In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: January 24, 2023
Refiled in Redacted Form: March 27, 2023

E. A.,	*	PUBLISHED
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Petitioner,	*	No. 18-1587V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Influenza ("Flu") Vaccine; Bell's Palsy.
	*	
Respondent.	*	
	*	

Ronald C. Homer, Conway Homer, P.C., Boston, MA, for Petitioner.
Amanda Pasciuto, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

I. INTRODUCTION

On October 12, 2018, E.A. ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that she suffered Bell's palsy as the result of an

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

influenza ("flu") vaccination administered on October 19, 2015. Petition at Preamble (ECF No. 1). Respondent argued against compensation, stating that "this case is not appropriate for compensation under the terms of the Vaccine Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 30).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that Petitioner has provided preponderant evidence that her flu vaccine caused her Bell's palsy, satisfying Petitioner's burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is entitled to compensation.

II. ISSUES TO BE DECIDED

Diagnosis is not at issue. Joint Pre-Hearing Submission, filed April 4, 2022 at 1 (ECF No. 98). The parties stipulated that Petitioner received a flu vaccine on October 19, 2015; that onset of her symptoms, consistent with Bell's palsy, was November 28, 2015; and that Petitioner experienced the residual effects of Bell's palsy for more than six months. Id.

The central issue is whether Petitioner has provided preponderant evidence of causation for all three Althen prongs. Petitioner asserts that she has met her burden under the Althen prongs. Petitioner's Motion for Ruling on the Record ("Pet. Mot."), filed Apr. 11, 2022, at 39-52 (ECF No. 107). Respondent disagrees and argues that Petitioner failed to submit preponderant evidence that her flu vaccine more likely than not caused her Bell's palsy. Resp. Response to Pet. Mot. ("Resp. Response"), filed June 10, 2022, at 15-31 (ECF No. 108).

III. BACKGROUND

A. Medical Terminology

Bell's palsy is defined as "unilateral facial paralysis of sudden onset, due to [a] lesion of the facial nerve[,] [] resulting in characteristic distortion of the face." Bell Palsy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=95779 (last visited Nov. 15, 2022).

The facial nerve, also referred to as the seventh cranial nerve, "directs the muscles on . . . the face, including those that control eye blinking and closing and facial expressions such as smiling."[3] Resp. Exhibit ("Ex.") C, Tab 12 at 1.[4] "The facial nerve also carries nerve impulses to

[3] The large motor root "supplies the muscles of facial expression." Nervus Facialis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92293 (last visited Jan. 9, 2023).

[4] Bell's Palsy Fact Sheet, NINDS, 2018, https://www.ninds.nih.gov/bells-palsy-fact-sheet (last modified May 13, 2020).

the tear glands, the saliva glands, and the muscles of a small bone in the middle of the ear."[5] Id. The facial nerve consists of three portions. Relevant here, the intratemporal portion of the facial nerve includes three segments: labyrinthine (extending from the internal auditory canal ("IAC") to the geniculate ganglion), tympanic (extending horizontally from the geniculate ganglion to the pyramidal process), and mastoid (extending vertically from the pyramidal process to the stylomastoid foramen). See Michael Gleeson, External and Middle Ear, in Gray's Anatomy: The Anatomical Basis of Clinical Practice 624, 638 (Susan Standring et al. eds., 41st ed. 2016); see also Resp. Ex. C, Tab 1 at 2.[6] Due to the narrow course at which the facial nerve travels, it is vulnerable to nerve compression and ischemia at several areas including the labyrinthine segment. Gleeson, supra, at 639; see also Resp. Ex. A, Tab 2 at 5 ("[W]ith little room for expansion, . . . inflammation of the nerve (due to any cause) is thought to cause compression resulting in paralysis.");[7] Resp. Ex. C, Tab 1 at 3-4 ("[T]he facial canal's diameter of the labyrinthine segment is possibly an anatomical risk factor.").

Bell's palsy is considered an "acute idiopathic demyelinating peripheral neuropathy of the facial nerve." Pet. Ex. 22 at 1.[8] Thus, the etiology of Bell's palsy is unclear. Pet. Ex. 47 at 1;[9] Resp. Ex. C, Tab 6 at 1.[10] However, autoimmune, inflammatory, and infectious etiologies have been postulated. Pet. Ex. 13 at 8-9; Pet. Ex. 18.[11]

B. Procedural History

Petitioner filed her petition on October 12, 2018, and filed medical records on February 12, 2019. Petition; Pet. Exs. 1-6. On July 12, 2019, Respondent filed a Rule 4(a) Report offering a preliminary summary of the filed medical records but indicated that medical personnel

[5] The nervus intermedius (smaller root) "contributes parasympathetic and special sensory fibers to the facial nerve." Nervus Intermedius, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92313 (last visited Jan. 9, 2023).

[6] Wenjuan Zhang et al., The Etiology of Bell's Palsy: A Review, 267 J. Neurology 1896 (2020).

[7] Stephen G. Reich, Bell's Palsy, 23 Continuum 447 (2017).

[8] Aharon Aviel et al., Peripheral Blood T and B Lymphocyte Subpopulations in Bell's Palsy, 92 Annals Otology Rhinology & Laryngology 187 (1983).

[9] Weigong Zhou et al., A Potential Signal of Bell's Palsy After Parenteral Inactivated Influenza Vaccines: Reports to the Vaccine Adverse Event Reporting System (VAERS) United States, 1991-2001, 13 Pharmacoepidemiology & Drug Safety 505 (2004).

[10] Cheng-Hsiu Chou et al., Bell's Palsy Associated with Influenza Vaccination: Two Case Reports, 25 Vaccine 2839 (2007).

[11] A. Greco et al., Bell's Palsy and Autoimmunity, 12 Autoimmunity Rev. 323 (2012). This article is also referenced by Respondent. Resp. Ex. A, Tab 1.

at the Division of Injury Compensation Programs ("DICP") had not yet been able to review the claim and offer an opinion as to Respondent's position. Resp. Rule 4(a) Rept. (ECF No. 15). Thereafter, Respondent filed a status report indicating his intent to defend the claim. Resp. Status Rept., filed Sept. 19, 2019 (ECF No. 16).

On September 26, 2019, Chief Special Master Corcoran issued an order outlining his preliminary impressions of Petitioner's claim. Order dated Sept. 26, 2019, at 2 (ECF No. 17). Chief Special Master Corcoran encouraged both parties to consider engaging in settlement negotiations given the claim's underlying nature. Id. The matter was subsequently transferred to the undersigned on October 3, 2019. Notice of Reassignment, filed Oct. 3, 2019 (ECF No. 19).

Prior to retaining an expert, and at Petitioner's request, the undersigned held a Rule 5 status conference on November 7, 2019. Rule 5 Order dated Nov. 7, 2019 (ECF No. 21); Pet. Status Rept., filed Oct. 18, 2019 (ECF No. 20). The undersigned stated that "ample case law and medical literature support a finding in favor of [P]etitioner in this matter." Rule 5 Order dated Nov. 7, 2019, at 1. "The undersigned referenced multiple cases, involving the flu vaccine and an alleged injury of Bell's palsy, all of which resulted in joint stipulations awarding damages to petitioners." Id. Nonetheless, Respondent still indicated his client was not interested in settlement. Id. at 2. The undersigned ordered Respondent to file his Rule 4(c) Report and recommended Petitioner strengthen her case by providing an expert report. Id.

Subsequently, on January 6, 2020, Respondent filed his Rule 4(c) Report stating that Petitioner is not entitled to compensation for failure to meet her causation-in-fact burden of proof under Althen, particularly, that Petitioner provided no evidence of a causal theory establishing the flu vaccine can cause and did cause Petitioner's Bell's palsy. Resp. Rept. at 4-6.

On April 9, 2020, Petitioner filed an expert report from neurologist Dr. Kazim Sheikh. Pet. Ex. 13. On July 24, 2020, Respondent filed expert reports from neurologist Dr. Dara Jamieson and immunologist Dr. Steven Tomkins. Resp. Exs. A, C. In response, Petitioner filed a supplemental report from Dr. Sheikh on November 2, 2020. Pet. Ex. 42.

At the request of the parties, a second Rule 5 status conference was held on December 17, 2020. Pet. Joint Status Rept., filed Sept. 18, 2020 (ECF No. 52); Rule 5 Order dated Dec. 17, 2020 (ECF No. 59). Since the Rule 5 status conference in November 2019, expert reports and medical literature had been filed. Rule 5 Order dated Dec. 17, 2020, at 1. In addition, the undersigned stated she had the opportunity to review "similar cases involving flu vacc[ination] and Bell's palsy and therefore ha[d] obtained more comprehensive knowledge of the clinical course of Bell's palsy, the literature, and theories behind causation of the disease." Id. The undersigned stated that because both parties' experts agreed with the diagnosis of Bell's palsy and the onset of approximately 40 days post-vaccination, the remaining issue to be resolved was causation. Id. The undersigned made a preliminary finding that Petitioner had provided preponderant evidence of causation based on the Althen prongs and posited "that if this case went to a hearing, she would probably find in favor of [P]etitioner." Id. at 3. However, given the risk of litigation, she recommended that "this case should be resolved by settlement." Id.

The parties entertained settlement negotiations from January to July 2021. See ECF Nos. 60, 64-65, 67, 69, 7, 73. Thereafter, the parties reached an impasse in settlement discussions. Pet. Status Rept., filed July 21, 2021 (ECF No. 73). Following a status conference on August 3, 2021, Respondent filed a supplemental report of Dr. Tompkins on October 18, 2021, and Petitioner filed a second supplemental expert report of Dr. Sheikh on February 15, 2022. Resp. Ex. E; Pet. Ex. 63; see Order dated Aug. 3, 2021 (ECF No. 74). Petitioner also filed updated medical records. Pet. Exs. 62, 95.

On February 17, 2022, the parties conveyed their preference to proceed with a ruling on the record in lieu of an entitlement hearing. Pet. Joint Status Rept., filed Feb. 17, 2022 (ECF No. 91). Petitioner filed a Motion for Ruling on the Record on April 11, 2022. Pet. Mot. Respondent filed a response to Petitioner's Motion for Ruling on the Record on June 6, 2022. Resp. Response. Petitioner filed her reply on July 19, 2022. Pet. Reply to Resp. Response ("Pet. Reply"), filed July 19, 2022 (ECF No. 111).

This matter is now ripe for adjudication.

C. Medical History

Prior to the vaccination at issue, Petitioner had a prior medical history significant for chronic myofascial pain syndrome involving her neck and upper thoracic spine. Pet. Ex. 12 at ¶ 6; Pet. Ex. 2 at 66, 231. She effectively managed this condition with trigger point injections. Pet. Ex. 12 at ¶ 6. Petitioner had a history of degenerative spine disease. Pet. Ex. 2 at 480. She also had a history of heart palpitations, carpal tunnel release, Dupuytren's contractures, fibromatosis in the feet, seasonal allergies, and several orthopedic injuries. Id. at 12-13, 187. These were controlled with medications. Pet. Ex. 12 at ¶ 6. Regarding family history, Petitioner reported that her half-brother is deaf due to rubella. Pet. Ex. 2 at 274.

Petitioner was 62 years old when she received the quadrivalent flu vaccine at issue in her left deltoid on October 19, 2015. Pet. Ex. 1 at 2.

In November 2015, Petitioner traveled from her home in Virginia to Wisconsin to visit with a large group of friends and family for the Thanksgiving holiday.[12] Pet. Ex. 12 at ¶ 9. While there, Petitioner thought she may be developing a cold and took Mucinex. Pet. Ex. 2 at 675. On November 28, 2015, 41 days after her flu vaccination, Petitioner awoke with left facial numbness and weakness. Pet. Ex. 12 at ¶ 10. Her friend's daughter, a physician, prescribed Petitioner 60 mg of prednisone that she took that night. Id.; Pet. Ex. 2 at 675.

The following day, on November 29, 2015, Petitioner returned home and presented to the emergency department ("ED") at Walter Reed National Military Medical Center ("Walter Reed") for her left-sided facial complaints. Pet. Ex. 2 at 672. She reported the facial numbness began the previous morning and quickly turned to weakness of the left cheek and the inability to close her left eye. Id. at 672, 675. Her left eye was dry and was neither blinking nor closing

[12] Thanksgiving Day was November 26, 2015.

completely. Id. at 673, 675. Her partner of 25 years had died the month before, and she was very tearful. Id. at 673. A review of symptoms included "slight [upper respiratory infection] symptoms" but no signs of infection were documented. Id. at 675. Petitioner denied difficulty with speaking/swallowing and denied any difficulty with hearing. Id. at 673. Physical examination showed peripheral weakness in the seventh cranial nerve ("CN VII" or "CN7") on the left side but bilaterally normal ears. Id. at 675. No vesicles in the ear, or elsewhere, were noted. See id. Petitioner was diagnosed with Bell's palsy and was prescribed Valtrex.[13] Id. at 676. She was instructed to continue prednisone, to tape her eye closed, and to follow up with her primary care provider ("PCP"). Id.

