In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-869V

Filed: February 19, 2020

DIANE SOLAK, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Influenza Vaccine; Food Allergies

Andrew D. Downing, Van Cott & Talamante, PLLC, for Petitioner
Colleen C. Hartley, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On September 18, 2014, Diane Solak ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Petitioner developed multiple allergic reactions as a

[1] This Decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this Decision will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

result of the inactivated influenza ("flu") vaccine she received on September 30, 2011.[3] Pet. at 2, ECF No. 1.

Upon review of the evidence in this case, I find that Petitioner has failed to show that the influenza vaccine she received on September 29, 2011 caused her to develop food allergies or other allergic reactions. The petition is accordingly dismissed.

I. Procedural History

Petitioner filed her Petition on September 18, 2014.[4] Petitioner filed her statement of completion of January 8, 2016 (ECF No. 31) and an amended statement of completion on February 24, 2016 (ECF No. 35).

On April 21, 2016, Respondent filed a Rule 4(c) Report, presenting his analysis of Petitioner's claims and concluding this case is not appropriate for compensation under the terms of the Vaccine Act. ECF No. 38.

Petitioner filed an expert report from Dr. David Axelrod, along with supporting medical literature on September 20, 2016. ECF Nos. 48, 49. Petitioner also filed her Social Security Disability file on September 27, 2016. ECF No. 50.

On December 12, 2016, Respondent filed a responsive expert report from Dr. Emil J. Bardana. ECF No. 53. Respondent filed the medical literature associated with this report on January 13, 2017. ECF No. 56.

This case was assigned to my docket on November 29, 2017 (ECF No. 61). On January 25, 2018, Petitioner filed a supplemental expert report from Dr. Axelrod. ECF No. 63. Petitioner filed the medical literature associated with this report on February 1, 2018 and March 13, 2018. ECF Nos. 64-65.

Respondent filed a supplemental responsive expert report along with supporting medical literature from Dr. Bardana on May 2, 2018. ECF No. 67. On July 27, 2018, I held a status conference where I posed specific questions to both experts. *See* Scheduling Order of July 27, 2018, ECF No. 68.

On September 14, 2018, Petitioner filed a third expert report from Dr. Axelrod addressing my questions. ECF No. 69. Petitioner filed the medical literature associated with this report on the same day. ECF Nos. 69, 70.

---

[3] This appears to be an error in the Petition. Petitioner received her influenza vaccination on September 29, 2011. Ex. 5 at 1.

[4] At the time of filing, Petitioner was rapidly approaching the statute of limitations of September 30, 2014. Pet. at 1. Petitioner indicated that she would file an amended Petition at some point in the future; no amended Petition was ever filed. Pet. at 2.

On October 21, 2018, Respondent filed an expert report from Dr. Bardana addressing my questions, along with the associated medical literature. ECF Nos. 71, 72. On August 21, 2019, the parties filed a joint status report indicating that they were prepared for a ruling on the record.

Petitioner filed her memorandum in support of a decision on the record on October 22, 2019. ECF No. 75. Respondent filed his response on March 26, 2020. ECF No. 79. Petitioner filed a reply brief on April 27, 2020. ECF No. 81.

This matter is now ripe for adjudication.

II. Medical Records

A. Relevant Pre-Vaccination History

Petitioner was born in 1970. Ex. 6 at 125. Prior to her vaccination, Petitioner's medical history was significant for allergies to penicillin and codeine. Ex. 6 at 125, 129.

Petitioner received seasonal flu vaccinations on three occasions prior to September 29, 2011. *See* Ex. 5 at 1 (seasonal flu vaccine given on October 14, 2008, November 12, 2009, and October 18, 2010). Petitioner also received an H1N1 vaccine on November 10, 2009. *Id.* There is no documentation in the pre-vaccination history that Petitioner suffered any ill effects from these previous vaccines.

On December 21, 2009, Petitioner was seen by Dr. Marie Mateo for a sore throat and ear discomfort. Ex. 3 at 29. The notes at this visit indicate that Petitioner received the H1N1 vaccination in November 2009. *Id.* Petitioner was noted to be allergic to codeine and penicillins. *Id.* at 30. Dr. Mateo diagnosed Petitioner with possible acute pharyngitis, "probably secondary to viral infection." *Id.* at 33. The medical records do not indicate any follow-up visits for this illness.

On June 20, 2010, Petitioner was admitted to the emergency room with "throat pain [made] worse with swallowing, aching all over, headache and fever." Ex. 6 at 123. Petitioner was diagnosed with possible strep throat and treated with antibiotics. *Id.* at 122. Petitioner's medical history noted allergies to penicillin, codeine, and nuts. *Id.* at 133. No reactions to these substances were documented in Petitioner's medical history.

Petitioner was seen on August 11, 2010 by Dr. Amy Wright. Ex. 6 at 115. At this time, she was diagnosed with fibroids. *Id.* at 111.

On September 10, 2010, Petitioner was seen by Dr. William Murdoch for soreness and irritation in her right eye. Ex. 3 at 24. Dr. Murdoch diagnosed Petitioner with possible pink eye and prescribed Tobradex. *Id.* at 25.

On November 2, 2010, Petitioner underwent a hysterectomy. Ex. 6 at 1. When allergies were noted at this surgery, "penicillin, codeine, and nuts" were listed. *Id.* at 47. Additional records created on the same day noted Petitioner's allergies to include "penicillin and codeine." *Id.* at 152. Nuts were not included as an allergy on this record.

On February 17, 2011, Petitioner presented with an earache, runny nose, itchy and watery eyes, and post-nasal drainage that began on February 15, 2011. Ex. 3 at 20. Petitioner was diagnosed with seasonal allergies and prescribed Claritin. *Id.* at 22.

On June 6, 2011, Petitioner presented with burning in her eyes, itchy eyes, itchy throat, sneezing, watery eyes, ear pain, and dry cough, which began on June 4, 2011. Ex. 3 at 17. Petitioner was diagnosed with allergic rhinitis and prescribed Flonase, with instruction to continue taking Claritin. *Id.* at 19.

On June 27, 2011, Petitioner presented with a cough, "production of yellowish sputum", fatigue and malaise. Ex. 3 at 16. Petitioner was diagnosed with an upper respiratory infection, and was told to take Tylenol, gargle with warm water, and inhale steam. *Id.* The next day, Petitioner presented again at the doctor's office, this time with a "dry hacking cough" and "stuck" mucus. *Id.* at 10. Petitioner's other symptoms included chills, cough, fatigue, hoarseness, nasal congestion, post-nasal drainage, shortness of breath, sore throat, weight loss, and wheezing. *Id.* Petitioner's history of allergies was noted; the attending physician also noted that Petitioner "did not have a history of asthma." *Id.* Petitioner was specifically diagnosed with acute laryngopharyngitis, "likely viral in nature." *Id.* at 11.

On September 29, 2011, Petitioner received her flu shot. Ex. 5 at 1

B. Post-Vaccination History

On October 4, 2011, Petitioner presented to St John Medical Center Urgent Care with "fever, achey [sic] all over, scra[t]c[h]y throat, highest [fever] 103, cough x 2-3 day." Ex. 2 at 1. She was prescribed Motrin, Tessalon[5], and Tamiflu. *Id.* Petitioner was diagnosed with the flu. *Id.*

On October 10, 2011, Petitioner was seen in the emergency room, this time by Dr. Kranthi Raynell. Ex. 3 at 5. Petitioner's symptoms included cough, chills, fatigue, fever, and nasal congestion. *Id.* Her respiratory effort was described as "shallow", and her cough was "unproductive." *Id.* at 7. Dr. Raynell noted that Petitioner had been experiencing a "cough and URI symptoms x 10 days." *Id.* at 20. Petitioner was noted to have a history of allergies at this visit, including specifically penicillin and codeine. *Id.* at 5, 16. Petitioner also had a rash on her abdomen, arms, and back at this visit. The onset of this rash was described as "sudden." *Id.* The rash was diagnosed as a "maculo papular eruption with a fairly wide distribution." *Id.* at 9. Possible reasons for the rash included a "drug eruption, hives, or atypical pityriasis rosea." *Id.* It was noted at this visit that Petitioner had previously been taking Albuterol, Motrin, Tamiflu, Mucinex and Claritin. *Id.* at 6. Petitioner also received a chest x-ray. Ex. 4 at 20.

On October 17, 2011, Petitioner was seen for a follow up for flu and bronchitis. Ex. 3 at

[5] Tessalon is a medication used to treat cough. *See* Tessalon package insert, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event= BasicSearch.process (last visited Feb. 18, 2021).

1. Petitioner's remaining symptoms included a dry cough, which had improved. *Id.* Symptoms of tiredness, fatigue, and rash had resolved completely; she had only one day of her course of steroids left at this visit. *Id.*

On November 10, 2011, Petitioner was seen at the at the Michigan Asthma and Allergy center. In her intake questionnaire, Petitioner noted that she was there for "hives, stomach problems, vomiting after digested [sic] dairy products, hives/severe reaction after receiving flu shot." Ex. 7 at 56. Petitioner described her reaction to penicillin as "hives/swelling of face, lips, tongue/throat tight." *Id.* Petitioner's reaction to codeine was described as "hives/lip & tongue swelling." *Id.* Petitioner did not list a nut allergy at this visit. Dr. Dhillon conducted a skin test which detected a mild positive reaction to almonds, apples, string beans, Brazil nut, cashews, celery, clam, corn, egg white, egg yolk, milk, peach, pecan, chocolate, broccoli, blueberry, and onion.[6] Ex. 7 at 62. Petitioner did not test positive to the peanut allergen. *Id.*

Within three minutes of this allergy testing, Petitioner started having the sensation of an itchy throat. Ex. 7 at 61. Dr. Dhillon had her lie down and administered an EpiPen. *Id.* According to the record, "P[atien]t was much better within 2 min." *Id.*

On November 11, 2011, Petitioner visited the emergency room for an allergic reaction. She was seen by Dr. Nirmal Nandukumar. Ex. 4 at 16, 128. The medical records did not indicate a specific reaction ("allergic reaction, unspecified"). *Id.* at 124. Dr. Nandakumar described Petitioner's condition as follows:

> The patient presents with allergic reaction and throat swelling. The onset was just prior to arrival. The course/duration of symptoms is worsening. Location: throat. The character of symptoms is swelling. The degree at onset was moderate. The degree at present is moderate, Potential allergen(s) to food(s). Risk factors consist of food allergies. patient states she had recent ALLERGY testing done yesterday per Dr. Gillen [sic] had received an epinephrine injection yesterday. This morning. States she ate something she thinks she might be ALLERGIC to developed difficulty breathing, throat swelling upon the [sic] arrival. Patient appears quite anxious, but in no acute distress. No evidence [of] airway compromise. Oxygen saturations on her [sic] percent on room air. No stridor. No rash. No angioedema noted on exam.

Id. at 128. Petitioner's blood pressure was slightly elevated, at 137/94. *Id.* at 129. Petitioner's physical exam was normal. *Id.* at 128. Petitioner's respiratory exam showed no abnormalities, but her breathing was described as "shallow" pre-treatment. *Id.* at 152, 153. A review of all systems was normal. *Id.* at 130. A skin inspection revealed no acute rashes, lesions, or induration. *Id.* at 129.

While in the hospital, Petitioner was also seen by Dr. Dhillon. Dr. Dhillon described Petitioner's symptoms as "flushed" and that she felt like there was a "glob" in the throat. Ex. 4 at

[6] Even though it is not marked, it appears that Petitioner also should have "filbert/hazelnut" listed as a positive response. *See* Ex. 7 at 62.

132. According to Petitioner she, noticed her throat closing when she was eating oatmeal with friends. *Id.* Dr. Dhillon's impression was that Petitioner had 1) "an acute allergic reaction to oatmeal"; 2) an "angioedema"; and 3) "multiple food allergies". *Id.* at 134. He noted that Petitioner's past medical history included a history of hives. *Id.* When Dr. Dhillon conducted a physical examination of Petitioner, he found no abnormalities. *Id.* at 133.

On November 13, 2011, at 2:49 PM, Petitioner presented to Dr. Catherine Loniewski at the emergency room. Ex. 4 at 104. Petitioner's chief complaint was "allergic to multiple foods, today feel [sic] like lips swollen, tingly, dizzy", no rash, "feel [sic] flushed," "it's coming and going". Dr. Loniewski noted that Petitioner was "Seen here on Friday [November 11, 2011] for same thing." Ex. 4 at 108, 110. Dr. Loniewski described Petitioner's symptoms as follows:

> The patient is a 41-year-old female. The patient was in our emergency department Friday due to an allergic reaction associated with allergy testing she had the day before. She is currently taking a Medrol Dosepak and she took some Benadryl just prior to coming in. The patient works at Crittenton Hospital. When she came here Friday she left her car in the parking lot. Today is Sunday. She had a family member drive her to the hospital today to pick up her car and while they were driving here she felt the above symptoms which is tingling in her lips, dizziness and flushing to her head and chest. She states she can still breathe and she can still drink water. She took a Benadryl, but she feels like it is stuck a little bit in her throat. Now her symptoms are easing up. She was not certain what to do so she came to the emergency department. She does have an Epi Pen but did not use it. She has been following the list of foods that were given to her that are permissible to eat, but today she had a nondairy creamer in her coffee and she is not certain if there was something in the nondairy creamer that she reacted to. This whole experience is also making her feel anxious, worried and upset. Currently she just feels a little bit flushed, but has no other symptoms. She never broke out in hives. She never felt like her throat was closing, it just felt a little tight.

