In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 23, 2021

THOMAS BAKKER,	*	UNPUBLISHED
Petitioner,	*	No. 19-1814V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Findings of Fact; Influenza (Flu); Onset; Preexisting Gastroesophageal Reflux Disease (GERD); Vocal Cord Paralysis; Coughing; Hoarseness; Vocal Problems; Swallowing Problems; Arm Weakness.
Respondent.	*	

William H. Sandweg, III, Sandweg & Ager, P.C., for petitioner.
Claudia B. Gangi, United States Department of Justice, Washington, DC, for respondent.

FINDINGS OF FACT[1]

Thomas Bakker ("petitioner") asserts that as a result of an influenza ("flu") vaccine received on October 3, 2017, he subsequently suffered vocal cord paralysis, vocal problems, (dysphonia); swallowing problems (dysphagia), and loss of strength and mobility in his left shoulder and arm and an aggravation of pre-existing gastroesophageal reflux disease (GERD). At the parties' request, I hereby provide findings of fact relating to petitioner's symptoms before versus after the vaccination.[2]

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the decision will be available to anyone with access to the Internet.** Before the decision is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). "An objecting party must provide the court with a proposed redacted version of the decision." *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court's website without any changes.** *Id.*

[2] Pursuant to Section 13(a)(1), in order to reach my decision, I have considered the entire record, including all of the medical records, expert testimony, and literature submitted by the parties. This opinion discusses the elements of the record I found most relevant to the outcome.

I. Procedural History

On November 27, 2019, petitioner filed this claim in the Vaccine Injury Compensation Program.[3] Petition, accompanied by Petitioner's Exhibits ("Pet. Exs.") 1 - 7 (ECF No. 1). The claim was assigned to my docket. On January 16, 2020, during an initial status conference, respondent's counsel advised that based on her preliminary review, there was a question as to the onset of the injuries alleged. *See* Initial Order (ECF No. 12) at 2.

On March 13. 2020, petitioner filed an amended petition with corrected citations to the medical records and affidavits, accompanied by additional evidence regarding onset as Pet. Exs. 7-20 (ECF No. 15). Petitioner also filed his attorney's memorandum addressing onset ("Pet. Onset Memo") (ECF No. 16). Petitioner acknowledges that he has had periodic episodes of hoarseness due to his longstanding GERD. Pet. Onset Memo at 3. He avers that initially upon seeking medical treatment, he conflated an episode of hoarseness that occurred during a road trip to South Dakota in late September 2017, with the new, distinctly different symptoms of breathlessness while speaking, loss of vocal power while speaking, and fatigue while speaking which were eventually diagnosed as vocal cord paralysis and which began after the October 3, 2017 vaccination. *Id.* at 2-3.

While waiting for respondent's formal review of the claim, on October 30, 2020, petitioner filed updated medical records as Pet. Exs. 21-22 as well as an initial expert report from Donald Marks, M.D., Ph.D., accompanied by Dr. Marks's curriculum vitae and medical literature as Pet. Exs. 23-73 (ECF No. 20).

On December 29, 2020, respondent filed his report pursuant to Vaccine Rule 4(c), in which respondent recommended against compensation, (ECF No. 21). Respondent averred that: "As a threshold matter, with respect to the alleged injuries of voice issues, swallowing issues, and vocal cord paralysis, there is evidence that onset of petitioner's symptoms occurred before the subject vaccination." *Id.* at 9. Respondent also averred that the medical records supported an onset for petitioner's left arm symptoms approximately four months after vaccination, which is not a medically acceptable timeframe to infer causation. *Id.* at 10.

On February 3, 2021, petitioner filed his expert's second report and literature as Pet. Exs. 74-81, as well as his own third affidavit as Pet. Ex. 82 (ECF No. 22). Petitioner also requested a status conference to set further proceedings. Pet. Status Report (ECF No. 23).

During a status conference on March 18, 2021, both parties requested findings of fact to guide further proceedings in the case. After the status conference, I further reviewed the evidence submitted to date and determined that findings of fact could be helpful in focusing the issues in the case. My law clerk emailed both parties' counsel to advise that partial findings of fact were forthcoming. Accordingly, this matter is ripe for at least partial factual adjudication.

[3] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

The determination of a factual chronology in this case is particularly difficult because of numerous inconsistencies in the medical records both internally and in comparison to the affidavits from petitioner, his wife, and his daughter. Establishing the chronology is also complicated by petitioner's apparently imprecise recitation of his history at multiple medical appointments and/or his medical provider's imprecise recording of that history, as well as imprecise recollections in the affidavits.

In the following document I have set forth a chronology of important and relevant medical events as set forth in the medical records and affidavits. From that chronology I have set forth substantially established facts. The general chronology is to be used to guide further evaluation and expert analysis of this case. The findings of fact are to be accepted by any expert opining on the case.

