In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 10-865V

Filed: July 24, 2013

* *	TO BE PUBLISHED
MICHAEL TRAINER, *	
*	Special Master
*	Hamilton-Fieldman
*	
Petitioner, *	Petitioner's Motion for Ruling on the
v. *	Record; Insufficient Proof of Causation;
*	Vaccine Act Entitlement; Denial of
SECRETARY OF HEALTH *	Compensation Without Hearing.
AND HUMAN SERVICES, *	
*	
Respondent. *	
* *	

Diana Stadelnikas, Sarasota, FL, for Petitioner.
Julia McInerny, Washington, DC, for Respondent.

RULING ON THE RECORD[1]

On December 15, 2010, Michael Trainer ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program"), 42 U.S.C. §300aa-10, *et seq.* (2006),[2] alleging that he developed bilateral tinnitus and hearing loss as a result of

[1] The undersigned intends to post this Ruling on the Record on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq*. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

receiving a hepatitis A vaccination on December 17, 2007. Pet. at 1, ECF No. 1. For the reasons set forth below, the undersigned finds that the information in the record does not support Petitioner's claim of entitlement to an award under the Program.

I. Procedural History

On December 15, 2010, Petitioner filed a petition for compensation against the Secretary of the Department of Health and Human Services ("Respondent") and this case was assigned to Special Master Vowell. Pet. at 1, ECF No. 1; Notice at 1, ECF No. 2. On January 26, 2011, an initial status conference was held pursuant to Vaccine Rule 4(b); Petitioner appeared pro se and Julia McInerny appeared on behalf of Respondent. Minute Entry, 01/26/2011. Petitioner filed medical records, a statement of completion, and a notarized affidavit on May 13, 2011. Notice, ECF No. 6. On July 18, 2011, Respondent filed a Rule 4(c) Report, in accordance with Vaccine Rule 4(c) and Special Master Vowell's Order dated May 18, 2011. Resp't's Report, ECF No. 9.

During status conferences that took place on January 26, 2011, August 31, 2011, December 22, 2011, and February 9, 2012, Special Master Vowell informed Petitioner that he needed to obtain an expert to opine concerning causation and encouraged Petitioner to locate an attorney to represent him in this case. Minute Entry, 01/26/2011; Minute Entry, 08/31/2011; Minute Entry, 12/22/2011; Minute Entry, 02/09/2012 (notes from the status conferences that are contained in the physical file document Special Master Vowell's discussions with Petitioner on above mentioned dates). Diana Stadelnikas entered her appearance as counsel of record for Petitioner on March 28, 2012. Motion, ECF No. 17. Petitioner, however, was unable to find an expert to opine favorably, despite obtaining counsel and being granted several extensions to do so. Motions for Extension of Time, ECF Nos. 22, 28, 30, 32, 33, 35.

On March 4, 2013, Petitioner's counsel filed an "Unopposed Motion for Stay of Proceedings," requesting thirty days to file appropriate pleadings in the case, and Petitioner' counsel stated that an expert report would not be filed. Motion, ECF No. 37. On March 18, 2013, Petitioner's counsel requested that Petitioner be granted the opportunity to present his own material, including a scientific theory regarding causation. Minute Entry, 03/18/2013. Special Master Vowell granted Petitioner thirty days to file this material and Respondent thirty days to file a response. Scheduling Order, ECF No. 38.

On April 19, 2013, this case was transferred to Special Master Hamilton-Fieldman. Order, ECF No. 40. Based on a discussion that took place during a status conference on June 4, 2013, Petitioner was given until June 14, 2013 to reply to Respondent's Rule 4 Report. Scheduling Order Non-PDF, 06/14/2013. On June 17, 2013, Petitioner's counsel filed a "Motion for a Decision on the Written Record," requesting a ruling upon the record in this case pursuant to Vaccine Rule 8. Motion, ECF No. 43. That Motion is granted and the undersigned issues the following ruling based on the information submitted by the parties.