On December 15, 2015, Petitioner saw her PCP, Dr. Huma Chaudhery, for a follow-up visit "on recent Bell's palsy diagnosis." Pet. Ex. 2 at 233. Petitioner reported she developed left-sided facial weakness about three to four weeks prior and that her symptoms had started to improve. Id. Her symptoms included the "inability to lift her left eye[]brow, close her left eye, or smile on the left side." Id. at 233, 235. These symptoms were observed upon physical examination and "[a]bnormal diffuse left CN VII weakness" was noted. Id. at 235. Petitioner denied vision changes or left eye pain but noted intermittent left preauricular pain. Id. at 233. Her ear exam was normal. Id. at 234. Again, no vesicles in the ear, or elsewhere, were noted. See id. She had been following good eye care techniques that Dr. Chaudhery instructed her to continue including using artificial tears, wearing protective eyeglasses, and using a patch on her eye at night while sleeping. Id. at 233, 236. Due to the "severity of dysfunction and minimal improvement after nearly one month," Dr. Chaudhery wanted to check for Lyme[14] antibodies and obtain a brain magnetic resonance imaging ("MRI"). Id. at 236. At this visit, Dr. Chaudhery noted Petitioner's chronic myofascial pain and her upcoming appointment with pain management for trapezius and peri-scapular trigger points.[15] Id. Dr. Chaudhery also noted Petitioner's recent loss of her partner and that she was "teary during the encounter." Id. at 233.

[13] Valtrex is trademark name for valacyclovir hydrochloride. Valtrex, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52497 (last visited Jan. 9, 2023). Valacyclovir hydrochloride is "the hydrochloride salt of the l-valyl ester of acyclovir, used as an antiviral agent in the treatment of genital herpes and herpes zoster in immunocompetent adults." Valacyclovir Hydrochloride, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=52462 (last visited Jan. 9, 2023).

[14] Lyme disease is "a recurrent, multisystemic disorder caused by the spirochete *Borrelia burgdorferi*; vectors for human infection are the ticks *Ixodes scapularis* and *I. pacificus*." Lyme Disease, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=70552 (last visited Jan. 9, 2023).

[15] Petitioner continued to receive trigger point injections for her chronic myofascial pain throughout her course of treatment for Bell's palsy. Pet. Ex. 2 at 236, 262-64, 282-83, 297-99, 311-12, 329-33, 366-69, 391-93, 431-32.

Petitioner underwent an MRI of the brain and IAC on December 24, 2015. Pet. Ex. 2 at 249. Dr. Robert Shih's impression of the MRI was "[a]bnormal enhancement along the intratemporal left CN7 is nonspecific and can be seen in the setting of Bell's palsy." Id. at 251.

At a follow-up visit with Dr. Chaudhery on February 16, 2016, Petitioner reported additional improvement of symptoms in the past four to six weeks. Pet. Ex. 2 at 246. However, she reported a new onset of left ear pressure and a "bubbling sensation/machine sound" in the past month. Id. She denied left ear pain, drainage, hearing loss, ringing, fever, and vertigo. Id. On physical examination, she was able to elevate her eyebrow and her frown/smile was slightly diminished on the left. Id. at 248. Other than the onset of "ipsilateral increased pressure/bubbling sound" in her left ear, her "left sided facial paralysis [had] slowly improv[ed] over the past [four] months." Id. at 251. Dr. Chaudhery recommended Petitioner resume her previously discontinued antihistamines and nasal steroids for allergic rhinitis (seasonal allergies), which he felt may improve her symptoms. Id. He also recommended that she follow-up with an ear, nose, and throat ("ENT") specialist. Id.

Petitioner was evaluated by Dr. Sally Stasio and Dr. Paula Jackson at the Walter Reed Otolaryngology (ENT) Clinic on February 24, 2016. Pet. Ex. 2 at 255. Petitioner's chief complaint was "clicking in the ear." Id. She reported that after her slow improvement at the end of December, "she felt sharp pains in her face and twitching of her left face. Her nerve ha[d] continued to improve, and she ha[d] noticed presence of clicking or thumping sounds in her left ear. These [did] not match her heartbeat, and worsen[ed] when she contract[ed] her face." Id. at 255-56. She endorsed autophonia[16] and "mild sensation of fullness that does not clear with [V]alsalva."[17] Id. at 256. Still, she denied the presence of vesicles, vertigo, and "sounds of her eyes moving in her head." Id. at 255-56. On examination, her hearing was functional, no abnormalities were noted on nasal endoscopy, and her facial sensation was intact. Id. at 256. She had mild facial weakness at the frontal and marginal branches of CN VII on the left,

[16] Autophonia or autophony is the "abnormal hearing of one's own voice and respiratory sounds." Autophony, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=5016 (last visited Jan. 9, 2023).

[17] Valsalva is the "forcible exhalation effort against occluded nostrils and a closed mouth causes increased pressure in the auditory tube and middle ear, so that the tympanic membrane moves outward." Valsalva Maneuver, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=87881 (last visited Jan. 9, 2023).

classified as a House-Brackman ("HB")[18] grade two, and no synkinesis[19] with animation. Id. at 256, 261. Dr. Stasio remarked that Petitioner's "left ear thumping seems to be related to her facial movement, suggesting [synkinesis] of CN VII innervation to the stapedius muscle."[20] Id. at 260. Tinnitus (left ear), bilateral unspecified hearing loss, and "patulous eustachian tube[21] (voice echoes in her head)" were also reported in Dr. Stasio's assessment. Id. Given Petitioner's history, Dr. Jackson, recorded Bell's palsy as the diagnosis, with Ramsay Hunt syndrome[22] as a differential diagnosis, but noting that the presentation of that was "not classic." Id. at 261. Dr. Jackson also noted Petitioner had a "near complete recovery" of the Bell's palsy, going from HB grade 6 (per her review of Petitioner's video of her acute onset symptoms) to HB grade 2, and that "time alone may result in further recovery." Id. However, because there was a question of enhancement in the left medial IAC, an MRI was ordered to be repeated in six to eight months. Id.

On March 29, 2016, Petitioner returned to Dr. Chaudhery for a follow-up. Pet. Ex. 2 at 268. He reported "significant improvement" and scheduled an MRI for December 16, 2016. Id.

On April 15, 2016, Petitioner presented to the Walter Read Audiology Clinic for "left ear problems since Bell[']s [p]alsy on 28 November 2015." Pet. Ex. 2 at 274. At this visit, Petitioner reported no difficulty hearing over background noise or understanding speech. Id.

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[18] House-Brackmann is facial nerve scaled grading system of facial dysfunction. Pet. Ex. 18 at 2. Grade two refers to "[s]light weakness noticeable only on close inspection. At rest: normal symmetry of forehead, ability to close eye with minimal effort and slight asymmetry. No synkinesis, contracture, or hemifacial spasm." Id. at 3. Grade six refers to total paralysis. Id.

[19] Synkinesis is "an unintentional movement accompanying a volitional movement, such as the facial contortions accompanying severe exertion." Synkinesis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=48544 (last visited Jan. 9, 2023).

[20] The stapedius muscle is in the tympanic cavity (middle ear) and "attaches to the posterior surface of the neck of the stapes." Michael Gleeson, External and Middle Ear, in Gray's Anatomy: The Anatomical Basis of Clinical Practice 624, 637 (Susan Standring et al. eds., 41st ed. 2016).

[21] The eustachian tube is "a channel . . . lined with mucous membrane, that establishes communication between the tympanic cavity and the nasopharynx and serves to adjust the pressure of gas in the cavity to the external pressure, as well as for mucociliary clearance of the middle ear." Tuba Auditiva, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=115257 (last visited Jan. 9, 2023).

[22] Ramsay Hunt syndrome is a "herpes zoster involving the facial and vestibulocochlear nerves, often associated with transitory ipsilateral facial paralysis and herpetic vesicles of the external ear or tympanic membrane; there may or may not be tinnitus, vertigo, and hearing disorders." Ramsay Hunt Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=111266 (last visited Jan. 9, 2023).

However, she did report listening to the TV and radio louder since November 2015. Id. She denied earache, ear pressure, fullness, and discharge. Id. "Tinnitus [t]riggered by Bell[']s [p]alsy" was noted. Id. Petitioner reported "left ear tinnitus sounds like an ocean with machine gun sound when she talks" and that she "[h]ears herself 'weird, it's like banging on left ear.'" Id. She reported her physician attributed "this 'machine gun' sound to facial nerve activating the stirrup." Id. On that date,[23] an audiometric hearing test was performed and revealed "[m]ixed conductive and sensorineural hearing loss, unilateral left ear, with unrestricted hearing on the contralateral side: Patient has essentially normal hearing, bilaterally." Id. at 276. Additionally, it was noted that Petitioner would not "have difficulty understanding speech in every day listening environments" and was not a candidate for a hearing aid. Id. Petitioner was advised that if the tinnitus worsened, she could attend a Progressive Tinnitus Management workshop. Id. She was to follow-up with ENT due to the conductive component in her left ear and it was recommended to have another audiologic evaluation in one year to monitor her hearing status. Id.

Petitioner visited the Water Reed Optometry Clinic on April 19, 2016 for an annual exam. Pet. Ex. 2 at 278. Petitioner did not report any vision problems. Id. She was diagnosed with bilateral dry eyes syndrome. Id. at 280.

At a follow-up visit with Dr. Chaudhery on June 28, 2016, Petitioner had "recovered most of her function" but felt that her "progress has plateaued." Pet. Ex. 2 at 292. Her tinnitus was still "moderately bothersome." Id. at 289. Physical examination found "facial sensation to light touch decreased on the left, left sided ptosis." Id. at 290. She was advised to follow up with ENT for her tinnitus and she was referred to physical therapy for facial rehabilitation. Id. at 292.

On July 6, 2016, Petitioner followed-up with the Otolaryngology Clinic for Bell's palsy and tinnitus. Pet. Ex. 2 at 293. She was seen by Dr. Joseph F. Goodman. Id. Her main concern was the tinnitus and described a "repetitive thumping/knocking (like a machine gun)" sound in her left ear that was brought on by "smiling, grimacing, and tilting her head down." Id. She reported continued difficulty hearing out of her left ear and her recent audiogram showing mild 10dB hearing loss in her left ear was noted. Id. She also complained of continued difficulty with dry eyes, which was controlled by eye drops, and dry mouth, which was controlled by a mouth rinse and lozenges. Id. Petitioner reported increased nasal congestion and "ear fullness" since stopping Flonase. Id. She denied postnasal drip, reflux, and sore throat. Id. There was no "middle ear effusion" evident on examination but Petitioner reported "sensation of fluid in ears on [V]alsalva." Id. at 294. Facial sensation to light touch was symmetric bilaterally. Id. Facial strength was HB 3/6 on the left with "weakness of marginal branch and some asymmetry at rest, but complete eye closure." Id. Dr. Goodman noted residual weakness primarily in the marginal and cervical branches of the facial nerve." Id. at 295.

Given her history and the sensation of fluid in her ears, Dr. Goodman recommended starting her on a nasal regimen of oxymetazoline for five days, Flonase daily, and saline rinses.

[23] A hearing test was performed in 2013 but those results are not available. Pet. Ex. 2 at 274; see also Resp. Ex. A at 5, 5 n.2.

Pet. Ex. 2 at 294. Dr. Goodman's assessment was "[t]innitus likely caused by stapedius myoclonus[24] and synkinesis after the recovery from [Bell's palsy]. If extremely bothered by this and no relief from nasal spray regimen to open the Eustachian tube may refer to Dr. Gupta to assess for possible laser ablation of stapedius tendon." Id. Petitioner indicated she was not interested in that option at the time. Id. Dr. Goodman also stated the tinnitus had "not improved and worsens with smiling, grimacing, and looking down." Id. at 295. He determined "given history of CN 7 injury her symptoms are likely 2/2 synkinesis of stapedius muscle or tensor tympani muscle."[25] Id. He added that Petitioner "may have had an atypical presentation of Ramsey-Hunt given the severe ear pain she experienced about one week after the onset of facial paralysis, also given her mild middle ear symptoms." Id.

On July 13, 2016, Petitioner had her first physical therapy session at the Jackson Clinics with Deborah Gilpin. Pet. Ex. 3 at 1. Petitioner presented with complaints of facial weakness and asymmetry following her "acute onset of [left] sided Bell's palsy." Id. She reported waking up with left-sided facial paralysis on November 28, 2015, went to the ED and started medication, and that three weeks later she started to regain facial movement but then got tinnitus in her left ear. Id. She noticed improvement in the following months but was still having numbness along the left side of her face. Id. at 2. She still had difficulty eating and drinking "due to weakness and motor control" and would have "involuntary twitching along upper lip and eyelid." Id. She expressed wanting to be able "to smile and open and close her [left] eye symmetrically to her [right eye]." Id. Petitioner also reported feeling like she "slurr[ed] her words occasionally" and that she was found to have some "mid[-]range" hearing loss. Id. On evaluation, Ms. Gilpin noted that Petitioner demonstrated "some volitionary use of her [left] facial muscles—just end range weakness and tight scalenes[26] and [sternocleidomastoid muscle ("SCM")][27] that may be

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[24] Myoclonus are "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." Myoclonus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com /dorland/definition?id=32802 (last visited Jan. 9, 2023).

[25] The tensor tympani and stapedius muscles are located in the tympanic cavity (middle ear). Gleeson, supra note 20, at 637. "When noises are loud, and immediately before speaking, a reflex contraction of stapedius and tensor tympani takes place that helps dampen down the movement of the ossicular chain before vibrations reach the ear." Id.

[26] Scalenes are lateral vertebral (neck) muscles. John C. Watkinson & Michael Gleeson, Neck, in Gray's Anatomy: The Anatomical Basis of Clinical Practice, supra note 20, at 442, 451. "Scaleni anterior, medius and posterior extend obliquely between the upper two ribs and the cervical transverse process." Id. Scalene muscles help elevate the first or second ribs and bend the cervical portion of the vertebral column forward and/or laterally and rotate it towards the opposite side. Id.

