. Tr. at 45-46. This not only impaired his visual field, but secreted prolactin, a hormone which in excess is associated with depression. *Id*. Justin had surgery for this condition and thereafter took medication to deal with his pituitary issues. Tr. at 46. Justin also had thyroid problems associated with the diseased pituitary gland. Tr. at 48. According to Dr. Winkler, if someone had an underactive thyroid, his blood pressure could rise or drop depending on the magnitude of the pituitary problem. Tr. at 47. However, Justin was on Synthroid, a replacement thyroid hormone which should have controlled the problem. Admittedly, Dr. Winkler did not believe that this thyroid problem was relevant to Justin's death. *Id*.

Dr. Winkler went on to testify that the autonomic effects of GBS such as an abnormal heart rate are confined to acute illness and do not persist beyond 18 months except in relapse cases. Instead, Dr. Winkler attributed the abnormal heart rate to the medications Justin was taking. Specifically, Dr. Winkler noted that Oxycodone was found in Justin's blood at autopsy. The amount was .31 milligrams per liter and the toxic level is .2 milligrams per liter. Tr. at 50. The other medications Justin was taking, according to Dr. Winkler, would have added to the

effect of the Oxycodone. *Id*. Thus, the drop in Justin's blood pressure was due to the level of medication in Justin's body at the time of his demise. *Id*.

Dr. Winkler further disputed that Justin's March 19, 2005 hospital admission was due to a relapse of GBS even though the medical records specifically characterize it as such. Instead, Dr. Winkler believed that the hospitalization was due to the combined effect of sedatives Justin was taking. Tr. at 51, 52. The circumstances that led to the March hospital admission were that Justin fell asleep on the bathroom floor and later experienced weakness in his legs. *Id*. Dr. Winkler believed that Justin was not asleep, but in a sedated condition. Tr. at 51. The later weakness that Justin experienced in his legs was attributable to gluteal compartment syndrome, a condition in which the muscles undergo breakdown with marked swelling due to not shifting one's position while seated because of paralysis or sedation. Tr. at 52, 53. When asked about the duration of being asleep on the floor, Dr. Winkler said Justin was asleep for more than an hour, but gave no basis for that. On cross-examination, Dr. Winkler admitted that the records in fact stated that Justin was asleep for one hour. Dr. Winkler further agreed that for gluteal compartment syndrome to develop, it would take four to ten hours. Tr. at 70-71.

Dr. Winkler also denied that the second hospital admission was due to a relapse of GBS. Tr. at 53. Instead, Dr. Winkler testified that Justin had a febrile illness which caused his peripheral nervous system to function less well. Tr. at 52-53.

Dr. Winkler disputed the autopsy report which stated that the cause of death was hypertension. Tr. at 55. Dr. Winkler testified that Justin's cause of death was most likely hypotension due to the quantity of medication Justin had been taking for pain and depression. *Id*. In sum, Dr. Winkler's theory was that the cumulative effect of the narcotic pain medication and

the sedatives for his depression was to depress the blood pressure to the extent that he died. Tr. at 59. Dr. Winkler disputed that Justin was taking pain medication due to pain associated with GBS. Instead, Dr. Winkler believed it was due to a pre-existing lower back pain. According to Dr. Winkler, Justin had a long history of low back pain dating back to 1998. Tr. at 54. Further, Dr. Winkler testified that acute pain is a part of the acute phase of GBS rather than the chronic form of the disease. Tr. at 55. On cross-examination, however, Dr. Winkler admitted that there was nothing in the medical records to indicate that Justin had ever required narcotic medications for his low back pain prior to the onset of GBS. Tr. at 62.

Dr. Winkler attributed Justin's bladder problems and megacolon to the pain medication rather than Justin's GBS and resulting autonomic instability. Dr. Winkler testified that the medications caused constipation which distended the colon resulting in the megacolon. Tr. at 58. The medications also caused the bladder problems because a side effect of narcotic and sedative medications is urinary retention. *Id*. Dr. Winkler did admit that the bladder problems were at least in part caused by the GBS. *Id*.

Dr. Winkler testified that, in addition to the medication to treat pain, Justin was taking sedative medication to treat his depression for which he had a family history. Tr. at 59. He conceded, however, that GBS would significantly aggravate his pre-existing depression. Tr. at 60-61. Further, on cross-examination, Dr. Winkler admitted there was nothing in the medical records that showed Justin had a history of depression prior to the onset of GBS. Tr. at 63.

Dr. Winkler next testified that after the first episode of GBS, Justin's ability to walk was affected and he experienced bowel, bladder, and sexual dysfunction. Tr. at 64. After the first episode, Justin's bowel, bladder, and sexual dysfunction never returned to normal, and he

continued to suffer problems with them until his March 2005 readmission. Tr. at 64, 65. Dr. Winkler agreed that based on these symptoms, Justin had chronic bladder dysfunction. Tr. at 66. Dr. Winkler, however, would not agree that the bladder dysfunction was necessarily an indication of a dysfunction of the autonomic nervous system, stating instead that it could be related to the voluntary nerves. Tr. at 67, 68. When questioned whether Justin's loss of bladder function could be associated with compartment syndrome, Dr. Winkler stated that it would have nothing to do with compartment syndrome, but was due to the high doses of pain medication. Tr. at 76.