II. Factual Background

A. Medical Information Pre-Administration of Vaccination[3]

On July 5, 1995, Petitioner presented to Steven R. Chesnick, MD ("Dr. Chesnick") with complaints of "some tinnitus in the left ear" and possibly also in the right ear, which he had been experiencing for the past two weeks. Pet'r's Ex. 13 at 6. Dr. Chesnick attempted to rule out potential causes of Petitioner's tinnitus, and indicated that Petitioner had "a negative history of noise exposure, no vertigo, no familial hearing loss, and no hearing loss" and "does not abuse caffeine, aspirin or quinine." *Id.* A standard head and neck examination performed during the visit did not reveal any evidence of objective tinnitus. *Id.* The "[p]hysical examination showed the external canals and drums to be just fine" and "[t]he rest of the standard head and neck exam was normal as [was] [Petitioner's] audiogram." Pet'r's Ex. 13 at 1, 6.

Petitioner underwent magnetic resonance imaging ("MRI"), on August 25, 1995, to rule out the presence of an acoustic fibroma as a potential cause of his tinnitus. Pet'r's Ex. 13 at 8. The MRI did not reveal the presence of an "acoustic neuroma or similar lesion." Pet'r's Ex. 13 at 7. Michael Steltz, MD ("Dr. Steltz"), however, indicated that the MRI revealed that Petitioner had a "[l]arge abnormal mass of the left C1-2 neural foramen, causing mild displacement of the cervical cord to the right," which was "highly suggestive of a neurinoma." Pet'r's Ex. 13 at 11. Dr. Simeon, a neurosurgeon, removed a neurofibroma from the area around Petitioner's cervical spine and Petitioner reportedly had a second smaller neurofibroma that was not removed.[4] Pet'r's Ex. 13 at 7; Pet'r's Ex. 1 at 7, 9; Pet'r's Ex. 2 at 16. A follow-up MRI was performed by R. Rai, MD ("Dr. Rai") on July 24, 1996, which "revealed no mass or contrast enhancing lesion." Pet'r's Ex. 13 at 12-13. Dr. Rai noted that "[t]he lesion seen on the previous examination is not seen on the current examination and most likely has been surgically removed." *Id.*

On January 2, 1996, Petitioner was examined and again found to have no signs of objective tinnitus. Pet'r's Ex. 13 at 7. The examination showed Petitioner's "external canals and drums to be normal," and an "audiogram [] [was] absolutely normal and he ha[d] normal tympanograms." *Id.* The underlying cause of Petitioner's tinnitus was not identified, and Dr. Chesnick noted that "[i]t is entirely possible that there may be an inherited reason for the patient to have tinnitus but in the absence of any additional insults such as noise trauma, aspirin, quinine

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[3] *See* Order, June 4, 2012 (regarding numbering of medical records).

[4] The actual records from the surgery that was performed by Dr. Simeon were not submitted by Petitioner; therefore, information on the surgery was ascertained from notations in Petitioner's medical records that were made by other physicians. Pet'r's Ex. 1 at 31-32; Pet'r's Ex. 2 at 13-14; Pet'r's Ex. 13 at 7-8, 13.

or caffeine as chronic habits, I am at a bit of a loss as to why he has tinnitus." *Id.* Dr. Chesnick noted that Petitioner's tinnitus was "not disturbing his life style." *Id.* It was noted that Petitioner "has neurofibromatosis," and Dr. Chesnick indicated that Petitioner was "aware that patients who do have neurofibroma have a higher incidence of getting acoustic neuromas and he understands that we will be following him very closely." *Id.*

On July 16, 1996, Dr. Chesnick noted that Petitioner "continues to complain of tinnitus right greater than left,"[5] and "on at least one occasion his hearing seemed to be transiently down but returned to its normal levels." Pet'r's Ex. 13 at 8. An examination was performed that "showed his external canals and drums to be normal," and "[a]n audiogram was obtained which was normal." *Id.*

