In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-197V

Filed: August 31, 2020

RYAN LEONG,	*	To Be Published
Petitioner,	*	
v.	*	Ruling on Onset; Subacute Cutaneous Lupus Erythematosus ("SCLE"); Human Papillomavirus ("HPV") Vaccine
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew Downing, Esq., Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner.
Mallori Openchowski, Esq., U.S. Department of Justice, Washington DC, for respondent.

FINDING OF FACTS AND RULING ON ONSET[1]

Roth, Special Master:

On February 10, 2017, Ryan Leong ("Mr. Leong" or "petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. 300aa-10 *et seq*.[2] ("Vaccine Act" or "the Program"). Petitioner alleges that the human papillomavirus ("HPV") vaccination he received on February 14, 2014 caused him to suffer a severe adverse reaction ultimately diagnosed as subacute cutaneous lupus erythematosus ("SCLE"). Petition ("Pet."), ECF

[1] This Ruling has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to 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, the whole Ruling will be available to the public. *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).

No. 1. He further alleges that his condition worsened after the second and third HPV vaccinations on March 23, 2015 and August 11, 2015. Pet. at ¶¶7-9, ECF No. 1.

In support of his petition, petitioner filed an affidavit asserting onset of his rash in the spring/summer of 2014. Petitioner's Exhibit ("Pet. Ex.") 1 at 1-2, ECF No. 7. Petitioner's onset contradicted the medical records which place onset in January of 2015. *See* Pet. Ex. 2 at 139, ECF No. 7. When special masters are confronted with discrepancies between medical records and affidavits, they are encouraged to hold a hearing to evaluate the testimony of the affiants. *See Campbell v. Sec'y of Health & Human Servs.,* 69 Fed. Cl. 775, 779-80 (2006).

An onset hearing was held in Washington, D.C. on March 5, 2019. Petitioner and his mother, Mrs. Leong testified. This fact ruling is intended to clarify the onset of petitioner's symptoms and **must be given to each expert witness. In writing their reports, the experts must rely on the factual findings contained in this Ruling,** which is focused on the events that transpired between petitioner's first HPV vaccination on February 14, 2014 through and including the months following his second and third HPV vaccinations on March 23, 2015 and August 11, 2015, respectively, and thereafter into 2017.

Having carefully considered the medical records, affidavits and testimony, I find that the contemporaneous medical records and histories provided by petitioner and Mrs. Leong to medical providers closer in time to the events more accurately reflect the onset of petitioner's medical condition. Specific factual findings are set forth in detail below. I find that petitioner began to experience the rash associated with his ultimate diagnosis of SCLE in January of 2015, when a swim teammate purportedly pointed out something on petitioner's back, 11 months after the first HPV vaccination.

I. Procedural History

The petition was filed on February 10, 2017 and assigned to me on that date. ECF Nos. 1, 4. On February 16, 2017, petitioner filed his affidavit and medical records. Pet Ex. 1-2, ECF No. 7. Additional records were filed on March 31, 2017, with a Statement of Completion filed on April 6, 2017. Pet. Ex. 3, ECF No. 8; Statement of Completion, ECF No. 9.

Respondent filed his Rule 4(c) Report on July 17, 2017. ECF No. 13. Additional evidence was filed through 2017. Pet. Ex. 4, ECF No. 12; Pet. Ex. 5, ECF No. 16; Pet. Ex. 6, ECF No. 17.

On January 4, 2018, petitioner filed an expert report from Dr. Werth. *See* ECF Nos. 14, 18, 19. Dr. Werth wrote: "Petitioner had onset of a photosensitive skin eruption several months after receiving his first Gardasil vaccine in 2014." Pet. Ex. 7 at 6. Supporting literature was filed on January 11, 2018. Pet. Ex. 9-16, ECF No. 20. On January 23, 2018, petitioner filed an expert report from Dr. Shoenfeld. Pet. Ex. 17-18, ECF No. 21. Dr. Shoenfeld wrote: "Shortly after receiving the first dose of vaccine petitioner developed severe facial rash which spread to additional body areas and significantly exacerbated follow (sic) the second dose of vaccine given with ongoing deterioration after the third dose, despite being treated. Therefore, there appears to be a direct time relationship between vaccination and symptom onset as well as exacerbation." Pet. Ex. 17 at 9. Additional medical literature was filed on February 28, 2018. Pet. Ex. 19-64, ECF Nos. 23-27.

During a March 13, 2018 status conference, respondent's counsel expressed concerns about onset in this matter, stating the medical records supported an onset in January of 2015. Scheduling Order at 1-2, ECF No. 29. Petitioner was ordered to file a supplemental report from Dr. Werth which addressed both onset and causation. *Id*. at 2.

On March 21, 2018, a supplemental report from Dr. Werth was filed but did not address the issue of onset but merely stated, "Given the time frame for onset of SCLE in this patient after vaccination…the timing of the onset of disease flaring fits with a vaccine trigger in this case. We may never know for certain what triggered petitioner's SCLE." Pet. Ex. 65, ECF No. 30.

Petitioner filed additional medical literature in support of Dr. Shoenfeld's expert report on March 28 and 30, 2018. Pet. Ex. 66-74, ECF No. 31; Pet. Ex. 75, ECF No. 32.

On August 7, 2018, respondent filed expert reports from Dr. Rose and Dr. McGeady. Respondent's Exhibit ("Resp. Ex.") A, ECF No. 35; Resp. Ex. C-D, ECF No. 36. Respondent filed supporting medical literature on August 29, 2018. Resp. Ex. C, Tabs 1-5, ECF No. 37. Both Dr. Rose and Dr McGeady, relying on the medical records filed in this matter, concluded a ten to eleven month lapse between the first HPV vaccination and the onset of the rash. Resp. Ex. A at 8; Resp. Ex. C at 5.

At a September 4, 2018 status conference, the issue of onset was again discussed. In his affidavit, petitioner placed onset during the summer of 2014, approximately five to six months after his first HPV vaccination received on February 14, 2014. Respondent pointed to the contemporaneous medical records documenting onset in December of 2014/January of 2015. Scheduling Order at 1-2, ECF No. 38. An onset hearing was discussed.

On November 3, 2018, petitioner filed a status report with counsels' availability for an onset hearing. ECF No. 39. An Order issued for an onset hearing on March 5, 2019. ECF No. 40. Petitioner filed an affidavit from his mother, Ling Leong, on January 31, 2019. Pet. Ex. 76, ECF No. 41. On February 21, 2019, petitioner filed photographs taken in 2013 and 2014 for use at hearing. Pet. Ex. 77-80, ECF No. 42.

Following the onset hearing held on March 5, 2019, an Order issued for the filing of medical literature, photographs, and medical records referenced during the hearing. ECF No. 44. The following day, another Order issued for the metadata associated with the photographs relied upon during the hearing. ECF No. 45.

The ordered evidence was filed on May 3, 2019, May 9, 2019, May 28, 2019 and June 10, 2019. Pet. Ex. 82-86, ECF No. 53; Pet. Ex. 87-91, ECF No. 54; Pet. Ex. 92, ECF No. 56; Pet. Ex. 93-94, ECF No. 57; Pet. Ex. 95, ECF No. 59.

No post-hearing briefs were requested. On July 9, 2019, the record was closed for purposes of issuing a Ruling on Onset. ECF No. 60.

The matter is now ripe for ruling.

II. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing his claims by a preponderance of the evidence. § 13(a)(1). 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 [he or 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 & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). 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 v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs*., 28 Fed. Cl. 516, 523 (1993); *see Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Id*.

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as in cases where records are deemed to be incomplete or inaccurate. *See Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike 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."). 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. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)), compensation denied, *Sanchez*, 2018 WL 5856556 (Fed. Cl. Spec. Mstr. Oct. 9, 2018), *mot. rev. denied*, 124 Fed. Cl. 247

(2019), *vacated and remanded on other grounds*, 809 Fed. Appx. 843 (Fed. Cir. 2020); *see, e.g.*, *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Moreover, despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs.*, No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"). In short, "the record as a whole" must be considered. § 13(a).

III. Summary of Evidence

A. SCLE in General

Subacute cutaneous lupus erythematosus ("SCLE") is a nonscarring, non-atrophy producing photosensitive dermatosis which commonly develops in sun-exposed areas, including the upper back, shoulders, extensor arms, neck, and upper torso, while the face is often spared. Resp. Ex. A, Tab 1 at 2;[3] Pet. Ex. 10 at 1.[4] SCLE is a distinct subset of cutaneous lupus erythematosus and presents clinically with erythematous, annular polycyclic or papulosquamous cutaneous eruptions in sun exposed areas. Pet. Ex. 10 at 1. While SCLE can be idiopathic or drug-induced, the causes are immunologically, histopathologically, and clinically indistinguishable. *Id.*

A Swedish study of SCLE and its association with drugs found that one-third of SCLE cases were attributed to previous drug exposure. Pet. Ex. 13 at 1.[5] Thiazides, terbinafine, calcium channel blockers, angiotensin-converting enzyme inhibitors, tumor necrosis factor-α inhibitors, and chemotherapeutic agents have all been implicated as suspected or probable causes of drug induced SCLE. *Id*. at 7-8; Pet. Ex. 10 at 1. Other drugs associated with SCLE include proton-pump inhibitors, antifungals, amoxicillin, antidepressants, NSAIDS, and antihistamines. Pet. Ex. 13 at 8; Pet. Ex. 10 at 1-2; Pet. Ex. 15 at 1.[6] "The time from drug exposure to onset of SCLE varie[d] widely, ranging from 3 days to 11 years with a median latency of 6 weeks." Pet. Ex. 13 at 2.

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[3] Sudumpai Jarukitsopa et al., *Epidemiology of Systemic Lupus Erythematosus and Cutaneous Lupus Erythematosus in a Predominantly White Population in the United States*, 67 ARTHRITIS CARE RES. 817-28 (2015), filed as "Resp. Ex. A, Tab 1."

[4] Nitish Aggarwal, *Drug-Induced Subacute Cutaneous Lupus Erythematosus Associated with Proton Pump Inhibitors*, 3 DRUGS REAL WORLD OUTCOMES 145-54 (2016), filed as "Pet. Ex. 10."

[5] C.M. Gronhagen et al., *Subacute Cutaneous Lupus Erythematosus and its Association with Drugs: A Population-Based Matched Case Control Study of 234 Patients in Sweden*, 167 BR. J. DERMATOL. 296-305 (2012), filed as "Pet. Ex. 13."

[6] G. Lowe et al., *A Systematic Review of Drug-Induced Subacute Cutaneous Lupus Erythematosus*, 164 BR. J. DERMATOL. 465-76 (2011), filed as "Pet. Ex. 15."

B. Petitioner's Medical Records

1. Petitioner's Pre-Vaccination Medical History

Petitioner was born on January 8, 1999. He had a history of allergic rhinitis, asthma which occasionally required the use of a nebulizer, enlarged tonsils and adenoids with loud snoring, recurrent throat infections with tonsil, and adenoid removal in 2005. Pet. at ¶1; Pet. Ex. 95 at 7, 11, 15, 19, 22.

The records reflect skin infections requiring antibiotics, myositis from medication and non-compliance with prescribed medications due to ineffectiveness or reactions. Pet. Ex. 95 at 25, 33-35, 49, 50.

Comprehensive metabolic panels beginning in February 2007 revealed abnormal liver function with elevated AST[7] and glucose, and low calcium. Pet. Ex. 95 at 53, 57. Urinalysis was abnormal, with blood and glucose in the urine. *Id*. at 54. Repeat blood tests in March of 2007 revealed low alkaline phosphatase and elevated bilirubin, AST, ALT,[8] and CPK. *Id*. at 59.

In August of 2007, abnormal liver function along with failure to show immunity to hepatitis B, despite receiving a series of three hepatitis B vaccinations, was documented. Pet. Ex. 95 at 81-82, 84-85. The hepatitis B series of three vaccinations was started again on September 11, 2007. *Id*. at 62. Petitioner was also noted to be suffering from epistaxis.[9] *Id*. at 62, 69. He received a second hepatitis B vaccination on October 11, 2007.[10] *Id*. at 67. The third hepatitis B vaccination in this series was apparently administered on March 17, 2008, but there is no record of a visit. The vaccine is listed on the vaccine record. *Id*. at 74.

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[7] "AST" stands for "aspartate aminotransferase" and is also known as serum glutamic oxaloacetic transaminase. *See Mosby's Manual of Diagnostic and Laboratory Tests* 107-09 (Pagana eds., 6th ed. 2018) [hereinafter "*Mosby's*"]. AST is an enzyme found in the heart muscle, liver, and skeletal muscle. Injury or disease affecting any of these organs will cause elevated AST levels. *Id*. If the injury or disease is chronic, the levels will be persistently elevated. *Id*. Increased AST levels are an indicator of primary muscle diseases like myopathy and myositis. *Id*.

[8] "ALT" stands for "alanine aminotransferase" and is also known as serum glutamic-pyruvic transaminase. *Mosby's* at 36-37. ALT is an enzyme found predominantly in the liver. *Id*. Injury or disease affecting the liver will cause elevated ALT levels; therefore, this test is used to help identify liver diseases. *Id*.

[9] "Epistaxis" means bleeding from the nose. *Epistaxis*, STEDMAN'S MEDICAL DICTIONARY 299160, accessed via Westlaw.com (last visited August 20, 2020) [hereinafter "STEDMAN'S"].

[10] The records appear to be incomplete. There are references to blood work and visits not contained in the record; the Bates stamps numbers do not line up with the page numbers on the documents; there are no records for 2008; there is one office visit for 2009 but no lab results, though blood work was taken; and no medical records from 2010 through and including 2012.

Petitioner's next documented medical visit was on September 15, 2009 for pharyngitis and ear infection. Pet. Ex. 95 at 70. Blood testing for mononucleosis and repeat liver function tests were performed. *Id*. The results of this testing could not be found in the record.

Petitioner's next medical record was January 24, 2013, when petitioner came under the care of Kaiser Permanente ("Kaiser") and was an email from Mrs. Leong regarding vaccinations necessary for petitioner, then 14 years old, to travel to China in June 2013. Pet. Ex. 2 at 6. There was no record of any vaccinations documented for that trip.[11]

On August 12, 2013, petitioner presented to Kaiser for his first well-teen and sports physical at that facility with Dr. Barboza. Pet. Ex. 2 at 11-12. Petitioner was noted to be healthy. *Id*. at 14.

On August 23, 2013, petitioner presented to Kaiser for hepatitis A, varicella, and meningococcal conjugate vaccinations. Pet. Ex. 2 at 29-31. Blood work and urinalysis on that date were abnormal, with elevated protein in the urine and elevated ALT. *Id*. at 34, 36-37.