Experts are not precluded from consideration of records not included in this document but I have attempted to include all those bearing on the issues of dysphonia, dysphagia, and left arm impairment as well as damage to the sternocleidomastoid and trapezius muscles without including, for example, records of petitioner's surgery to repair an arterio-venous fistula in the brain which has no bearing on the issues in this case.

I. Legal Standard

Pursuant to Vaccine Act § 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act § 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Curcuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs*., 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful

recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may determine that the first symptom or manifestation of an injury occurred at a particular time, "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period," based upon "a preponderance of evidence" of when onset occurred. 42 U.S.C. § 300aa-13(b)(2).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

II. The Relevant Factual Record

The petitioner, Thomas Bakker, was born in 1947. He was a trial lawyer for over 40 years before retiring in 2015. He submitted two affidavits recalling the events in question. *See* Pet. Exs. 2, 19, 82. Petitioner lived with his wife of over 50 years, Charlotte Bakker. Pet. Exs. 3, 20. Petitioner's adult daughter Sarah Madderom and a longtime friend, Jeff Kraker, also submitted supporting affidavits particularly attesting to his loss of speaking power and dysphagia. Pet. Exs. 4, 5. Overall, the affidavits reflect that petitioner was active and involved with his church congregation, volunteering, regular travel, and time with his wife, two adult children, and three grandchildren. He regularly did public speaking before this time both as a trial lawyer and during church services.

A. Pre-Vaccination History

It is undisputed that prior to the October 3, 2017, flu vaccination, petitioner had a history of GERD (a/k/a reflux), sinusitis, post-nasal drip, vasomotor rhinitis, and occasional hoarseness. For example, on February 16, 2016, on referral from his primary care provider, petitioner presented to Valley ENT, P.C., in Scottsdale, Arizona. Pet. Ex. 18 at 2-3. Kurt Heiland, M.D., recorded that petitioner was seeking the consultation due to his multi-year history of post-nasal drip and runny nose, which caused him to blow his nose a lot. *Id.* at 2. Dr. Heiland performed a flexible nasopharyngolaryngoscopy,[4] which documented a Grade I arytenoid erythema in the

[4] A flexible nasopharyngolaryngoscopy (also called fiberoptic nasendoscopy, flexible nasolaryngoscopy, or flexible fiberoptic nasopharyngolaryngoscopy) is a diagnostic procedure used for examination of the nose, throat, and

larynx. *Id.* at 3. But importantly, Dr. Heiland observed: "The true vocal cords have a normal appearance and normal mobility." *Id.* at 3. Dr. Heiland diagnosed petitioner with deviated nasal septum, for which he would consider nasal and sinus surgery. *Id.* Petitioner also had chronic rhinitis and post-nasal drip, for which he should increase use of Atrovent (ipratropium) nasal spray.[5] *Id.* Petitioner also had laryngopharyngeal reflux, for which he should continue to avoid dietary reflux triggers and continue to take omeprazole. *Id.* Dr. Heiland also recorded that there was no evidence of sinusitis. *Id.*

On May 13, 2016, petitioner saw his primary care provider Jay Friedman, M.D., for a chief complaint of pain in his left arm, neck, and lower back. Pet. Ex. 14 at 129-34. Dr. Friedman ordered an MRI of the cervical spine, which was notable for mild to moderate bilateral foraminal narrowing at C4-5 and a left foraminal protrusion component at C6-7 which caused mass effect on the left C7 nerve root and moderate to severe left-sided C6-7 foraminal narrowing. *Id.* at 127-28. Petitioner reported using a rowing machine multiple times each week and walking several miles at a time. *Id.* at 130-31. Petitioner also admitting "having ongoing left shoulder issues and he has some neurogenic symptoms radiating from the anterior shoulder down to his second and third digits. He does notice this in bed. In certain positions he has good range of motion of the shoulder." *Id.* at 131.

On February 7, 2017, petitioner returned to Dr. Friedman, complaining of "a chronic cough for 4 months with perhaps a three-week period where he did not have cough." Pet. Ex. 14 at 118. He had a tickle in his throat, semi-productive cough with clear mucus, a post-nasal component which "might be green in color," and being "perhaps a little dyspneic [short of breath] while exercising." *Id.* Dr. Friedman's differential diagnosis for "cough" included reflux and allergies. *Id.* at 122. Dr. Friedman wrote a new prescription for a steroid nasal spray (in addition to his ongoing ipratropium nasal spray), but also ordered a chest x-ray and bloodwork, which were unremarkable. *Id.* at 122-25.