On September 7, 1999, Dr. Chesnick again noted that Petitioner "has bilateral tinnitus worse in his left ear," but that "his exam today shows the external canals and drums to be normal." Pet'r's Ex. 13 at 9. Dr. Chesnick again noted that Petitioner "has neurofibromatosis." *Id.*

On September 27, 1999, results from an MRI of Petitioner's brain, cervical spine, and lumbar spine were recorded. Pet'r's Ex. 13 at 14-15. Petitioner's MRI showed "no evidence of acoustic schwannomas or other intercranial masses." *Id.* No additional records pre-vaccination (vaccine administered December 17, 2007) were submitted by Petitioner. Thus, there is no record documenting when, or if, the tinnitus Petitioner had experienced form July 1995 through the final record on September 7, 1999, decreased or resolved.

B. Medical Information Post-Administration of Vaccination

Petitioner was fifty-five years-old[6] when he received a hepatitis A vaccination[7] during a visit with his primary care physician, Dr. Lawrence Mass ("Dr. Mass"), on December 17, 2007. Pet'r's Ex. 9 at 2; Pet'r's Ex. 8 at 1; Pet'r's Ex. 1 at 4. During this visit, Petitioner indicated that he had been experiencing a cough for the past two and a half weeks, and Dr. Mass diagnosed him

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[5] Most of Petitioner's medical records indicate that he presented with complaints of tinnitus that was greater in his left ear than his right ear. Pet'r's Ex. 13 at 6; Pet'r's Ex. 13 at 9; Pet'r's Ex. 9 at 5; Pet'r's Ex. 7 at 11. A letter that Dr. Chesnick wrote on July 22, 1996 regarding Petitioner's July 16, 1996 visit, however, indicates that his tinnitus was greater in his right ear. Pet'r's Ex. 13 at 8.

[6] Date of Birth: 01/26/1962. *See, e.g.*, Pet'r's Ex. 13 at 6.

[7] Hep A Lot # AHAVB144AD, Exp. 09/13/2009. Pet'r's Ex. 9 at 2.

with an upper respiratory infection and bronchitis. Pet'r's Ex. 9 at 1-2; Pet'r's Ex. 1 at 5; Pet'r's Ex. 8 at 1. Petitioner received his second hepatitis A vaccination but declined "further Hep B shot" and the influenza vaccination. Pet'r's Ex. 9 at 2; Pet'r's Ex. 8 at 1; Pet'r's Ex. 1 at 4.

On December 26, 2007, Petitioner returned to Dr. Mass and indicated that his cough had not improved. Pet'r's Ex. 9 at 3. Petitioner was again diagnosed with bronchitis and he was prescribed Azithromycin ("Z-Pack"). Pet'r's Ex. 9 at 4; Pet'r's Ex. 1 at 2. Petitioner indicated that he had been experiencing tinnitus "since getting Hep A shot." *Id.*

On November 10, 2008, Petitioner presented to Jerome E. Sag, MD ("Dr. Sag"), complaining that he had been experiencing tinnitus for one year and a brain MRI was ordered. Pet'r's Ex. 9 at 11; Pet'r's Ex. 5 at 8.

On February 6, 2009, Petitioner returned to Dr. Sag, but Petitioner indicated that he never had the tests recommended during the last visit because he was busy at work. Pet'r's Ex. 9 at 11; Pet'r's Ex. 5 at 8.

On January 19, 2010, Petitioner was evaluated by an otolaryngologist at Penn Medicine, Michael J. Ruckenstein, MD ("Dr. Ruckenstein"). Pet'r's Ex. 9 at 5-7; Pet'r's Ex. 7 at 2, 9. Petitioner presented with "complain[t]s of constant tinnitus bilaterally, possibly greater left ear" and reported that he was experiencing "some hearing difficulties." Pet'r's Ex. 7 at 9. Petitioner's tinnitus was documented as having begun two years prior to the visit with an "[o]nset 3 hours after hep A vaccine." Pet'r's Ex. 9 at 5. Dr. Ruckenstein noted that Petitioner did not have a history of "trauma, ototoxins, COM, or noise." Pet'r's Ex. 9 at 5. An audiogram was performed and the results were abnormal, showing high frequency sensorineural hearing loss.[8] Pet'r's Ex. 9 at 10; Pet'r's Ex. 7 at 9, 13. During this visit, Dr. Ruckenstein ordered an MRI for Petitioner. Pet'r's Ex. 9 at 7; Pet'r's Ex. 7 at 4.