2. Petitioner's Post-Vaccination Medical History

a. 2014

Petitioner received his first HPV vaccination on February 14, 2014. Pet. Ex. 4 at 1; Pet. Ex. 2 at 54-57. There was no visit documented for this vaccination.

He next presented to Dr. Barboza on July 28, 2014, with fever, cough, and nasal congestion for five days. Pet. Ex. 2 at 62. A full examination was documented, with "[n]o skin rash noted." *Id*. at 63. Pneumonia was suspected and Zithromax prescribed. *Id*. The plan was chest x-ray if there was no improvement. *Id*.

The following day, July 29, 2014, Mrs. Leong emailed Dr. Barboza and advised petitioner was "really weak and the coughing hurt more than yesterday." Pet. Ex. 2 at 69. Dr. Barboza responded by telephone and spoke with Mr. Leong to advise if petitioner's symptoms were unchanged from the day before, a chest x-ray should be obtained, but if he was worse, he should be taken to the emergency room. *Id*. at 72. There was no record either was done.

On August 8, 2014, Mrs. Leong emailed Dr. Barboza to advise petitioner needed a sports physical for cross-country, but insurance only covered one physical a year and petitioner's last physical was on August 20, 2013. Pet. Ex. 2 at 76. Dr. Barboza attached a copy of the prior year's questionnaire to an email, stated if nothing had changed, a sports clearance letter would be left at the front desk for pick up. *Id*. at 79. Mrs. Leong emailed that petitioner had been sick a few weeks prior, when Dr. Barboza examined him and prescribed antibiotics. *Id*. He was healthy now but still had some coughing. *Id*. The sports clearance letter was provided. *Id*. at 92**.**

b. 2015

[11] These records also appear to be incomplete.

Petitioner's next medical visit was seven months later, on March 23, 2015. Petitioner reported a slightly itchy rash on his trunk for two months, unchanged over the past two weeks. Pet. Ex. 2 at 94. He had not tried any treatments and had no recent topical or systemic exposures in the month prior to onset. *Id*. at 95. A tele-dermatology consult with Dr. Tuerk was conducted. *Id*. at 93-94. Photographs provided to Dr. Tuerk by Dr. Barboza showed "scaly annular papules on chest/back."[12] Dr. Tuerk's assessment was pityriasis rosea ("PR"),[13] which petitioner and his father were advised "usually resolves in 3 mos." *Id*. at 93. Triamcinolone cream for itchiness twice daily for two weeks was prescribed. *Id*. The side effects of topical steroids, including skin atrophy, skin discoloration, and telangiectasia, were discussed. *Id*. at 94. Petitioner was to follow up with a dermatologist in four weeks if there was no improvement. *Id*. HPV and hepatitis A vaccinations were administered. *Id*. at 97.

On June 3, 2015, Mrs. Leong emailed Dr. Barboza that petitioner's skin condition seemed worse; he had more of the rash on his back and arm but no itchiness. Pet. Ex. 2 at 115. Dr. Barboza responded the rash could last one to three months, sometimes a bit longer. "I had mentioned to his dad that as the week (sic) goes by he might have more of the rash particular (sic) on the back." *Id.* at 114. Mrs. Leong responded they did not know when exactly the rash started "but we are sure it has been more then (sic) 5 months"[14] and she was worried. *Id*. at 113. Mrs. Leong further advised she did not pick up or use the prescription for the topical steroid, because the rash did not itch. *Id.* Petitioner was referred to Dr. Do, a dermatologist. *Id*. at 113, 136.

On June 16, 2015, petitioner presented to Dr. Do reporting rash on his torso, arms, and face of six months' duration. Pet. Ex. 2 at 139. Dr. Do described the severity of the rash as "mild." *Id.* Petitioner reported mild itching at times, with a "similar rash last summer but not this extensive." *Id*. He was otherwise healthy. *Id*. at 140. An examination performed from the waist up revealed "scattered papular tan to light pink papules predominantly on face, upper shoulders, outer arms > central areas on chest and back." *Id*. at 141. Skin scraping revealed a yeast infection. *Id*. Petitioner was diagnosed with dermatitis, prescribed fluconazole oral tablets, hydrocortisone cream and instructed to return in six weeks. *Id*. Petitioner's diagnosis of a yeast infection on this date was three months after he received his second HPV and hepatitis A vaccinations on March 23, 2015. Pet. Ex. 2 at 97, 139. The medication to which Mrs. Leong refers was started on June 16, 2015, making the worsening of the rash at some point thereafter.

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[12] The photographs from this appointment were not filed.

[13] Pityriasis rosea is an acute exanthematous eruption with a distinctive morphology and often with a characteristic self-limited course. Initially a single plaque lesion develops, usually on the trunk. One to two weeks later, a generalized secondary eruption develops in a typical distribution pattern. The whole process remits spontaneously within six weeks. Reactivation of human herpesvirus 6 and 7 is the most probable cause. *See Fitzpatrick's Color Atlas and Synopsis of Clinical Dermatology* 65 (8th ed. 2017) [hereinafter "*Fitzpatrick's*"]. The Kaiser record documents PR as a harmless skin rash that usually starts as a scaly, reddish-pink spot on the stomach or back. *See* Pet. Ex. 2 at 106. It usually lasts one to three months and goes away on its own. *Id*. It has no known cause but some doctors believe it to be a reaction to a virus. *Id*.

[14] This would indicate that the rash began in January or December.

On August 4, 2015, petitioner returned to Dr. Do and reported no improvement with the medication. Pet. Ex. 2 at 149. Dr. Do documented "mild" rash starting at the "beginning of 2015" and lasting for seven months. *Id*. Examination revealed "scattered papular tan to light pink papules predominantly on lateral face, upper shoulders, outer arms > central areas on chest and back (almost within seborrheic distribution). No overlying scales." *Id*. at 151. Dr. Do's assessment was dermatitis. *Id*. A punch biopsy was performed on petitioner's right upper arm. *Id*. at 151, 155-61.

The biopsy results revealed "interface dermatitis with increased dermal mucin," suggestive of cutaneous lupus erythematosus. Pet. Ex. 2 at 164. Histologic differential diagnosis included "interface drug eruption, although the periadnexal inflammation and mucin deposition are more suggestive of connective tissue disease." *Id*. Clinical correlation was recommended. *Id*.

Petitioner presented to Dr. Barboza for a sports physical on August 11, 2015. Pet. Ex. 2 at 173. He was noted to be a well teen with dermatitis followed by dermatology. *Id*. at 187. Petitioner received the third HPV vaccination and a Menactra vaccination on that date. *Id*. at 174, 204-05.

On August 12, 2015, Mrs. Leong sent an email about an infection at the biopsy site. Pet. Ex. 2 at 228. Wound check and culture were done on August 13, 2015. *Id*. at 236. There was no mention of a reaction to the HPV or Menactra vaccinations.

On August 18, 2015, petitioner returned to Dr. Do for suture removal at the biopsy site. Pet. Ex. 2 at 246. Wound culture results showed *staphylococcus aureus. Id*. at 243, 261. Ten days of Keflex was prescribed, along with wound care cleaning and topical mupirocin at the biopsy site. *Id*. at 261.