Id. at 104-05. Petitioner's allergies listed included penicillin, codeine, and nuts. The medical record did not indicate any documented reaction to any of these substances. *Id.* at 111. Dr. Loniewski noted that Petitioner had "very mild flushing to her front of her chest and face, no obvious swelling to lips or tongue." *Id.* at 105. She noted in the record, "I do not see any significant signs of an allergic reaction." *Id.* There were no signs of her airway closing, and no rashes or hives. *Id.* By 4:00 PM that day, or approximately one hour after Petitioner arrived at the emergency room, Petitioner denied feeling any symptoms and was discharged. *Id.* at 112.

On December 22, 2011, Petitioner was again seen for an allergic reaction at the emergency room by Dr. Loniewski. Ex. 4 at 59. At this visit, a medical history was obtained from Petitioner. Petitioner noted penicillin, codeine, and nut allergies in her history. *Id.* at 79. Under the "health status" section of the medical records, Petitioner's file notes that no reactions to penicillin, codeine, or nuts were documented in Petitioner's medical history. *Id.* at 67.

During this visit, Petitioner's chief complaint was "peanut allergy, tight throat, no rash." Ex. 4 at 78. Dr. Loniewski described Petitioner's symptoms as follows:

> [P]atient arrives complaining of a tightness in her throat. And slight trouble breathing. Patient was recently diagnosed with multiple food allergies. She does work at Crittenden Hospital. There was a package of food that arrived and apparently had peanuts in it. She did not eat it or touch it she was just in the same room and started to feel dizzy. She has an epinephrine pen but did not use it. Her coworkers brought her to the emergency department. She was given breathing treatments with DuoNeb before I saw her but the respiratory therapist said she did not hear any wheezing. No hives. No rash. No syncope. No vomiting. No diarrhea.

Id. at 67. An examination of all systems returned normal results. *Id.* at 68, 82. Petitioner's oxygen saturation was 99%. *Id.* at 84. Petitioner's physical examination was normal. *Id.* at 68. An examination of Petitioner's ear, nose and throat revealed "no acute abnormality. Hearing grossly normal. Pharynx clear and non-erythematous." Petitioner additionally had normal results on her cardiovascular, respiratory, gastrointestinal, and neurological exams. *Id.* Petitioner was discharged with instructions to follow up with Dr. Dhillon within three to five days. *Id.* at 84.

On January 6, 2012, Petitioner was seen by Dr. Dhillon. Ex. 7 at 59. Petitioner told Dr. Dhillon she felt "weird" after someone brought a nut basket into the office. *Id.* He diagnosed her with a food allergy and instructed her to return in three to five days. *Id.*

On January 29, 2012, Petitioner presented to the emergency room at St. John Medical Center with an allergic reaction. Ex. 9 at 1. Petitioner was noted to be allergic to "peanuts" and that she would experience "throat swelling" and become "flushy" after eating seafood. *Id.* at 4. Upon examination, Petitioner had no allergic swelling, no rash, no pruritis, no associated signs or symptoms, and a review of systems revealed no abnormality. *Id.* at 4. A general examination revealed no symptoms. *Id.* at 5. Dr. Bascom noted that "there was no evidence of anaphylaxis. Pt treated empirically for throat tightness. Possible anxiety." *Id.* at 7. Petitioner stayed overnight at the hospital. *Id.* On January 30, 2012, Dr. Bascom further noted that Petitioner experienced "subjective throat tightening symptoms yesterday." *Id.*

Petitioner also gave a medical history to Dr. Jennifer Rau, in which she stated that she "is allergic [to] corn and accidentally ate some vegetable oil, pt states that she is having trouble breathing, pt gave herself an epipen and Benadryl." Ex. 9 at 29. Petitioner's medical history stated that she was allergic to codeine, corn, peanuts and penicillin. *Id.* at 37. Each allergy had an unspecified onset date. *Id.*

On February 2, 2012, Petitioner was seen by Dr. Dhillon for a follow up appointment. Ex. 7 at 55. Dr. Dhillon's impression was that Petitioner suffered from acute food anaphylaxis. *Id.* Dr. Dhillon instructed Petitioner to keep a food diary and an Epipen. *Id.*

On April 2, 2012, Petitioner was seen by Dr. Dhillon and prescribed Xanax. Ex. 7 at 56.

On April 12, 2012, Petitioner presented to the emergency room at 10:44 AM with an "acute allergic reaction", with dizziness and throat closing. Ex. 4 at 3, 47. Petitioner was described as

having a "known allergy of [sic] nut allergy." *Id.* Petitioner's symptoms when she arrived at the emergency room were described as follows by Dr. Loniewski:

> Patient arrives complaining of an allergic reaction. Patient states she is allergies [sic] to every type of nut. Including dust from the nuts. She denies allergies to environmental substances. She's been under the care of an allergist and had a full workup. today she states she walked into her office at work. All the [sic] sudden she felt dizzy and lightheaded and nauseated and tingling to her lips. A tightness in her throat but not closing of her throat. She states every day she normally takes Claritin and Tagamet. She took a couple of days off of these medications. This initially started having her symptoms she went ahead and took a Claritin and Tagamet. A coworker brought her to the emergency department. At this point she states her symptoms are pretty much resolved. She feels a little tingling in her lips. She did not feel short of breath. She did not break out in a rash. She has no idea what caused her reaction today. Patient is offered steroids but declines them.

Ex. 4 at 35. Upon arrival to the emergency room, a medical history was taken from Petitioner. Petitioner claimed allergies to nuts, codeine, and penicillin. Ex. 4 at 35; Ex. 7 at 42. Petitioner's medical history did not indicate any documented allergic reactions to these substances. Ex. 4 at 35. Dr Loniewski also included a second summary after Petitioner had been admitted, writing:

> The patient is a 42-year-old female who was at work today since 8:00 this morning. The patient, around 10:30, noticed that she had flushing of her face, feeling dizzy and also fluttering of her right eyelid. The patient felt that her throat was closing a little bit, although she did not take any nuts. The patient was surrounded by her coworkers. The patient asked the question if she had any nuts or any nut products that same morning. The patient did not get any positive history from any of the coworkers regarding nut intake or having nuts in the office. The patient felt better after she took the Claritin. Since she was flushed had some rash on her left arm, she was advised to come to the emergency room for further evaluation. Since the patient got to the emergency room, she did not have any worsening of her shortness of breath symptoms. The patient's blood pressure was 135/76 in the emergency room. The patient is feeling much better. She states that she has been not [sic] taking her Claritin or Tagamet on a daily basis, only when she feels like she is going out on the weekends does she take her medication. The patient states her last reaction was January 30, when she had to [take] the epinephrine and was seen at St. John's emergency room. The patient did not have any reactions since then. She states that she has been avoiding nuts and other foods which she is allergic to on outpatient testing.

Ex. 4 at 38. Petitioner's physical examination was normal with "no swelling to lips, airway patent no stridor in the neck." *Id.* at 36. Petitioner's skin examination revealed no rash, welts, or hives. *Id.* An examination of Petitioner's respiration was also normal; Petitioner's breathing was "unlabored" and her breathing pattern was "regular." *Id.* Petitioner's heart rate was measured at 70 beats per minute, and her blood pressure was 135/76. *Id.* at 43, 50. Following admittance,

Petitioner's complaints of swallowing difficulty also appear to have resolved approximately thirty minutes after her arrival. *Id.* ("felt difficultyin [sic] swallowing PTA – resolved now").

Dr. Dhillon was also consulted at this visit. He noted that Petitioner was "flushed and had some rash on her left arm" and that was why she came to the emergency room. Ex. 4 at 37. Upon his examination, he found no rash, but that her "left arm was slightly itchy." *Id.* at 38. His notes, however, say "slight petechial rash on her upper left arm." *Id.* In contrast with previous medical records stating that Petitioner consumed three drinks daily, Dr. Dhillon noted that Petitioner does not smoke or drink. *Id.*

Nurse Christine Macklin performed a reassessment of Petitioner at 12:30 that day and noticed "rash redness to upper arms and feels itchy." Ex. 4 at 48. Prior to discharge, Dr. Dhillon assessed Petitioner once more, stating that:

> The patient had resolution of her symptoms 2 hours post intake of the Claritin. The patient will be monitored at home. She has EpiPen at her bedside. The patient knows how to use epinephrine. She feels comfortable going home. I do not think at this time, the patient will need to be given any steroid taper because the symptoms are completely resolved. The patient was given teaching that sometimes a delayed reaction can occur and she should not feel afraid to use epinephrine if she has recurrent lip and tongue swelling. The patient is supposed to see me next week as an outpatient in the office for checkup.

Id. at 39. Petitioner's symptoms eventually resolved approximately two hours after taking Claritin. Ex. 7 at 34. Petitioner was discharged following a diagnosis by Dr. Dhillon of "Acute allergic reaction", "Acute of urticaria" and a "History of allergic rhinitis." *Id.*

On April 26, 2012, Petitioner was seen by Dr. Dhillon for a follow up. Ex. 7 at 54. Dr. Dhillon diagnosed her with food allergies and noted she was taking Claritin every day. *Id*. On June 28, 2012, Petitioner was seen by Dr. Dhillon, who refilled her Xanax prescription. *Id.*

On October 25, 2012, Petitioner was seen by Dr. Dhillon who wrote that Petitioner had a reaction to the flu shot. Ex. 7 at 52. Dr. Dhillon noted that Petitioner should not have any more flu shots. He also noted that Petitioner had a food and egg allergy. *Id.*

On November 8, 2012, Petitioner was seen by Dr. Dhillon. Ex. 7 at 53. This page is largely indecipherable, but it appears that Petitioner has come to Dr. Dhillon because she believes that she had a reaction to the flu shot. *Id.* Dr. Dhillon wrote that he believed Petitioner suffered an adverse reaction to the flu shot secondary to an egg allergy. *Id.* Dr. Dhillon also wrote a letter on this date, stating that Petitioner "has documented allergy to eggs and also last 4 years she had reactions to the flu shot soon after administration."[7] Ex. 13 at 1.

On February 20, 2013, Petitioner was seen for knee pain. Ex. 6 at 181. She was noted to be taking Claritin for allergies at this visit. *Id.* at 195. On March 1, 2013, Petitioner was seen

[7] Petitioner's previous medical records do not indicate any reaction to the flu shot.

again for knee pain and noted to be allergic to penicillin and codeine. *Id.* at 184, 198.

On February 17, 2014, Petitioner was seen by Dr. Dhillon for a follow-up appointment. Ex. 7 at 52.[8] Dr. Dhillon described Petitioner as having a peanut allergy. Petitioner was told to avoid peanut exposure. *Id.*

On March 12, 2014, Petitioner presented to the Detroit Medical Center ER where she was seen by Dr. Jeanise Butterfield. Ex. 8 at 1. Petitioner was noted to have allergies to codeine, egg, nuts, and penicillin. *Id.* at 2. Petitioner stated that she had an "airborne allergy" to nuts and "someone was eating t[h]em around her." *Id.* at 7. Petitioner was noted to have given herself an EpiPen injection and that her airway was clear. *Id.* Blood pressure was measured as 148/84. *Id.* at 14. A review of Petitioner's systems was found to be normal. *Id.* at 10. Petitioner's heart rate was 79 and she was found to be in "no apparent distress." *Id.* at 14.

At this visit, Petitioner was also seen by Dr. Jessica Ruffino. Dr. Ruffino stated that:

> Patient is a 44-year-old female who presents to the emergency department with the above complaint. Patient states that she has a severe allergies [sic] to nuts. She states that she was at work when some [sic] eat a candy bar in front of her that contained nuts. She states that she felt her throat began to close. She felt weak and dizzy and had some difficulty breathing. She also felt that her tongue was swelling. An EpiPen was used. She is brought to the emergency department by EMS. She states that she has had anaphylactic reaction to nuts in the past. She was given Benadryl by EMS prior to arrival. She states that her symptoms feel like they are now improving. Denies any change in her voice.

Id. at 13. Dr. Ruffino's exam showed Petitioner' systems to be largely normal:

> Patient presents to the emergency department complaining of an allergic reaction. She is afebrile and hemodynamically stable. Physical exam findings as described above. She does appear to have minimal edema of the tongue but no edema of the posterior oropharynx. Patient does have an extensive history of allergies and anaphylaxis in the past.

Id. at 14.

On April 16, 2014, Dr. Dhillon noted that Petitioner had a reaction on March 12, 2014. Upon his examination, Petitioner presented with normal countenance. Ex. 7 at 52. Dr. Dhillon's impression was that Petitioner suffered from "anaphylaxis to peanut." *Id.*

On June 6, 2014, Dr. Dhillon noted that Petitioner would like paperwork for disability. Ex. 7 at 51. Dr. Dhillon noted a peanut allergy for Petitioner at this visit but "didn't have a reaction so far. Had no [sic] to any nuts." Ex. 10 at 3.

[8] I note that many of Dr. Dhillon's handwritten notes are indecipherable as they are illegibly handwritten.