On June 8, 2010, Petitioner visited Dr. Ruckenstein to obtain the results from the MRI. Pet'r's Ex. 9 at 8; Pet'r's Ex. 7 at 11. In his report, Dr. Ruckenstein noted that there was a "[c]linicial suspicion of acoustic neuroma." *Id.* Impressions from the MRI indicated that there were "[n]o mass in the internal auditory canals or cerebello-pontine angle," but Dr. Ruckenstein noted that "[s]mall lesions could be missed in the absence of intravenous contrast." *Id.*

On September 27, 2010, Petitioner again presented to Dr. Sag with complaints of vertigo and tinnitus "after Hep A vaccine." Pet'r's Ex. 5 at 6.

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[8] "Normal hearing thorough 1kHz sloping to a moderate to severe sensorineural hearing loss in the high frequencies bilaterally. Normal word recognition at suprathreshold levels. Normal tanograms bilaterally." Pet'r's Ex. 7 at 9.

On April 14, 2011, Petitioner presented to Lawrence A. Kerson, MD ("Dr. Kerson") with complaints of numbness, tingling, and pain in left hand, arm, leg, and foot that began four weeks prior. Pet'r's Ex. 1 at 31-32; Pet'r's Ex. 2 at 13-14; *see also* Pet'r's Ex. 1 at 10, 26; Pet'r's Ex. 2 at 4, 8 (excerpted from scan taken on October 21, 2011, after Petitioner presented with complaints of numbness in left arm). Dr. Kerson noted that Petitioner:

> has a known L3 schwannoma that has not changed in size in recent years. He has some chronic right leg numbness from time to time. He also had a left C1-C2 schwannoma removed by Dr. Simeone in 1995, which was found incidentally. Recently, there was an evaluation by Dr. Ruckenstein at Penn regarding his tinnitus. An MRI of his head was done and was reportedly negative. The tinnitus **worsened** following a hepatitis A injection.

Pet'r's Ex. 1 at 31-32; Pet'r's Ex. 2 at 13-14 (emphasis added). Dr. Kerson also noted that Petitioner had "[m]ildly diminished hearing on the right compared to the left." Pet'r's Ex. 2 at 14.

On May 3, 2011, during an annual skin examination conducted by Jonathan T. Wolfe, MD ("Dr. Wolfe") Petitioner complained of new skin lesions. Pet'r's Ex. 3 at 2-4.

On August 24, 2011, Petitioner had an MRI that was performed without intravenous contrast, which showed "[s]pondylotic changes in the cervical spine, somewhat worse from before. Focal enlargement of the ventral division of the left C-2 nerve root, unchanged in comparison to prior study. Possible small neurofibroma along the cauda equine unchanged in comparison to MRI performed in 1999. Degenerative changes in the lumbar spine worse at L4-L5 level . . . ." Pet'r's Ex. 1 at 14-15; Pet'r's Ex. 2 at 19-20.

III. Discussion

To receive compensation under the Program, the petitioner must prove either: (1) that the petitioner suffered a "Table Injury" -- i.e., an injury falling within the Vaccine Injury Table -- corresponding to one of his vaccinations, or (2) that the petitioner suffered an injury that was actually caused by his vaccination. *See* 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). To establish causation-in-fact, the petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. The petitioner is required to prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bring about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

In *Althen*, the Federal Circuit set forth a three-prong test used to establish causation under the preponderance of the evidence standard. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). The *Althen* test requires the petitioner to set forth: "(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." *Id.* To establish causation by a preponderance of the evidence, a petitioner is required to satisfy each of the three prongs of *Althen*. *Id.* A petitioner who demonstrates an injury caused by vaccination by a preponderance of the evidence is entitled to compensation, unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *Id.*