On August 24, 2015, the final pathology reports from the biopsy concluded "increased dermal mucin without significant fibroblast proliferation," or thickened skin due to increased skin collagen. Pet. Ex. 2 at 267. "Such features can be seen in various dermal mucinosis, e.g. focal mucinosis, papular mucinosis (lichen myxedematosus, self-healing juvenile cutaneous mucinosis)." *Id*. at 267, 288.

On August 28, 2015, Dr. Do conferred with Mrs. Leong by telephone to discuss her concerns the biopsy was "too small" and not representative of his remaining lesions. A second biopsy was offered and ordered along with blood work. Pet. Ex. 2 at 287-89, 292. There was no mention by Mrs. Leong of any reaction to the August 11, 2015 HPV or Menactra vaccinations.

Results of blood tests performed on August 29, 2015 revealed elevated ALT and triglycerides but normal TSH[15] and hepatitis C antibody. Pet. Ex. 2 at 300-01, 303-05 (half of one page was blacked out and noted as "redacted." *Id*. at 304). Urine analysis and serum protein electrophoresis revealed "[n]o homogeneous band or spike." *Id*. at 309. The results were reported to petitioner's father along with advice for dietary changes and an offer for referral to a nutritionist, which was declined. *Id*. at 310.

[15] "TSH" stands for thyroid stimulating hormone; it stimulates the growth and function of the thyroid gland and is used to as a diagnostic test to differentiate primary and secondary hypothyroidism. *TSH*, STEDMAN'S at 943430; *thyroid-stimulating hormone, id*. at 415310; *thyrotropin, id*. at 920310.

Ryan emailed Dr. Barboza on September 10, 2015 to discuss his high cholesterol and high ALT results. Pet. Ex. 2 at 318. He did not report any reaction to the HPV or Menactra vaccinations received August 11, 2015.

On September 14, 2015, Dr. Do emailed Mrs. Leong to advise petitioner may have a rare skin condition called self-limited cutaneous dermal mucinosis. "We have ruled out most concerning underlying causes already." According to the literature, the majority of lesions resolve after a few weeks and up to several months. None of the current treatment in the literature seems promising. Pet. Ex. 2 at 326. A topical corticosteroid, Lidex cream, was suggested "to see if they would go away or not." Pet. Ex. 2 at 324, 329.

On October 9, 2015, petitioner returned to Dr. Do following one month of fluconazole and topical hydrocortisone. Pet. Ex. 2 at 358. Dr. Do noted that extensive work-up for malignancy, TSH, DM, and hepatitis infection all returned negative. *Id*. Topical corticosteroids were used on one location; "mom thinks lesions are flatter but just more red." *Id*. The rash began in 2015 and was ongoing for nine to ten months. *Id*. Examination revealed "scattered popular tan to light pink papules predominantly on the lateral face, upper shoulders, outer arms > central areas on chest and back (almost within seborrheic distribution) -- more lesions are flatter and more pink today. [N]o overlaying scales. [P]ink hypertrophic scar on right upper arm, from his recent biopsy site." *Id.* at 360. The leading diagnosis was self-healing dermal mucinosis. *Id*. A three-month trial of Plaquenil was recommended. *Id*. Mrs. Leong opted for referral to a pediatric dermatologist in Oakland for a second opinion. *Id*. A flu vaccine was administered. *Id*. at 365.

On October 16, 2015, petitioner presented to Dr. Beets-Shay for a second opinion. Pet. Ex. 2 at 368. Dr. Beets-Shay documented a 16-year-old who developed pink papules of the face, arms, upper back, and chest around December of 2014. *Id*. The rash was occasionally itchy. *Id*. Biopsy of the right arm revealed dermal mucinosis. *Id*. He was otherwise healthy and ran cross country at school. *Id*. Two weeks of Lidex did not work. *Id*. He developed an infection after a biopsy. *Id.* Examination was documented as follows:

> Multiple pink follicular papules of the upper arms bilat. (sic) [a]ppears blanched directly around the hairs. Multiple 1 cm or less round pink papules of the upper and lower back. Some with scale (sic) on lower back. Smaller pink papules of the upper chest. Legs are clear. Pink patches and thin plaques of the face and behind the ears. Eyebrows are without erythema…No lesions of the scalp. Palms are clear. No oral lesions.

Id. at 369. A punch biopsy was performed. *Id*. The plan was to rule out follicular mucinosis, stop Lidex, and check ANA at the next visit. *Id*. Biopsy results revealed "perivascular and perifollicular inflammatory dermatitis with increased interstitial dermal mucin" with "Rare dyskeratotic cells are seen…suggesting the possibility of subtle interface change. Connective tissue disease (including lupus erythematosus and dermatomyositis) is the favored diagnosis. Eosinophils are focally noted in the inflammatory infiltrate raising the remote possibility of drug-induced lupus." *Id*. at 371.

On October 26, 2015, Mrs. Leong emailed Dr. Do to report an infection at the biopsy site. Pet. Ex. 2 at 394. Wound check revealed cellulitis with moderate growth of *staphylococcus aureus*. *Id*. at 412, 418. Petitioner was prescribed Keflex and topical mupirocin topical. *Id*. at 412, 416. ANA assay screens for 11 specific antinuclear antibodies were negative. *Id*. at 389, 464.

On October 28, 2015, Dr. Beets-Shay emailed Mrs. Leong to advise, based on the biopsy, the diagnosis was most likely tumid lupus, which only involves the skin and not the internal organs. Pet. Ex. 2 at 436. Sunscreen and skin covering when outdoors was recommended. *Id*. Mrs. Leong responded petitioner "seem[ed] to be allergic" to all sunscreen. Vanicream sunscreen was suggested. *Id*. at 434-35.

On October 30, 2015, Mrs. Leong emailed Dr. Beets-Shay questioning whether HPV vaccine could trigger petitioner's condition. Pet. Ex. 2 at 430. She wrote he became tired after his first HPV vaccination in February of 2014 and had acne and a rash on his face for a while before she realized "it was something strange [in] early 2015." At that time, he already had the rash on his back and chest. "It could have started the mid year (sic) of 2014." *Id*. Mrs. Leong wrote a new mattress and the HPV vaccine were the two major things that happened in early 2014. *Id*. Mrs. Leong sent a link to an article regarding HPV-vaccine associated lupus writing "I do suspect Ryan's symptom[s] could be induced by the vaccine." She was concerned about further vaccinations. *Id*. at 427. Dr. Beets-Shay responded that a large study did not find an increased incidence in autoimmune disorders after the HPV vaccine and petitioner had already received three HPV vaccines, so there was no need for another. *Id*. at 425.

On November 6, 2015, petitioner had a "telephone visit" with Dr. Do during which strict sun protection was discussed, sunscreen use encouraged and Cloderm cream and Plaquenil prescribed. Pet. Ex. 2 at 425. Dr. Do confirmed the conversation by email and advised skin lupus is very sensitive to the sun. Tips for sun protection were included. *Id*. at 500-01.

On November 9, 2015, Mrs. Leong emailed Dr. Do with concerns of the side effects of Plaquenil. She advised petitioner had not started taking it. Pet. Ex. 2 at 493. Later that day, Mrs. Leong emailed Dr. Do questioning the relationship between petitioner's lupus and HPV vaccinations. *Id*. at 488. She wrote, "The timeline of Ryan's problem seemed to fit into the timing of the short (sic)." He complained of being tired "in the last two years after the HPV shot," his condition worsened while taking medication for "treating yeast," which she thought was from the pill, but now thinks the second HPV vaccination made it worse.[16] *Id*. Dr. Do responded, "I hope Ryan's rash will improve soon as well." *Id*. at 485. Dr. Do did not respond to Mrs. Leong's concerns related to the HPV vaccine. *Id*.