On August 19, 2015, Petitioner presented to Dr. Dhillon to get a form filled out for disability assistance. Ex. 10 at 1. Dr. Dhillon explained to Petitioner "in detail [that he] doubt[s] food allergy can qualify as disability." *Id.*

On September 25, 2015, Petitioner brought a disability form to Dr. Dhillon pre-filled out for his signature. Ex. 10 at 2. Dr. Dhillon explained to Petitioner that "I have to fill the form, what I feel as a medical doctor should go on the disability form." Dr. Dhillon wrote "pt gets mad, states, so you are saying that my peanut allergy is not airborne?" I explained that pea nut [sic] allergy is food borne and its very difficult to get anaphylaxis to peanuts – if somebody opens a bag in the room without her touching it or eating eat and also I said her skin testing is > 3 years old. Pt. was getting mad that I'm not filling out the form [with] what she needs. I put on the form that I refuse to fill the form – pt left." *Id.*

III. Expert Opinions

A. Petitioner's Expert's Qualifications

1. Dr. David Axelrod

Dr. Axelrod received both his bachelor's degree and his medical degree from the University of Michigan. Ex. 34 at 1 (hereinafter "Alexrod CV"). He completed two residencies in internal medicine, one at the University of Toronto and one at William Beaumont Hospital, followed by additional fellowships in allergy, immunology, and rheumatology at McGill University. *Id*. He then served as a fellow for the National Institutes of Health in the Clinical Immunology Laboratory. *Id*. Dr. Axelrod served in the United States Army in both an active duty and a reserve capacity for seven years. *Id.* Dr. Axelrod holds board certifications in allergy and immunology, adult rheumatology, and medical laboratory immunology. *Id*. He currently works in private practice at Allergy & Asthma Consultants, Inc. in York, Pennsylvania. *Id.* at 2. Dr. Axelrod holds numerous publications to his name, dating between 1985 and 2012. *Id.* at 2-3.

B. Respondent's Expert's Qualifications

1. Dr. Emil Bardana

Dr. Bardana received his undergraduate degree from Georgetown University in Washington D.C. Ex. B at 1 (hereinafter "Bardana CV"). He completed his medical degree at McGill University in Montreal, Quebec, Canada. *Id.* Dr. Bardana completed his residency at Oregon Health Sciences University in Portland, Oregon in internal medicine. *Id.* He served as Chief Resident from 1967-1968. *Id.* at 2. Dr. Bardana also completed a fellowship and a research program in immunology, allergy, and rheumatology at Oregon Health Sciences University. *Id.* at 2.

Following his training, Dr. Bardana spent three years in the military before returning as a professor at Oregon Health & Science University. *Id.* at 3. He has spent most of his career as a professor in the Division of Allergy and Clinical Immunology at Oregon Health and Science University, while also maintaining a clinical practice. *Id.* at 3. He holds board certifications in

allergy and immunology and holds several professional society and board memberships. *Id.* at 3-11. He has served on multiple national organizations as an expert in allergy and immunology and has published numerous articles. *Id.* at 5-41.

C. Expert Reports

1. Dr. Axelrod's First Report

Petitioner filed an expert report from Dr. Axelrod on September 20, 2016. (filed as Ex. 17) (hereinafter "First Axelrod Rep."). Dr. Axelrod began his first report with an overview of Petitioner's medical history. *Id.* at 1. Dr. Axelrod noted that on October 4, 2011, approximately five days after her influenza vaccination, Petitioner presented with a cough, shortness of breath, a 103 degree fever, swollen glands, headache, myalgia, ear ache, red eyes, chest and abdominal pain, as well as a skin rash.[9] *Id.* He also noted her symptoms on October 10, 2011, included dry cough, fatigue, fever chills, nasal congestion, and "a pruritic rash about her face, neck, arm, [and] trunk[,] described as urticaria."[10] *Id.* Dr. Axelrod noted that by October 17, 2011, Petitioner's rash had resolved.

Dr. Axelrod then described Petitioner's symptoms on November 10, 2011, noting that she "presented with hives"[11] and gastrointestinal symptoms after eating dairy products. First Axelrod Rep. at 2. He noted that skin testing revealed several food allergies and Petitioner was diagnosed with an allergic reaction. *Id.* The next day, Petitioner experienced throat swelling after eating oatmeal. *Id.* Dr. Axelrod noted that Petitioner's examination was normal, and she had "no evidence" of airway compromise. *Id.* Nevertheless, Petitioner received a diagnosis of acute allergic reaction and acute urticaria. *Id.* Dr. Axelrod then noted doctor's visits on November 13, 2011, December 22, 2011, January 6, 2012, January 29, 2012, April 12, 2012, November 8, 2012, February 17, 2014, March 12, 2014 and March 1, 2015 where Petitioner suffered allergic reactions or was given a diagnosis of a new allergy. Finally, Dr. Axelrod noted that on June 6, 2011, prior to her vaccination, Petitioner had been diagnosed with allergic conjunctivitis and allergic rhinitis. *Id.* at 3.

Dr. Axelrod opined that Petitioner's symptoms on October 4, 2011, were not the result of an influenza infection, as diagnosed by her treating physicians, but rather were symptoms consistent with a systemic adaptive immune reaction. First Axelrod Rep. at 3. He believes that these symptoms continued into mid-October. *Id.*

---

[9] In his second report, Dr. Axelrod acknowledged that Petitioner did not have a rash at her October 4, 2011 visit. *See* Second Axelrod Rep. at 3.

[10] Urticaria is defined as a vascular reaction in the upper dermis, usually transient, consisting of localized edema caused by dilation and increased capillary permeability with wheals. *Urticaria*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (33rd ed. 2020) at 1856 (hereinafter "Dorland's).

[11] This appears to be inaccurate, as is discussed later in this Decision.

In further discussing this opinion, Dr. Axelrod suggested that the Th2 cells caused the allergies from which Petitioner suffered. First Axelrod Rep. at 6. According to Dr. Axelrod, "immunization with the inactivated influenza vaccine…results in an immune system more prone to allergy." *Id.* Specifically, the Th2 cells combined with CD4 cells result in the production of Interleukin-4, which amplifies the generation of the Th2 phenotype. According to Dr. Axelrod, the Th2 phenotype results in allergy. *Id.* Dr. Axelrod noted that the function of Th2 cells and Interleukin-4 are similar in murine models and in humans. *Id.*; *see also* E. Maggi, *The TH1/TH2 Paradigm in Allergy*, 3 IMMUNOTECHNOLOGY 4, 233-44 (1998) (filed as Ex. 29) (hereinafter "Maggi").

Dr. Axelrod supported his theory with two studies. First Axelrod Rep. at 6. In the mouse model, Dr. Axelrod claims that the authors showed that the inactivated flu vaccine led to Th2 phenotypic responses, but live-attenuated flu vaccines led to Th1 phenotypic responses. *Id.*; *see also* Moran et al., *Th2 Responses to Inactivated Influenza Virus Can Be Converted to Th1 Responses and Facilitate Recovery from Heterosubtypic Virus Infection*, 180 JOURNAL OF INFECTIOUS DISEASES, 579-85 (1999) (filed as Ex. 30) (hereinafter "Moran").

2. Dr. Bardana's First Report

In response to Dr. Axelrod, Respondent filed an expert report from Dr. Emil Bardana. (filed as Ex. A) (hereinafter "First Bardana Rep.").

Dr. Bardana began his report by noting several instances in Dr. Axelrod's report where Dr. Axelrod had omitted what Dr. Bardana believed to be "pertinent data" from Petitioner's medical records. First Bardana Rep. at 16. In particular, Dr. Bardana noted that Petitioner was diagnosed with "nut allergy" on June 20, 2010, allergic rhinitis on February 17, 2011, and a "history of allergies" on June 28, 2011. *Id.* Dr. Bardana also disagreed with Dr. Axelrod's characterization of Petitioner's symptoms on October 4, 2011, five days after her flu vaccination, writing that he interpreted her symptoms as "fever, generalized aches, scratchy throat, and cough for two or three days." *Id.* Dr. Bardana noted there is no documentation of any rash during this appointment. *Id.*

Dr. Bardana's interpretation of Petitioner's October 4, 2011 appointment differed greatly from that of Dr. Axelrod. While Dr. Axelrod believed that the October 4, 2011 illness was not an infectious process, and persisted to mid-October, Dr. Bardana stated that there is no support for this assertion. First Bardana Rep. at 19. While Dr. Axelrod asserted that Petitioner suffered symptoms on October 4 as a result of a systemic adaptive immune reaction, Dr. Bardana suggested that Petitioner's treating physicians were correct on October 4, 2011, when they diagnosed her with the flu. *Id.*

Dr. Bardana also disputed Dr. Axelrod's version of events on October 10, 2011. First Bardana Rep. at 16. He noted that rather than being given steroids, as Dr. Axelrod asserted, Petitioner was given Albuterol. *Id.* He also noted that Petitioner's fever had dissipated and that her rash, which Dr. Axelrod described as urticaria, had "come on suddenly that morning over the abdomen, arms and back" and that "itching was not intense." *Id.* Dr. Bardana described Petitioner's rash as a "pruritic maculopapular" rash and postulated it could have been either a drug eruption or urticaria. *Id.* He noted that such rashes were a known side effect of Tamiflu. *Id.*

Finally, Dr. Bardana noted that Petitioner's rash had cleared up by her October 17, 2011 visit. Therefore, her maculopapular rash lasted fewer than seven days. *Id.*

Dr. Bardana also disagreed with Dr. Axelrod's interpretation of Petitioner's symptoms at her November 10, 2011 visit. First Bardana Rep. at 16. According to Dr. Bardana, Dr. Axelrod indicated that Petitioner presented with hives and GI symptoms after eating dairy products; Dr. Bardana noted that Petitioner did not have any hives but "was observed to have food intolerance and nut allergy." *Id.* During allergy testing, Petitioner developed an "itchy throat," but no other symptoms or physical findings were recorded. *Id.* at 16-17.

Dr. Bardana also believed that Dr. Axelrod omitted key details from Petitioner's November 11, 2011 visit, and Petitioner's November 13, 2011 visit. Dr. Bardana noted that on November 11, 2013, while the treating physician's final diagnosis was "allergic reaction and urticaria", she probably had neither. First Bardana Rep. at 17. As support for his opinion, Dr. Bardana pointed to Dr. Dhillon's (Petitioner's allergist) consultation note which "excludes any urticaria." And, on November 13, 2011, Dr. Bardana believed it to be significant that Petitioner was "anxious, worried, and upset." *Id.* at 17.

Regarding Petitioner's December 22, 2011, appointment, Dr. Bardana found it significant that Dr. Axelrod did not mention that Petitioner "reacted" to a basket of nuts in her office without "proximity, touching, or tasting." First Bardana Rep. at 17. Dr. Bardana noted that at her exam, Petitioner was concerned about peanuts in the basket; however, her peanut allergy test was negative. *Id.* at 17.

Dr. Bardana also noted several instances where Dr. Axelrod left out other possible diagnoses besides allergy from the medical records. First Bardana Rep. at 17. On January 6, 2012, Petitioner was seen by Dr. Dhillon and diagnosed with food allergy; Dr. Axelrod left out that she was also diagnosed with "palpitations." *Id.* at 17. On January 29, 2012, Dr. Axelrod similarly noted Petitioner's emergency room visit was for "possible allergic reaction to peanut," but left out the diagnosis of "possible anxiety" and treatment with Xanax. *Id.* Dr. Axelrod left out similar alternative diagnoses from appointments on February 2, 2012, April 3, 2012, and April 12, 2012.

Dr. Bardana also noted that Dr. Axelrod did not discuss Petitioner's February 17, 2014, April 16, 2014, and June 6, 2014 appointments with Dr. Dhillon. First Bardana Rep. at 18. Dr. Bardana noted that these visits related to "peanut allergy and Petitioner's desire to obtain total disability." *Id.* On April 16, 2014, when Dr. Dhillon stated that Petitioner has "anaphylaxis to peanuts," Dr. Bardana believed this statement to be "unfounded", as skin testing conducted on November 10, 2011 was negative for peanut allergy. *Id.* at 18.

Dr. Bardana also stated that Dr. Axelrod failed to mention Petitioner's August 19, 2015 and September 25, 2015 visits with Dr. Dhillon. First Bardana Rep. at 18. Dr. Bardana noted that Dr. Dhillon explained to Petitioner that "remote passive exposure to nuts [was] unlikely to trigger reactions." First Bardana Rep. at 19.

Dr. Bardana did note that on October 25, 2012, Petitioner's allergist gave Petitioner a prescription certifying she should not have further influenza vaccinations because of a previous reaction and an egg allergy. First Bardana Rep. at 18.

Following his clarifications of the medical record, Dr. Bardana next turned to Dr. Axelrod's diagnosis of Petitioner's injury. First Bardana Rep. at 19-20. Dr. Bardana summarized Dr. Axelrod's theory of the case as follows:

> [Petitioner] developed immune complex disease secondary to idiotypic networks. Her immune status shifted to a Th2 phenotype, which worsened her allergic diathesis and resulted in life-threatening food allergies diagnosed by her physicians. Dr. Axelrod felt that this displayed a causal relation between vaccination and the development of immune complex disease with worsening of allergies.

Id. at 21.

Dr. Bardana then discussed his own opinions regarding Petitioner's injury. As an initial matter, Dr. Bardana believes that Petitioner suffers from undocumented asthma. First Bardana Rep. at 22. Dr. Bardana opined that Petitioner may have some mild allergy to some selected food allergens, but "there is no credible scientific evidence linking these allergies to her September 29, 2011 vaccination." *Id.* at 23. As support for his theory, Dr. Bardana noted that the majority of Petitioner's forty-five allergy skin test reactions were entirely negative, while sixteen were "minimally positive." *Id.* Dr. Bardana noted that no test result reached the level of "strongly positive." *Id.* As further support for his theory, Dr. Bardana noted that Petitioner's November 13, 2011, January 29, 2012, April 12, 2012, March 12, 2014, and March 1, 2015 emergency room visits resulted in "negative" examinations, with the exception of one occasion when an examiner noted "minimal swelling of the tongue." *Id.* at 22. Dr. Bardana concluded this section of his report with the opinion that the most likely scenario is that Petitioner experienced "anticipatory anxiety in association with her established food hypervigilance…" *Id.* at 23-24.