Petitioner, in this case, sought redress for his injury under the Vaccine Act's compensatory provision for off-Table injuries. The undersigned examined Petitioner's medical records and did not find any evidence that Petitioner suffered an off-Table Injury caused by the hepatitis A vaccination. Further, the records do not contain a medical expert's opinion, or any other evidence indicating that Petitioner's tinnitus or hearing loss were caused by the hepatitis A vaccination; no physician expressed such an opinion in the record. Moreover, Petitioner has not proven that the hepatitis A vaccination can cause or did cause the aforementioned tinnitus and hearing loss. The undersigned will outline below why Petitioner fails to satisfy all prongs of *Althen*.

A. Althen Prong I

Under the first prong of *Althen*, Petitioner was required to set forth a plausible medical theory explaining how the hepatitis A vaccination could cause tinnitus or hearing loss. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). Scientific certainty is not required to establish causation under the Vaccine Act. *Id.* at 1280 (indicating that the purpose of the Vaccine Act's preponderance of the evidence standard "is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."). Petitioner did not obtain an expert to opine concerning causation, but Petitioner, who describes himself as a scientist,[9] did submit medical literature, which he relied on to set forth a scientific theory that purports to establish a causal connection between the hepatitis A vaccination and tinnitus and hearing loss. *See Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (noting that although the petitioner "need not produce medical literature or epidemiological evidence to establish causation under the

[9] When filling out an assessment with The Neurology Group Petitioner listed his occupation on the form as "scientist." However, he has not asserted that he is an expert in any field of medicine, such as pharmacology or immunology. Pet'r's Ex. 1 at 8; Pet'r's Ex.7 at 5; Pet'r's Ex. 2 at 17.

Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.").

The medical literature submitted by Petitioner consists of five scholarly articles. Pet'r's Ex.'s 16 – 20; *see also* Pet'r's Ex. 15 at 1–4 (discussing the submitted medical literature). The individual articles from the medical literature that Petitioner submitted do not establish a causal link between tinnitus or hearing loss and the hepatitis A vaccination. Under the Vaccine Act, however, the lack of medical literature directly connecting the hepatitis A vaccination to tinnitus or hearing loss is not dispositive with regards to establishing causation. *Althen*, 418 F.3d at 1280*; see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) (acknowledging that there are circumstances in which "well-grounded but innovative theories will not have been published."). Based on the medical literature, Petitioner sets forth his own scientific theory and posits that neomycin sulfate present in the hepatitis A vaccination could have caused his tinnitus and hearing loss. Pet'r's Ex. 15 at 1-3.

Neomycin sulfate is an antibiotic used to treat certain bacterial infections that can cause ototoxicity. Pet'r's Ex's 16, 17. Petitioner submitted medical literature indicating that therapeutic doses of neomycin sulfate can cause ototoxicity, including tinnitus or hearing loss. Pet'r's Ex's 16-18. Because the cell growth media used to produce the hepatitis A vaccination includes neomycin sulfate, and one of the excipients in the hepatitis A vaccination is "neomycin sulfate (not more than 40 ng/mL),"[10] i.e., a trace amount of the antibiotic, Petitioner theorizes the neomycin sulfate in the vaccination he received caused his tinnitus and hearing loss.

There are several flaws in this theory evident in the medical literature filed by Petitioner, having to do with the method of vaccine administration, dosage calculations, and bioavailability, that fundamentally undermine the viability of the theory. Those flaws include Petitioner's assertion that "the Havrix vaccine is injected into the bloodstream," Pet'r's Ex. 15 at 2, despite the fact that the package insert for Havrix states that it is a "Suspension for Intramuscular Injection," Highlights of Prescribing Information, *available at* http://us.gsk.products/assets/us_havrix.pdf; an erroneous assumption derived from the bloodstream assertion that the trace amount of neomycin sulfate in the vaccine is 100% bioavailable versus the fact that "the transfer of neomycin from oral administration to the blood stream is very poor," Pet'r's Ex 15 at 2; and an attempt to translate the maximum allowable oral dose of neomycin sulfate to a corresponding "serum concentration" that contains several errors in data interpretation and calculation. In sum, Petitioner's dosage calculations and the theory based on them fail to establish that the small, trace amounts of neomycin sulfate in the vaccine can create the same side effects as a therapeutic orally administered dose of the antibiotic.