On November 10, 2015, Mrs. Leong emailed Dr. Barboza for a referral to a pediatric rheumatologist before starting petitioner on Plaquenil. Pet. Ex. 2 at 529.

On November 20, 2015, Dr. Beets-Shay telephoned Mrs. Leong to advise that a consensus following presentation of petitioner's case at Ringrose Grand Rounds, was connective tissue

[16] Petitioner was diagnosed with a yeast infection on June 16, 2015, three months after he received HPV and hepatitis A vaccinations on March 23, 2015. Pet. Ex. 2 at 97, 139. The medication to which Mrs. Leong refers was started on June 16, 2015, making the worsening at some point thereafter.

disease with SCLE, dermatomyositis ("DM") and drug-induced lupus to be considered. Pet. Ex. 2 at 567. All agreed Plaquenil should be used. *Id*. at 569. Dr. Beets-Shay also advised petitioner's ALT was high but his ANA and ser. Ql were negative. *Id*. at 576-78. It was recommended that he follow up with local dermatology, have his ANA tested every year and have blood work performed every 6 months for future systemic involvement. *Id*. at 567.

On November 25, 2015, a new patient consult was conducted by Dr. Mombourquette, a pediatric rheumatologist with Mrs. Leong. Pet. Ex. 2 at 600. Mrs. Leong provided a history of rash that started "1-1 ½ years ago," included the face, chest, back and arms and was erythematous, popular, and itchy at times. *Id*. Petitioner was treated by his primary care physician for dermatitis then referred to Dr. Do in June of 2015. *Id*. A biopsy on August 4, 2015 revealed dermal mucinosis, was treated with topical corticosteroids but did not respond. *Id*. He was then referred to Dr. Beets-Shay in October of 2015, another biopsy revealed perivascular and perifollicular inflammatory dermatitis with increased interstitial dermal mucin, favoring a diagnosis of possible connective tissue disease, such as cutaneous lupus. *Id*. Petitioner started Plaquenil "yesterday" and stopped using Cloderm after the second biopsy. *Id*. She reported that petitioner suffered from intermittent abdominal pain and diarrhea "every month or so for the past few years." *Id*. There was no blood in his stool or constipation. *Id*. Mrs. Leong did not think the rash was photosensitive. *Id*. "HPV vaccination series started in the Spring 2014 – finished in 2015." She was concerned the HPV vaccination caused petitioner's current cutaneous problems.[17] *Id*.

Dr. Mombourquette's assessment was 16-year-old "with new diagnosis of a cutaneous connective tissue disorder diagnosed by recent skin biopsy." Pet. Ex. 2 at 602. The differential diagnosis included cutaneous lupus, dermatomyositis ("DM"), or drug-induced lupus. *Id*. Mrs. Leong reported "no history consistent with a prior drug or infection exposure prior to start of rash, although this was over a year ago." *Id*. Dr. Mombourquette recommended Plaquenil. *Id*. at 603. Additional lab work was ordered to evaluate for other signs of systemic autoimmunity. *Id*. In a follow up email to Dr. Barboza, Dr. Mombourquette advised of her findings with no suspicion of systemic autoimmune disease. She noted though assured of no connection, "mom sounds like she's pretty convinced it was the [HPV] vaccine." Pet. Ex. 2 at 606-07.

Dr. Mombourquette emailed Mrs. Leong that day to advise she would not change the current treatment. Pet. Ex. 2 at 609. She further assured Mrs. Leong while not a vaccine expert, she is a lupus expert and "there is no good scientific evidence to link vaccines to causing autoimmune disease." *Id*. She provided websites for Mrs. Leong to look at and asked that she stay away from websites with ".com" in the address, as they "are generally not linked to good or accurate health information." *Id*.

Petitioner suffered stomach issues associated with Plaquenil. Pet. Ex. 2 at 629-63, 640. Dr. Mombourquette directed Mrs. Leong to wait a week and restart the Plaquenil to make sure the diarrhea was not from something else. *Id*.

By December 14, 2015, Ryan reported to Dr. Mombourquette that he had stopped all medications since nothing was helping; the rash was worse and spreading and he had stiffness in

[17] The record did not mention the Menactra, hepatitis A, or flu vaccines, or any exacerbation or aggravation of petitioner's condition after the second and third HPV vaccinations.

the morning but no joint pain or swelling. Pet. Ex. 2 at 654. Examination revealed "[s]everal coalescing raised circular erythematous plaques with discrete borders in malar distribution, on forehead, chest, neck and upper arms. Lesions on back and some on chest and arms appear to be developing a grayish, almost scaly appearance, with a few lesions on chest with a small central dusky discoloration. Lesions are dry feeling but not rough." *Id*. at 655. The assessment was cutaneous rash that was autoimmune in origin, not concerning for systemic disease with intermittent abdominal pain and diarrhea, possibly associated with Plaquenil. *Id*. at 656. Dr. Mombourquette deferred to dermatology for specific diagnosis and treatment but "[r]ecommended the family attempt restarting Plaquenil." *Id*. The additional tests ordered by Dr. Mombourquette were negative with no evidence of systemic lupus. *Id*. at 669, 676. Routine blood tests ordered by Dr. Barboza revealed high triglycerides; Dr. Barboza advised, if this result was truly a fasting blood test, petitioner needed to meet with the nutritionist. *Id*. at 693.

On December 29, 2015, petitioner's mother requested a referral to a specialist at Stanford; Dr. Barboza agreed. Pet. Ex. 2 at 706-07.

c. 2016

On January 4, 2016, Mrs. Leong emailed Dr. Barboza that petitioner continued to have stomach issues with Plaquenil which went away when he stopped taking it. Pet. Ex. 2 at 707. She also reported the rash was spreading and worsening. *Id*.

On February 15, 2016, petitioner presented to Dr. Teng at Stanford for evaluation of a rash persisting for several years involving his face, scalp, neck, bilateral arms, chest and upper back. Pet. Ex. 3 at 2. The history noted that an initial biopsy revealed dermal mucinosis treated with corticosteroids without improvement. *Id*. A subsequent biopsy was more consistent with connective tissue disorder; Plaquenil was prescribed with no improvement and was stopped. *Id.* A trial with fluconazole for a month showed no improvement. *Id*. Mrs. Leong provided petitioner's records showing cutaneous connective tissue disorder, negative laboratory studies, and differential diagnoses of lupus, dermatomyositis, or drug-induced lupus and records showing which doctors petitioner had been examined by. *Id*. He used to swim five times per week but was no longer exercising. *Id*. He had avoided the sun since November of 2015 but did not wear sunscreen. *Id.* In 2007, he had abnormal CPK and liver function tests. *Id*. Examination was notable for pink papules and plaques with thin white scales on the face, ears, nose, malar cheeks, upper chest, upper back, and upper arms. *Id*. at 3. He had prominent perilingual dilated capillary loops on all ten digits. *Id.* Photographs were taken. *Id*. Dr. Teng's assessment was rash, not otherwise specified; the differential diagnoses included photosensitive dermatitis versus connective tissue disease, limited to cutaneous involvement, as well as undifferentiated connective tissue disease ("UCTD") versus ANA-negative lupus. *Id*. at 4. Other diagnoses, such as EAC[18] and systemic hypersensitive reaction, were also possible, but unlikely. *Id.* A host of topical skin care items were recommended, including triamcinolone cream, Lidex, and benzoyl peroxide, along with a beta carotene supplement for photoprotection. *Id*.