Dr. Bardana also opined that the medical literature Dr. Axelrod cited in his report with respect to serum sickness was not relevant to Petitioner's case. *See* First Bardana Rep. at 24 ("the literature cited by Dr. Axelrod relies upon situations where doses of the foreign protein are many orders of magnitude greater than in the vaccination scenario"). And, although Dr. Axelrod postulates that the development of idiotypic networks led to the development of an autoimmune disorder in Petitioner, Dr. Bardana noted that Petitioner had no symptoms, physical findings, or laboratory biomarkers which would indicate she had an autoimmune disorder. *Id.* at 24-25. Dr. Bardana also noted that Dr. Axelrod's assertion that the influenza vaccination shifted Petitioner's immune balance from Th1 to Th2 was highly speculative and he had only cited mouse/murine models to support this theory. *Id.*

Dr. Bardana concluded his report by opining that Petitioner developed recurrent panic-induced anxiety attacks related to a belief that she was "sensitized" to airborne food allergens. First Bardana Rep. at 25.

3. Dr. Axelrod's Second Report

On January 25, 2018, Petitioner filed an expert report from Dr. Axelrod responding to Dr. Bardana's first expert report. (filed as Ex. 39) (hereinafter "Second Axelrod Rep."). Dr. Axelrod began his report by summarizing Dr. Bardana's corrections to the medical record. Dr. Axelrod largely agreed with Dr. Bardana's corrections pre-October 2011, including the fact that Petitioner likely did not suffer a rash on October 4, 2011. *Id.* at 3. However, he maintained that Petitioner's rash was caused by her influenza vaccination, asserting that nine days is an appropriate time frame within which onset of a rash would develop following vaccination. *Id.*; *see also* Lawley et al., *A Prospective Clinical and Immunologic Analysis of Patients with Serum Sickness,* 311 N. ENG. J. MED. 22, 1407-13 (1984) (filed as Ex. 22) (hereinafter "Lawley"); Miller, et al., *The Speed of the Secondary Immune Response to Tetanus Toxoid with a Review of War Reports and Observations on Simultaneous Injection of Toxoid and Antitoxin*, 3 PEDIATRICS 49, 64-76 1948) (filed as Ex. 20). Dr. Axelrod also disagreed with Dr. Bardana that Petitioner's rash disappeared within seven days; rather, he believes that Petitioner's Prednisone treatment suppressed expression of the rash. *Id.*

Dr. Axelrod continued to assert that Petitioner developed hives prior to her November 10, 2011 appointment with Dr. Dhillon. Second Axelrod Rep. at 4. He noted that Petitioner's skin allergy testing read as positive to tree nuts, apple, peach, blueberry, celery, corn, broccoli, egg white, egg yolk, and onion. *Id.* Dr. Axelrod also disagreed with Dr. Bardana that low tryptase levels would rule out a significant allergic reaction. *Id.* at 5. To support his point, Dr. Axelrod cited a study in which the authors showed that tryptase levels, drawn shortly after the onset of fatal or near-fatal anaphylaxis related to food, were not elevated. *Id.*; Hugh A. Sampson, *Update on Food Allergy*, 113 J ALLERGY CLINICAL IMMUNOLOGY, 805-19 (2004) (filed as Ex. 41) (hereinafter "Sampson").

Dr. Axelrod clarified that he believed Petitioner suffered an angioedema/anaphylaxis that recurred for more than six months following her September 29, 2011 vaccination. He believes that the onset of nine days is "consistent" with an immune reaction to the vaccine, and the initial manifestation of a rash is consistent with an immune complex reaction. Second Axelrod Rep. at 11. Further he believes that the angioedema lasted for at least three months. *Id.* at 5.

Dr. Axelrod also addressed Dr. Bardana's concerns regarding the theory of causation. Second Axelrod Rep. at 9. Dr. Axelrod clarified that he believes that Petitioner's October 4, 2011 symptoms could have been related to a cytokine response, rather than an influenza infection. *Id.* Dr. Axelrod also dismissed Petitioner's nut allergy listed prior to September 29, 2011, as "listed by a non-physician, and not mentioned again until after the September 29, 2011 influenza vaccination." Second Axelrod Rep. at 10.

Dr. Axelrod also disagreed with Dr. Bardana's assertion that the influenza vaccine is "unlikely" to initiate a serum sickness-like process. Dr. Axelrod cited a study which found that fourteen subjects developed a serum sickness-like reaction following inactivated influenza vaccination to support the theory that Petitioner developed such a reaction. Second Axelrod Rep. at 11; *see also* Apisarnthanarak, et al., *Serum Sickness-Like Reaction Associated with Inactivated Influenza Vaccination among Thai Health Care Personnel: Risk Factors and Outcomes*, 49 CLINICAL INFECTIOUS DISEASES, 18-22 (2009) (filed as Ex. 46) (hereinafter "Apisarnthanarak").

Dr. Axelrod conceded that Petitioner may have suffered from anxiety, but maintained that if Petitioner did, she suffered from anxiety as a result of her allergies, and that the two conditions existed together, rather than Dr. Bardana's suggestion that Petitioner suffered from anxiety instead of food allergies. Second Axelrod Rep. at 5, 11. To support his point, Dr. Axelrod cited a study which found that subjects who experienced anaphylaxis to food allergy felt that their symptoms were more severe than subjects with allergy without anaphylaxis. *Id.* at 5. Dr. Axelrod further opined that Petitioner did suffer hives, swelling, and the closing of her throat on several occasions and that these symptoms were consistent with a diagnosis of angioedema/anaphylaxis. *Id.* at 11.

4. Dr. Bardana's Second Report

Respondent filed a second expert report from Dr. Bardana responding to Dr. Axelrod's second report. (filed as Ex. C) (hereinafter "Second Bardana Rep.").

Dr. Bardana began his report by again summarizing the points in the medical record where he disagrees with Dr. Axelrod. Regarding Petitioner's rash, Dr. Bardana noted that, while Dr. Axelrod opined that Petitioner's rash was consistent with a primary immune response to the influenza vaccine, her most recent vaccination was less than a year prior and likely would have been associated with lingering immunogenicity. Second Bardana Rep. at 2. Dr. Bardana noted that, regardless of whether Prednisone suppressed the rash or it resolved on its own, the rash did not recur after October 17, 2011. *Id.*

Dr. Bardana continued to disagree with Dr. Axelrod that Petitioner's November 10, 2011 visit did not describe the presence of hives. Second Bardana Rep. at 2. Dr. Bardana indicated that the confusion may stem from the fact that Petitioner filled out a questionnaire in which she listed general historical issues which included "hives/severe reaction after receiving a flu shot." *Id.* Dr. Bardana also noted that Dr. Axelrod's reference to part of Petitioner's physical examination actually appears to be historical diagnoses based on Petitioner's questionnaire. *Id.* Dr. Bardana reiterated that the physical examination conducted by Dr. Dhillon found Petitioner to be "alert, in no distress, no oropharyngeal findings, no lip swelling, no tongue swelling, chest clear to auscultation, etc." *Id.* Dr. Bardana also reiterated that none of Petitioner's skin test results returned as strongly positive. *Id.* at 3. Dr. Bardana agreed with Dr. Axelrod that tryptase is not generally elevated with food allergic reactions. *Id.* at 3.

Dr. Bardana also reiterated that Petitioner's November 13, 2011 trip to the emergency room resulted in a normal examination. Second Bardana Rep. at 3. He stated that Petitioner's symptoms were "strikingly consistent" with anxiety-induced acute hyperventilation syndrome. *Id.* Dr. Bardana did not disagree with the Herbert article, but believes it does not apply in this case because there is no documentation that Petitioner ever had anaphylaxis. *Id.* Similarly, Dr. Bardana opined that the records created (saying that Petitioner suffered an "allergic reaction which was improving") following the December 22, 2011 visit were based entirely on Petitioner's history. The examination at this visit was normal and her symptoms were consistent "with an anxiety-induced panic attack". *Id.* Dr. Bardana noted that Petitioner's examination at her January 6, 2012 emergency room visit was also normal, and she presented with no hives or angioedema. *Id.* at 4.

On January 29, 2012, Petitioner presented to the emergency room again and gave a history of peanut allergy. Although Petitioner was treated "aggressively," Dr. Bardana opined that there were no objective physical findings confirming allergy at this exam, and that the Xanax she received was "clearly the most effective therapy for her symptom complex." Second Bardana Rep. at 4. Similarly, although Petitioner's allergist, Dr. Dhillon, diagnosed her with a tuna allergy on February 2, 2012, Dr. Bardana opined that at this visit her examination was "completely normal" and therefore anaphylaxis is essentially "excluded" as a diagnosis. *Id.*

Dr. Bardana also stated that Dr. Dhillon's diagnosis of "allergic rhinitis and acute urticaria" on April 12, 2012 is incorrect, as neither diagnosis is supportable based on "objective findings." Second Bardana Rep. at 4. Dr. Bardana did concede that Petitioner may have experienced a mild allergy or intolerance to food on April 12, 2012. *Id.* at 4.

Dr. Bardana noted that, although Petitioner was advised to avoid future influenza vaccination based on her minimally positive skin test reaction to egg white/yolk, a) the validity of this observation was not confirmed by a more rigorous test, and b) LAIV appears to be safe for use in children who have a bona fide egg allergy. Second Bardana Rep. at 5; *see also* Turner et al., *Safety of live attenuated influenza vaccine in atopic children with egg allergy*, 136 J ALLERGY CLIN IMMUNOL. 376-81 (2015) (filed as Ex. C, Tab 8).

Dr. Bardana then summarized Petitioner's doctor's visits and emergency room visits on February 17, 2014, March 12, 2014, April 16, 2014, and March 1, 2015, noting that at each of these visits, Petitioner claimed an allergy upon arriving to the emergency room, but the examinations conducted were largely normal. Second Bardana Rep. at 5-6.

Following his summation of the medical records, Dr. Bardana outlined his disagreement with Dr. Axelrod's theory of causation. At this point, Dr. Bardana expressed his understanding of Dr. Axelrod's theory to be that Petitioner "reacted to an inactivated influenza vaccination on September 29, 2011 by developing a serum sickness-like reaction on October 1, or 2, 2011." Second Bardana Rep. at 6. Dr. Bardana continued to disagree with Dr. Axelrod that Petitioner's October 4, 2011 symptoms were anything other than an acute influenza infection. *Id.* He maintained his position that her October 10, 2011 rash was likely caused by a drug reaction which disappeared after seven days and did not recur. *Id.* He also continued to suggest that Dr. Axelrod's theory of the case was largely theoretical in nature and Dr. Axelrod had provided no support for it. *Id.* at 6-7.

Dr. Bardana concluded his report by stating that there is no instance in the available records which would support a finding of anaphylaxis in Petitioner. Second Bardana Rep. at 7. Dr. Bardana noted that on five occasions, the examining physician observed no objective physical findings which would support a finding of allergy. *Id.* at 8. Finally, Dr. Bardana postulated that the Apisarthanarak article cited by Dr. Axelrod was not relevant to Petitioner's case because 1) the vaccine in question was manufactured in Thailand; 2) the authors of the article made no claim of causality of the vaccine to the serum sickness-like reaction; and 3) the authors were not able to determine the overall incidence of serum sickness-like reaction. *Id.* at 9.

5. Dr. Axelrod's Third Report

On July 27, 2018, I entered a scheduling order asking the experts from each side eight questions. *See* Scheduling Order of July 27, 2018, ECF No. 68. Petitioner filed a third expert report from Dr. Axelrod addressing these questions on September 12, 2018. (filed as Ex. 49) (hereinafter "Third Axelrod Rep.").

Dr. Axelrod began his report by stating that the reaction of someone exposed to allergens, whether mildly positive or minimally positive, is unique to the person who experiences the reaction. Third Axelrod Rep. at 1-2; *see also* Pettersson et al., *Prediction of the Severity of Allergic Reactions to Foods*, 73 EUR. J. ALLERGY AND CLINICAL IMMUNOLOGY 1532-40 (2018) (filed as Ex. 50). Dr. Axelrod stated that the type of a reaction is "ultimately perceived by the individual suffering the reaction. The perception relates to prior reaction and the knowledge (or lack of knowledge) of the individual to the experienced symptoms and the psychiatric make-up of the individual." *Id.* at 2.

Dr. Axelrod also opined that it was possible to suffer an allergic reaction from inhalation of an allergen. Third Axelrod Rep. at 2. To support his point, Dr. Axelrod cited a study in which the authors reported anaphylaxis following the ipratropium bromide solution in a subject with a preexisting soybean and peanut allergy. *Id.*; see also Ramire & Bahna, *Food Hypersensitivity by Inhalation*, 7 CLINICAL AND MOLECULAR ALLERGY 4-10 (2009) (filed as Ex. 51). While an unrelated point, Dr. Axelrod also noted that individuals with a peanut allergy "might anticipate life-threatening reactions to inhalation of peanut particles." *Id.*

I also asked Dr. Axelrod what type of O_2 saturation levels he would expect to see in someone suffering an acute allergic reaction. Dr. Axelrod cited two studies in which patients with asthma were largely found to have normal oxygen saturation and oxygen saturation levels did not relate to clinical findings. Third Axelrod Rep. at 2; *see also* Richard Hardern, *Oxygen Saturation in Adults with Acute Asthma*, 13 J. ACCIDENT & EMERGENCY MED. 28-30 (1996) (filed as Ex. 52); Melbye et al., *Drop in Lung Function During Asthma and COPD Exacerbations – Can it be Assessed without Spirometry?*, 11 Int'l J. COPD 3145-3152 (2016) (filed as Ex. 53).