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[10] Pet'r's Ex. 15 at 2; Highlights of Prescribing Information, *available at* http://us.gsk.com/products/assets/us_havrix.pdf.

In an attempt to establish a link between the hepatitis A vaccination and tinnitus and hearing loss, Petitioner also provided Vaccine Adverse Events Reporting System ("VAERS") Reports and anecdotal evidence from other individuals alleging that they suffered from tinnitus or hearing loss after receiving the hepatitis A vaccination. Pet'r's Ex. 11 at 1-3. Petitioner obtained information from PatientsVille,[11] a crowdsourcing website that allows users to compile information on the side effects of prescription drugs, which associated the hepatitis A vaccination with tinnitus and hearing loss.[12] Pet'r's Ex. 11 at 1-2. Petitioner also provided testimony from an individual who indicated that he experienced pain and severe tinnitus that led to temporary hearing loss after receiving the hepatitis A vaccine, and that he was "absolutely sure that Hepatitis vaccine is the direct cause."[13] Pet'r's Ex. 11 at 3. There are too many unknown variables that make such raw information inherently unreliable. Therefore, Petitioner's attempt to demonstrate a causal link between the hepatitis A vaccination and tinnitus or hearing loss with this information fails.

The undersigned considered the medical literature and associated evidence submitted by Petitioner, but found no plausible medical theory contained in the record regarding how the hepatitis A vaccine can cause tinnitus or hearing loss. There was no expert witness, no literature establishing a causal connection, and no place in Petitioner's medical records where his treating physicians posited that the hepatitis A vaccination can cause tinnitus or hearing loss. Petitioner did not meet his burden of proof under the first prong of *Althen*.

B. Althen Prong II

Under the second prong of *Althen,* Petitioner is required to establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005); *see Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1327 (Fed. Cir. 2006) ("There may well be circumstances where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine."). Here, Petitioner failed to provide support in the form of either medical records or the opinion of a competent physician, providing a causal link between his tinnitus or hearing loss

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[11] *See* Pet'r's Ex. 11 at 1-2; PatientsVille, *available at* http://patientsville.com/vaccines/hepa/tinnitus-hep-a-vagta-2007.htm (Dec. 15, 2010).

[12] PatientsVille, *available at* http://patientsville.com/mission/ (indicating that the mission of PatientsVille "is to Raise Awareness About Drug Side Effects, and to help provide better knowledge to patients and healthcare professionals to ultimately give people a better quality of life.").

[13] Pet'r's Ex. 11 at 3, *available at* http://www.dealingwithtinnitus.com/knee-tinnitus/ (Dec. 15, 2010).

and the hepatitis A vaccination. § 300aa-13(a)(1) (indicating that an award for compensation under the Vaccine Act cannot be based solely on a petitioner's own claims).

Petitioner asserted that "[o]totoxic reactions or loud sounds are the most probable cause for tinnitus which progresses, in both ears, from zero intensity to an extremely high intensity in a short period, as experienced by Petitioner," that he "was not exposed to any other causative factors [] that could have caused his tinnitus and hearing loss," and that the "tinnitus quickly developed, in both ears, within hours after receiving the Hepatitis A vaccine." Pet'r's Ex. 14 at 3. Petitioner claims that "[t]he Hepatitis A vaccine was the only possible source of an ototoxic substance" and, therefore, "his tinnitus and hearing loss were caused-in-fact by the Hepatitis A vaccine." *Id.* The medical literature suggests that there are mutations in the mitochondrial DNA that make some individuals more susceptible to the ototoxic effects of neomycin sulfate. Pet'r's Ex's 16, 17. Individuals with a genetic predisposition to the ototoxic effects of neomycin sulfate may experience rapid and irreversible hearing loss even after administration of a single dose of neomycin sulfate. *Id.* Petitioner, however, fails to present any evidence indicating that he has a mitochondrial DNA mutation that would make him more susceptible to developing tinnitus or hearing loss following exposure to neomycin sulfate.