[18] "EAC" stands for erythema annulare centrifugum. It is a chronic, expanding, recurring erythematous eruption consisting of small and large lesions, usually of unknown cause. *Erythema annulare centrifugum*, STEDMAN'S at 302500.

On March 10, 2016, Stanford Pathology and Cytology reviewed slides of petitioner's biopsies performed on August 4, 2015 that showed "an interface dermatitis with associated periadnexal inflammation and notably increased dermal mucin deposition." Pet. Ex. 3 at 10. The review suggested cutaneous lupus erythematosus noting "histologic differential diagnosis would include an interface drug eruption, although the peri-adnexal inflammation and mucin deposition are more suggestive of connective tissue disease." *Id*.

On June 9, 2016, petitioner returned to Dr. Teng and was advised Dr. Teng had presented his case at grand rounds with a diagnosis of photo-sensitive connective tissue disease favored. Pet. Ex. 3 at 17. Plaquenil was restarted, with some improvement in erythema and thickness of papules and plaques. Petitioner reported associated GI issues. He had not applied any topical steroids to his face or body. *Id*. The assessment was rash, not otherwise specified, with differential diagnoses of photosensitive dermatitis versus connective tissue disease (including ANA-negative lupus or UCTD), limited to cutaneous involvement. *Id*. at 19. "There is a small percentage of patient[s] with CLE [who] will develop systemic disease, therefore long term follow up is important." *Id.* The plan was to continue Plaquenil, treat topically with triamcinolone ointment, Lidex, and wet wraps for flares, and start vitamin D supplementation and beta carotene. *Id*. at 19-20.

Petitioner returned to Dr. Teng on August 1, 2016. He had taken the Plaquenil, without GI upset or bleeding and vitamin D supplement since the last visit with no improvement. Pet. Ex. 3 at 31. He had not used the topical steroids as prescribed and did not use sunscreen. *Id*. at 31, 34. Dr. Teng wrote "Patient not concerned about his lesions. Patient wants to stop all medications, since he does not feel they are helping." *Id*. at 31. His parents agreed. *Id*. at 31, 34. A complete skin examination was conducted with photographs. *Id*. at 32-33. KOH scraping and ANA were negative. *Id*. at 33. Subacute cutaneous lupus erythematous remained the favored diagnosis. *Id.* at 34. Daily Vitamin D and beta carotene supplements were to continue. *Id*. Dr. Teng wrote "Rash initially started in June/September 2014…Mom concerned that initial lesions were caused by HPV immunization in Feb 2014. Feb 2015 went to see Kaiser folks for rash and during that visit got another HPV vaccination, mother thinks rash got worse at that time." *Id*. at 31.

At a November 1, 2016 visit, Dr. Teng wrote petitioner was first seen on February 5, 2016 for a rash that "started several months after initial HPV vaccine and exacerbated by subsequent HPV vaccinations." Pet. Ex. 3 at 47. Petitioner denied significant itching but reported "pain like a bee sting" and spread of the rash on his back. *Id*. He stopped all medication since his last visit. *Id.* Examination showed possible expansion of plaques compared to pictures from June 2016. *Id*. at 48-49. There were prominent periungual dilated capillary loops on all 10 digits. *Id*. at 49. Repeat CK and aldolase were negative. *Id*. Petitioner was frustrated with the lack of improvement with all prior therapies. *Id*. at 50. Petitioner admitted difficulty applying topicals because of widespread involvement and needing help from his mother to apply them to his back. *Id*. Dr. Teng wrote "Accordingly, it is difficult to determine if topical therapy was a treatment failure or rather due to non-compliance." *Id*. Dr. Teng recommended a trial of topical therapy to a limited area to determine efficacy. *Id*. Petitioner was to continue Vitamin D and beta carotene supplement. *Id*.

On November 1, 2016, while at Stanford, petitioner presented for a multidisciplinary pediatric rheumatology/dermatology assessment. Pet. Ex. 3 at 61. Petitioner was seen by a pediatric dermatologist, Dr. Khuu, her fellow Dr. Zinn, and a pediatric rheumatologist, Dr. Lee,

and her fellow Dr. Lai. *Id*. Petitioner's father provided the history of rash starting two to three years ago on his face that was thought to be acne. *Id*. It spread over his chest and back. *Id*. "It was temporally associated with HPV vaccination a few months prior. With re-vaccination, the rash worsened in February 2015." *Id*. He took Plaquenil with no improvement but was associated with GI problems. *Id*. He was not taking or using any of the prescribed medicines. *Id*. There was mention of oral prednisone, but no notes showing whether he took it. *Id*. His father bought a Chinese herbal topical medication which they used occasionally. *Id*. Petitioner reported he was no better but no worse since his last doctors visit. *Id*. Petitioner denied using sunscreen or that symptoms were exacerbated by sun exposure. *Id*. at 62. "He used to run cross country but has not done much outdoor activity since his skin issues started." *Id*. The assessment was 17-year-old with rash on his face, chest, and back for two to three years with biopsy findings of interface dermatitis. *Id*. at 66. Evaluation for systemic connective tissue disease was normal. *Id*. He was to continue the topical steroid on a target area for the next three months. *Id*.

That same day, petitioner was seen by Dr. Lee, a rheumatologist at Stanford. Pet. Ex. 2 at 211-12, 220-25. Dr. Lee noted no signs of systemic disease but suggested annual rheumatology visits to monitor for progression. *Id*. at 225. Dr. Lee agreed with the use of Plaquenil. *Id*.

d. 2017

Petitioner returned to Stanford on February 9, 2017. He reported trying the topical medication on a selected area for two months without improvement, so he stopped using it. Pet. Ex. 3 at 73. He reported the rash as unchanged, but his father reported it to be worse on his back. *Id*. He denied exacerbation with sun exposure. *Id*. He felt well, with no other complaints. *Id*. The diagnosis was presumptive SCLE without systemic involvement. Due to reported progression, a trial of systemic immune suppressive therapy was discussed, with biopsy prior to starting therapy. *Id*. at 76. The biopsy on that date reflected mild histologic features, including increased dermal mucin deposition with subtle pigment incontinence and sparse superficial perivascular infiltrate of lymphocytes. The results "could be compatible with partially treated cutaneous lupus, or mild tumid lupus" but the "characteristic features of lichen planus or mycosis fungoides" were not identified. *Id*. at 82. Plaquenil was to be restarted, with a trial of prednisone taper. *Id*. Ranitidine was prescribed to mitigate gastrointestinal effects. *Id*. A steroid sparing agent would be considered at a follow up in a month. *Id*.

On June 8, 2017, petitioner returned to Stanford. He had not taken the Plaquenil as prescribed. Pet. Ex. 5 at 19. He did take a 30-day prednisone taper but did not follow up after finishing it. *Id*. He reported no improvement and thought the rash had spread since the last appointment. *Id*. Examination revealed the face, ears, nose, malar cheeks, upper chest, upper back, upper arms had confluent light pink to white minimally scaly plaques with faint circumferential halos. *Id*. at 20-21. There was evidence of Koebnerization.[19] *Id*. at 21. Petitioner was leaving for college in Tulsa, Oklahoma, "therefore now is not an optimal time to start a systemic immune suppressing medication which requires close follow up, particularly given his history of medication/follow up non-compliance." *Id*. at 22. Blood tests again showed elevated ALT and

[19] Koebnerization, or Koebner's phenomenon, is the appearance of skin lesions in areas of trauma. THOMAS P. HABIF ET AL., SKIN DISEASE: DIAGNOSIS AND TREATMENT 306 (4th ed. 2017).