On March 30, 2017, petitioner returned to Valley ENT, P.C., requesting a renewed prescription for the ipratropium nasal spray, which was "the most effective therapy" for his chronic, non-allergic rhinitis. Pet. Ex. 18 at 7-8. Petitioner also reported a subjective "intermittent feeling of 'tightness' in the throat" and pointed specifically to the thyroid cartilage. *Id.* at 7. However, a repeat nasopharyngolaryngoscopy found that: **"The hypopharynx and larynx are normal including normal appearance and mobility of the vocal cords**." *Id.* at 8 (emphasis added). This was the last ENT appointment prior to receipt of the flu vaccine in October 2017.

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airway. The otorhinolaryngologist (ENT specialist) inserts a fiberoptic camera at the end of a flexible tube, through the nasal passages and down the throat to the larynx. The image is projected onto a video screen during the procedure. *See, e.g.*, Alvi & Harsha, *Flexible Nasopharyngoscopy* (last updated Oct. 27, 2020], in: StatPearls [Internet], available at https://www.ncbi.nlm.nih.gov/books/NBK539740/ (accessed March 23, 2021).

[5] Respondent avers that Atrovent (ipratropium) is "an oral inhalation medication used to prevent wheezing, shortness of breath, and chest tightness." Resp. Report at n. 2. However in this case, the medical records (*see, e.g.*, Pet. Ex. 18 at 3) and petitioner's supplemental affidavit (Pet. Ex. 82 at ¶ 2) establish that petitioner was prescribed this medication as a nasal spray, for purposes of treating his chronic runny nose.

On May 16, 2017, petitioner visited Dr. Friedman for his annual physical examination. Pet. Ex. 14 at 100-06. Petitioner reported utilizing an exercise bike and walking in the mall. *Id.* at 102. The review of systems and physical examination were negative for dyspnea, chest tightness, or any neurological or musculoskeletal problems. *Id.* at 102-03.

Petitioner's wife recalls that they took a road trip to South Dakota in "late September" 2017. Pet. Ex. 3 at ¶ 11; *see also* Pet. Ex. 18 at 86 (January 2018 medical record confirming the timeframe). The return date is unclear.

B. High Dose Fluzone Vaccination

Once a week, petitioner volunteered at Honor Health Scottsdale Shea Medical Center, where he would assist in discharging patients, helping visitors, and other tasks. Pet. Ex. 2 at ¶ 4; Pet. Ex. 3 at ¶ 1. **On October 3, 2017,** at approximately 7:50 a.m., at Scottsdale Shea Medical Center, **petitioner received the seasonal high-dose Fluzone vaccination in the right deltoid muscle**. Pet. Ex. 7 at 1 (emphasis added).

C. Post-Vaccination History

Petitioner and his wife recall that after they returned from the road trip to South Dakota and after the flu vaccination, beginning in late October or November 2017, he developed qualitatively different symptoms than he had ever experienced before. Pet. Ex. 2 at ¶ 5; Pet. Ex. 3 at ¶ 11 Pet. Ex. 19 at ¶ 9; Pet. Ex. 20 at ¶ 5.

Petitioner recalls that the onset was gradual and that "in no particular order," he developed weakness and loss of range of motion in his left arm and shoulder; his voice became horse, weak and raspy; he had trouble swallowing; he began to have coughing fits; and his GERD "got out of control." Pet. Ex. 2 at ¶¶ 5-10. There was some overlap of symptoms (e.g., with the hoarseness that he recalls began during the road trip) and petitioner initially did not relate the new symptoms to his vaccination. Pet. Ex. 19 at ¶ 17. However, with the benefit of hindsight, he averred that he now understands that he did not have voice, swallowing, coughing, or left upper extremity problems before the flu vaccination on October 3, 2017, and that these new symptoms began in November and December 2017. *Id.*

More specifically, petitioner's wife recalls that after they returned from the South Dakota road trip, he developed a cough. Pet. Ex. 3 at ¶ 11; *see also* Pet. Ex. 20 at ¶ 5 (adding that petitioner's cough "was more violent than any [the wife] had seen before"). She waited for a cold to develop but one never did. Pet. Ex. 3 at ¶ 11. Over time, his voice began to get hoarse and it sounded like laryngitis. *Id.* In early November 2017, she urged him to see his primary care provider, Dr. Friedman. *Id.*

Petitioner's wife also recalls that petitioner began complaining that he could not lift his arm above his head or use his left arm as before. Pet. Ex. 3 at ¶ 12. Petitioner was left-handed and this was a big problem for him in bathing and grooming. *Id.* His left arm got weaker and weaker. *Id.* Like petitioner, his wife recalls that the left arm problems began in "late October"

2017. *Id.* But as reflected below, this problem is not reflected in any medical records until February 2018.