Several of Petitioner's treating physicians noted that there was a temporal relationship between Petitioner's December 17, 2007, hepatitis A vaccination and the onset of Petitioner's tinnitus, but none of Petitioner's treating physicians expressed the view that Petitioner's tinnitus or hearing loss were caused by the hepatitis A vaccination. *See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010) (indicating that evidence from a treating physician regarding causation is not required but that such evidence can be probative with regards to causation). Under the Vaccine Act, temporal proximity is one factor that is considered in the causation analysis, but a temporal association alone is insufficient to establish causation by a preponderance of the evidence. *Id.* at 1323. Even in the absence of an alternative cause of Petitioner's tinnitus, the totality of the evidence that Petitioner submitted is insufficient to meet the preponderance of the evidence standard necessary for a finding in Petitioner's favor. *Althen*, 418 F.3d at 1278 ("neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.").

While Petitioner's treating physicians never definitively established the cause of the tinnitus that Petitioner experienced before or after vaccination, Petitioner was known to have neurofibromatosis, and Petitioner's treating physicians continued to suspect that his tinnitus was caused by an acoustic neuroma. *See, e.g.*, Pet'r's Ex. 13 at 8 (pre-vaccination MRI to rule out the presence of an acoustic neuroma as the cause of Petitioner's tinnitus); Pet'r's Ex. 9 at 8 (post-vaccination MRI with notation indicating that there was clinical suspicion of acoustic neuromas).

Petitioner also has a long history of tinnitus that predates the December 17, 2010 administration of the hepatitis A vaccination. *See, e.g.*, Pet'r's Ex. 13 at 6; Pet'r's Ex. 13 at 9. Petitioner attempts to differentiate between the tinnitus that he experienced prior to vaccination and his current tinnitus, by contending that the tinnitus that he experienced prior to vaccination "was generally in one ear at very low intensity, continued to diminish and ended in 1999." Pet'r's Ex. 14 at 3. Petitioner, however, failed to submit any medical records from the period between 1999 and 2007 to support his assertion that the tinnitus that he experienced prior to vaccination had disappeared. Petitioner indicates that the "present tinnitus, starting on December 17, 2007, is of very high intensity in both ears and has not changed over 3 years," Pet'r's Ex. 14 at 2-3; Pet'r's Ex. 14 at 3, and that unlike the tinnitus that Petitioner experienced prior to vaccination, which "never impacted the Petitioners'[sic] life," the tinnitus that he has been experiencing since he received the vaccination "causes loss of sleep, loss of concentration, and difficulty understanding some speech." Pet'r's Ex. 14 at 3. Petitioner's treating physicians have not distinguished between the two episodes in terms of causation, however, and have continued to identify an acoustic neuroma or similar lesion as the most likely cause of Petitioner's current and prior tinnitus. Pet'r's Ex. 9 at 8; Pet'r's Ex. 7 at 11; Pet'r's Ex. 13 at 7.

The second prong of the *Althen* test is not satisfied because Petitioner has failed to prove by medical records or the opinion of a competent medical expert that the December 17, 2007, hepatitis A vaccination caused his tinnitus and hearing loss. The medical records and the opinions of Petitioner's treating physicians demonstrate that it is more likely that his tinnitus was caused by a preexisting condition than the vaccination. Furthermore, there is no indication that it was not merely a coincidence that Petitioner's tinnitus reemerged or worsened around the time that he received the hepatitis A vaccination. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1327 (Fed. Cir. 2006) (indicating that the second prong of *Althen* is not satisfied where "the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.").