[27] The sternocleidomastoid muscle ("SCM") "descends obliquely across the side of the neck and forms a prominent surface landmark, especially when contracted." Watkinson & Gleeson, supra note 26, at 448-49. The SCM rotates the head upward and to the opposite side. Id.

contributing to impingement of the facial nerve. She also demonstrate[d] impaired balance which speaks to some involvement of the vestibular nerve as well." Id. Ms. Gilpin indicated Petitioner's "excellent" rehab potential to "strengthen those muscles and normalize her motor ability" on the left side of her face and recommended one to two physical therapy sessions per week. Id. at 1-2.

By August 12, 2016, Petitioner had attended four physical therapy sessions "focusing on facial motor learning, myofascial release[,] and progressing a home exercise program of facial exercises to restore symmetry and movement to the [left] side of her face" for her "sudden onset on 11/28/15" of Bell's palsy. Pet. Ex. 3 at 17. In addition to her home exercise program, a protocol to use her "portable electrical stimulation machine"[28] was implemented for Petitioner "to improve recruitment of the muscles innervated by the facial nerve." Id. at 8, 17. During this time of treatment, Petitioner reported "some improvement in her ability to smile on the [left side], open her eye, and to blow a feather. Muscles still fatigue significantly by the end of the day and she is still having some difficulty with eating and drinking." Id. at 17. Continued physical therapy was recommended. Id.

On August 17, 2016, Petitioner returned to the Otolaryngology Clinic for a follow-up on her Bell's palsy and tinnitus. Pet. Ex. 2 at 300. "[R]esidula synkinesis after left sided Bell's palsy, as well as some tinnitus and stapedial muscle spasm" was noted. Id. at 305. Petitioner expressed concern about the transcutaneous electrical nerve stimulation ("TENS") unit "worsening her synkinesis." Id. at 300. It was explained that she may continue using it if it provides symptomatic relief but that it would "likely not help or hurt her synkinesis." Id. at 304. She was to continue with physical therapy. Id. at 305. Petitioner again did not wish to pursue surgical options at this time. Id. at 304. A hearing aid to "help mask her underlying tinnitus was discussed and Petitioner requested a referral to audiology to discuss it further. Id. Botox was also discussed as a potential way to improve facial symmetry in the future. Id.

Petitioner presented to the Audiology Clinic at Walter Reed on October 24, 2016. Pet. Ex. 2 at 316. Petitioner reported hearing loss and tinnitus in her left ear that comes and goes and described as an "ocean sound." Id. She also reported the "machine gun" noise which was "intermittent in the left ear associated with talking, chewing[,] and/or smiling." Id. It was noted that this was "secondary to recovered Bell's palsy episode on 28 Nov[ember] 2015. Recent ENT eval[uation] suggests that this sound/sensation is likely secondary to stapedius myoclonus." Id. A hearing test was performed and revealed "no significant change in hearing" since her last visit. Id. at 316-17. An amplification hearing aid, which would not help the intermittent "machine gun" noise but could help with the "ocean" sounding tinnitus, was discussed. Id. at 317. Petitioner did not want to try the hearing aid at that time. Id.

Petitioner saw Dr. Chaudhery again on February 28, 2017. Pet. Ex. 2 at 398. She stated she felt her recovery had "plateaued." Id. Dr. Chaudhery noted she had tried physical therapy

[28] The portable electrical stimulation machine is referred to in Petitioner's declaration and future medical records as a "TENS" unit, short for transcutaneous electrical nerve stimulation. See, e.g., Pet. Ex. 12 at 23; Pet. Ex. 2 at 300.

but it was "without benefit." Id. Petitioner mentioned she would be retiring soon and requested a referral to Johns Hopkins Facial Paralysis and Pain Treatment Center. Id.

On March 27, 2017, Petitioner presented to the Optometry Clinic for a comprehensive eye exam. Pet. Ex. 2 at 409. Reason for visit was "residual dryness from Bell's palsy November 2015." Id. at 407. Petitioner reported she felt "like there is a tightening across the eyelid that decreases her fissure width." Id. Bilateral dermatochalasis[29] and dry eyes were noted. Id. at 409. She was interested in a therapy referral to improve her facial nerve function. Id. at 407.

On March 28, 2017, at the Hearing Conservation Clinic, Petitioner reported her tinnitus was "mildly bothersome." Pet. Ex 2 at 419. No hearing loss was noted, and her automated pure tone threshold audiogram was normal. Id.

Petitioner had a consultation with Dr. Amir Hossein Dorafshar at the Johns Hopkins Plastic Surgery Clinic on April 6, 2017. Pet. Ex. 5 at 6. Petitioner presented with concern of facial asymmetry, twitching, and synkinesis. Id. On examination, Dr. Dorafshar noted "excessive skin and hooding of the left upper eyelid. She has ptosis of the left upper eyelid. Her left nasolabial fold is pronounced. She has hypertrophy of her neck platysmal muscles. There is twitching of her upper and lower lips and chin." Id. Prognosis and treatment options discussed included Botox for the twitching, upper eyelid ptosis and removal of the excess skin, tissue rearrangement to improve facial symmetry, and removal of platysmal bands on the left side. Id. Petitioner was to consider her options and attend physical therapy. Id.

An MRI of the brain and IAC was performed on April 7, 2017 due to "left facial nerve paresis with incomplete recovery." Pet. Ex. 2 at 710. The results were normal. Id. The enhancement of the left facial nerve seen on the MRI of December 24, 2015 was no longer present. Id.

On April 26, 2017, Petitioner presented to the Ophthalmology Clinic at Walter Reed for "evaluation of synkinesis follow[ing] left Bell's palsy." Pet. Ex. 2 at 444. Her chief complaint was "left upper eyelid 'pulling' closed." Id. "When she yawns, sneezes, or coughs, her left eye completely closes. She also bites the left side of her mouth frequently." Id. Ophthalmologist Dr. Eva Chou evaluated her and noted that Petitioner had not yet seen an ophthalmologist or neurologist since developing Bell's palsy. Id. Dr. Chou discussed with Petitioner that "her periorbital symptoms and left upper eyelid relative ptosis could most likely be lessened with Botox treatments." Id. at 445. Two days later, on April 28, Petitioner had her first periorbital Botox treatment at nine injection sites. Id. at 455.

Petitioner presented with her referral from Dr. Dorafshar to her first physical therapy appointment at Johns Hopkins on May 9, 2017. Pet. Ex. 5 at 30. She had five physical therapy sessions for "management of residual facial synkinesis" from May to December 2017. Id. at 30-

[29] Dermatochalasis is a "disorder[] of the elastic fiber network in which the skin lacks elasticity and resilience." Cutis Laxa, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=68177 (last visited Jan. 9, 2023).

105. At her subsequent appointments in June, August, and December, she reported improvement in facial synkinesis since starting the Botox treatment. Id. at 68, 81, 94.

Dr. Kevin Cannard, a neurologist at the Walter Reed Neurology Clinic, evaluated Petitioner for "left facial synkinesis following recovery from Bell's palsy" on June 27, 2017. Pet. Ex. 2 at 480. Petitioner was sent to Dr. Cannard to expand Botox injections to the lower muscles of her facial expression. Id. Dr. Cannard's assessment was left hemifacial spasm with associated synkinesis as a residual effect of Bell's palsy. Id. Dr. Cannard said Petitioner had "obtained excellent results of the involuntary contractions of her obicularis oculi muscles" following her first Botox injection in Ophthalmology. Id. He noticed the spasms were less apparent that day because she was "currently at the peak effect of her first Botox injection" administered on April 28. Id. Dr. Cannard's assessment also included palsy of the seventh cranial nerve "with subtle residual weakness; onset 28 November 2015." Id. He discussed with Petitioner that the "asymmetry secondary to the weakness [would] not be compensated for with Botox injections and may even become more pronounced. . . . Fortunately, the effects of Botox [would] be transient." Id. Dr. Cannard planned to expand the injection pattern established by Dr. Chou as well as "inject some of her lower muscles of facial expression in hopes of achieving a more comprehensive suppression of her symptoms." Id. at 481.

On August 17, 2017, Petitioner received her first Botox injection from Dr. Cannard for "control of left hemifacial spasm and synkinesis." Pet. Ex. 2 at 512. On this date Dr. Cannard noted "[i]t [was] clear . . . that the patient does indeed have some persistent weakness as a residual effect of her Bell's palsy back in 2015." Id. at 511.

Petitioner continued to receive these injections approximately every three to four months. Pet. Ex. 2 at 562 (November 30, 2017); Pet. Ex. 2 at 590 (March 15, 2018); Pet. Ex. 2 at 612 (July 23, 2018); Pet. Ex. 2 at 645 (October 24, 2018); Pet. Ex. 10 at 6 (March 4, 2019); Pet. Ex. 10 at 37 (June 17, 2019); Pet. Ex. 10 at 60 (October 16, 2019); Pet. Ex. 60 at 53 (January 28, 2020). Dr. Cannard noted "[e]ach time we inject the patient she is getting [a] slightly better response with [the] minor adjustments we are making." Pet. Ex. 10 at 50. Due to the Covid-19 pandemic, Petitioner's regular Botox injections were delayed. Pet. Ex. 60 at 28. Petitioner resumed injections on July 6, 2020. Id.; Pet. Ex. 60 at 9 (October 5, 2020); Pet. Ex. 61 at 68 (January 28, 2021); Pet. Ex. 61 at 34 (June 7, 2021); Pet. Ex. 61 at 11 (October 5, 2021).

While receiving the periodic Botox treatments, Petitioner sought additional consultations regarding her facial asymmetry. On February 27, 2019, Petitioner presented to the Johns Hopkins Facial Plastic & Reconstructive Surgery Clinic. Pet. Ex. 11 at 14. Dr. Patrick Joseph Byrne noted Petitioner presented for the diagnosis of facial paralysis. Id. In addition to the facial paralysis and asymmetry, Petitioner had continued complaints of "tinnitus with smile, eye closure when talking[,] and tightness of her left chin." Id. Facial injections were performed at this visit. Id. at 15. Dr. Byrne's assessment was "incomplete left facial paralysis following Bell's palsy in [November] 2015." Id. He discussed with Petitioner injectable treatments, platysmectomy (facial retraining), and surgical interventions. Id.

Petitioner presented to Dr. Michael Timothy Gocke at Virginia Oral, Facial & Implant Surgery on October 4, 2019. Pet. Ex. 8 at 3. Petitioner reported that the "[B]otox ha[d] been

helpful with [spasms,] opening up of left eye[,] and [synkinesis,] but ha[d] not helped with smile and lower part of face." Id. Surgical options were discussed. Id. Dr. Gocke recommended Botox or collagen lift threads. Id. at 5.

Seeking a facial nerve expert, on May 11, 2021, Petitioner had a telehealth consultation with plastic surgeon, Dr. Babak Azizzadeh, of Beverly Hills, California. Pet. Ex. 62 at 1. Dr. Azizzadeh recommended reconstruction surgery. Id. At a follow-up with Dr. Cannard, Petitioner discussed her consultation with Dr. Azizzadah. Pet. Ex. 61 at 35. Dr. Cannard advised against surgical intervention as it could "make her response to Botox therapy more challenging and because she has very little disfiguration as a result of the residual weakness from her Bell's palsy." Id.

Petitioner followed-up with Dr. Azizzadeh for an in-person evaluation on January 24, 2022. Pet. Ex. 62 at 1. Her main goal was improving her smile. Dr. Azizzadeh's surgical plan including selective neurectomy, symmetrical facial repositioning, chin augmentation, and bilateral eye lifts, was further discussed. Id. at 1, 4-5.

No further records have been filed.

D. Petitioner's Declaration[30]

In her declaration, Petitioner stated she worked as a registered nurse ("RN"), served as a Commissioned Officer in the U.S. Public Health Service ("USPHS"), and worked as an attorney for the U.S. Department of Health and Human Services ("HHS"), Office of General Counsel ("OGC"). Pet. Ex. 12 at ¶¶ 1-2, 5. She retained her status as an active-duty nurse officer in the USPHS for thirty years until her retirement from HHS, OGC in 2017. Id. at ¶ 5.

Prior to her Bell's palsy, Petitioner stated her "main ongoing health issue was chronic upper back and neck myofascial pain syndrome." Pet. Ex. 12 at ¶ 6. She effectively managed this issue with "trigger point injections, foam rolling, stretching, regular exercise, and occasional pain medications and muscle relaxants." Id. She has degenerative changes in her spine, and has had periodic musculoskeletal and joint problems, such as wrist and ankle fractures that required surgical repair. Id. She also stated a "history of seasonal allergy symptoms and heart palpitations that are controlled for the most part with medications." Id. With these conditions under control, she considered herself to be "generally very healthy and active." Id. at ¶ 7. She attributed this to healthy eating and vigorous fitness classes she "participated in 3-5 times weekly since 2011, except for the periods when [she] was recovering from ankle surgery." Id.

Petitioner received the flu vaccine at a USPHS Federal Occupational Health Center on October 19, 2015. Pet. Ex. 12 at ¶ 8. As an active duty USPHS nurse officer, she was required to get the annual flu vaccine. Id.

[30] This exhibit is titled "Affidavit" but it is not notarized, and therefore, the undersigned references it as a declaration.

The following month, Petitioner travelled to Milwaukee, Wisconsin to visit friends for the Thanksgiving holiday. Pet. Ex. 12 at ¶ 9. On November 26, 2015, she had dinner at her friend's house with over 20 people in attendance. Id. The next day, the day before the onset of her Bell's palsy, she went to a Pilates class and out shopping with a friend. Id. She asserted she "was feeling so good, so [she] was shocked when [she] woke up with facial paralysis the next day." Id.