On November 13, 2017, his first post vaccination medical appointment, petitioner presented to Dr. Friedman, who recorded the following history: "The patient has had runny nose and a plugged up nose and postnasal symptoms and hoarse voice and he has had some shortness of breath. He is not aware of any wheezing. He really has a hard time clearing his throat. Flonase caused some nasal bleeding. Has been on ipratropium bromide nasal [Atrovent]. He is also on Claritin. He also performs a daily nasal lavage. He has had symptoms for several months. He does have an intermittent cough." Pet. Ex. 14 at 91 (emphasis added). **On physical examination, Dr. Friedman noted unlabored breathing: "But he does have some hoarseness**. His lungs are clear. I do not appreciate any wheezing. His O2 saturation is excellent at 97 with a heart rate is [of?, sic] 66." *Id.* at 94 (emphasis added). Dr. Friedman's assessment was shortness of breath, which he suspected to be a "reactive airway component to what seems to be a postnasal phenomenon as well." *Id.* Following the results of a spirometry test, Dr. Freidman prescribed a Breo Ellipta inhaler. *Id.* at 94-95.

The affidavits indicate that throughout November and December 2017, petitioner continued to cough, his voice became weaker, and he began having problems with swallowing. *See, e.g.*, Pet. Ex. 2 at ¶¶ 5-10; Pet. Ex. 3 at ¶¶ 13-14; Pet. Ex. 19 at ¶ 9; Pet. Ex. 20 at ¶ 5. Petitioner's daughter, who saw him two or three times a week for many years, recalls that she first noticed changes in his voice "around Thanksgiving of 2017." Pet. Ex. 4 at ¶¶ 3-6. His voice seemed to be hoarse and she thought perhaps he had a cold. *Id.* at ¶ 6. Over time his voice became weak and difficult to hear. *Id.* He was coughing all the time and could not stop once he started. *Id.* he had to use extra effort to speak and his voice tired easily. *Id.*

The daughter also recalled that "also around this time," petitioner began to complain of difficulty eating and swallowing, as well as left-sided pain and weakness in his arm and shoulder. Pet. Ex. 4 at ¶ 7. The daughter does not tie these particular symptoms to particular holidays or other events.

The next medical appointment was on December 13, 2017, with Dr. Heiland. Pet. Ex. 18 at 10. Petitioner's chief complaint was "throat clearing from silent reflux, chronic sinusitis and sensorineural hearing loss." *Id.* at 10. Dr. Heiland recorded the following history: "The patient just returned from a road trip and he was drinking wine with dinner each night. He likes a couple carbonated beverages per day and occasional chocolate. He sees Dr. Michael Shapiro for esophageal dysplasia and pre-Barrett's. The patient has little more throat clearing when the reflux is problematic. He has taken a proton pump inhibitor without relief of the throat clearing and tendency towards dysphagia." *Id.* Dr. Heiland appeared focused on petitioner's reflux. However, he performed **a repeat flexible nasopharyngolaryngoscopy which visualized in relevant part: "There is grade II arytenoid erythema and grade I arytenoid hypertrophy. Mild vocal fold atrophy**." *Id.* at 11 (emphasis added).

The affidavits state that petitioner's condition continued to progress. His wife "specifically recall[s] that over Christmas of 2017, [she] noticed a 'wispiness' in Tom's voice

that I had never heard before. His voice continued to deteriorate after Christmas." Pet. Ex. 20 at ¶ 5.

The next medical appointment was on January 16, 2018, again with Dr. Heiland. Pet. Ex. 18 at 13-15. Dr. Heiland recorded that petitioner's "most pressing complaint [was] dysphonia," which had been present "x 3 months." *Id.* at 13. However, Dr. Heiland also described petitioner's history that he first noticed a change in his voice "last fall while on a road trip to the Black Hills region and through South Dakota," during which he "had some wine at dinner and had some late dinners." *Id.* Dr. Heiland still appeared focused on petitioner's reflux. Dr. Heiland again did a flexible nasopharyngolaryngoscopy which in relevant part showed: **"The left vocal fold is relatively sluggish today. The left vocal fold has relatively normal abduction but the adduction is slightly lacking and there is overcompensation on the right. There is a grade I arytenoid hypertrophy on both sides."** *Id.* at 14 (emphasis added). Dr. Heiland also observed hypertophic turbinates and a deviated septum, which were long standing problems. *Id.* Dr. Heiland's diagnoses on this day were: "paralysis of vocal cords and larynx, unilateral. Chronic maxillary sinusitis. Deviated nasal septum. Laryngopharyngeal reflux and sensorineural hearing loss. *Id.*at 15. Dr. Heiland noted that petitioner would be going on a cruise in February. *Id.*

Dr. Heiland ordered various CT and MRI studies to further evaluate the cause of petitioner's vocal cord paralysis. Pet. Ex. 18 at 15. On February 2, 2018, the radiologist reading the MRI noted: **"T2 hyperintensity in the left vocal cord. Redundancy of the left supraglottic larynx and soft tissue. Mild prominence of the left piriform sinus. Findings may represent left vocal paralysis**. Correlate with physical exam. No lesion was seen along the course of either recurrent laryngeal nerve." *Id.* at 21 (emphasis added).