C. Althen Prong III

Under the third prong of *Althen*, Petitioner is required to show that there was a proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). Petitioner submitted records that purport to establish a temporal association between when Petitioner received the hepatitis A vaccination and the reemergence or worsening of his tinnitus. On December 17, 2007, Petitioner received the hepatitis A vaccination when he presented to his doctor complaining of a cough. Pet'r's Ex. 9 at 2; Pet'r's Ex. 8 at 1; Pet'r's Ex. 1 at 4. Petitioner returned to the doctor, on December 26, 2007, complaining that his cough had not improved. Pet'r's Ex. 9 at 3. The doctor documented in Petitioner's medical records that he had been experiencing tinnitus "since getting the Hep A shot." Pet'r's Ex. 9 at 4; Pet'r's Ex. 1 at 2. Petitioner's medical records from an appointment with an otolaryngologist, on January 19, 2010, indicate that the onset of the tinnitus was "3 hours after hep A vaccine." Pet'r's Ex. 9 at 5. Petitioner's medical records from April 14, 2011,

indicate that his "tinnitus worsened following a hepatitis A injection." Pet'r's Ex. 1 at 31-32. Additionally an audiogram from January 19, 2010, approximately two months after vaccination, was abnormal, showing high frequency sensorineural hearing loss. Pet'r's Ex. 9 at 10; Pet'r's Ex. 7 at 4, 9, 13.

The temporal relationship between Petitioner's tinnitus and the hepatitis A vaccination is consistent with the medical literature that Petitioner submitted regarding the onset of ototoxicity following administration of neomycin sulfate. *See, e.g.*, Pet'r's Ex.'s 16 - 18. As described under the first prong of the *Althen* analysis, however, the scientific theory set forth by Petitioner connecting the neomycin sulfate in the hepatitis A vaccination to tinnitus and hearing loss is flawed. Absent a valid scientific theory connecting the hepatitis A vaccination to Petitioner's injury, the asserted temporal association alone is insufficient to establish entitlement to compensation. *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010). Furthermore, Petitioner has a history of tinnitus that pre-dates vaccination. *See, e.g.*, Pet'r's Ex. 13 at 6; Pet'r's Ex. 13 at 9. Petitioner claims that the tinnitus that he was experiencing prior to vaccination had disappeared, Pet'r's Ex. 14 at 2, but Petitioner failed to provide documentation in the form of contemporaneous medical records to support this assertion.

Finally, as previously discussed in the analysis of the second prong of *Althen*, even though Petitioner's medical records indicate that he reported experiencing tinnitus shortly following the administration of the hepatitis A vaccination, or alternatively that his tinnitus worsened following vaccination, none of Petitioner's physicians opined that there was a causal connection between Petitioner's tinnitus and the hepatitis A vaccination, nor did any of Petitioner's treating physicians indicate that Petitioner's hearing loss was causally connected to vaccination.

IV. Conclusion

In sum, the weight of the scientific and clinical evidence set forth by Petitioner does not support Petitioner's assertion that the hepatitis A vaccine was the cause-in-fact of Petitioner's tinnitus and hearing loss. Even if the theory set forth by Petitioner was "biologically plausible" and satisfied the first prong of the *Althen* test, and even if it was assumed that there was a temporal association between vaccination and Petitioner's injury, Petitioner failed to satisfy the second prong of the *Althen* test. To be entitled to compensation, under the Program, Petitioner must satisfy all three prongs of *Althen*.

The undersigned is sympathetic to the fact that Michael Trainer suffers from tinnitus and hearing loss. However, under the law, the undersigned can authorize compensation only if a medical condition or injury either falls within one of the "Table Injury" categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. No such proof exists in the record. It is clear from the record in this case that Petitioner has not demonstrated either

that he suffered a "Table Injury" or that his condition was "actually caused" by a vaccination. Therefore, the undersigned has no choice but to hereby DENY this claim. In the absence of a timely-filed motion for review of this decision (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

/s/ Lisa Hamilton-Fieldman
Lisa Hamilton-Fieldman
Special Master