Shortly after waking up on November 28, 2015, Petitioner discovered the left side of her face "seemed paralyzed." Pet. Ex. 12 at ¶ 10. She was getting ready to go to a Pilates class like the day before, when she noticed that "the left side of [her] face was drooping and felt numb. When [she] tried to brush [her] teeth, [she] could not keep the toothpaste in [her] mouth. [She] could not move any facial muscles on [her] left side, and [she] could not close [her] left eye." Id. Petitioner did a self-assessment to rule out a stroke, then realized she "might be experiencing Bell's palsy." Id. She was otherwise feeling fine, but because of the facial paralysis she skipped the Pilates class. Id. Her friend's daughter, a physician, gave her a prescription for Prednisone which she started taking immediately. Id. She also bought eyedrops because she recalled her "left eye became dry and irritated from not spontaneously blinking." Id. "[She] had difficultly drinking and eating due to [her] my facial paralysis. [She] had to hold [her] lips closed while drinking and chewing, and use [her] finger to manually extract food that got stuck in [her] left cheek."

Petitioner changed her flight to return home early to seek evaluation from Walter Reed, where she had received medical care from for decades. Pet. Ex. 12 at ¶ 11. She always travels with 12-hour Mucinex. Id. She takes is whenever she has allergy symptoms such as post-nasal drip and excess mucus. Id. She also uses Flonase for allergies which she stated can sometimes cause nosebleeds. Id. On the flight home, Petitioner was upset. Id. Her partner of 25 years recently passed away. Id. She was "dealing with sudden paralysis on the left side of [her] face while simultaneously grieving [her] partner's recent death." Id.

Petitioner reported to the Walter Reed ED on Sunday, November 29, 2015. Pet. Ex. 12 at ¶ 12. Petitioner recalled feeling overwhelmed in the ED waiting room; she was tearful, emotional, and blowing her nose. Id. After examination, she was diagnosed with Bell's palsy. Id. She received anti-viral medication, eye care materials, and was instructed to continue the Prednisone. Id. She was advised that most people with Bell's palsy fully recover within three to six months. Id.

Petitioner felt "very self-conscious about [her] appearance and had some uncomfortable physical symptoms." Pet. Ex. 12 at ¶ 13. But because there were no limitations on her physical activity, she resumed her usual daily routine (early morning fitness classes followed by a full day in the office). Id. at ¶¶ 12-13. She had an "extremely dry" mouth, impaired speech, and "difficulty enunciating and was slurring [her] words at times." Id. at ¶ 13. Her left eye was "very dry." Id. She had blurry vision and working on the computer for "extended periods of time per usual was difficult and uncomfortable." Id. She developed intermittent pain around her left ear and toward the back of [her] head." Id.

According to Petitioner, approximately two to three weeks after the onset of her Bell's palsy, she was "able to initiate some minimal voluntary movements on the left side of [her] face. [Her] lips moved slightly on the left side when [she] tried to smile, and [she] could raise [her] left eyebrow a bit." Pet. Ex. 12 at ¶ 14.

She saw her PCP, Dr. Chaudhery, on December 15, 2015, and had the recommended MRI on December 24. Pet. Ex. 12 at ¶¶ 15-16. The MRI "results were consistent with Bell's palsy." Id. at ¶ 16.

Approximately one month after the onset of her Bell's palsy, the left side of her face "was less droopy although [her] lower face was still shifted toward the left." Pet. Ex. 12 at ¶ 17. The left side of her lips "moved outward a bit more when [she] tried to smile, but they did not move well or in sync with the right side when [she] spoke." Id. She could voluntarily close her left eye "about halfway" and eventually "fully . . . with some effort." Id. "[H]owever, it did not fully close with spontaneous blinking." Id.

While her facial paralysis symptoms gradually improved, she started to develop new symptoms. Pet. Ex. 12 at ¶ 18. She "felt pressure and a gurgling/bubbling sensation in [her] left ear at rest." Id. Petitioner also had "an ocean-like sound in [her] left ear while at rest and [her] voice seemed to echo within [her] head" when speaking. Id. She noticed a "rapid thumping tinnitus (a machine-gun sound) with facial movements, such as smiling or talking." Id. Petitioner recalled the sounds were distracting and that she "had an embarrassing tendency to raise [her] voice while talking in an attempt to mask them and concentrate on what [she] was saying." Id. Her left naval passage "felt partially collapsed" and she had difficulties inhaling through that nostril. Id. When she "pulled [her] left nasal passage open with [her] finger," she could breathe better. Id.

Petitioner developed synkinesis. Pet. Ex. 12 at ¶ 19. She explained that her "droopy left eye would close more, and [her] left eyelids would twitch when [she] talked or chewed food. [Her] left eye would also close more when [she] smiled, swallowed, yawned, opened [her] mouth wide, or pursed [her] lips." Id. Additionally, her left cheek, chin, and lips would "pull upward and outward when [she] closed [her] eyes, opened [her] eyes wide, or raised [her] eyebrows." Id. Her chin "remained cockeyed toward the left side of [her] face and was dimpling." Id. She had involuntary twitching and developed "painful tightness and pulling sensations" around her left eye and from her left cheek to chin. Id. She also noticed "bulging" of her left neck muscles. Id.

Petitioner was told by ENT physicians at Walter Reed that she had "mild hearing loss in her left ear." Pet. Ex. 12 at ¶ 20. She was advised of treatment that may alleviate the "machine-gun sound" including surgery and a hearing aid. Id. She attempted several nasal remedies to improve her ability to clearly inhale through her left nostril, but they did not help. Id.

Six months after the onset of her Bell's palsy, she was referred to physical therapy. Pet. Ex. 12 at ¶ 21. She continued to have difficulty drinking, eating, and occasional slurring of her words. Id. From July to August 2016, she had four physical therapy treatment sessions where she practiced facial exercises focused on restoring muscle strength, movement, and symmetry. Id. at ¶ 22. She noticed improvement in her ability to raise her left eyelid "(although it fatigued

quickly and drifted back down)," and in her ability to lift the left corner of her lips when smiling "(although [her] smile was still lopsided/asymmetrical)." Id. She still had synkinesis, twitching, and difficulty eating and drinking. Id. Self-massage on her cheek and neck muscles provided temporary relief. Id. at ¶ 23. After using the TENS unit for about a week, she became concerned that it was making her synkinesis worse. Id. She discontinued use of the TENS unit. Id.

Petitioner requested a referral to the Johns Hopkins Facial Paralysis and Pain Treatment center. Pet. Ex. 12 at ¶ 24. She had a consult with Dr. Dorafshar in early April 2017. Pet. Ex. 12 at ¶ 25. Botox and reconstructive surgery were recommended. Id. Because Petitioner had already scheduled a Botox appointment at Walter Reed, she wanted to wait to see how Botox would help before considering surgical innervation. Id.

Dr. Chou administered Botox injections around Petitioner's left eye in late April 2017. Pet. Ex. 12 at ¶ 26. She was pleased with the results because it "opened up [her] droopy eye, and reduced the pain, synkinesis, and twitching." Id. Because Dr. Chou could not administer Botox to other areas of her face, Petitioner was referred to Dr. Cannard. Id.

From May to December 2017, Petitioner had four physical therapy sessions. Pet. Ex. 12 at ¶ 27. She was instructed on facial retraining exercises and massage therapy. Id. While Petitioner "diligently adhered" to the home exercise program, she did not notice "much improvement" in her residual effects during that time. Id. "As time progressed, it also seemed as if [her] full smile was worse with little lip parting, and fewer teeth showing, on [her] left side." Id.

Following an initial neurology evaluation with Dr. Cannard in June 2017, Dr. Cannard administered Botox injections around Petitioner's left eye and other areas of her face in August 2017. Pet. Ex. 12 at ¶¶ 28-29. Petitioner continued to receive Botox injections for the next three to four months. Id. at ¶ 29. She received some beneficial results that were most noticeable about five days after injections, up until about two months later, when the Botox "[wore] off." Id. at ¶ 30.

E. Expert Reports

1. Petitioner's Expert, Dr. Kazim A. Sheikh[31]

a. Background and Qualifications

Dr. Sheikh is a board-certified neurologist who specializes in neuromuscular and peripheral nervous system disorders. Pet. Ex. 13 at 1. Dr. Sheikh received his medical degree from King Edward Medical College in Pakistan. Id. Thereafter, he completed a neurology residency at the Neurological Institute at Columbia University in New York and was a postdoctoral fellow in peripheral nerve disorders at Johns Hopkins in Baltimore, Maryland. Id.; Pet. Ex. 14 at 1. Dr. Sheikh is currently both a physician and a professor. Pet. Ex. 14 at 1.

[31] Dr. Sheikh submitted three expert reports in this matter. Pet. Ex. 13, 42, 63.

Dr. Sheikh is a tenured Professor of Neurology and the Director of the Neuromuscular Program at the University of Texas ("UT") Medical School. Pet. Ex. 14 at 1. He also serves as the Director of the Neuromuscular Disorders Center at the Mischer Neuroscience Institute at Memorial Hermann-Texas Medical Center and the Director of the Muscle and Nerve Laboratory. Id. He has authored or co-authored over 150 publications related to immune neuropathies and has served on numerous review panels related to immune and inflammatory neuropathies. Pet. Ex. 13 at 1. As a neurologist and neuromuscular and peripheral nerve specialist, Dr. Sheikh has an active inpatient and outpatient clinical practice at the UT Medical School at Houston and affiliated hospitals. Id. He has seen and managed over 150 cases of Bell's palsy throughout his career. Id. at 2.

b. Opinion

Dr. Sheikh opined that approximately 40 days after receiving the flu vaccine, Petitioner developed left Bell's palsy and to a "reasonable degree of medical probability," the flu vaccine was the etiology of her Bell's palsy by an autoimmune response. Pet. Ex. 13 at 1, 7.

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Dr. Sheikh opined the flu vaccine can cause Bell's palsy either through an autoimmune process or an infectious process. Pet. Ex. 13 at 8, 10. Here, Dr. Sheikh favored the theory of autoimmunity. Pet. Ex. 42 at 1-2; Pet. Ex. 13 at 8 (noting a "cell-mediated autoimmune mechanism has been suggested as the pathogenesis of Bell's palsy" (quoting Pet. Ex. 18 at 4)).

Regarding infectious etiologies, Dr. Sheikh stated that both *Borrelia burgdorferi* and herpes zoster have been "well documented to result in Bell's palsy." Pet. Ex. 13 at 8. Dr. Sheikh explained that in the case of herpes zoster, there is a direct infection of geniculate ganglion.[32] Id. In some cases, herpes simplex virus ("HSV") "is the cause of Bell's palsy and reflects virus reactivation from latency in the geniculate ganglion rather than primary infection." Id. He referred to several studies indicating that the flu vaccine can reactivate different strains of HSV in the nervous system. Id. (citing Pet. Ex. 15;[33] Pet. Ex. 16;[34] Pet. Ex. 17).[35] However, Dr.

[32] The geniculate ganglion is "the sensory ganglion of the facial nerve, situated on the geniculum of the facial nerve." Ganglion Geniculi Nervi Facialis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78055 (last visited Jan. 9, 2023).

[33] L.M. Hassman & D.A. DiLoreto, Immunologic Factors May Play a Role in Herpes Simplex Virus 1 Reactivation in the Brain and Retina After Influenza Vaccination, 6 ID Cases 47 (2016).

[34] Allan Lieberman & Luke Curtis, HSV2 Reactivation and Myelitis Following Influenza Vaccination, 13 Hum. Vaccines & Immunotherapeutics 572 (2017).

[35] J.-F. Chen et al., Pityriasis Rosea Following Influenza (H1N1) Vaccination, 74 J. Chinese Med. Assoc. 280 (2011).

Sheikh noted several shortcomings to the infectious theory. For example, "Bell's palsy is almost exclusively motor in nature without any mucocutaneous manifestations typically seen with herpes viral reactivation." Pet. Ex. 42 at 5-6. Additionally, "HSV-1 causes recurrent reactivations, which raises the question of why Bell's palsy is an isolated episode in the overwhelming majority of cases." Id. at 5-6 (quoting Pet. Ex. 18 at 4). Therefore, Dr. Sheikh focused on the autoimmunity theory. Id. at 1-2.

Dr. Sheikh first explained that autoimmune conditions are "characterized by an aberrant activation of the adaptive immune response with T and/or B cells reacting to tissue specific self-antigens," here, in the seventh cranial nerve. Pet. Ex. 42 at 1. Dr. Sheikh explained that the stimulation of the immune system from a triggering event such as vaccination "disrupt[s] the balance needed to maintain immunologic homeostasis" thus "making the host susceptible to autoimmune diseases." Id. at 2. This "provides the potential basis for rarity with which Bell's palsy develops in an individual after exposure to triggers such as vaccines." Id.

Dr. Sheikh described the cell-mediated autoimmune process, otherwise known as molecular mimicry: "If the antigens present on the vaccine share any homology with host antigens, then the immune response will be directed at both the injected antigens and host antigens, leading to an autoimmune response." Pet. Ex. 13 at 10; see generally Pet. Ex. 34.[36] Particularly, he stated that vaccines have been recognized to "lead to autoimmune responses directed against antigens on peripheral nerves, such as the facial nerve," triggering demyelination, and "resulting in inflammatory polyneuropathies." Pet. Ex. 13 at 10; see also Pet. Ex. 35.[37] Dr. Sheikh stated that this suggests the importance of cell-mediated autoimmune mechanisms in the pathogenesis of Bell's palsy. Pet. Ex. 13 at 9.