On February 12, 2018, petitioner saw Dr. Friedman. He stated that his voice became very weak quickly and that this has "been going on since September 2017." Pet. Ex. 14 at 73. Dr. Friedman recorded that petitioner would be leaving in one week for a five-day cruise to Hawaii. *Id.* at 78.

Next, on February 16, 2018, petitioner had an initial neurology consult with Dr. Nina Laurin, M.D. Pet. Ex. 16 at 3. Dr. Laurin recorded: "The patient reports that in September last year, he noticed that his voice changed and became hoarse. He was seen by Dr. Friedman and later by Dr. Heiland who diagnosed partial left vocal cord paralysis… The patient has some difficulty swallowing dry food and that has been going on for a while but denies choking on it or on water. No change in taste or smell. The patient reports that in the last two to three weeks, he developed weakness of the left arm and cannot lift it up to his head or above the shoulder. He had C7 radiculopathy and neck pain on the left a couple of years ago but did not have any weakness. Had cortisone injection with resolution of pain. Now he has some neck discomfort but no pain going down the into the arm." *Id.* The review of systems was positive for left arm weakness (5-/5 left triceps and supraspinatus on physical exam), left-sided neck pain, ringing in both ears, hearing loss, sinus problems, change in voice, slight difficulty swallowing and snoring. *Id.* Dr. Laurin also noted very mild left side scapular winging, but no muscle atrophy or fasciculations. *Id.* at 4. Dr. Laurin considered a C5 nerve root issue. *Id.* But then she and a neuroradiologist reviewed a May 2016 MRI of petitioner's cervical spine and found no

significant abnormalities in the upper levels other than an old C6-7 foraminal narrowing which she did not consider contributory. *Id.* Dr. Laurin considered an EMG study after petitioner returned from a cruise. *Id.*

Petitioner and his wife recall that during their Hawaii cruise, his coughing became so violent that he had episodes of choking and vomiting. Sometimes he had to leave the deck and return to their cabin because the coughing was nearly constant. It was disturbing the other passengers. He even had to see the ship's doctor to get some cough medicine, which did not help. Petitioner and his wife also recall that the cruise was in January 2018. Pet. Ex. 19 at ¶ 13; Pet. Ex. 20 at ¶ 6. However, the contemporaneous medical records reflect that the cruise was in late February 2018. Pet. Ex. 18 at 15; Pet. Ex. 14 at 78; Pet. Ex. 16 at 4.

At a March 14, 2018 follow-up appointment, after returning from the cruise. Dr. Heiland recorded that petitioner had returned from a recent trip with his grandchildren, during which he had difficulty with dysphagia, cough, and microaspiration. Pet. Ex. 18 at 22. A repeat flexible nasopharyngolaryngoscopy showed: "The turbinates are hypertrophic in appearance**. Left vocal fold is parotid today with very little movement. There is some minor adduction to the right... There is grade I arytenoid hypertrophy left and right."** *Id.* at 23.

At a March 16, 2018 follow-up appointment, Dr. Laurin recorded that petitioner had recently come back from a cruise to Hawaii. Pet. Ex. 16 at 1. Petitioner reported having more difficulty swallowing, like his food gets stuck in his esophagus. *Id.* He was scheduled for a swallowing study. *Id.* The review of systems was positive for difficulty swallowing, change in voice, left sided neck pain, ringing in both ears, sinus problems, snoring and minimal left arm weakness. *Id.* But under impression, Dr. Laurin recorded: "Recent onset of left proximal arm muscle weakness has resolved." *Id.* Dr. Laurin also noted that a March 2018 repeat MRI of the cervical spine showed improvement of lateral disc protrusion at C6-7, which was no longer causing left foraminal narrowing as the disc dessicated. *Id.* Dr. Laurin's impression was dysphagia with vocal cord paralysis and left hemidiaphragm paralysis, for which petitioner would see a neuromuscular specialist, Dr. Sivakumar. *Id.*

On April 3, 2018, Dr. Heiland recorded that petitioner developed idiopathic left vocal cord paralysis "with a trip to South Dakota six months ago." Pet. Ex. 18 at 25. He recorded that another flexible nasopharyngolaryngoscopy showed: **"The left vocal cord is paralyzed in a relatively median position. There is normal right vocal fold movement. There is grade II arytenoid hypertrophy and grade I arytenoid erythema left and right**." *Id.* at 26 (emphasis added).