Dr. Axelrod stated that food challenges are considered the "standard criterion" to determine the presence or absence of food allergies. Third Axelrod Rep. at 3. He also noted that skin prick tests are "not perfect" predictors of true food allergy. *Id.; see also* MacGinnitie & Young, *The Role of Food Challenges in Clinical Practice*, 6 J. ALLERGY CLINICAL IMMUNOLOGY PRACTICE 353-60 (2018) (filed as Ex. 56). Dr. Axelrod also noted that the benefit of all allergy testing is dependent upon the pre-test probability of a given food allergy. Third Axelrod Rep. at 3; *see also* Kim, et al., *Diagnostic Accuracy, Risk Assessment, and Cost-Effectiveness of Component-Resolved Diagnostics for Food Allergy: A systematic Review*, 73 ALLERGY 1609-21 (2017) (filed as Ex. 57).

I asked Dr. Axelrod to explain whether Petitioner met the criteria for anaphylaxis. Dr. Axelrod listed the eleven signs and symptoms of anaphylaxis, and postulated that "following the influenza vaccination, following a period of 4-5 days (sufficient to build a memory response), [Petitioner] developed allergy symptoms that could represent anaphylaxis. Third Axelrod Rep. at

4; *see also* Lieberman et al., *Anaphylaxis – A Practice Parameter Update 2015*, 115 AM. ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY 341-84 (2015) (filed as Ex. 58).

Dr. Axelrod stated that there was support in the medical records which showed that Petitioner developed an angioedema. Third Axelrod Rep. at 4. At one point, Petitioner's physical examination stated her "lips were swollen". *Id.* Dr. Axelrod believes that this was most likely an "angioedema that responded to epinephrine." *Id.* Similarly, Dr. Axelrod indicated that Petitioner had an angioedema when she presented to the emergency room with throat swelling after eating oatmeal. *Id.*

Finally, Dr. Axelrod addressed the issue of Petitioner's possible acute hyperventilation syndrome. Third Axelrod Rep. at 5. He noted that hyperventilation is defined as "either fast or deeper breathing, or a combination of both, resulting in hypocapnia." *Id.*; *see also* Meuret & Ritz, *Hyperventilation in Panic Disorder and Asthma: Empirical Evidence and Clinical Strategies*, 78 INT'L J. PSYCHOPHYSIOLOGY 68-79 (2010) (filed as Ex. 61). This study suggested that "sudden decreases" of carbon dioxide in the blood preceded naturally occurring panic attacks. *Id.* As Petitioner did not have carbon dioxide tests, Dr. Axelrod opined that it is not possible to know whether she suffered from hypocapnia. *Id.* However, Dr. Axelrod concluded his report by reiterating his point that it would not be surprising if Petitioner suffered anxiety as a result of her "potentially lethal" allergies. *Id.*

6. Dr. Bardana's Third Report

Respondent filed a third report from Dr. Bardana on October 21, 2018, addressing my questions, and providing comment on Dr. Axelrod's answers to my questions. (filed as Ex. D) (hereinafter "Third Bardana Rep.").

Dr. Bardana began his report by noting that a food allergy is defined as "an adverse health effect arising from a specific immune response that occurs reproducibly upon exposure to a given food." Third Bardana Rep. at 2; *see also* Boyce et al., *Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel*, 126 J. ALLERGY CLINICAL IMMUNOLOGY S1-S58 (2010) (filed as Ex. D, Tab 10). After listing several factors which may affect the degree to which a person experiences an allergic reaction, Dr. Bardana stated that a "minimal reaction" to a Skin Puncture (Prick) Test or an Antigen-Specific Serum IgE test would be "indicative of an equivocal (probably clinically irrelevant) response and would not be expected to produce objective signs or symptoms in the patient." Third Bardana Rep. at 3. He further stated that a "mild reaction" might induce "transient abdominal pain, nausea, vomiting or diarrhea in a small percent of individuals or the development of urticaria with or without angioedema in a small percentage of individuals." He indicated that he would not expect any generalized anaphylaxis or respiratory reactions in the case of a mild reaction. *Id.* at 3-4.

Dr. Bardana next addressed whether it is possible to have an allergic reaction to breathing fumes from peanuts. He noted that peanut dust "does not aerosolize" nor does peanut butter vapor contain any protein. Third Bardana Rep. at 5. And, even if a person touched peanut dust, Dr. Bardana noted that "skin contact might cause local irritation, but not systemic reactions." *Id.*; *see also* Matthew Greenhawt, *Environmental Exposure to Peanut and the Risk of an Allergic Reaction*,

120 AM. ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY 476-81 (2018) (filed as Ex. D, Tab 4) (hereinafter "Greenhawt"). Similarly, Dr. Bardana noted that there is "little risk posed from non-oral exposure to peanut in the environment from casual contact, proximity, or inhalation." *Id.* He also dismissed the Ramirez paper cited by Dr. Axelrod, saying it failed to incorporate recent research related to casual exposures. *Id.*

In response to my question regarding expected O_2 saturation levels following an acute allergic reaction, Dr. Bardana stated that a reduction in oxygen saturation would be expected in two settings: acute allergic asthma, and acute allergic anaphylaxis. Third Bardana Rep. at 5. Dr. Bardana cited a study from Thailand, which showed that patients with status asthmaticus (a form of acute severe asthma) had oxygen saturation levels of 94%, a two percent drop when compared to other asthmatic patients. *Id*; *see also* Amnuaypattanapon et al., *Characteristics and Outcomes of Treatment in Status Asthmaticus Patients at Emergency Department*, 37 ASIAN PACIFIC J. ALLERGY AND IMMUNOLOGY 2, 87-93 (2019) (filed as Ex. D, Tab 6).

Dr. Bardana defined anaphylaxis as the "most severe form of an allergic reaction usually presenting as a generalized systemic reaction with a variety of clinical signs and symptoms." Third Bardana Rep. at 5. Dr. Bardana cited a study by Brown which showed that patients experiencing anaphylaxis generally had SpO_2 equal to or less than 92% and a systolic blood pressure of less than 99 mm/Hg. *Id*.; *see also* Simon Brown, *Clinical Features and Severity Grading of Anaphylaxis*, 114 AM. ACADEMY OF ALLERGY, ASTHMA, AND IMMUNOLOGY 2 (204) (filed as Ex. D, Tab 7). Dr. Bardana noted that hypoxia was generally defined as an SpO_2 saturation level of 92% or less. Third Bardana Rep. at 5. He also asserted that the "only IgE-mediated acute allergic reactions that would induce a change in oxygen saturation are acute severe asthma (status asthmaticus) and anaphylaxis." *Id.* Dr. Bardana disagreed with Dr. Axelrod's interpretation of the Hardern paper, noting that although Dr. Axelrod indicated that most of the subjects had normal oxygen saturation levels, Table 2 indicated that the mean SpO_2 level upon arrival to the emergency room was 92.5%, with a range of 89.2% to 95.8% *Id.* at 6. O2 levels only increased after treatment. *Id.*

Dr Bardana reiterated that the most important test for diagnosing food allergy is the patient's clinical history. Third Bardana Rep. at 7. He noted that "a diagnosis of food allergy is not generally based on a single test. A stepped approach is usually preferred in which the history leads to test selection, and the result of that test…can be used to determine whether oral food challenge…is warranted." *Id.* Dr. Bardana also noted that studies have shown "wide discrepancies" in wheal sizes, although the same dose of histamine was administered. *Id.* Dr. Bardana reiterated that positive or negative tests do not necessarily indicate the presence or absence of an allergy; testing must be contextualized alongside a patient's clinical history. *Id.* at 7-8.

Dr. Bardana next addressed the criteria for anaphylaxis. Third Bardana Rep. at 8. Listing the common symptoms, Dr. Bardana stated that "Urticaria and angioedema occur in 88% of cases, dyspnea and wheeze in 42%, dizziness, syncope and hypotension in 33%, nausea, vomiting, and diarrhea crampy abdominal pain in 30%. Flushing occurs in 40%, and upper airway edema in 56%." *Id* at 9; *see also* Phillip Lieberman, *Recognition and First-Line Treatment of Anaphylaxis*, 127 AM. J. MED. 1A (2014) (filed as Ex. D, Tab 9).

Dr. Bardana then stated that Petitioner "never met the published criteria for anaphylaxis." Third Bardana Rep. at 9. It is his opinion that Petitioner "never had a presentation that met the criteria of an anaphylaxis and on most subsequent emergency room visits there were no objective physical findings." *Id.* Dr. Bardana "totally disagrees" with Dr. Axelrod's conclusion that Petitioner's symptoms on October 4, 2011 were a presentation of allergic reaction. *Id.*

Dr. Bardana next discussed the criteria for angioedema. Dr. Bardana did not directly discuss the criteria for angioedema, but rather discussed the criteria for idiopathic histamine acquired angioedema (IH-AAE), which is a cause of recurrent angioedema without wheals. *Id.* at 9; *see also* Faisant et al., *Idiopathic Histaminergic Angioedema Without Wheals: A case Series of 31 Patients*, 185 CLINICAL AND EXPERIMENTAL IMMUNOLOGY 81-85 (2016) (filed as Ex. D, Tab 10). In this case series, the authors noted that "the face was the most frequent location of angioedema episodes (80.6% of cases). Fifty-four percent had at least one attack in the upper respiratory tract including the oral mucosa (17 patients), the tongue in 29% of cases and the larynx in one patient. The mean duration of attacks was 28 hours." Third Bardana Rep. at 10. Dr. Bardana is of the opinion that Petitioner never suffered a bout of angioedema. *Id.* In response to Dr. Axelrod, Dr. Bardana noted that the references to angioedema in Petitioner's medical records rely upon oral medical histories provided by Petitioner, unverified by actual examination, and therefore can be discounted as "unsubstantiated and unconvincing." *Id.* at 10-11.

Lastly, Dr. Bardana addressed the criteria for acute hyperventilation syndrome. Third Bardana Rep. at 11. Although Dr. Bardana is not aware of any formal criteria for the diagnosis of acute hyperventilation, he noted that the diagnosis was based on the "character of presenting symptoms." *Id*. at 12. These symptoms most often include dyspnea, fatigue, paranesthesia, palpitations, myalgias, cramps, anxiety, and irritability. *Id.* at 11; *see also* Gregory Magarian, *Hyperventilation Syndromes: Infrequently Recognized Common Expressions of Anxiety and Stress*, 61 MED. 4 (1982) (filed as Ex. D, Tab 11). Dr. Bardana noted that Petitioner had many instances suggestive of anxiety-induced hyperventilation, although she was never formally diagnosed with the condition. *Id.* at 11-12. Dr. Bardana asserted that Dr. Axelrod's findings on the issue were irrelevant because he discussed hyperventilation in the setting of panic disorder and asthma, and Petitioner did not have established asthma or anaphylaxis. *Id.* at 12.

IV. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before

[she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate 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 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under *Althen* prong one, a petitioner must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs*., 941 F.3d 1351, 1359-60 (Fed. Cir. Nov. 7, 2019).

A petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on a petitioner in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs*., No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*,

569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical 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 particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *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); *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section

13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019), *vacated on other grounds*, 809 Fed. Appx. 843 (Fed. Cir. 2020); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing

Lampe, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

V. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. Petitioner Has Not Carried Her Burden of Proof

1. *Althen* Prong 1

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

At the outset, I will note that Petitioner seemingly presented several discrete theories with respect to how the flu vaccine caused her injuries. I do not find these theories were connected in a persuasive manner.

According to Petitioner, "Dr. Axelrod's theory can be broken into two parts—1) The development of an immune complex disease and 2) the progression into a chronic, Th2-driven allergic state." Pet'r's Brief at 12. More specifically, Petitioner's expert indicates that Petitioner's flu vaccination caused her to develop an immune complex disease or a systemic adaptive immune response. The systemic adaptive immune reaction led to chronic autoimmune disease. Petitioner's immune response shifted to a Th2 phenotype. Petitioner's autoimmune disease then persisted based on the development of idiotypic networks.

Dr. Axelrod opined that Petitioner experienced symptoms consistent with a systemic adaptive immune reaction. He cited the Lawley article for this proposition. This paper discusses the evaluation of 12 patients with bone marrow failure who were treated with "daily infusions of horse antithymocyte globulin." Lawley at 1408. Clinical signs of serum sickness developed in 11 of the 12 patients between 8 and 13 days after the initiation of therapy. *Id.* Dr. Bardana disputed that flu vaccine can cause serum sickness based on the articles cited by Dr. Axelrod. He noted that the large quantity of anti-thymocyte globulin administered in the Lawley study was "vastly different" than that administered in a vaccine dose. *See* First Bardana Rep. at 19.