Dr. Sheikh opined that flu vaccines "can induce autoimmunity by molecular mimicry by more than one mechanism." Pet. Ex. 42 at 4. He explained that mimicry can involve T and/or B cells and can occur at sequential or structural levels.[38] Id. at 5. He also discussed non-homologous molecular mimicry. Id. He primarily focused on the mimic of myelin basic protein and anti-ganglioside responses.

[36] M.B.A Oldstone, Molecular Mimicry, Microbial Infection, and Autoimmune Disease: Evolution of the Concept, 296 Current Topics Microbiology & Immunology 1 (2005).

[37] Lawrence Schonberger et al., Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, 110 Am. J. Epidemiology 105 (1979).

[38] He described autoimmune responses through the reactivation of B and T cell receptors, as well as decreased T cells documented in the acute phase of Bell's palsy. Pet. Ex. 13 at 10; Pet. Ex. 37 at 1; Pet. Ex. 24 at 2.

In support of molecular mimicry generally, Dr. Sheikh analogized Bell's palsy with Guillain-Barré syndrome ("GBS").[39] Pet. Ex. 13 at 9. While he acknowledged that Bell's palsy and GBS "represent two extremes on the spectrum of clinical syndromes," Dr. Sheikh highlighted that Bell's palsy, like GBS, is an acute demyelinating disease of the peripheral nervous system. Id. (citing Pet. Ex. 18 at 4). He further emphasized their immunological similarities[40] suggest that Bell's palsy is autoimmune by nature, that Bell's palsy is often considered a mononeuritic variant of GBS, and that Bell's palsy and GBS "may share a similar etiology and pathogenesis." Id. (citing Pet. Ex. 18 at 4, 9); see also Pet. Ex. 22 at 1, 3. Accordingly, Dr. Sheikh intermittently referred to GBS literature in support of molecular mimicry, a well-established causal theory for GBS.

For example, Dr. Sheikh cited an article by Abramsky et al.,[41] which supported a cell-mediated autoimmune mechanism in Bell's palsy. Pet. Ex. 13 at 9; Pet. Ex. 19 at 1. The study "demonstrated a defined in vitro response to a human basic protein (P1L) of peripheral nerve myelin in patients with Bell's palsy" resulting in immunologic lymphocyte alterations. Pet. Ex. 19 at 5. This response suggests that the sensitization of lymphocytes to the self-protein "may be an important factor in the pathogenesis of the paralysis." Id. at 7. Moreover, Jahnke et al.[42] and Lucchese et al.[43] provide evidence of sequence peptide mimicry with a number of myelin and neuronal peptides. Pet. Ex. 42 at 4 (citing Pet. Ex. 48; Pet. Ex. 49).

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[39] GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. . . . Variant forms include acute autonomic neuropathy, Miller-Fisher syndrome, acute motor axonal neuropathy, and acute motor-sensory axonal neuropathy." Guillain-Barré Syndrome, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=110689 (last visited Jan. 9, 2023).

[40] Dr. Sheikh discussed similarities among GBS and Bell's palsy patients such as lymphocyte sensitization to the same P1L protein of peripheral nerve myelin, the percentage of reduced T lymphocytes, and the changes in peripheral blood leukocyte numbers. Pet. Ex. 13 at 9 (citing Pet. Ex. 19 at 6; Pet. Ex. 29 at 1; Pet. Ex. 18 at 4; Pet. Ex. 22 at 3; Pet. Ex. 30 at 1).

[41] O. Abramsky et al., Cellular Immune Response to Peripheral Nerve Basic Protein in Idiopathic Facial Paralysis (Bell's Palsy), 26 J. Neurological Sci. 13 (1975).

[42] Ulrike Jahnke et al., Sequence Homology Between Certain Viral Proteins and Proteins Related to Encephalomyelitis and Neuritis, 229 Science 282 (1985).

[43] Guglielmo Lucchese et al., Peptide Sharing Between Influenza A H1N1 Hemagglutinin and Human Axon Guidance Proteins, 40 Schizophrenia Bulletin 362 (2014). Lucchese et al. discussed H1N1 viral peptides. Id. The flu vaccine Petitioner received contained an H1N1 strain. Resp. Ex. E, Tab 5 at 11.

Dr. Sheikh then turned to Nachamkin et al.,[44] which looked at whether flu vaccines can elicit anti-ganglioside (anti-GM1)[45] responses absent *Campylobacter jejuni* ("*C. jejuni*") contamination. Pet. Ex. 50 at 1. Nachamkin et al. found that each flu vaccine used[46] induced antibodies to anti-GM1 but not to *C. jejuni*. Id. at 5. They also found antibody responses to hemagglutinin, a viral surface glycoprotein found in the flu vaccine. Id. Therefore, they determined hemagglutinin could bind to cellular gangliosides and mimic an anti-ganglioside antibody. Id.

Accordingly, Dr. Sheikh opined that "it can be postulated that either the [flu] vaccine can induce anti-ganglioside responses either through GM1-like epitopes it contains or through the components of the vaccine (hemagglutinin protein) that can bind to host's own antigens to overcome self-tolerance." Pet. Ex. 42 at 4. Importantly, he explained that gangliosides are "enriched in peripheral and cranial nerves," and that "anti-GM1 antibodies are associated with motor neuropathic disorders." Id. (citing Pet. Ex. 51 at 1;[47] Pet. Ex. 52 at 1).[48]

In support of his opinions, Dr. Sheikh cited several studies and case reports on the association between the flu vaccine and Bell's palsy.

Zhou et al.,[49] found a signal or "possible association between [flu] vaccines and an increased risk of Bell's palsy." Pet. Ex. 47 at 5. Zhou et al. reviewed and analyzed reports from the Vaccine Adverse Event Reporting System ("VAERS") to evaluate the risk of Bell's palsy following the administration of flu vaccines given by the parenteral route (intramuscular injection) from 1991 to 2001. Id. at 1. Of the 197 reports, a Bell's palsy diagnosis was verified in 154, and among those, 145 cases received the flu vaccine alone. Id. The authors noted that while the etiology and pathogenesis of Bell's palsy is not clear, "[i]mmune response mechanisms

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[44] Irving Nachamkin et al., Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barré Syndrome, 198 J. Infectious Diseases 226 (2008).

[45] Ganglioside GM-1 is "one of several gangliosides considered a target antigen in the pathogenesis of GBS." Pet. Ex. 50 at 5.

[46] They used surviving samples of the 1976 "swine flu" vaccine and vaccines from the 1991-92 and 2004-05 flu seasons to immunize mice. Pet. Ex. 50 at 1.

[47] Ortwin Rott et al., Influenza A Virus Hemagglutinin is a B Cell-Superstimulatory Lectin, 184 Med. Microbiology & Immunology 185 (1996).

[48] Vladimir A. Slepshukin et al., Interaction of Influenza Virus with Gangliosides and Liposomes Containing Gangliosides, 173 Eur. J. Biochemistry 599 (1988).

[49] Weigong Zhou et al., A Potential Signal of Bell's Palsy After Parenteral Inactivated Influenza Vaccines: Reports to the Vaccine Adverse Event Reporting System (VAERS)-United States 1991-2001, 13 Pharmacoepidemiological Drug Safety 505 (2004).

have . . . been considered," and concluded that this "study provided multiple lines of evidence for a signal that Bell's palsy may be associated with the [flu] vaccine[]." Id. at 4-5.

Mutsch et al.,[50] reported 46 cases of Bell's palsy associated with the inactivated intranasal flu vaccine administered over a seven-month period in Switzerland. Pet. Ex. 40 at 1-2. The risk of Bell's palsy after intranasal vaccination was 19 times higher than the risk seen in control subjects. Id. at 2. Of the 412 patients, the authors identified 91 patients who developed Bell's palsy following the flu vaccine and found "[t]he risk was highest during the second month after intranasal vaccination." Id. at 5-6. There were also reports of Bell's palsy in those who received the vaccine parenterally (by injection).[51] Id. at 5. The authors concluded "the intranasal [flu] vaccine used in Switzerland during the 2000–2001 [flu] season greatly increased the risk of Bell's palsy among vaccinees," and they described the association as "strong, temporal, and specific." Id. at 6.

Dr. Tompkins, Respondent's expert, opined that the intranasal vaccine contained *Escherichia coli* ("*E. coli*") heat-labile enterotoxin and that itself caused the increased incidence of post-vaccinal Bell's palsy. Resp. Ex. C at 5. However, referencing Couch,[52] which was written responsive to Mutsch et al., Dr. Sheikh stated "there are no direct anatomical connections that would explain transfer of *E. coli* heat-labile enterotoxin to facial nerve motor axons or neurons (facial motor nucleus) after intranasal administration." Pet. Ex. 63 at 1-2 (Couch "concluded that indirect mechanisms rather than direct toxicity [were] involved in post-vaccinal Bell's palsy cases."); Pet. Ex. 66 at 2. In contrast, molecular mimicry between bacterial glycoconjugates and peripheral nerve gangliosides has been implicated. See Pet. Ex 42 at 4-5; Pet. Ex. 63 at 3-5.

Moreover, Dr. Sheikh stated that the post-vaccinal interval of developing Bell's palsy is inconsistent with the *E. coli* heat-labile enterotoxin hypothesis. Pet. Ex. 63 at 2. He referenced literature that concluded "direct toxicity of *E. coli* heat-labile enterotoxin in post-vaccinal cases was not relevant due to interval between vaccination and onset of Bell's palsy." Id. For example, the risk period identified in Mutsch et al. was spread from one to 91 days with the

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[50] Margot Mutsch et al., Use of the Inactivated Intranasal Influenza Vaccine and the Risk of Bell's Palsy in Switzerland, 350 New Eng. J. Med. 896 (2004).

[51] The authors stated that "27 of the 182 patients with Bell's palsy (14.8%) . . . had been immunized with [the] parenteral [flu] vaccine." Pet. Ex. 40 at 4. With regard to this data, the authors stated that "there was essentially no risk of Bell's palsy after receipt of the traditional, parenteral vaccine." Id. However, these findings were commented on in the Stowe et al. paper as follows: "Although [the Mutsch et al.] study showed no association very few patients had received the parenteral vaccine and the study design had a number of limitations and biases that may have led to missing a true association." Resp. Ex. C, Tab 8 at 1. Julia Stowe et al., Bell's Palsy and Parenteral Inactivated Influenza Vaccine, 2 Hum. Vaccines 110 (2006).

[52] Robert B. Couch, Nasal Vaccination, *Escherichia coli* Enterotoxin, and Bell's Palsy, 350 New Eng. J. Med. 860 (2004).

highest number of cases seen within 31-60 days post-vaccination. Pet. Ex. 40 at 1. Ronthal & Greenstein[53] commented that "[t]he peak occurrence of Bell's palsy was between 31 and 60 days after intranasal vaccination, suggesting that the palsy was not due to a direct toxic response but rather an induced immune response." Pet. Ex. 65 at 3.

Finally, a study by Bardage et al.,[54] which examined the risk of neurological and autoimmune adverse events to people vaccinated with the 2009 pandemic H1N1 flu vaccine compared to unvaccinated people, found that the relative risk of developing Bell's palsy was significantly increased within 45 days of vaccination. Pet. Ex. 41 at 1. Dr. Sheikh cited several other case reports supporting the immunological theory. Pet. Ex. 13 at 10 (see, e.g., Pet. Ex. 38 (describing a child that suffered Bell's palsy following diphtheria-pertussis-tetanus ("DPT") and polio vaccines);[55] Pet. Ex. 39 (describing a child who suffered Bell's palsy and brachial neuritis following a DPT vaccine)).[56]

Dr. Sheikh acknowledged, to Dr. Jamieson's, Respondent's expert's, credit that the epidemiologic evidence of the current flu vaccine to an increased incidence of Bell's palsy is not well-established. Pet. Ex. 42 at 4. He stated that if such "definite epidemiologic evidence for increased incidence of Bell's palsy with any vaccine (including [flu] vaccine) was available, then that particular vaccine would not be in widespread use." Id. at 3. Thus, Dr. Sheikh noted that studies showing an association of flu vaccination and Bell's palsy are more meaningful than epidemiological studies that did not find an increased incidence of Bell's palsy after flu vaccination. Id. at 3.[57]

He reasoned "[o]ne of the central tenets of epidemiology . . . is that a rare event cannot be ruled out using statistical tools applied to a population," therefore, "a study that finds no association between two variables does not rule out the possibility that a rare association could still exist." Pet. Ex. 42 at 3. Accordingly, he stated, "our argument is biologic and not epidemiologic as epidemiologic studies do not take into account the heterogeneity and comorbidities of each individual" like Petitioner. Id.

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[53] Michael Ronthal & Patricia Greenstein, Bell's Palsy: Pathogenesis, Clinical Features, and Diagnosis in Adults, UpToDate, https://www.uptodate.com/contents/bells-palsy-pathogenesis-clinical-features-and-diagnosis-in-adults (last updated May 11, 2020).

[54] Carola Bardage et al., Neurological and Autoimmune Disorders After Vaccination Against Pandemic Influenza A (H1N1) with a Monovalent Adjuvanted Vaccine: Population Based Cohort Study in Stockholm, Sweden, 343 BMJ 1 (2011).

[55] John J. Manning & Kedar K. Adour, Facial Paralysis in Children, 49 Pediatrics 102 (1972).

[56] Gilbert I. Martin & Michael I. Weintraub, Brachial Neuritis and Seventh Nerve Palsy – A Rare Hazard of DPT Vaccination, 12 Clinical Pediatrics 506 (1973).