On April 18, 2018, petitioner had an initial consult with Dr. Kumaraswamy Sivakumar, a neuromuscular specialist at Barrow Institute in Phoenix, Arizona. Pet. Ex. 13 at 13. Dr. Sivakumar recorded petitioner's history of "Subacute onset of hoarseness, dysphagia and left arm weakness possibly occurring in sequence starting in September of 2017. The symptoms started within a few weeks of a flu shot and progressed over a few weeks to a month before it plateaued." *Id.* By the time of this April 18, 2018 encounter, petitioner's dysphagia had stabilized and his dysphonia fluctuated. *Id.*; *see also id.* at 2, 5, 8 (records from Dr. Sivakumar's follow-up appointments, which repeat the same history verbatim). Dr. Sivakumar noted that

petitioner was found to have a left-sided diaphragmatic-phrenic nerve palsy which appeared to be many years old. Pet. Ex. 13 at 13. An MRI of the cervical spine has not identified any basis for the left arm weakness. *Id.* Dr. Sivakumar observed on physical exam: **"A spinal accessory neuropathy on the left side and possibly a glossopharyngeal neuropathy. The soft palate deviates to the right. There is no tongue atrophy. The sternomastoid on the left is completely gone probably significantly atrophied. The trapezius upper and middle heads are also atrophied resulting in scapular winging on the left. He cannot abduct the left arm above the horizontal with scapular winging. The biceps and deltoid are preserved. Reflexes are symmetrical and no sensory loss."** *Id.* (emphasis added). Dr. Sivakumar diagnosed a **"glossopharyngeal/vagal//recurrent laryngeal neuropathy as well as a spinal accessory neuropathy on the left side that probably started together 3-4 weeks after a flu shot."** *Id.* (emphasis added). Despite the lack of pain, based on the exclusion of structural processes, Dr. Sivakumar suspected that this was a variant of Parsonage Turner Syndrome. *Id.*; *see also id.* at 2, 5, 8 (maintaining this assessment).

On May 29, 2018, petitioner underwent an upper GI endoscopy and biopsy. A single plaque in the lower third of the esophagus was seen and biopsied which showed abundant clear cytoplasm consistent with glycogen accumulation which was noted to be a common finding, usually of no clinical significance. Pet. Ex. 17 at 2. There was significant angulation of the stomach due to diaphragmatic paresis. *Id.* at 4. The summary impression was 1) gastroesophageal reflux disease with intestinal metaplasia of cardia, 2) dysphagia and cough due to oropharyngeal dysfunction and cranial neuropathy and history of colon adenoma, periampullary diverticulum and colon diverticulosis. *Id.* at 5. There was no Barrett's specialized columnar epithelium and no evidence of eosinophilic esophagitis or fungal organisms. *Id.* at 2. Mild reflux esophagitis pattern was noted. *Id.*

On June 12, 2018, petitioner underwent a speech and swallowing evaluation at Honor Health Scottsdale Shea Medical Center on prescription from Dr. Friedman. He provided a history beginning in the fall of 2017. He stated, "the prime manifestation was my voice started getting hoarse. Then I developed a cough which persists today." Pet. Ex. 10 at 3. His throat was highly sensitive to dry particulate foods. *Id.* His swallow function continued to deteriorate. *Id.* He began having difficulty lifting his left arm and resting his left arm on the table when eating. *Id.* He provided the therapist with the diagnostic workup done by Dr. Sivakumar which was repeated verbatim as set forth above.

Petitioner was also evaluated for voice and swallow function. The summary of findings after this evaluation included:

1) Mild unilateral (left) velopharyngeal weakness and asymmetry;
2) Moderate-Severe Neurogenic Dysphonia: characterized by reduced vocal intensity, hoarse, raspy, gravelly vocal quality, and reduced endurance. This is consistent with the patient's medical history and Left glossopharyngeal/vagal/recurrent laryngeal as well as spinal accessory neuropathy that started together 3-4 weeks after a fu shot.
3) Mild pharyngeal Dysphagia: characterized by reduced pharyngeal constriction, pharyngeal globus, difficulty swallowing dry, dense solids, and occasional coughing when attempting to swallow thin viscosity liquid in large amounts at a fast rate.

His voice handicap Index was rated as functionally severe and physically severe. Pet. Ex. 10 at 3-8.

III. Findings of Fact

1) The petitioner has a long-standing history of GERD and rhinitis with post-nasal drip. This included periodic hoarseness and episodes of coughing. He also has a history of an old partial diaphragmatic paralysis arising from the phrenic nerve.

2) His physical exam by Dr. Friedman in May 2017 was essentially normal, and Dr. Friedman noted that petitioner regularly used an exercise bike, a rowing machine and walking through the mall. He noted no nervous system or muscular problems.

3) Petitioner was prescribed Atrovent (ipratropium) only as a nasal spray and not for wheezing, shortness of breath, or chest tightness.

4) Petitioner acknowledges that he had some hoarseness and voice changes – similar to those that had come on from time to time for years – during and shortly after the trip to the Black Hills in September 2017 which was shortly before receipt of the high-dose Fluzone vaccine on October 3, 2017. These symptoms were likely to be secondary to his long-standing history of GERD.