Petitioner also cited to the Apisarnthanarak article, which reported that 14 of 495 healthcare personnel developed a serum sickness-like reaction within 3-28 days after receipt of the influenza vaccination. Apisarnthanarak at 2. Specifically, they developed fever, myalgia, centrifugal arthralgias, and injection cite erythema with a median duration of symptoms of six days. *Id.* at 2, 4. Dr. Bardana disputed the relevance of this article, noting that the vaccine was manufactured in Thailand, thus it is unclear whether the rigorous standards the U.S. uses in vaccine manufacture were applied in this context. Second Bardana Rep. at 9. Dr. Bardana further noted that the article makes no claim of vaccine causality. *Id.* Considering the above positions, I find that Petitioner has presented preponderant evidence that the flu vaccine can cause serum sickness, although as discussed later in this decision, I do not find that it did so in this case.[12]

Dr. Axelrod opined that after she developed an immune response to the flu vaccine, Petitioner's immune response shifted to a Th2 phenotype, causing her to develop severe food allergies and urticaria. Dr. Axelrod generally described the Th2 response as follows:

> Both CD8+ T-cells and CD4+ T-cells are able to clear influenza virus. CD4+ T-cell stimulation results in at least 2 subtypes of CD4+ T-cells. These cells are labeled Th1 and Th2 cells, identified by the chemicals that these 2 subtypes release. CD4+ Th1 cells release high levels of γ-interferon that helps clear virus infected cells. CD4+ Th2 cells release high levels of Interleukin-4. Interleukin-4 further amplifies the generation of the Th2 phenotype. The Th2 phenotype suppresses the generation of Cytotoxic Lymphocytes, reducing the ability to clear virus infected cells. The Th2 phenotype results in allergy, noted by the release of a number of cytokines, including IL-4.

[12] I note that I have found flu vaccination can cause serum sickness in a prior case. *See Bryan v. Sec'y of Health & Hum. Servs.*, No. 14-898V, 2020 WL 7089841 (Fed. Cl. Spec. Mstr. Oct. 9, 2020). The evidence presented in Bryan was different than the case at bar. Specifically, in that case, Petitioner's treating doctors diagnosed him with serum sickness that they attributed to his flu vaccine.

First Axelrod Rep. at 6.

Petitioner cited to the Moran article to support her theory that influenza vaccination generates a Th2 response. Moran observed that "the inactivated virus immunization primed for a Th2 type response, whereas live virus elicited a Th1 response." Moran at 581.

Petitioner also cited to the Sun article to support the theory that the influenza vaccination causes an increase in Th2 cytokines, specifically IL-4. *See* Sun et al., *Altered influenza virus haemagglutinin (HA)-derived peptide is potent therapy for CIA by inducing Th1 to Th2 shift*, 8 CELLULAR & MOLECULAR IMMUNOLOGY, 348-58 (2011) (filed as Ex. 31) (hereinafter "Sun"). In this article, Sun described a study whereby collagen induced arthritis (CIA) was induced in mice by immunization with type II collagen. Sun studied the mice after injecting an altered influenza virus haemagglutinin (HA)-derived peptide (altered HA308–317), a wild-type HA308–317 peptide, and an irrelevant peptide. *Id.* at 349. The study concluded that the altered peptide ameliorated CIA. *Id.* at 352. The article noted that "Wild-type HA peptide also decreased the levels of Th1 cells … and increased the levels of Th2 cells … [h]owever, the effect was much milder than altered HA peptide." *Id.* Specifically the study found "The wild-type HA peptide treatment resulted in no significant change in the serum levels of IL-10 and MCP-1, a mild reduction in the serum levels of IL-6 and a mild increase of IL-4 as compared with the levels in irrelevant peptide-treated mice." *Id.* at 353. Because there has been no further discussion or analysis of his article, it is unclear what a "much milder" effect or a "mild increase of IL-4" signifies. Further, it is also unclear whether and to what extent a wild-type haemagglutinin-derived peptide is relevant to demonstrate that similar results would exist with an inactivated flu vaccine.

Petitioner cited to the Dourado article for the proposition that increased IL-4 production has been demonstrated in atopic disease. Dourado et al., *Role of IL-4 in aversion induced by food allergy in mice*, 262 CELLULAR IMMUNITY, 62-68 (2010) (filed as Ex. 33). Petitioner also cited Maggi to link Th2 cells to allergy. At the outset, it is important to note that the Maggi article stated, "The mechanisms responsible for the preferential development of allergen-reactive Th2 cells in atopic subjects have not yet been completely clarified." Maggi at 4. However, Maggi does provide some connection between Th2 and allergy. "Recent evidence has been accumulated to suggest that allergen-reactive type 2 helper T cells (Th2) play a triggering role in the activation and/or recruitment of IgE antibody-producing B cells, mast cells and eosinophils, i.e. the cellular triad involved in the allergic inflammation." *Id.* at 1. Maggi further wrote that "Strong evidence has been accumulated to support this concept that Th2 cells play a central role in atopy." *Id.* at 3. Maggi concluded by stating, "Th2 cells are generated from precursor naive Th cells when they encounter the specific antigen in an IL-4-containing microenvironment. However, the source of IL-4 required at the initiation of response for the development of naive Th cells into Th2 effectors is still unknown." *Id.* at 10. This point seems to be significant. Specifically, Maggi appears to state that the source of the IL-4 in initiating a Th2 phenotype is important with respect to whether an allergic response ensues.

Petitioner's theory is that this shift to a Th2 phenotype results in allergy. Dr. Axelrod stated, "This suggests that inactivated influenza vaccination (that includes hemagglutinin) can shift an already active Th1 phenotype response to an active Th2 phenotype response, sufficient to

change the function of the immune response to an allergy phenotype (Th2 phenotype)." First Axelrod Rep. at 6. While the articles cited by Petitioner do support the point that flu vaccine may cause the upregulation of Th2 cytokines, there has been no discussion of how the upregulation of these cytokines is anything other than transient. Further, it is not clear how upregulation of Th2 cytokines is "sufficient to change the function of the immune response to an allergy phenotype" (emphasis added).

Dr. Axelrod's theory then moves from serum sickness and Th2 immunity to the development of idiotypic networks. Specifically, he opined that "[t]he development and persistence of an autoimmune disease following vaccination is possible based upon the development idiotypic networks". First Axelrod Rep. at 5. Dr. Axelrod described idiotypic networks as follows:

> The immune response mounts an adaptive immune response to the immunogen (vaccine). The immune response to the vaccine produces antibodies and cell receptors that have unique structures that interact with the vaccine. These unique structures then induce immune responses to these unique structures that are structurally similar to the vaccine structures to which the initial anti-body or cell receptor interacted.

First Axelrod Rep. at 5.

Dr. Axelrod cited to Jerne in support of his theory that Petitioner's autoimmune condition persisted due to the development of idiotypic networks. *See* N.K. Jerne, *Towards a Network Theory of the Immune System,* ANN. IMMUNOL., 373-89 (1974) (filed as Ex. 24) (hereinafter "Jerne").

Dr. Bardana noted that the Jerne paper was a "theoretical forecast" that "expresses the authors opinion that the precise immunopathogenesis remains to be determined." First Bardana Rep. at 20. I find Dr. Bardana's summary is accurate. Below is the first sentence of the Jerne article:

> While listening to this week's colloquium on *the genetics of immunoglobulins and of the immune response,* I have given some thought to the long road along which immunology has travelled since the days of Louis Pasteur. I should like to place my concluding remarks in this perspective, by briefly looking at the past, and at our present situation, and by attempting to predict in what direction immunological theory will develop in the next years.

Jerne at 1. I also note that the paper was written in 1974. A theoretical paper that discusses predictions for immunological theory, when considered in the context of this case is not sufficiently reliable to pass muster under *Althen* prong one.

In sum, the pieces of Petitioner's theory appear somewhat disjointed. For example, it is unclear how Petitioner's systemic adaptive immune response connects to the shift to a Th2 profile.

Also unclear is how the shift to a Th2 profile has anything to do with the development of idiotypic networks. These almost appear to be separate, stand-alone theories.

I will also note that Petitioner has provided no medical literature which supports a connection between the flu vaccine and the development of food allergies. While this type of evidence is not required in order for Petitioner to establish a reputable prong one theory, the absence of such evidence does not serve to advance Petitioner's case. "[A] scientific theory that lacks any empirical support will have limited persuasive force." *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 134 (2011), *aff'd without opinion*, 463 F. App'x 932 (Fed. Cir. 2012).

Ultimately, for the reasons discussed above, I find that Petitioner has not presented preponderant evidence in the form of a reputable medical theory which demonstrates that the flu vaccine can cause food allergies.

2. *Althen* Prong 2

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 U.S. Claims LEXIS 1023 at *75 (Fed. Cl. Spec. Mstr. July 30, 2012), *aff'd* 108 Fed. Cl. 743 (Fed. Cl. 2013).

Petitioner's theory in this case is that her flu vaccination led to a systemic adaptive immune response which in turn caused her chronic autoimmune disease in the form of severe allergies and chronic urticaria. For the reasons discussed below, I find that Petitioner has not demonstrated she developed a systemic adaptive immune response, or that she suffered from chronic urticaria or severe allergies; further, Petitioner did not present evidence that she experienced an autoimmune process.

a. *Petitioner did not Experience a Systemic Adaptive Immune Reaction in early October 2011, but instead had a Viral Infection*

Petitioner's theory is that her vaccination led to a systemic adaptive immune reaction which in turn caused her chronic autoimmune disease in the form of severe allergies. On October 4, 2011, Petitioner presented to St. John's Urgent Care with a fever, body aches, scratchy throat, congestion, dizziness, shortness of breath, muscle pain, swollen glands, headache, and a cough that she had been experiencing for two to three days. Ex. 2 at 1. Dr. Michael Kurzawa assessed her with "influenza/viral syndrome". *Id.* He prescribed Motrin, fluids, Tessalon, and Tamiflu. *Id.*

Fundamental to Petitioner's theory is that this initial reaction constituted a systemic adaptive immune response to vaccination. Dr. Axelrod opined that "[a]lthough infection with the

influenza virus can cause the symptoms with which she presented, those symptoms can also be produced by vaccination." Second Axelrod Rep. at 9. Dr. Axelrod pointed to the increased cytokine production after vaccination as an explanation for Petitioner's signs and symptoms on October 4, 2011. *Id.* According to Petitioner, "it is logical to conclude that Mrs. Solak felt flu-like after administration of the influenza vaccination and did not actually have an infection." Pet'r's Brief at 14. However, it is unclear how a cytokine response could have caused some of Petitioner's symptoms. In fact, Dr. Bardana called this theory "scientifically untenable". First Bardana Rep. at 24. Specifically, he stated "Ms. Solak's scratchy throat, nasal congestion, and shortness of breath are clearly not features that are seen in immune complex disease." *Id.*

I find the evidence preponderantly establishes that Petitioner had a viral infection on October 4, 2011. Dr. Kurzawa's opinion on this matter is especially probative, as he examined and treated Petitioner on this date. After his examination, Dr. Kurzawa treated Petitioner with Motrin, fluids, Tessalon, and Tamiflu. Dr. Bardana's analysis that Petitioner would not have experienced scratchy throat, nasal congestion, or shortness of breath as a result of immune complex disease further supports the fact that Petitioner had a viral infection. Because the first step in Petitioner's theory, that her vaccination led to a systemic adaptive immune reaction, has not been established, Petitioner has failed to meet her burden of preponderant proof under *Althen* prong two. Although the analysis could end here, I find additional evidence in Petitioner's medical records merits discussion.

b. *Petitioner did not Experience Chronic Autoimmune Disease in the Form of Severe Allergies or Chronic Urticaria*

An additional step in Petitioner's theory is that her systemic adaptive immune reaction led to autoimmune disease in the form of chronic urticaria and severe allergies. In short, the evidence presented in this case does not establish that Petitioner had chronic urticaria or severe allergies or that she experienced an autoimmune process.

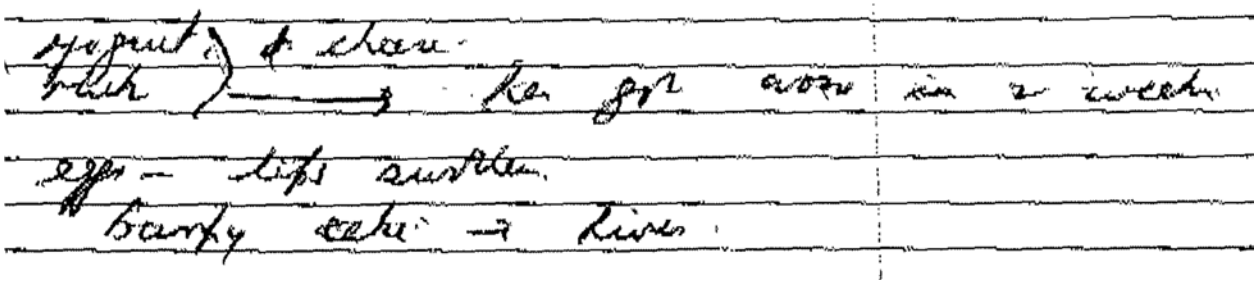
i. Petitioner's Urticaria

On October 10, 2011, Petitioner visited Dr. Ragireddy at Wayne State University Family Medicine for an upper respiratory infection and a rash. Ex. 3 at 5. During this visit, the medical records note that Petitioner experienced fatigue, fever, chills, cough, and nasal congestion. *Id.* The record further indicates that Petitioner developed a maculopapular rash[13] on her arms, face, neck, chest, and trunk, that morning. *Id.* at 5, 7. Urticaria is noted as an associated factor. *Id.* at 5. Petitioner was assessed with "Bronchitis, acute, with bronchospasm" and "Maculopapular rash generalized", "D/D [differential diagnosis] drug eruption Vs urticaria." *Id.* at 8. Dr. Ragireddy prescribed Zithromax and Prednisone. *Id.* According to Dr. Axelrod, Petitioner "was given

[13] A maculopapular rash is defined "as a rash characterized by both macules and papules." *Maculopapular*, Dorland's at 1079. A macule is defined as "a stain, spot, or thickening; an area distinguishable from its surroundings by color or other characteristic." *Id.* A papule is defined as "a small circumscribed, superficial, solid elevation of the skin less than 1 cm (0.5 cm according to some authorities) in diameter." Dorland's Online, https://www.dorlandsonline.com/dorland/definition?id=36692 (last visited Feb. 19, 2021).