AST, abnormal complement C4 serum, and negative ANA. *Id*. at 35-36. The results were noted as an abnormal metabolic panel. *Id*. at 45. A urinalysis was also abnormal. *Id*. at 47.

No further medical records were filed.

C. The Petition, Affidavits, and Testimony of the Witnesses

In his petition, petitioner alleges he suffered a "severe adverse reaction" within "[a] couple of months after the receiving the Gardasil shot" on February 14, 2014, with facial skin problems attributed to acne. Pet. at 1. "Later in 2014, after his mother noticed that his complexion was not improving, she advised him to begin using an over-the-counter- skin treatment." Pet. ¶3. "In early 2015, [petitioner] began to notice that he also was breaking out on other parts of his body." Pet. ¶4. A swim teammate pointed out "growths on his back." *Id*. "In mid-March 2015, [petitioner's] mother asked him if he was continuing to use the skin treatment medication that she had given him because his complexion was still quite bad. [Petitioner] advised his mother that he had what he described as a rash on his chest and back." Pet. ¶5. Petitioner's "condition got worse after the [HPV] second shot" on March 23, 2015 and he returned to the doctor on June 16, 2015. Pet. ¶7. Petitioner's "rash began to change colors and the bumps became more raised and noticeable…on August 11, 2015…[he] received his third and final Gardasil vaccination." Pet. ¶8. "[Petitioner's] skin condition again changed for the worst after the third vaccination." Pet. ¶9. In mid-October 2015, he was diagnosed with tumid lupus. *Id*.

Petitioner and Mrs. Leong testified and were sequestered during each other's testimony.

1. Affidavit and Testimony of Ling Leong

Mrs. Leong is petitioner's mother. Pet. Ex. 76 at 1. She testified that prior to February of 2014, petitioner was a normal kid, going to school, getting good grades, swimming, and playing piano. Tr. 10. She referenced a photograph taken after petitioner's piano recital in November of 2013, stating he "had perfect skin, smooth, and dark in color" from playing sports. Tr. 12; Pet. Ex. 77. He had no autoimmune diseases, skin conditions, or acne. Tr. 10-11. He then got the first HPV vaccination in February of 2014. Tr. 12.

Mrs. Leong's affidavit stated, "Exactly when petitioner's symptoms started to show is difficult to say. He did not give much attention to his skin changes at first, and he did not tell me about them right away" but she noticed "things growing on his face by late spring or early summer 2014." Pet. Ex. 76 at 1; Tr. 28. She referenced a trip to Yosemite in June of 2014 stating petitioner started "to have that kind of little bumps on his forehead." Tr. 13, 51-52, 54. She pointed to a photograph in July of 2014 as showing bumps on his forehead then stated the bumps had been there for two to three months at that time. Tr. 14-15; Pet. Ex. 76 at 2; Pet. Ex. 79. She explained her reference in an email that "it could have started midyear of 2014" as meaning June. Tr. 35-36; Pet. Ex. 2 at 422. Mrs. Leong was unable to recall any specifics about family vacations in June or July of 2014. Tr. 53.

Thinking it was acne, Mrs. Leong "gave him my Proactive (sic) Solution face wash and lotion,"[20] but was unhappy to learn he had not used it when she looked closely at his face later in February of 2015. Pet. Ex. 76 at 1. She testified to his skin problems worsening between July 2014 and December of 2014; he had more bumps on his face and it was "more recognizable." By February of 2015, his face was worse, like a mask, and he had spots on his chest and back. Tr. 17-18, 67-68.

Mrs. Leong did not know when petitioner first noticed "bumps" on his chest; a swim team friend told him he had something on his back in "late 2014 or January of 2015." Pet. Ex. 76 at 1. She stated in February of 2015 her "heart sunk at the close look" when she realized that it did not look like acne. *Id*. He told her the rash was on his chest; when she looked under his shirt it was on his back as well. *Id*.; Tr. 17-18, 67-68. "I have never seen any skin problem like that before on anyone in my whole life, and I was really concerned. So I contacted his doctor for [an] appointment." *Id*. at 2.

Mrs. Leong explained the timeframe between the family trip in July of 2014, and the next time she looked "closely" at petitioner's face in February of 2015 as a time in which the family spent little time together. She worked all day, helped her husband with their new store at night and on the weekends. Her mother-in-law stayed with petitioner and his sister and gave them dinner before she and her husband came home. Tr. 31, 50, 51. There were no family gatherings, they did not celebrate any occasions and no pictures were taken after July of 2014. "We didn't even celebrate our birthday…we didn't take pictures…Christmas is [the] only day we are off. We might have celebrated, but I don't…I don't have any pictures." Tr. 31-32. Neither she or her husband went to any of petitioner's track or swim meets during the 2014-15 season. Tr. 47-49, 67. She did not know if there were any school, track or swim team pictures, adding they "are not photo people." Tr. 32-33. She denied taking any pictures in 2014 and 2015, because she was too busy. She stated that she provided whatever pictures she had from that timeframe to counsel prior to the hearing. Tr. 44-45. She stated there were no rules at the pool about swimming with skin rashes and the coach never mentioned anything. Tr, 72-73.

Mrs. Leong did not attend the March 23, 2015 visit with Dr. Barboza, her husband did, but it was her understanding that petitioner had pityriasis rosea, which was "supposed to get better in a couple of months," was harmless, and would heal without medication. Pet. Ex. 76 at 2. Petitioner was prescribed a cream for itchiness; she put it on his back, but the rash got worse over time. She admitted he did not use the cream religiously, but stated the rash was not itchy. Tr. 21, 70-71; Pet. Ex. 76 at 2. In an email to Dr. Barboza in June 2015, she advised she never picked up the prescription for the topical cream and wanted a referral to a skin specialist, writing that the rash had been there for more than five months and was getting worse. *See* Pet. Ex. 2 at 113; Pet. Ex. 76 at 2; Tr. 34. Mrs. Leong disagreed with Dr. Barboza's history of "Patient with slightly itchy rash on trunk for 2 months," stating it had been there more than two months. Tr. 19-21; Pet. Ex. 2 at 94.

Mrs. Leong affirmed on June 16, 2015, petitioner saw Dr. Do, who scraped some skin, looked at it under a microscope, said it was a yeast infection and prescribed medication. The medication made the rash worse. Pet. Ex. 76 at 2. She explained in detail how the medication for

[20] There is no indication in the record of when this specifically occurred.

the yeast infection turned the rash "pinkish/red," the bumps became more noticeable, and "[t]he rash on his face started to connect together…he also developed more bumps on his chest and back. Most of the rash on his arms was developed during this time." *Id*. That was when she asked for a biopsy which was done on August 4 showing dermal mucinosis. The medication prescribed for that did not work. *Id*.