Dr. Winkler agreed that GBS left Justin with impaired bladder function. Tr. at 77. He also agreed that petitioner had pain. Tr. at 78. Dr. Winkler said it was possible that Justin's not recovering from GBS depressed him, but it is also true that steroids can cause depression. Justin was put on steroids when he was hospitalized for exacerbation of his GBS. Tr. at 79. There may have been a medication dependence from taking medication for a long time. Tr. at 82. Dr. Winkler thought it fair to say that some people in the face of not recovering from GBS and who have pain in their lower extremities and an inability to move their bladder would be depressed. Tr. at 80-81. He admitted, however, that if Justin were taking medications to reduce pain and depression because of his failure to recover from GBS, then his death was GBS-related. Tr. at 82.

Other Submitted Material

Attached to respondent's reply to petitioner's post-hearing brief as tab 1, filed December 9, 2005, after the Omnibus hearing, was a report from Dr. Leist. On autopsy, Mr. Peugh's spinal cord was not examined. After Mr. Peugh was hospitalized subsequent to a motor vehicle accident in February 1992, he had an increased creatinine level of 1.6. Dr. Leist states that

increased creatinine levels can indicate renal injury as a consequence of hypertension. Mr. Peugh's blood pressure on April 11, 1998 was 140/99. He had hypertensive cardiovascular disease. Mr. Peugh's symptoms progressed over two to two and one-half hours to their maximum on April 11, 1998, and Dr. Pflieger opined a vascular event was the cause of Mr. Peugh's presentation on that date. Dr. Leist states that the results of Mr. Peugh's lumbar puncture and EMG support a conclusion of destructive anterior cord process. He had a history of trauma to his lower spine and known L5-S1 subluxation and had undergone chiropractic maneuver to remedy low back pain in the weeks prior to his leg weakness onset. Dr. Leist concludes that, based on the clinical, laboratory, and EMG data, Mr. Peugh had a sustained spinal cord infarct unrelated to the administration of hepatitis B vaccine. The findings on autopsy further confirm the presence of hypertensive cardiovascular disease suggested by findings in February 1992 and April 1994. Hypertension, collagen vascular diseases, hypercholesterolemia, and trauma are co-morbid conditions reported in individuals presenting with spinal cord infarcts and were present in Mr. Peugh. Tab 1, pp. 1-2.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must offer "(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[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Close calls are to be resolved in favor of petitioners. Capizzano, supra, at 1327; Althen, supra, at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, Justin would not have had GBS and died, but also that the vaccine was a substantial factor in bringing about his GBS and death. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, supra, 418 F.3d at 1278; Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

The Federal Circuit stated in Althen, supra, at 1280, that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."

The Federal Circuit in Capizzano emphasized the opinions of petitioner's four treating doctors in that case. 440 F.3d at 1326.

Having reviewed all the medical records, the Sindern case report, and the testimony of Dr. Tornatore and Dr. Leist, the undersigned held in her Order of April 21, 2006 that Mr. Peugh had GBS with inflammation of his spinal cord (interpreted numerous times as TM) and that the cause of his GBS with central nervous system involvement was hepatitis B vaccine. There are numerous MRIs in the medical records which consistently show that Mr. Peugh's spinal cord did not have any lesions. Dr. Tornatore's testimony that, had Mr. Peugh had a spinal cord infarct, an MRI would have shown it seems far more credible than Dr. Leist's explanation that the area of the spine involved was at the end of the range of the MRI and was not examined properly.

It is hard to credit Mr. Peugh's two prior motor vehicle accidents in 1992 and 1994 with his neurologic symptomatology in 1998. He was persistently evaluated for serious injury after

his motor vehicle accidents, but he recovered without permanent damage to his spinal cord. Eight days after his fourth hepatitis B vaccination, on April 11, 1998, Mr. Peugh had stocking-glove loss to pinprick at midcalf level with paresthesias to the inguinal area with absent ankle jerks. MRIs of his cervical, thoracic, and lumbar spines were normal. The appropriate diagnosis, GBS, was made.

Initially, he was thought to have a spinal cord lesion or a clonus lesion because he lost bladder-bowel function at the second hospital to which he went (Trinity/Mother Francis) and could not dorsiflex his legs. However, MRI screens were negative and cerebrospinal fluid studies showed minimally elevated protein of 64. Medical personnel therefore evaluated difficulty in the clonus area, the same area where Dr. Leist said Mr. Peugh had an infarction, and discounted it as a cause. Dr. Rountree's impression was that Mr. Peugh had an axonal variant of GBS, predominantly caudal involvement of the nerve roots.

Dr. Rountree and Dr. Flavill, both neurologists, considered hepatitis B vaccine as the likely cause of Mr. Peugh's axonal variant of GBS with spinal cord involvement. The Federal Circuit in Capizzano, supra, at 1326, stated that it is error not to consider the opinions of the treating physicians who conclude that hepatitis B vaccine is the cause of petitioner's injury.