Azithromycin and Prednisone with a taper, for a presumed drug eruption." First Axelrod Rep. at 1. This statement acknowledges that Petitioner's treating doctor believed Petitioner's rash/urticaria was caused by a drug eruption. Further, Dr. Bardana stated that Tamiflu has been associated with "a variety of dermatologic side effects including urticaria…" First Bardana Rep. at 16. Petitioner's rash resolved by October 17, 2011. *Id.* at 1.

Although Dr. Axelrod contends that Petitioner experienced urticaria on other occasions, the basis for this assertion is unsupported in the record. For example, Dr. Axelrod stated that on November 10, 2011, Petitioner presented "with hives and gastrointestinal symptoms after eating dairy products." First Axelrod Rep. at 2. However, in examining that record, Petitioner completed a questionnaire for her allergist, Dr. Dhillon, wherein she wrote that the main reason for her visit was "[h]ives, stomach problems, vomiting after digested [sic] dairy products, hives/severe reaction after receiving flu shot". Ex. 7 at 56. Dr. Axelrod further stated that "it is likely that the cause of the hives (be they allergic or idiopathic) persisted" based on notes from Dr. Dhillon on November 10, 2011. Second Axelrod Rep. at 6; *see also* Ex. 7 at 60. However, in examining these notes, this entire page reflects a patient history and not a physical examination. The notes describe her sister's apple allergy, Petitioner's recounting that she developed the flu after the flu vaccine, as well as other historical information. *See* Ex. 7 at 60. The disputed portion of the record reads as follows:



I read these notes to say:

yogurt and cheese → has gotten worse in 2 weeks
rash
eggs – lips swollen
bunty cake → hives

Again, this information appears to be historical in nature and not based on Dr. Dhillon's physical examination. In short, I do not see any indication that Dr. Dhillon observed Petitioner to be suffering from hives on November 10, 2011.

Additionally, on November 11, 2011, Petitioner presented to the Crittenton Hospital ER complaining of throat swelling after eating oatmeal. Ex. 4 at 128. Dr Axelrod stated that "she received a diagnosis of an acute allergic reaction and acute urticaria." First Axelrod Rep. at 2. However, it appears her diagnosis was "allergic reaction, unspecified". Ex. 4 at 131. Further, it does not appear that Petitioner was diagnosed with urticaria or that she had any type of skin problems during this visit. Of note, the examination of her skin indicated that she had "no acute rashes, lesions or induration". *Id.* at 129.

On April 12, 2012, Petitioner went to the ER after experiencing "flushing of her face, feeling dizzy, and … fluttering of her right eyelid." Ex. 4 at 38. Under "general", the record notes, "Awake and alert, answers questions appropriately. Normal mood, No rash, no welts no hives." *Id.* at 36. The review of systems section of this record says in part, "No rash except her left arm is slightly itchy." *Id.* at 38. That description is contradicted later in the record when the skin section of the examination indicates, "She has slight petechial rash[14] on her left upper arm." *Id.* at 39. The final impressions/diagnosis include: 1. Acute allergic reaction. 2. Acute of urticaria. 3. History of allergic rhinitis. *Id.* Based on the overall context of this ER visit, it appears that "Acute of urticaria" is missing the word "history" and should instead read "Acute history of urticaria" or "History of acute urticaria." I base this observation on the fact that there is no mention of Petitioner experiencing hives during this assessment. As discussed in the footnote, a petechial rash is not the equivalent of hives.

Dr. Axelrod contends that Petitioner "suffered a chronic (greater than 6 weeks) urticaria." First Axelrod Rep. at 5. Based on the above discussion, I do not find Petitioner experienced chronic urticaria. She developed a rash with associated urticaria on October 10, 2011 that her doctor attributed to medication. This rash/urticaria went away within one week. There is no objective support in any of the medical records that Petitioner presented with hives on any other occasion. Further, as Dr. Bardana noted, "Even if she had well-demonstrated egg allergy (which is not the case), the urticaria appearance would be an atypical reaction to egg allergen given 11 days before." Second Bardana Rep. at 5.

ii. Petitioner's Food Allergies

Petitioner visited Dr. Dhillon on November 10, 2011 for allergy testing. It appears that the testing performed was the SPT (skin puncture/prick test). The Bird article describes the SPT as "a safe, effective method of detecting specific IgE antibodies." Bird et al., *Clinical Management of Food Allergy*, 3 J ALLERGY CLIN IMMUNOL PRACT, 1-11 (Jan/Feb 2015) (filed as Ex. A, Tab 3) (hereinafter "Bird"). The Bird article goes on to state that "the clinician should be aware that a positive test does not equate to clinical reactivity." *Id.* This point is reinforced by Dr. Bardana: "SPTs effectively detect the presence of IgE, but many patients have serum IgE without clinical food allergy." Third Bardana Rep. at 2.

During the SPT, a test allergen is placed on the skin and then the skin under the allergen is pricked with a needle. In order for the test to be positive, the test allergen must result in a wheal (or a hive) that is at least three millimeters in diameter after subtracting the control. In this case, the control was two millimeters. *See* First Bardana Rep. at 23; Ex. 7 at 62. The Sampson article supports this point. "Allergens eliciting a wheal at least 3 mm larger than that produced by the negative control are considered positive, indicating the possibility that the patient has symptomatic reactivity to the specific food, with strongly positive results (eg, median wheal diameter >8-10

[14] Dr. Bardana defined petechiae as "non-blanchable and non-palpable pinpoint macules (less than a few millimeters in diameter) that result from capillary inflammation and red blood cell extravasation. These can be the result of steroid therapy, minor trauma, arthropod bites, etc. They are not allergic in nature." Second Bardana Rep. at 4.

mm) indicating a greater likelihood of clinical reactivity." Sampson at 811. With respect to negative results, the Sampson article stated, "Negative skin test responses essentially confirm the absence of IgE-mediated allergic reactivity (negative predictive accuracy, >95%)." *Id.* "A negative SPT can be particularly useful to rule out suspected food allergens due to the relatively high negative predictive value of SPT." Bird at 4.

Dr. Dhillon performed 46 puncture allergy tests. According to Dr. Bardana, twenty-five of the tests were negative, sixteen showed minimal reactions (four-millimeter wheal) while three (cashew, milk, blueberry) demonstrated a mildly positive reaction (five-millimeter wheal).[15] First Bardana Rep. at 22. Notably, Petitioner's peanut allergen test was negative. Ex. 7 at 62; *see also* First Bardana Rep. at 17.

Dr. Bardana described the terms "minimally positive" and "mildly positive" as follows:

> …a minimal reaction would be indicative of an equivocal (probably clinically irrelevant) response and would not be expected to produce objective signs or symptoms in the patient.
>
> …
>
> [A] mild reaction would not produce any objective signs or symptoms in a significant percent of patients. It might induce transient abdominal pain, nausea, vomiting or diarrhea in a small percent of individuals or the development of urticaria with or without angioedema in a small percentage of individuals. I would not expect any generalized anaphylaxis or respiratory reactions.

Third Bardana Rep. at 3-4.

Dr. Bardana pointed out that SPT testing is generally one step in diagnosing food allergies, and that the gold standard for such diagnoses is double blind placebo-controlled food challenge. Third Bardana Rep. at 2-3. He goes on to state that "If such a challenge is positive and the symptoms correlate with the medical history, and are supported by laboratory tests, then the diagnosis of food allergy is supported." *Id.* at 3. Petitioner did not have any of this additional testing performed.

1. Airborne Peanut Allergy

Dr. Bardana also discussed the likelihood of Petitioner having an airborne nut allergy. He stated that "1. Peanut dust does not aerosolize; 2. Peanut butter vapors contain no protein; 3. Surfaces can be effectively cleaned of peanut residual; 4. Skin contact might cause local irritation,

[15] I will note that this does not account for all the testing performed (25 + 15 + 3 = 43). *See* Ex. 7 at 62. Dr Axelrod stated that Petitioner's testing was positive with respect to "tree nuts, apple, peach, blueberry, celery, corn, broccoli, egg white, egg yolk and onion." First Axelrod Rep. at 2; Second Axelrod Rep. at 6. Ultimately, the specific results (e.g. whether Petitioner tested minimally positive for broccoli (for example)) is not an essential component of this decision.

but not systemic reactions." Third Bardana Rep. at 4. Dr. Bardana cited to the Greenhawt article in support of these points. Specifically, Greenhawt stated, "To date, there is no supporting evidence that peanut or peanut dust becomes airborne or that inhaling vapors from peanut butter triggers reaction." Greenhawt at 477. Based on these observations, Dr. Bardana opined that "[t]here is little risk posed from non-oral exposure to peanut in the environment from casual contact, proximity or inhalation. Studies have recently confirmed that a dose of 1.5 mg of peanut protein would be tolerated by 95% of the peanut allergic population based on objective symptoms to challenge-based studies affirming earlier studies." Third Bardana Rep. at 4. This opinion is consistent with the opinion expressed by Dr. Dhillon. *See* Ex. 10 at 1 (Dr. Dhillon stated, "peanut allergy is food borne and it's very difficult to get anaphylaxis to peanuts – if somebody opens a bag in the room without her touching it or eating it.").

Petitioner disputes this point and contends that Petitioner could have an airborne nut allergy. Dr. Axelrod cited a paper by Ramirez which stated that "Persons who come into contact with food, in either occupational or non-occupational settings, can inhale food particles that may lead to adverse reactions in highly sensitive individuals, or may cause *de novo* sensitization." Ramirez & Bahna, *Food hypersensitivity by inhalation*, 7 CLINICAL AND MOLECULAR ALLERGY (2009) (filed as Ex. 51) (hereinafter "Ramirez"). Dr. Bardana does not find the Ramirez article compelling because it relies heavily on observations in the occupational setting, and "fails to incorporate recent research related to casual exposures." Third Bardana Rep. at 4. I find Respondent's literature and expert opinion to be more compelling on this point. The Greenhawt article was published in 2018 and is thus significantly more current that the Ramirez article. The opinions of Dr. Bardana and Dr. Dhillon carry significant weight. Also of particular note, Dr. Axelrod never discussed how Petitioner's negative peanut allergen test aligns with his theory of the case. For these reasons, I find there is not preponderant evidence which demonstrates that Petitioner has an airborne nut allergy.

2. Petitioner's ER Visits

Petitioner visited the ER on seven separate occasions after October of 2011, each time complaining of an allergic reaction. Below is a summary and discussion of each.

Petitioner's November 11, 2011 ER Visit

Petitioner visited the Crittenton Hospital ER on November 11, 2011 with a complaint of "allergic reaction this morning." Ex. 4 at 127. The medical records indicate that Petitioner ate oatmeal that morning and felt that she developed a reaction. *Id.* at 132. The Crittenton records indicate that she developed difficulty breathing[16] and throat swelling and then presented to the ER. *Id.* at 128. The physical exam revealed no stridor, no rash, and no angioedema, although she appeared "quite anxious". *Id.* at 128, 132. Petitioner was diagnosed with "allergic reaction, unspecified". *Id.* at 131. She was discharged after about six hours. *Id.* at 133.

Petitioner's November 13, 2011 ER Visit

[16] Petitioner was also examined by Dr. Dhillon while she was in the ER. Dr. Dhillon's records state, "The patient denies any symptoms of difficulty breathing." Ex. 4 at 132.

On November 13, 2011, Petitioner presented to the Crittenton Medical Center ER with symptoms which included "tingling in her lips, dizziness and flushing to her head and chest." Ex. 4 at 104. She took a Benadryl and felt that it was stuck in her throat. *Id.* Petitioner was described as feeling "anxious, worried, and upset." *Id.* at 105. The physical examination indicated that Petitioner had "very mild flushing to her front of her chest and face, but no obvious swelling to her lips or tongue." *Id.* Dr. Loniewski wrote "The patient was examined by myself. I do not see any significant signs of an allergic reaction. There are no signs of her airway closing. No rashes or hives." *Id.* She was described as feeling "anxious, worried, and upset." *Id.* at 104-05.

Petitioner's December 22, 2011 ER Visit

On December 22, 2011, Petitioner presented to the Crittenton Medical Center ER complaining of tightness in her throat and slight trouble breathing. Ex. 4 at 68. The HPI section of the record states, "There was a package of food that arrived and apparently had peanuts in it. She did not eat it or touch it she was just in the same room and started to feel dizzy." *Id.* Petitioner's physical examination revealed no hives, no rash, no edema, no wheezing. *Id.* at 67, 68. She was diagnosed with "Allergic reaction, unspecified". *Id.* at 69. Dr. Bardana opined that Petitioner's symptoms "are consistent with an anxiety-induced panic attack." Second Bardana Rep. at 3.