[57] Dr. Sheikh noted that Respondent's experts only presented evidence of increased incidence, not of association like he did. Pet. Ex. 42 at 3.

ii. Althen Prongs Two and Three

Dr. Sheikh opined that Petitioner's flu vaccine caused her Bell's palsy through an autoimmune mechanism described above. Pet. Ex. 42 at 7. Dr. Sheikh opined that "vaccine induced autoimmunity and related tissue (facial nerve) injury is plausible in *this* case." Id. at 3.

Dr. Sheikh stated "it is notable that her examination [on November 29, 2015] showed facial nerve palsy and normal ear examination and there were no vesicles in auditory canals to suggest Ramsay-Hunt syndrome. Further, the ED evaluation mentioned cold symptoms, but no signs of infection were documented on physical examination." Pet. Ex. 13 at 2. Again, he pointed out that an ear examination on December 15, 2015 was normal. Id. at 3.

Dr. Sheikh included in his review of Petitioner's medical history her MRI on December 24, 2015 that showed "[a]bnormal enhancement along the intratemporal left CN7" that is "seen in the setting of Bell's palsy." Pet. Ex. 13 at 3 (quoting Pet. Ex. 2 at 260). The Greco et al. article, referenced by Dr. Sheikh, discussed that the most common abnormality observed on MRIs indicative of Bell's palsy is the "enhancement of the distal intracanalicular and labyrinthine segments of the facial nerve. The geniculate ganglion may also be involved."[58] Pet. Ex. 18 at 2.

Dr. Sheikh opined that Petitioner's left facial weakness began on November 28, 2015, approximately 40 days, or less than six weeks, after her flu vaccination. Pet. Ex. 13 at 7. He found this onset to be "well within the biologic window in which post-[flu] vaccination [Bell's] palsy has been documented." Pet. Ex. 42 at 7.

Based on the explanation above that Bell's palsy is considered a variant of GBS, Dr. Sheikh reasoned the timing of post-vaccination GBS literature is applicable here. Pet. Ex. 13 at 10. For the onset of inflammatory demyelinating polyneuropathies following the flu vaccine, "the period of increased risk was concentrated within the 5-6 week period after vaccination but lasted for approximately 9 or 10 weeks." Id. (citing Pet. Ex. 35). The Institute of Medicine ("IOM"),[59] now the National Academy of Medicine, determined that six weeks is the period "during which post-vaccination adverse autoimmune complications can arise." Pet. Ex. 42 at 6; see generally Resp. Ex. A, Tab 13. Therefore, Dr. Sheikh stated that because "[Petitioner's] symptoms started 40 days following a[] [flu] vaccination, [that] timing [] would be within the biologic window (3-42 days) of an autoimmune event triggered by a vaccine." Pet. Ex. 13 at 10.

[58] As referenced earlier, the labyrinthine segment (which extends from the IAC to the geniculate ganglion) is part of the intratemporal portion of the facial nerve. See Gleeson, supra note 20, at 638; Resp. Ex. C, Tab 1 at 2.

[59] Inst. of Med., Influenza Vaccine, in Adverse Effects of Vaccines: Evidence and Causality 293 (Kathleen Stratton et al. eds., 2012).

Further, Zhou et al., which demonstrated association of Bell's palsy with parenteral inactivated flu vaccines in VAERS over a ten-year period, found that more than 5% of patients developed Bell's palsy between 31-60 days after vaccination. Pet. Ex. 47 at 4.

Dr. Sheikh concluded that in Petitioner's case, "not only is the timing appropriate, . . . but there is also a reasonable sequence of cause and effect." Pet. Ex. 13 at 10.

2. Respondent's Expert, Dr. Dara G. Jamieson[60]

a. Background and Qualifications

Dr. Jamieson is a board-certified neurologist licensed in New York. Resp. Ex. B at 2. She received her medical degree from the University of Pennsylvania, followed by a neurology residency and a cerebrovascular fellowship at the University of Pennsylvania Hospital. Resp. Ex. A. at 1. Dr. Jamieson was a practicing neurologist for 32 years before transitioning to a voluntary faculty appointment in 2018. Id. She is currently a Clinical Associate Professor of Neurology at Weill Cornell Medicine, where she teaches medical students in neurology courses and clinical inpatient clerkships, as well as lectures to residents and fellows. Id. She has also lectured extensively nationally and internationally on neurological topics. Id. at 2; Resp. Ex. B at 4-10. Dr. Jamieson serves on several editorial boards, including the Journal of Neuroimmunology, Current Treatment Opinions in Neurology, and Neurology Alert. Resp. Ex. A. at 2. She has authored or co-authored numerous publications in peer reviewed journals as well as authored books and book chapters on various neurological topics. Id.; Resp. Ex. B at 13-14.

b. Opinion

Dr. Jamieson opined to a "reasonable degree of medical probability" that Petitioner's "Bell's palsy with incomplete recovery was unrelated to her flu vaccine." Resp. Ex. A at 17.

i. Althen Prong One

Dr. Jamieson opined that an autoimmune theory is not supported by "data associating Bell's palsy with parenteral [flu] vaccinations." Resp. Ex. A at 10. Dr. Jamieson first noted there are significant differences between GBS and Bell's palsy. Id. at 9. Namely, "GBS is a cell mediated, autoimmune neuropathy involving multiple, bilateral peripheral nerves," whereas Bell's palsy involves "injury to a single unilateral cranial nerve." Id. However, she acknowledged "[c]ombining the viral and immunological theories has led to a suggestion that Bell's palsy could be an autoimmune, post-viral disease." Id.

Dr. Jamieson explained that while older studies have postulated an association between the flu vaccine and Bell's palsy, epidemiologic evidence is lacking in recent data. Resp. Ex. A at 13. Dr. Jamieson criticized Dr. Sheikh for relying on older literature evaluating Bell's palsy

[60] Dr. Jamieson submitted one expert report in this matter. Resp. Ex. A.

following vaccinations. Id. at 10. She stated that Dr. Sheikh merely "conflated older data, related to an intranasal, adjuvanted [flu] vaccine that is no longer in clinical use, with more current data from the parenteral vaccine used on [Petitioner]." Id.

Dr. Jamieson stated that "the cause of Bell's palsy is still unknown." Resp. Ex. A at 12. Nonetheless, she concluded there is no autoimmune mechanism to explain a causal association between the flu vaccine and Bell's palsy, and no epidemiological data that links the flu vaccine to Bell's palsy. Id. at 17. In support of her opinions, Dr. Jamieson cited several works of medical literature that she claimed, "discredit a causal association between parenteral [flu] vaccinees and Bell's palsy." Resp. Ex. A at 15.

Stowe et al. conducted a population-based study of 2,128 individuals who developed Bell's palsy from 1992 to 2005 and found "no evidence of an increased risk [of Bell's palsy] in the three months following parenteral inactivated [flu] vaccine." Resp. Ex. C, Tab 8 at 1-2. The highest incidence rate Stowe et al. found was during the risk period of 1 to 30 days. Id. at 2. The authors wrote, "[t]his study suggests that the association seen with the inactivated intranasal [flu] vaccine may be specific to the administration of the intranasal vaccine and the association observed cannot be extrapolated to the parenteral inactivated vaccine." Id. at 3.

Rowhani-Rahbar et al.[61] examined the association between Bell's palsy and vaccines in children from 2001 to 2006. Resp. Ex. A, Tab 17 at 1-2. Of the 822 children in the study, 233 received at least one vaccine in the 12 months prior to onset. Id. at 4. The authors found no association between vaccination (flu (trivalent), hepatitis B, or any vaccine) and Bell's palsy during their risk intervals of 1-14 days, 1-28 days, and 29-56 days. Id.

Dr. Jamieson cited to Wijnans et al., a self-controlled case series from the United Kingdom aimed "to determine whether there was an increased risk of Bell's palsy following vaccination with any [flu] vaccine containing A/California/7/2009 (H1N1)-like viral strains."[62] Resp. Ex. A, Tab 19 at 1. The study population was comprised of all Bell's palsy cases using a primary health care database in the United Kingdom from 2009 to 2013. Id. at 1-2. They found a relative incidence rate of Bell's palsy between one and 42 days post-flu vaccination to be 0.88. Id. at 5. When adjusted for confounders, the relative incidence rate decreased to 0.85. Id. The authors did not find "evidence of an increased risk of Bell's palsy following vaccination with any [flu] vaccine containing A/California/7/2009 (H1N1)-like viral strains, either pandemic or seasonal vaccines." Id. at 8. Additionally, they found "no evidence of an increased incidence of Bell's palsy consultations following seasonal [flu] vaccination overall, nor for monovalent pandemic [flu] vaccine in 2009." Id. at 7.

[61] Ali Rowhani-Rahbar et al., Immunization and Bell's Palsy in Children: A Case-Centered Analysis, 175 Am. J. Epidemiology 878 (2012).

[62] Petitioner's flu vaccine contained a similar strain. Resp. Ex. E, Tab 5 at 11.

Dr. Jamieson also cited to Greene et al.,[63] a study for adverse events, such as Bell's palsy, among individuals who received seasonal trivalent inactivated flu vaccines during specified flu seasons. Resp. Ex. A, Tab 15 at 1, 3. The risk of adverse events, including GBS and Bell's palsy, following flu vaccination was compared in each season with that in previous seasons. Id. at 1. After administration of 1,195,552 doses to children and 4,773,956 doses to adults, the authors found "no evidence of elevated risk following [flu vaccination] for any of [the] predefined adverse event categories." Id. at 9. Similarly, a 2014 study by Vaughn et al.[64] did not find a "statistically significant" association between vaccines and the reporting of adverse events, including facial paralysis. Resp. Ex. A, Tab 16 at 1, 13. However, Vaughn et al. noted that "small increases in the risk of such events cannot be ruled out" and identified Bell's palsy as an adverse event of special interest "considered worthy of closer safety monitoring" following administration of flu vaccination. Id. at 13-14.

Finally, Dr. Jamieson noted that IOM published a report in 2012 concluding that "[t]he evidence favors rejection of a causal relationship between inactivated [flu] vaccine and Bell's palsy." Resp. Ex. A, Tab 13 at 366. However, in coming to this conclusion, they only reviewed Stowe et al. and Greene et al. Id.

ii. Althen Prongs Two and Three

Dr. Jamieson agreed that Petitioner developed Bell's palsy on November 28, 2015. Resp. Ex. A at 11. However, she opined that Petitioner's development of symptoms were "coincidental[]" to the flu shot she received about 40 days, or six weeks, earlier on October 19, 2015. Id. at 17.

Dr. Jamieson believed that "the extent of [Petitioner's] facial weakness and her incomplete recovery [could be] suggestive of Ramsay Hunt syndrome, a varicella zoster virus (VZV infection)." Resp. Ex. A at 11. She reasoned that "[p]atients with Ramsay Hunt syndrome often have more severe facial paralysis at onset and are less likely to recover completely." Id. Dr. Jamieson explained that Ramsey Hunt Syndrome is a peripheral facial nerve palsy "associated with a[] vesicular rash on the ear ([herpes] zoster oticus) or in the mouth." Id. Importantly, "Ramsey Hunt Syndrome is caused by a VZV infection." Id. (citing Resp. Ex. A, Tab 2 at 12 (Ramsey Hunt Syndrome is "due to reactivation of [VZV] in the geniculate ganglion.")).

However, Dr. Jamieson stated that on Petitioner's physical examination on November 29, 2015, "[n]o skin lesions were identified that indicated an overt viral infection as a cause of the facial nerve injury." Resp. Ex. A at 11. Further, she acknowledged that "[t]his alternative

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[63] Sharon K. Greene et al., Near Real-Time Surveillance for Influenza Vaccine Safety: Proof-of-Concept in the Vaccine Safety Datalink Project, 171 Am. J. Epidemiology 177 (2010).

[64] David Vaughn et al., Safety Of AS03-Adjuvanted Inactivated Split Virion A(H1N1)Pdm09 and H5N1 Influenza Virus Vaccines Administered to Adults: Pooled Analysis Of 28 Clinical Trials, 10 Hum. Vaccines & Immunotherapeutics 2942 (2014).

diagnosis cannot be proven because acute VZV titers were not obtained at the time of the onset of [Petitioner's] weakness." Id. Instead, Dr. Jamieson opined that Petitioner had "Bell's palsy with incomplete recovery" and developed residual synkinesis. Id. at 17.[65]

Dr. Jamieson conceded that "[b]y the definition of the syndrome ["facial weakness of unknown cause"], there is no alternative cause of Bell's palsy that is identified in a person's medical history." Resp. Ex. A at 11. In fact, she stated that "[i]f a specific cause is found, such as Lyme disease . . . , it should not be referred to as Bell's palsy." Id. (quoting Resp. Ex. A, Tab 2 at 1). She added, "[i]f the cause of the facial weakness is known, then the entity is known as facial weakness due to that specific causative disease [or Ramsey Hunt Syndrome] and is not called a Bell's palsy." Id. at 12. While Dr. Jamieson acknowledged that "[r]eactivation of a latent herpes viral infection has been postulated as a [pathogenetic] mechanism, leading to the weak suggestion for acute treatment with antiviral medication," she stated that "the cause of Bell's palsy is still unknown with empiric steroid treatment used in a supposed effort to hasten facial reinnervation and decrease the incidence of synkinesis." Id. at 12. Reich et al. noted that "[t]he use of steroids and antivirals to improve the recovery of Bell's palsy is based on the . . . observations about the possible role[] of HSV type 1 in the . . . etiology" of Bell's palsy. Resp. Ex. A, Tab 2 at 13. However, the authors concluded that "adding an antiviral does not significantly improve the likelihood of recovery." Id. at 17. Here, Dr. Jamieson acknowledged that "[d]espite appropriate treatment with steroids and antivirals, [Petitioner's] return of facial symmetry was incomplete." Resp. Ex. A at 17.