5) There are no prior contemporaneous medical records of dysphonia, dysphagia, or left arm dysfunction other than the earlier C6-7 radiculopathy which was not considered consistent with his subsequent arm problem.

6) The lack of reference to dysphonia or dysphagia in the pre-October 2017 records and the consistent statements in the affidavits strongly suggest that petitioner had some periodic hoarseness associated with GERD before October 2017, but that he was an active public speaker and that he did not exhibit voice weakness or swallowing difficulty. His family and friend noticed a distinct diminution in voice power and swallowing problems in the October 2017 through February 2018 time period, which I find to be credible.

7) Consistent with the affidavits, petitioner experienced a distinct and qualitative difference in his physical condition that began and progressed during the fall and winter of 2017 – 2018. The new conditions include loss of voice power (dysphonia) with unilateral paralysis of the left vocal cord with significant breathlessness; swallowing difficulty (dysphagia) that has made it difficult to eat normal foods without constantly sipping water; and the damage to the sternocleidomastoid muscle and the trapezius on the left likely secondary to injury to the spinal accessory nerve.

8) While he did experience some hoarseness in September, the medical records appear to support the affidavits to the extent that the loss of voice power, breathlessness and dysphagia began in late October 2017 and increased in severity through November

2017, December 2017, January 2018, and at least February 2018. I base this conclusion on the fact that the last flexible nasopharyngolaryngoscopy prior to the flu shot showed vocal cords with normal appearance and normal mobility. There were no medical appointments between May and November 2018. His physical in May was essentially normal.

9) After the May 13, 2017, physical exam, petitioner did not seek medical care until November 13, 2017, when Dr. Friedman documented some hoarseness and some shortness of breath and difficulty clearing his throat. The thinking at that point appeared to focus on GERD or post-nasal drip. There was no mention of swallowing problems, voice weakness, or left arm issues at this appointment.

10) The next nasopharyngolaryngoscopy in December 2017 documented some atrophy of the left vocal cord. This was the first objective finding of vocal cord dysfunction.

11) In January 2018, the repeat nasopharyngolaryngoscopy showed sluggishness of the left vocal cord. For emphasis, I will again quote: "The left vocal fold is relatively sluggish today. The left vocal fold has relatively normal abduction, but the adduction is slightly lacking and there is overcompensation on the right. There is a grade I arytenoid hypertrophy on both sides." Pet. Ex. 18 at 14. For the first time Dr. Heiland diagnosed petitioner with "vocal cord paralysis and larynx, unilateral." *Id.* at 15.

12) As documented by the MRI of petitioner's neck on February 2, 2018, there was: "T2 hyperintensity in the left vocal cord. Redundant soft tissue in the region of the left posterior supraglottic larynx. The left piriform sinus was slightly asymmetrically dilated. There were no tumors, lesions on the recurrent laryngeal nerve and no mediastinal or cervical adenopathy." Pet. Ex. 18 at 21. The radiologist noted that the findings may represent vocal cord paralysis. *Id.*

13) The voice and swallowing evaluation done on June 12, 2018, adequately documents a significant loss of voice power with breathlessness and some degree of dysphagia. The evaluation found mild unilateral (left) velopharyngeal weakness and asymmetry as well as moderate to severe neurogenic dysphonia characterized by reduced vocal intensity, hoarse, raspy, gravelly vocal quality, and reduced endurance. The evaluation also documented mild pharyngeal dysphagia characterized by reduced pharyngeal constriction, pharyngeal globus, difficulty swallowing dry, dense solid foods, and occasional coughing when attempting to swallow thin viscosity liquid in larger amounts at a fast rate. His voice handicap Index was rated as functionally severe and physically severe. Records of the voice evaluation should be consulted for further detail. Pet. Ex. 10 at 3-8.

14) The upper GI endoscopy done in May 2018 documented only mild reflux esophagitis and pointed to dysphagia and cough due to oropharyngeal dysfunction and cranial neuropathy.

15) The description of the severe coughing on the cruise in late February 2018 and the development of progressively worse dysphagia in conjunction with the loss of voice over the October 2017 through February 2018 time period appears to be sufficiently in accord with the objective medical evaluations occurring during that time period to be found as fact.

16) I conclude that petitioner did develop at least a markedly increased level if not completely different type of symptomatology including dysphonia and dysphagia with vocal cord paralysis in this time period.