Petitioner's January 29, 2012 ER Visit

Petitioner presented to the St John Hospital ER on January 29, 2012 with a chief complaint of "allergic reaction". Ex. 9 at 1. The HPI section says, "Patient with allergy to peanuts with throat swelling and flushing after eating seafood." *Id.* at 4. The intake notes state that "pt is allergic corn and accidentally ate some vegetable oil, pt states that she is having trouble breathing. pt gave herself an epipen and Benadryl." *Id.* at 29. The record also states, "pt states was eating tuna fish today "and my throat felt like it was closing." pt states gave epi pen and benadryl and "felt better." *Id.* at 35. The records indicate that Petitioner did not have any allergic swelling, rash, or pruritis and that she had "subjective throat tightening symptoms." *Id.* at 4, 9. The doctor described her as having a "possible allergic reaction". *Id.* at 7. The record also states that "[t]here was no evidence of anaphylaxis pt treated empirically for throat tightness. Possible anxiety." *Id.* She was prescribed Xanax. Ex. 9 at 97.

Petitioner's April 12, 2012 ER Visit

Petitioner presented to the Crittenton Medical Center ER on April 12, 2012. She complained of an allergic reaction. Ex. 4 at 35.

> Patient states she is allergies [sic] to every type of nut [i]ncluding dust from the nuts. [T]oday she states she walked into her office at work[.] All [of a] sudden she felt dizzy and lightheaded and nauseated and tingling to her lips[;] a tightness in her throat but not closing of her throat.

Ex. 4 at 35. Petitioner's physical exam revealed no rash, no welts, no hives, no swelling to lips, no stridor in the neck. *Id.* at 36. She was diagnosed with "Allergic reaction, unspecified". *Id.* at 37.

Dr. Dhillon also examined Petitioner while she was in the ER. He noted that around 10:30 that morning, Petitioner began to experience some flushing of the face, feeling dizzy, and fluttering of her right eyelid. *Id.* at 38. Petitioner also told Dr. Dhillon that she felt her throat was closing a bit. *Id.* She indicated that she did not consume any nuts. *Id.* Further, she "did not get any positive history from any of the coworkers regarding nut intake or having nuts in the office." *Id.* Dr. Dhillon's review of systems indicates that she did not have any lip or tongue swelling. *Id.* He further stated that Petitioner was "slightly nervous today when that sensation was starting." *Id.* Finally, Dr. Dhillon indicated that there was "No rash except her left arm is slightly itchy."[17] *Id.*

Petitioner's March 12, 2014 ER Visit

On March 12, 2014, Petitioner presented to the Detroit Medical Center ER. Ex. 8. Petitioner reported that she "has an airborne allergy to nuts and someone was eating t[h]em around her." *Id.* at 7. Petitioner further reported,

> [S]he has a severe allergy to nuts. She states that she was at work when some[one] [ate] a candy bar in front of her that contained nuts. She states that she felt her throat beg[i]n to close. She felt weak and dizzy and had some difficulty breathing. She also felt that her tongue was swelling. An EpiPen was used. She is brought to the Emergency Department by EMS. She states that she has had anaphylactic reaction to nuts in the past.

Id. at 13. Petitioner's physical exam was normal except that she was noted to have "some minimal edema of the tongue." *Id.* at 14. With respect to this finding, Dr. Bardana opined that "Detection of minimal edema of the tongue in an unfamiliar patient is very difficult." Second Bardana Rep. at 5. I find that Dr. Bardana's opinion is persuasive, especially when considered in conjunction with the fact Petitioner tested negative for peanut allergy, and there is little risk posed from non-oral exposure to peanuts.

Petitioner's March 1, 2015 ER Visit

On March 1, 2015, Petitioner presented to Eastside Urgent Care for an allergic reaction after eating chicken. Ex. 12. The urgent care record notes that she had pharyngeal erythema (red throat) and decreased air exchange. *Id.* at 2.

These records also contain a hand-written list of allergies that Petitioner purportedly experiences when she eats certain foods or comes into contact with certain allergens. *See* Ex. 12 at 6. Petitioner informed the medical provider that she was allergic to: almonds, apples, beans (string), Brazil nuts, carrots, cashew nuts, celery, clams, corn, to include many derivatives such as corn syrups, fructose, dextrose, xanthum gum, caramel coloring, fluoride (tap water, some bottled),

[17] A separate notation states that "She has slight petechial rash on her left upper arm." Ex. 4 at 39.

plastics, dish soap, body soap, hand soap, eggs, milk, peaches, pecans, chocolate, broccoli, blueberry, onion, all nuts, beef, cantaloupe melon, chicken, cod fish, lobster, oranges, peas, pork, potato, rice, rye, salmon, shrimp, soybean, strawberry, tomato, whole wheat, ginger, pineapple, garlic, cherry, cucumber, yeast, mushroom, penicillin, and codeine. *Id.* Petitioner reported that she experienced airborne allergies to tree nuts, and peanuts,[18] to include things cooked in peanut oil like Thai food. *Id.* Several of the entries are denoted as "deadly" allergies. Petitioner reported that she experiences deadly allergies to almonds, Brazil nuts, cashew nuts, all nuts, corn, and eggs. *Id.* This list is markedly different than Petitioner's allergy testing results. *See* Ex. 7 at 62. Further, there is no documentation in the medical records that Petitioner is actually allergic to the additional substances she has enumerated during this appointment.

After visiting urgent care, Petitioner was then transferred to the St John Hospital and Medical Center Emergency Department. Ex. 11 at 12. The HPI states that Petitioner experienced "swelling of the tongue and lips at home". *Id.* at 17. The ED notes state

> Patient had previous allergic rx, tongue and throat were swollen, does not look swollen anymore but pt still does not feel back to normal. Pt used epi pen at home before going to urgent care. Urgent care did not feel comfortable sending pt home so pt was sent to ER.

Id. at 22.

In sum, Petitioner presented to the ER on seven separate occasions after October of 2011, and appears to have experienced objective signs during, *at most*, four of these visits (very mild flushing to the front of her chest and face on November 13, 2011, (although the attending doctor noted she had no significant signs of an allergic reaction during this visit), some disputed evidence of a slight petechial rash on her left upper arm during the April 12, 2012 visit, minimal edema of the tongue on March 12, 2014, and a red throat and decreased air exchange on March 1, 2015). There were no objective signs during her ER visits on November 11, 2011, December 22, 2011, and January 29, 2012. Also of note, Petitioner tested mildly positive to three allergens: cashew, milk, and blueberry. There is no report that she consumed any of these foods before presenting to the ER on any of the seven occasions. Additionally, Petitioner tested negative to peanut allergen yet claims to have an airborne allergy to nuts. Petitioner's treating doctors specifically mentioned anxiety in several of these treatment records. (*See* Ex. 4 at 128 where Petitioner "appears quite anxious"; Ex. 4 at 104-05 where Petitioner is described as "anxious, worried, and upset"; Ex. 4 at 38 where Petitioner was described as "slightly nervous today"; Ex. 9 at 97 documenting that Petitioner was prescribed Xanax for anxiety).

After reviewing Petitioner's medical records, Dr. Bardana opined that while Petitioner may have some mild bona fide food allergies, the majority of her symptoms were caused by anxiety. Based on my own review of the medical records, I find Dr. Bardana's opinion to be persuasive. I do not find there is preponderant evidence that Petitioner experienced *severe* food allergies.

iii. Evidence of Autoimmunity

[18] This record is cut off thus it is not clear the entry says "peanuts". I believe it does based on context (the next entry indicates "including things cooked in peanut oil."). *See* Ex. 12 at 6.

Dr. Bardana noted in his reports that Petitioner did not demonstrate any evidence of an autoimmune process or disorder. Specifically, she did not have evidence of "immune complex pathology such as cutaneous vasculitis, hepatitis, glomerulitis, or arthritis (synovitis), and she did not demonstrate autoantibodies or changes in the autoantibody titer or organ inflammatory changes related to an autoimmune disorder." *See* First Bardana Rep. at 24. She did not have autoimmune symptoms, physical findings, or laboratory biomarkers. *Id.* at 24-25. While this point, standing alone would not necessarily be dispositive, when considered in conjunction with the other evidence discussed above, it cuts against Petitioner with respect to the second *Althen* prong.

c. *Petitioner's Treating Physicians*

In weighing evidence, special masters are expected to consider the views of treating doctors. *Cappizano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Dr. Dhillon was Petitioner's treating allergist. On November 8, 2012, he wrote a letter on her behalf.

To Whom It May Concern:

Patient **Diane Solak** was seen in my office today. Patient has documented allergy to eggs and also last 4 years she had reactions to the flu shot soon after administration. So she was advised to not have influenza immunization. Patient is advised to wear a mask only when she is close patient contact and also advised to take time off work if she has any flu like symptoms. If you should have any other questions or concerns please contact me at the above phone or fax.

Ex. 13 at 1. Of note, there is no evidence in the contemporaneous medical records that Petitioner had an adverse reaction to any prior flu shot. In fact, on November 10, 2011, Petitioner completed an "Allergy-Immunology History Questionnaire". Ex. 7 at 56. One of the questions posed was "Any reactions to vaccines you have received?" *Id.* Petitioner responded: "flu shot 9-30-11". *Id.* The fact that she did not list a reaction to any prior flu vaccine suggests that she did not experience such an adverse reaction. In addition, on November 10, 2009, Petitioner received the H1N1 vaccine. Ex. 5 at 4. She signed an acknowledgment indicating that she had been informed of the contraindications of this vaccine, which included among other things "[p]revious hypersensitivity to any vaccine." *Id.* Presumably, because Petitioner received the shot on that date, she had not experienced any of the listed contraindications with respect to her vaccination on October 14, 2008. It appears that Dr. Dhillon based his letter on the history of prior reaction that Petitioner provided to him. While there is nothing improper about this, I do not find it to be compelling evidence that Petitioner had an adverse reaction to her prior flu vaccines or that her 2011 flu vaccine caused any of her medical problems.

On February 7, 2014, Petitioner completed a special accommodations eligibility questionnaire for a mortgage loan originator test. Ex. 7 at 64. On this form, Petitioner wrote that she has a "Severe Airborne Nut Allergy [includes ALL foods processed in factory that packages ANY nut products also including Thai and Chinese food]". *Id.* (emphasis in original). Dr. Dhillon then completed several questions. When asked "Describe the manner in which this disability impairs major life activity/functioning?" He wrote, "When patient gets exposed to nuts she gets anxious, trouble breathing tongue swelling and [sic]". *Id.* at 66. When asked "Identify the aspect(s) of the candidate's functioning which requires testing accommodations, and the effect of the disability on the candidate's functioning under standard testing conditions", Dr. Dhillon wrote "gets impaired judgment". *Id.*

On August 19, 2015, Petitioner visited Dr. Dhillon to have her disability paperwork completed. Dr. Dhillon wrote that he "explained to her I doubt food allergy can qualify as disability." Ex. 10 at 1.

On September 1, 2015, Dr. Dhillon completed a form entitled "Physical Residual Functional Capacity Questionnaire". Ex. 10 at 3-6. Dr. Dhillon indicated that Petitioner was diagnosed with food intolerance and nut allergy. *Id.* at 3. He reported that emotional factors, which include anxiety, contribute to the severity of Petitioner's symptoms and limitations. *Id.* at 4. In response to the question, "Are your patient's impairments (physical impairments plus any emotional impairments *reasonably consistent* with the symptoms and functional limitations described in this evaluation?", Dr. Dhillon responded "no." *Id.* In the comments section, he wrote that her symptoms are short lasting. *Id.*

Petitioner returned to Dr. Dhillon on September 25, 2015. Dr Dhillon summarized this appointment as follows:[19]

> Patient here to get disability form filled out. Patient brings a pre-filled form from [illegible] and advises me to fill what she thinks should be put on the form.
>
> I explained I have to fill the form [sic] what I feel as a medical doctor should go on the disability form[.] Patient gets mad states so you are saying that my "peanut allergy is not air borne." I explained that peanut allergy is food borne and it's very difficult to get anaphylaxis to peanuts – if somebody opens a bag in the room without her touching it or eating it. And also I said her skin testing is more than three years old. Patient was getting mad that I'm not putting on the form what she needs. I put on the form that I refuse to fill the form. Patient left.

Ex. 10 at 1. *See also*, Ex. 10 at 7. This entry from September 25, 2015 demonstrates Dr. Dhillon does not believe that Petitioner has an airborne nut allergy.

Petitioner's general theory in this case is that her vaccination led to a systemic adaptive immune reaction which in turn caused her chronic autoimmune disease in the form of severe allergies and chronic urticaria. The evidence presented in this case does not establish that Petitioner suffered from a systemic adaptive immune response, chronic urticaria, or severe

[19] Dr. Dhillon's handwriting is very difficult to read. I have transcribed his text as best as I was able.

allergies; further, Petitioner did not present evidence that she experienced an autoimmune process. Petitioner has therefore failed to preponderantly demonstrate that her flu vaccination "did cause" any of her medical problems and has thus not established the second prong of *Althen*.

3. *Althen* Prong 3

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

Dr. Axelrod opined as follows with respect to the third *Althen* prong:

> Diane Solak suffered a systemic immune reaction, initially manifested as an immune complex disease with a rash that intermittently recurred at least into March 2015. The time interval between the vaccination and the onset of her systemic immune reaction was 2-3 days, consistent with a secondary adaptive immune response to the inactivated influenza vaccine. This disorder then occurred episodically through March of 2015.

First Axelrod Rep. at 7. As explained earlier in this decision, I do not find that Petitioner experienced a systemic immune reaction, but instead find the medical records and medical opinion evidence support the fact that she had a viral infection. Accordingly, Petitioner has not demonstrated that the onset of her disease occurred in a medically appropriate timeframe. *Shapiro*, 101 Fed. Cl. at 542-43. She has not presented preponderant proof with respect to the third *Althen* prong.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, as well as the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[20]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[20] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.