Of note, while Dr. Jamieson stated that "[c]onditions associated with an increased risk of developing idiopathic facial weakness include diabetes, pregnancy, stress[,] and acute respiratory tract infections," Dr. Jamieson did not opine that Petitioner's Bell's palsy was caused by an upper respiratory infection. Resp. Ex. A at 12.

3. Respondent's Expert, S. Mark Tompkins, Ph.D.[66]

a. Background and Qualifications

Dr. Tompkins is an immunologist. Resp. Ex. C at 1. He received his Ph.D. in Immunology and Molecular Pathogenesis from Emory University in Atlanta, Georgia. Id.; Resp. Ex. D at 1. He does not hold a medical degree. Resp. Ex. D at 1. Dr. Tompkins' postdoctoral training focused on "immunologic mechanisms of induction of autoimmune disease, specifically interrogating antigen- and virus-induced models of experimental autoimmune encephalomyelitis; models for the neurologic autoimmune disease, multiple sclerosis." Resp. Ex. C at 1. His second postdoctoral fellowship focused on "understanding the immune response to [flu] infection and vaccination." Id. Dr. Tomkins is currently a Full Professor at the Center for Vaccines and Immunology and the Department of Infectious Diseases, both at the University of

[65] Moreover, the parties stipulated that Petitioner's diagnosis was Bell's palsy, thus it cannot be Ramsey Hunt syndrome. Joint Pre-Hearing Submission at 1.

[66] Dr. Tompkins submitted two expert reports in this matter. Resp. Exs. C, E.

Georgia ("UGA") College of Veterinary Medicine. Resp. Ex. D at 2. He also serves as the Assistant Department Head and Curriculum Coordinator of the Department of Infectious Diseases at the UGA College of Veterinary Medicine. Id. As a faculty member, Dr. Tompkins teaches immunology and virology to graduate students and trains doctoral fellows. Resp. Ex. C at 1. His research interest is on understanding the interactions of the flu virus and the flu vaccine with the host, or more generally, in the etiology of immune-mediated disease. Id.; Resp. Ex. D at 15-16. Dr. Tomkins explained that while "aspects of [his] research entail zoonotic [flu] viruses and understanding the determinants of infection, transmission, and pathogenesis, the core of [his] research remains understanding the immune response to viral infection and vaccination." Resp. Ex. C at 1. Dr. Tomkins has authored or co-authored numerous peer-reviewed papers, book chapters, and articles on immunology and virology. Id.; Resp. Ex. D at 29-40.

b. Opinion

Because Dr. Tompkins does not hold a medical degree and thus is not qualified to diagnose or treat patients, he did not dispute Petitioner's diagnosis of Bell's palsy or her development of symptoms approximately 40 days after her flu vaccination. Resp. Ex. C at 2. Instead, he focused on the potential association between the flu vaccine and the onset of Bell's palsy. Id.; Resp. Ex. E at 1. As such, his opinions are generally limited to Althen Prong One.

i. Althen Prong One

Dr. Tompkins first stated that the etiology of Bell's palsy is unclear. Resp. Ex. C at 2-3. He noted that Zhang et al. "summarized five major hypotheses including anatomical, viral infection, ischemia, inflammation, and cold stimulation." Id. (quoting Resp. Ex. C, Tab 1) (internal quotations omitted). But he opined there is no evidence that flu vaccination elicits Bell's palsy. Id. at 7; Resp. Ex. E at 7. Instead, Dr. Tompkins suggested "infection[] or viral reactivation due to stress and infection" as potential explanations for Petitioner's Bell's palsy. Resp. Ex. C at 6.

Like Dr. Jamieson, Dr. Tompkins took issue with Dr. Sheikh's comparison of GBS and Bell's palsy. He stated Zhang et al. and Greco et al., relied on by Dr. Sheikh, "use a circular argument that [Bell's palsy] and GBS may be related because the diseases share [these] hypothetical etiologies." Resp. Ex. C at 3. Dr. Tompkins acknowledged the similarities of GBS and Bell's palsy including changes in lymphocyte frequencies and potential responses to nervous tissue antigens, but opined that the conditions do not have a shared etiology. Id. He explained, however, it is "not surprising both diseases could have evidence of humoral or cellular immune responses to peripheral nerve antigens" as both "GBS and [Bell's palsy] may involve nervous tissue damage, which may elicit immune responses to self-antigens." Id. But Dr. Tompkins opined "this does not support the supposition by Dr. Sheikh that [Bell's palsy] is a variant of GBS." Id.

Dr. Tompkins acknowledged that molecular mimicry is a "well-established immunological concept" but opined there is no support for Dr. Sheikh's statement that "vaccines have been recognized to trigger autoimmune responses . . . directed against antigens on peripheral nerves, such as the facial nerve, resulting in inflammatory polyneuropathies." Resp.

Ex. C at 4 (quoting Pet. Ex. 13 at 10). He opined "there is no evidence that vaccination with current [flu] vaccines initiates immune responses to self-antigens through molecular mimicry." Id. at 7.

Additionally, Dr. Tompkins criticized Dr. Sheikh's literature on GBS and the potential antibody-mediated molecular mimicry. Resp. Ex. E at 6-7. Dr. Tompkins explained that "over time, human [flu] viruses accumulate glycosylation sites on the hemagglutinin protein," which he claimed "would increase the number of available carbohydrates to potentially elicit antiganglioside antibodies." Id. at 6. Yet he opined "the only vaccine associated with GBS is the A/NJ/1976 (H1N1) vaccine that contained limited glycosylation sites, undermining the persuasiveness of this hypothesis." Id. Dr. Tompkins cited to Wang et al.[67] and Lei et al.[68] to support his hypothesis that there is no correlation with flu vaccination and the induction of antiganglioside antibodies. Id. at 6-7. However, Wang et al. found that "both GM-1 and GM-2 antiganglioside [] antibodies cross-reacted with multiple H1N1 and H3N2 [flu] strains," and while that reaction varied among the strains it was "directly associated with the glycosylation of [hemagglutinin]." Resp. Ex. E, Tab 15 at 3. Additionally, they found that "[a]s the number of potential glycosylation sites increased on the [hemagglutinin], the reactivity of the virus with the antiganglioside antibody also increased." Id. Moreover, Lei et al "could not exclude the possibility that anti-GM1 antibodies might be generated rarely in [flu] vaccinees." Resp. Ex. E, Tab 16 at 5.

Regarding Mutsch et al., which found an increased risk of developing Bell's palsy after an intranasal flu vaccine (Nasalflu), Dr. Tompkins stated that Petitioner did not receive an intranasal vaccine, but instead received a parenteral vaccine (FluArix). Resp. Ex. C at 4; Resp. Ex. E at 2; Resp. Ex. E, Tab 5 at 1. He explained that besides the methods of delivery, the most significant difference between the two flu vaccines is that Nasalflu contained a potent adjuvant (*E. coli* heat-labile enterotoxin). Resp. Ex. C at 4. Dr. Tompkins opined "the association of the Nasalflu vaccine with [Bell's palsy] is due to the adjuvant and is unrelated to the [flu] antigens." Id. at 5. For support, Dr. Tompkins cited Lewis et al.[69] and Halsey et al.[70] Resp. Ex. E at 2. Lewis et al. discussed the risks of *E. coli* enterotoxins as adjuvants in intranasal vaccines. Resp. Ex. E, Tab 3 at 1. They found Bell's palsy occurred only where the individual received a heat-

[67] David J. Wang et al., No Evidence of a Link Between Influenza Vaccines and Guillain–Barre Syndrome–Associated Antiganglioside Antibodies, 6 Influenza & Other Respiratory Viruses 159 (2011).

[68] Ting Lei et al., Anti-ganglioside Antibodies Were Not Detected in Human Subjects Infected with or Vaccinated Against 2009 Pandemic Influenza A (H1N1) Virus, 30 Vaccine 2605 (2012).

[69] David J. Lewis et al., Transient Facial Nerve Paralysis (Bell's Palsy) Following Intranasal Delivery of a Genetically Detoxified Mutant of Escherichia Coli Heat Labile Toxin, 4 PLoS One e6999 (2009). This article is also cited by Petitioner. Pet. Ex. 67.

[70] Neal A. Halsey et al., The Safety of Influenza Vaccines in Children: An Institute for Vaccine Safety White Paper, 33 Vaccine F1 (2015).

labile enterotoxin adjuvant and not a vaccine antigen. Id. at 3; see also Resp. Ex. A, Tab 18 at 23-24. However, Lewis et al. was conducted using only the human immunodeficiency virus ("HIV") and tuberculosis vaccines, not a flu vaccine. Resp. Ex. E, Tab 3 at 1. Nonetheless, the clinical course and the timing of onset of post-vaccination Bell's palsy in the cases presented in Lewis et al. suggested an immune mediated response. Halsey et al., which discussed Mutsch et al. and Lewis et al., concluded that "[t]he most likely hypothesis for the association with . . . vaccines and Bell's palsy is that the *E. coli* enterotoxin resulted in inflammation and entrapment of the facial nerve in the facial canal." Resp. Ex. A, Tab 18 at 24. Dr. Tompkins therefore opined that "[t]he onset of [Bell's palsy] in three different vaccines containing the enterotoxin suggested the adjuvant was associated with [Bell's palsy], not the vaccine antigens." Resp. Ex. C at 5. However, Halsey et al. did find a signal of Bell's palsy in adults following the 2009 inactivated flu vaccine. Resp. Ex. A, Tab 18 at 24.

Dr. Tompkins then referenced case reports about the onset of Bell's palsy after flu vaccination. He particularly pointed out Stowe et al., which assessed the overall incidence of Bell's palsy at defined intervals after vaccination. Resp. Ex. C at 5. "They found no increase in [Bell's palsy] between 1-30, 31-60, 61-91, or 1-91 days after [flu] vaccination." Id. (citing Resp. Ex. C, Tab 8). Similarly, the IOM found no evidence of increased risk of Bell's palsy after inactivated flu vaccination. Id. at 5-6 (citing Resp. Ex. A, Tab 13 at 366).

Ultimately, Dr. Tompkins found no evidence of association between the parenteral flu vaccine and the risk of Bell's palsy. Resp. Ex. E at 4.

ii. Althen Prongs Two and Three

Dr. Tomkins agreed that Petitioner's onset of symptoms was approximately 40 days, or six weeks, after administration of the flu vaccine. Resp. Ex. C at 5. But he hypothesized "infection[] or viral reactivation due to stress and infection" are "possibilities here" for the etiology of Petitioner's Bell's palsy. Id. at 6. He opined that her Bell's palsy resulted from a mild respiratory infection she had hours or days before. Id. "The stress and acute viral infection noted in the medical records, along with seasonal cold temperatures at the time of [P]etitioner's onset [were] the most likely triggers of her [Bell's palsy]." Resp. Ex. E at 8. However, he acknowledged he is not a clinician. Resp. Ex. C at 2.

Dr. Tompkins noted that the medical records show a "day before the symptoms[,] [Petitioner] thought she might be developing a cold and took some [M]ucinex." Resp. Ex. C at 6 (quoting Pet. Ex. 2 at 675). Dr. Tompkins averred that "[w]hile this medical note was not further discussed, it is highly relevant as infections are associated with [Bell's palsy]." Id.

The National Institute of Neurological Disorders and Stroke ("NINDS") reported that "[m]ost scientists believe that reactivation of an existing (dormant) viral infection may cause the disorder. Impaired immunity from stress, sleep deprivation, physical trauma, minor illness[,] or autoimmune syndromes are suggested as the most likely triggers." Resp. Ex. C, Tab 12 at 1.

Moreover, Dr. Tompkins cited Mathew et al.,[71] which noted a seasonality of Bell's palsy that overlaps with several respiratory infections. Resp. Ex. C at 6 (citing Pet. Ex. 27 at 1). He also noted that Halsey et al. and Zhang et al. discussed herpesvirus reactivation as a potential etiology of Bell's palsy. See id. (citing Resp. Ex. A, Tab 18 at 23; Resp. Ex. C, Tab 1 at 2). However, Zhang et al. noted that "the behavior of patients with [Bell's palsy] is unusual compared to that of patients with other diseases more commonly associated with HSV" and "clinical evidence of HSV-1 infection in the geniculate ganglion remains elusive." Resp. Ex. C, Tab 1 at 5. Nonetheless, Dr. Tompkins concluded that this "evidence provide[s] a plausible explanation for the cause of [Petitioner's] [Bell's palsy]." Resp. Ex. C at 7.

He reasoned that because Petitioner "was traveling, visiting at least 20 people and shopping/dining during the Thanksgiving holiday, it is highly plausible that she was exposed to a common human respiratory pathogen, resulting in a respiratory infection, eliciting [Bell's palsy]." Resp. Ex. C at 6. Additionally, he noted Petitioner's recent loss of her partner. Id. He concluded "[t]his stress, combined with travel and a possible respiratory infection[,] could have enabled the reactivation of a latent herpesvirus infection, triggering the [Bell's palsy]." Id.