17) It is more difficult to draw a conclusion about the onset of the spinal accessory nerve pathology and arguably a brachial plexus pathology as alleged by petitioner. The affidavits indicate that petitioner began to experience impairment in his dominant left arm in the October/November 2017 time period. This history that he provided to Dr. Sivakumar reflected the same time period. However, Dr. Laurin was the first to document this complaint in any medical record on February 16, 2018, noting that the condition began two to three weeks before. The reliability of her notes may be questioned as in a subsequent note on March 14, 2018, she noted both that petitioner had mild left arm weakness and that his recent onset of left arm weakness had resolved. Further her note appears to be at least confusing when approximately one month later, on April 18, 2018, Dr. Sivakumar recorded that petitioner had left arm weakness which had begun gradually in the fall and which progressed, and Dr. Sivakumar personally observed that petitioner could not abduct the arm above the horizontal with scapular winging. Pet. Ex. 13 at 13. Dr. Sivakumar noted left scapular winging and loss of sternocleidomastoid and trapezius function. *Id.* Nevertheless, it seems odd that petitioner would not have raised the left arm issue with a medical doctor prior to February 16, 2018, particularly as the left was his dominant arm.

IV. Questions to be Addressed

1) This case appears to present a question of whether the new signs and symptoms of dysphonia, dysphagia, and left arm and shoulder impairment were more likely than not the result of an autoimmune response to cranial nerves 9, 10, and 11 and/or the brachial plexus, or alternatively, whether these symptoms represented the culmination of an erosive or irritant process caused by chronic GERD and/or post-nasal drip.

2) Expert testimony should address, in light of the full picture in this case, whether it is likely that the hoarseness experienced on the trip to South Dakota was an early stage of the more severe disease manifestation that occurred later in the fall, or whether the hoarseness experienced on that trip was more likely a response to GERD triggered by wine drinking and late dinners on the trip consistent with prior episodes as petitioner contends.

3) Experts should address whether the confluence of signs and symptoms including the well documented development of vocal cord paralysis described above which

occurred in the fall and winter of 2017-2018 are more likely caused by an autoimmune process or are more likely the result of a progressive process generated by GERD, post-nasal drip or some other long standing problem.

4) Experts should comment and explain whether the documented arytenoid erythema and hypertrophy are contributory to petitioner's dysphonia.

5) Petitioner may want to consider, but is not required, to undergo a laryngeal EMG and/or spinal accessory nerve EMG to substantiate that cranial nerves 9, 10, and 11 are the basis for his injury as opposed to a progressive GERD-based injury.

6) Any experts retained must consider all of the above history and in particular the facts found to be true in explaining the basis for concluding that petitioner's symptoms are based on an injury to the cranial nerves or on the contrary to a progression of his GERD symptoms.

7) Oral testimony may be required to clarify the onset of the left arm and neck issues as well as the extent of impairment both in terms of the magnitude and timing of the impairment. The medical basis of a diagnosis of a variant of Parsonage-Turner syndrome without any symptoms of pain will also have to be developed if petitioner intends to proceed on this theory, particularly as the cranial nerves considered to be at issue do not pass through the brachial plexus.

8) Similarly, oral testimony may be required to more fully elucidate the progression of petitioner's GERD during the fall/winter time period of 2017 and 2018.

9) Expert testimony will have to address the likely time course of the alleged cranial nerve injuries if they are secondary to a vaccination. While I have concluded that the significantly enhanced or different symptoms began to develop in late October or early November, it should be clear that they did not "plateau" within a few weeks to a month from onset as remarked in Dr. Sivakumar's note. Furthermore, experts may address whether the severity of the left arm symptoms and the condition of the sternocleidomastoid and trapezius muscles documented by Dr. Sivakumar's physical examination shed light on the time course of the development of the condition.

10) After developing expert opinion as to whether the injuries described above resulted from an autoimmune process, assuming at least petitioner's experts would so opine, as in all Vaccine Program cases, the *Althen* prongs must be addressed by experts explaining a theory as to how the vaccine at issue can cause the injury at issue, whether logically the vaccine did so in petitioner's specific case, and whether the timing of the injuries is medically acceptable for the theory proposed. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Dr. Sivakumar has written a report largely addressing his evaluation and diagnosis. Petitioner has also retained Dr. Marks who goes further in addressing the causation standard and proposes a theory of molecular mimicry. As the initial challenge of this case has been to address the chronology of medical events and the diagnoses, I have

not yet focused on the parties' expert reports. The parties and their experts should account for all facts found to be true herein before being finalizing any reports for filing.

V. Conclusion

The parties are ordered to provide these Findings of Fact to any experts with whom they consult or retain to offer an opinion in this case. An expert's assumption of any fact that is inconsistent with these Findings of Fact will not be credited. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the special master properly rejected an expert's opinion because it was based on facts not substantiated by the record). If the parties believe that a focused fact hearing targeted to the onset issues particularly as to the left arm would be helpful prior to the drafting of further expert reports, one may be requested.

Petitioner shall file supplemental expert report(s) based on these findings of fact **within 60 days, by Tuesday, June 22, 2021, unless petitioner and/or respondent request a focused fact hearing, in which case I will convene a status conference for scheduling purposes.**

If petitioner files supplemental expert reports, respondent shall file responsive expert report(s) or a status report proposing further proceedings **within 60 days thereafter**.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master