Dr. Leist's diagnosis of Mr. Peugh as having a spinal cord infarct or stroke due to his past motor vehicle accidents in 1992 and 1994 is not credible in light of the numerous examinations of Mr. Peugh after those accidents, including MRIs, with the total absence of any bowel or bladder symptomatology until eight days after his fourth hepatitis B vaccination. Of importance is the fact that Mr. Peugh's initial neurologic symptomatology of numbness and weakness did not include bowel and bladder symptomatology. At Titus Regional Medical Center on April 11,

1998, Mr. Peugh did not have anything abnormal with his bowel and bladder. Dr. Kurt Pflieger wrote that Mr. Peugh, a nurse, was in bed at home and about 1:30 a.m. developed a dull aching pain in both calves following a radiation of this pain with inability to use his toes or to walk. He could not bear weight on his legs. He had no recent injury, chills, or fever. He had no change in his bowel or bladder.

He was transferred to Trinity/Mother Francis. Only after his GBS had begun did Mr. Peugh experience what many doctors diagnosed as TM (the involvement of his bowel and bladder in his neurologic difficulties). This shows a neurologic disease in progress, not a residuum of an old trauma. Dr. Leist never explained all the other symptoms Mr. Peugh had (and which he had earlier) that were not caudally located, i.e., the numbness and weakness of his legs, the absence of reflexes.

As for causation from the hepatitis B vaccinations, the undersigned agreed with Dr. Tornatore in her Order of April 21, 2006 that the Sindern case report is remarkably similar to Mr. Peugh's case: a young man receives his fourth hepatitis B vaccination and a little over a week later, has axonal GBS with spinal cord involvement. The timing of vaccination and onset of neurologic illness is appropriate for an immune-mediated disease. The presence of hepatitis B surface antibodies in those with wild hepatitis B who develop GBS was noted in the Sindern case. Those who received the vaccine also have these antibodies which can deposit immune complexes leading in the rare case to disease.

According to the undersigned's April 21, 2006 Order, Mr. Peugh had GBS with inflammation of the spinal cord and the cause of his GBS with central nervous system involvement was hepatitis B vaccine.

Proceeding to the issue of whether the vaccine injury of GBS caused petitioner's death, we turn to well-established case law from the Federal Circuit which states that petitioner may prevail only if the vaccine injury led to the death of the vaccinee. Hodges v. Secretary of HHS, 9 F.3d 958 (Fed. Cir. 1993); Hellebrand v. Secretary of HHS, 999 F.2d 1565 (Fed. Cir. 1993).

In the hearing of January 30, 2007, the question was whether Justin's death was a sequela of the injury caused by the hepatitis B vaccination. The undersigned finds it more likely than not that the vaccine injury of an axonal variant of GBS and the sequela thereto (failure to recover completely, i.e., bladder and bowel not recovered, periodic episodes of leg numbness, use of pain and anti-depressant medication) caused Justin's death. The undersigned makes this finding based on Dr. Tornatore's testimony (Justin had an autonomic response to his failure to recover from GBS with accompanying pain causing hypertension leading to death) and also based, in the alternative, on Dr. Winkler's testimony (the effect of antidepressants and anti-pain medications caused hypotension leading to death).

In short, medical literature and Dr. Tornatore's testimony establish the not surprising conclusion that suffering can lead to constant hypertension. Although literature states that only for a limited time in GBS does the autonomic sign of hypertension exist, this literature assumes recovery from GBS. As Dr. Tornatore testified, when someone has residua from GBS, as Justin did, with axonal involvement that can never heal because the nerve itself is gone, the hypertension persists. Moreover, the hospital records that Justin had relapses of his GBS and that he died from hypertension (which is the cause listed in the death certificate and the autopsy, with a component of drugs that he was taking).

Dr. Winkler stated that Justin did not die from hypertension but from hypotension due to the synergy of the anti-depressants and anti-pain medication he took. Although he sometimes denied that the depression and pain were due to the residua of GBS, he also admitted in response to the undersigned's questions that, indeed, someone who does not recover completely from GBS will be in pain and be depressed and, accordingly, take anti-depressants and anti-pain medication.

It is unnecessary for the undersigned to pick between the two theories of the cause of Justin's death since both point to his GBS.

Petitioner has made a prima facie case that Justin's vaccine-caused GBS led to his death. Ordinarily, the undersigned would award the $250,000.00 in death damages per §300aa-15(1)(2):

> In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

But because the appeal of Zatuchni v. Secretary of HHS, 73 Fed. Cl. 451 (2006), on appeal as No. 07-5034, is pending before the Federal Circuit on the issue of whether petitioners are restricted to the $250,000.00 death award or may also recover survival type damages (unreimbursable medical expenses, lost wages, pain and suffering), the undersigned will wait until the Federal Circuit rules on the issue before issuing a damages order in this proceeding.

CONCLUSION

Petitioner has prevailed in this proceeding. However, the clerk will not enter judgment until the undersigned issues a damages order after the Federal Circuit's ruling in Zatuchni.

IT IS SO ORDERED.

May 8, 2007
DATE

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