While Dr. Tomkins acknowledged literature on immune responses to flu vaccination, he explained that such literature "generally focus[es] on time points between 7 and 28 days post-vaccination." Resp. Ex. C at 6. For example, Dolfi et al.[72] found a peak in CD4 T cell responses in elderly persons 7 to 14 days post-vaccination that returned to baseline levels 28 to 60 days post-vaccination. Resp. Ex. C, Tab 9 at 3. Co et al.[73] found small increases in CD8 T cell responses that waned by two months post-vaccination. Resp. Ex. C, Tab 10 at 5 tbl.1. Finally, Nougarede et al.[74] found increases in vaccine-specific antibody responses at days 14 and 21 but waned by day 180 post-vaccination. Resp. Ex. C, Tab 11 at 3 fig.1D.

Accordingly, while Dr. Thompkins agreed that the flu vaccine can elicit vaccine-specific antibody responses, and that those responses vary, they tend to wane as early as 14 days post-vaccination. Resp. Ex. C at 6. "So, while there is no evidence that [flu]-specific T cell responses are associated with [Bell's palsy]," he opined "the decreasing post-vaccine response further argues against potential involvement with [Petitioner's Bell's palsy] 40 days after vaccination." Id.

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[71] Thomas Mathew et al., Bell's Palsy and Guillain–Barré Syndrome May Be 2 Ends of the Same Spectrum, 59 Muscle & Nerve E48 (2019)

[72] Douglas V. Dolfi et al., Vaccine-Induced Boosting of Influenza Virus-Specific CD4 T Cells in Younger and Aged Humans, 8 PLoS e77164 (2013).

[73] Mary Dawn T. Co et al., Discordance Between Antibody and T Cell Responses in Recipients of Trivalent Inactivated Influenza Vaccine, 26 Vaccine 1990 (2008).

[74] Nolwenn Nougarede et al., Nine µg Intradermal Influenza Vaccine and 15 µg Intramuscular Influenza Vaccine Induce Similar Cellular and Humoral Immune Responses in Adults, 10 Hum. Vaccines & Immunotherapeutics 2713 (2014).

Additionally, and in support of his alternative theory, Dr. Tompkins added that the onset of Bell's palsy in children "usually occurs hours to days after an upper respiratory tract infection." Resp. Ex. C at 6 (quoting Resp. Ex. A, Tab 18 at 23). He averred this timing supports his hypothesis of Petitioner developing Bell's palsy hours or days after recognizing she might be sick. Id. at 7. However, Dr. Tomkins left out that Halsey et al. went on to add that the onset of Bell's palsy symptoms hours to days after infection "resolves spontaneously without treatment." Resp. Ex. A, Tab 18 at 23.

IV. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

"Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the respondent in determining whether the [P]etitioner has established a prima facie case." Flores v. Sec'y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec'y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir.

2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); de Bazan v. Sec'y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner's evidence on a requisite element of the [P]etitioner's case-in-chief."); Pafford, 451 F.3d at 1358-59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec'y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner's injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

B. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received caused her injury. To do so, Petitioner must establish, by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in Petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence

presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor).

V. ANALYSIS

A. Althen Prong One

Under Althen Prong One, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009); Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019); see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner has set forth a sound and reliable medical theory, molecular mimicry, to explain how the flu vaccine can cause Bell's palsy. The medical literature shows persuasive evidence of the similarity between GBS and Bell's palsy, that molecular mimicry is an appropriate causal mechanism of GBS, and therefore by analogy, is sound and reliable here.

The preferred theory proposed by Dr. Sheikh is an autoimmune or immune-mediated theory,[75] the most popular of which is that the same mechanism involved in the etiology of GBS is present for Bell's palsy—a post-vaccination monovariant polyneuropathy. In support of this theory, Dr. Sheikh provided persuasive literature.

The Greco et al. article provides a comprehensive analysis of the relevant immunological theories of causation, specifically molecular mimicry. The authors state, "[s]ome evidence implicates the involvement of immune mechanisms in Bell's palsy. Many reports have indicated

[75] While Dr. Sheikh also mentioned the possibility of an infectious theory, and Dr. Tompkins suggested an infectious theory instead of molecular mimicry, the undersigned focuses her discussion on the immune-mediated (molecular mimicry) theory as it is the preferred theory by Dr. Sheikh. Moreover, Dr. Tompkins acknowledged molecular mimicry as an immunological concept.

the association between facial paralysis and [GBS], a condition that was recently shown to be a cell mediated, autoimmune neuritis." Pet. Ex. 18 at 4. The authors go on to discuss the Abramsky et al. article, which found a "defined in vitro response to a human basic protein (P1L) of peripheral nerve myelin in patients with Bell's palsy. They suggested that cell-mediated autoimmune mechanisms may be of importance in the pathogenesis of Bell's palsy." Id.; see also Pet. Ex. 19 at 1. The literature also discusses the similarity between GBS and Bell's palsy with regard to lymphocyte sensitization to the same P1L protein. Bell's palsy, like GBS, is an acute demyelinating disease of the peripheral nervous system. This all suggests that Bell's palsy is a mononeuritic variant of GBS. There is a body of evidence showing there is an immune mediated, or autoimmunity causal theory that is sound and reliable, and the most likely of those mechanisms would be molecular mimicry.

The experts agree, and many of the medical articles filed, establish that GBS is known to be an autoimmune condition, and that molecular mimicry is a likely causal mechanism. Petitioner provided sound and reliable reasons for extending the application of molecular mimicry to Bell's palsy. Petitioner provided preponderant evidence, by expert opinion and medical literature, of an association between the flu vaccine and Bell's palsy, including numerous case studies reporting the development of Bell's palsy following the flu vaccine. For example, Zhou et al. concluded there "may be a signal of possible association between [flu] vaccines and an increased risk of Bell's palsy." Pet. Ex. 47 at 5. Bardage et al. found "a significantly increased risk for Bell's palsy" in "those vaccinated in the early phase of the vaccination campaign (≤ 45 days), when high risk groups predominated." Pet. Ex. 41 at 4. While the authors of these studies did not reach any conclusions as to the pathogenesis of Bell's palsy, some hypothesized an immune-mediated response mechanism to be at play. Additionally, studies cited by Respondent's experts noted that an immune-mediated response is thought to play a part in the development of demyelinating polyneuropathies.

The lack of epidemiological evidence is not dispositive. It is difficult to use epidemiology to determine whether a vaccine is implicated in causation. Because while adverse reactions like this do not appear in the epidemiological evidence cited by Respondent's experts, it may be that events are too rare to be captured. Moreover, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Andreu, 569 F.3d at 1378 (quoting Capizzano, 440 F.3d at 132-26); see also Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in Petitioner's favor). The undersigned does not find the epidemiological literature to be definitive or determinative in this regard.

For these reasons, the undersigned finds that Petitioner has provided preponderant evidence of a sound and reliable causal theory, satisfying Althen Prong One.

B. Althen Prong Two

Under Althen Prong Two, Petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must

show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). The Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In regard to Althen Prong Two, the undersigned finds Petitioner provided preponderant evidence of a logical sequence of cause and effect showing that her vaccination was the cause of her Bell's palsy. First, Petitioner's clinical course is consistent with the medical literature and case reports of Bell's palsy following vaccination.

Petitioner received the flu vaccine on October 19, 2015, and approximately 40 days later, she reported facial paralysis. Petitioner's MRI showed enhancement of the seventh cranial nerve, which can be seen in Bell's palsy, and suggests a demyelinating process. Petitioner's MRI also showed a questionable enhancement in the medial left IAC, or internal auditory canal nerve, again suggestive of Bell's palsy. Petitioner's follow up MRI showed no enhancement. These diagnostic findings are consistent with the clinical course of this condition as supported by medical literature provided by Petitioner and Dr. Sheikh.

Next, the undersigned finds Petitioner's clinical course is consistent with the proposed causal mechanism. The MRI finding, suggesting a demyelinating process, supports the current understanding that Bell's palsy is mononeuropathy variant of GBS, which supports the theory of molecular mimicry. Dr. Sheikh explained that for onset of inflammatory demyelinating polyneuropathies following the flu vaccine, "the period of increased risk was concentrated within the 5-6 week period." Pet. Ex. 13 at 10 (internal citation omitted). Importantly, Petitioner's onset of symptoms was 40 days after vaccination which is less than six weeks.

Further, the undersigned finds no evidence of any alternative cause, and Dr. Jamieson concedes there is no such evidence. Dr. Jamieson stated, "[b]y the definition of the syndrome ["facial weakness of unknown cause"], there is no alternative cause of Bell's palsy that is identified in a person's medical history." Resp. Ex. A at 11. There was a suggestion by a treating physician that Petitioner could have had an atypical presentation of Ramsey Hunt syndrome, but there is no evidence in the record to suggest that Petitioner had VZV or HSV. Moreover, she did not have vesicles, a rash, or lesions. She also did not test positive for Lyme disease.

While Dr. Tompkins proposes that infection and/or stress caused Petitioner to develop Bell's palsy, Dr. Sheikh highlighted that there were no signs of infection documented on Petitioner's ED physical examination. Therefore, Dr. Tompkins' theory is merely speculative.

It is important to note that Dr. Tompkins is not a medical doctor, but a Ph.D., and based on the undersigned's review of his curriculum vitae, he does not have the requisite training, education, experience, or qualifications to diagnosis or treat patients who have neurological illnesses, like Bell's palsy. In other words, he has not diagnosed a patient with Bell's palsy. And he has not determined whether a patient's Bell's palsy was caused by infection or stress as opposed to a vaccine. While Dr. Tompkins is imminently qualified to opine in the area of his expertise—immunology and molecular pathogenesis—the undersigned finds that his opinions as to diagnosis and/or alternate cause carry less weight in this particular case, especially given the statement in his expert report, where Dr. Tompkins states that he "will not dispute whether [Petitioner] was suffering from [Bell's palsy]. This is outside my expertise." Resp. Ex. C at 2.

Dr. Jamieson, who is a medical doctor (neurologist), did not offer an opinion that infection or stress caused Petitioner's condition. Because Dr. Jamieson is well qualified to opine on diagnosis and the etiology of that diagnosis by virtue of her training, experience, and qualifications, the undersigned finds her opinions more persuasive. "In weighing the persuasiveness of opinion testimony, special masters may consider the relative expertise of the witness." Koehn v. Sec'y of Health & Hum. Servs., No. 11-355V, 2013 WL 3214877, at *32 (Fed. Cl. Spec. Mstr. May 30, 2013), aff'd, 773 F.3d 1239 (Fed. Cir. 2014); see also Dwyer v. Sec'y of Health & Hum. Servs., No. 03-1202V, 2010 WL 892250, at *64 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (giving greater weight to M.D. epidemiologists' opinions on medical issues than to Ph.D. epidemiologist's opinion); Pafford, 451 F.3d at 1359 (affirming the special master's rejection of expert's testimony because he lacked proper qualifications in the specialty areas in which he testified). While the undersigned acknowledges the Circuit Court's directive in Koehn, here, Dr. Tompkins has explained that the question of diagnosis is specifically outside of his expertise. Koehn, 773 F.3d at 1244. Like diagnosis, the question of whether Petitioner's Bell's palsy was caused by infection, stress, or vaccination involves the practice of medicine, which requires specific training, experience, and qualifications, and in general, experience in caring for patients. Thus, the relative specialties of the experts here are more proscribed and defined.

Moreover, Dr. Tompkins failed to state his opinion as to alternate cause to a reasonable degree of probability. He opined infection and/or stress "provide a plausible explanation" for both "the onset of [Bell's palsy]" and for "the cause of [Petitioner's] [Bell's palsy]." Resp. Ex. C at 6-7. He also stated that infection and/or stress are "the most likely triggers" and are "both possibilities here" regarding the etiology of onset. Id. at 6; Resp. Ex. E at 8. But he used the words "most likely" and "possibilities" which are inconsistent standards. Further, possibilities are insufficient to establish an alternative cause for Petitioner's Bell's palsy. Moberly, 592 F.3d at 1322 (emphasizing that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury" does not equate to proof of causation by a preponderance of the evidence); Waterman, 123 Fed. Cl. at 573-74 (denying Petitioner's motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard); Boatmon, 941 F.3d at 1359-60; Paterek v. Sec'y of Health & Hum. Servs., 527 F. App'x 875, 883 (Fed. Cir. 2013).

While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351. Accordingly, because Dr. Tompkins' opinions are inconsistent with regard to the applicable standard, the undersigned finds that they do not rise to the level required by the Vaccine Act, as such, they do not carry sufficient weight to support alternative causation.

Thus, the undersigned finds that Petitioner provided preponderant evidence of a logical sequence of cause and effect, satisfying Althen Prong Two.

C. Althen Prong Three

Althen Prong Three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn, 773 F.3d at 1243; Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

The parties stipulated, and the experts agree, that Petitioner received a flu vaccine on October 19, 2015, and approximately 40 days later, on November 28, 2015, she developed Bell's palsy. This onset timeframe is appropriate given the purported autoimmune mechanism of molecular mimicry. Therefore, Petitioner has provided preponderant evidence satisfying Althen Prong Three.

D. Alternative Causation

Because the undersigned concludes that Petitioner established a prima facie case, Petitioner is entitled to compensation unless Respondent can put forth preponderant evidence "that Petitioner's injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374, 376 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Hum. Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above in the Althen Prong Two analysis, the undersigned found Respondent failed to establish evidence to show that Petitioner's Bell's palsy was caused by a source other than vaccination. Thus, Respondent did not prove by a preponderance of evidence that Petitioner's injury is "due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

VI. CONCLUSION

For the reasons discussed above, the undersigned finds that Petitioner has established by preponderant evidence that her flu vaccine caused her Bell's palsy. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master