At hearing, Mrs. Leong blamed the second and third HPV vaccines received on March 23, 2015 and August 11, 2015 for petitioner's rash getting worse, stating after the second vaccination petitioner's skin was "significantly getting worse and worse" the rash became more extensive, Tr. 22-23, 78; after the third vaccination his "skin condition continued to get worse gradually and I requested a second opinion." Pet. Ex. 76 at 2. She referenced a photograph taken in November of 2015, stating after the third HPV vaccine, the rash turned red and became bigger. Tr. 22-23; Pet. Ex. 6 at 2-3. She was asked if she took and/or provided photographs to any of the medical providers to show the rash was worse following the vaccinations. At first, she stated the doctors were taking pictures and she was taking pictures as well, but then stated she did not take any pictures or send the doctors any pictures that the rash was getting worse. Tr. 23-25.

Mrs. Leong affirmed petitioner was diagnosed with tumid lupus after a biopsy from a different location was done by Dr. Beets-Shay in October of 2015. Pet Ex. 76 at 2. At that time, she researched HPV vaccine and used photographs to create a timeline tracing onset back to petitioner's first HPV vaccine in February of 2014, when the acne started and worsened after the second and third shots. Tr. 76-78; Pet. Ex. 76 at 3. "[H]e was getting worse…each time he went to see [the] doctor." Tr. 76. That was when she sent the email in October of 2015, to see if the doctor could tell her about the connection between the HPV vaccines and his rash. Tr. 76-78.

Mrs. Leong testified she felt the doctors were "clueless." Tr. 78-79; Pet. Ex. 2 at 421. Between March of 2015 and February of 2016, the doctors at Kaiser could not figure out the right diagnosis and she asked for a transfer to Stanford. Tr. 79-80; Pet. Ex. 76 at 3.

Mrs. Leong provided petitioner's history during a phone consultation with Dr. Mombourquette on November 25, 2015 which included rash for a year to a year and half and "HPV vaccination series starting spring of 2014 – finished in 2015" which caused his skin problems. Tr. 36-38; Pet. Ex. 2 at 600. Mrs. Leong explained culturally, "February is our spring festival, spring festival starts in the spring." Tr. 38.

Mrs. Leong affirmed Dr. Teng at Stanford was in agreement with all petitioner's treating doctors and "prescribed the same lupus treatment medication for [petitioner]" but the brand name. Pet. Ex. 76 at 3. Petitioner had fewer side effects from the brand named medication but his rash did not improve. *Id*. Petitioner discontinued all medication because none worked. Pet. Ex. 76 at 3. "He has stayed out of the sun since [October of 2014], and he dropped out of cross county running and the swim team." *Id*. at 3-4. "I don't think staying out of sunlight helped, but [the] doctors were adamant that sunlight was harmful to him." *Id*. at 4.

Mrs. Leong acknowledged using the email system at Kaiser to communicate with doctors and secured copies of petitioner's medical records for the lawsuit and for Stanford from the Kaiser website. Tr. 41-42. She denied reading the medical records to assist in writing her affidavit, but

admitted to using the records to check dates, like the date that the shot was given. Tr. 42-43. She stated that she used pictures on her phone to write her affidavit. Tr. 44. She denied taking any photos on her camera in 2014 and 2015, she was too busy. Tr. 44. She stated that she provided whatever pictures she had to counsel prior to the hearing. Tr. 45.

Mrs. Leong did not question the accuracy of the medical record. Tr. 82-83.

2. Affidavit and Testimony of Ryan Leong

Petitioner affirmed, prior to receipt of his first HPV vaccine on February 14, 2014, he was active in sports, competed in cross-county and winter swim team at school, and regularly participated in snow sports, camping, and hiking with his family. Pet. Ex. 1 at 1. He referenced a photograph from November of 2013 after his piano recital, to show he had no skin issues and clear skin. Tr. 87; Pet. Ex. 77.

Petitioner did not recall the February 14, 2014 appointment. Tr. 88. He affirmed, "[o]ver the next few months" he "began to notice some skin problems," but assumed it was a "severe flare up of acne." Pet. Ex. 1 at 1. At hearing he tried to explain this statement. "Severe, I don't know, in my terms now, requires some sort of pain. I don't know if I'd necessarily say severe now. I probably – I think a better word for it would be like a strong almost, a strong flare-up. It wasn't ever painful, but I think strong would represent the fact that it had become visible if you had really looked into it." Tr. 143-44. Despite referring to it as a "flare up of acne", he denied any acne prior to June/July of 2014. Tr. 143; Pet. Ex. 1 at 1. At another time he admitted he had pimples in the past, but not "many of them at the same time." Tr. 90-92.

Petitioner testified during the summer of 2014 he had small bumps appear on his forehead and later spread. Asked when during the summer he first noted the bumps, he stated "summer" was late May to early June, because school ends in California for summer break in May. Tr. 88-89, 91.

Petitioner referred to pictures from a family vacation in July of 2014, stating little bumps could be seen on his forehead between his eyebrows and hairline, consistent with his cutaneous lupus. Tr. 92, 140; Pet. Ex. 79-80. He then testified that a photograph from his grandmother's birthday on May 20, 2014[21] showed the bumps had been there for three months. Tr. 92-93. He did not think much of it because he was at an age where acne was common, so he did not mention it to his mother. Tr. 80, 93, 144. At hearing petitioner stated shortly after July of 2014 his mother gave him her Proactive to use for acne. He had previously affirmed this occurred "later" in 2014. *See* Tr. 93-94; Pet. Ex. 1 at 1. The Proactive did not help; he did not use it. Tr. 94.

Questioned again later about whether the July 2014 photographs showed his "rash," petitioner responded, "It's really hard to tell with the shirt on. Because it is most of this area and the upper arm. It pretty much stops as soon as you like get past the T-shirt line. So I can't really tell based on what's under the shirt. And the photo is a little bit hazy. I can't tell if there is

[21] This photograph, dated May 29, 2014, was filed after the hearing, on May 6, 2019. *See* Pet. Ex. 88 at 2, ECF No. 54.

something on my face or if it's just lighting. I'm not sure." Tr. 139; Pet. Ex. 79. He then stated he did not recall when these photographs were taken, because they go to a lot of places that look the same. Tr. 137-38.

Petitioner stated after July of 2014, the bumps on his face "got bigger and they started spreading to my chest and my back. And my arms." Tr. 99. He could not recall when he first noted the rash on his chest, "It's kind of blurry, because, you know, I have been with it for quite a while. And I – it's just something that I am used to see (sic) on my body. The start, I don't remember exactly when it came to be." Tr. 99. He never mentioned anything to his parents, because the rash did not bother him. Tr. 103; Pet. Ex. 1 at 1.

According to petitioner after July 2014 and until school started, he spent his time indoors, and playing online video games with friends. He did not go out or use the family pool. There were no gatherings with friends and/or family, and no photographs taken because his family was opening a new business and his parents spent all their time working on the business. He specifically stated he would not have been in the pool at the same time as his mother, if he did use the pool. Tr. 131-35.

In the fall of 2014, he ran cross country, but wore a tank top which would have covered where the rash was on his back and chest. Tr. 145. He did not change in a locker room; he was expected to come to practice ready. Tr. 100-01. If he needed to change, he did so in a bathroom. Tr. 100-01. No one from the team commented on his skin, he never ran without a shirt on and he was the slowest on the team, so he would not run with anyone next to him. Tr. 145, 148.

Petitioner affirmed in early 2015, not only was his face not getting better, but he also noticed bumps on his chest. Pet. Ex. 1 at 1. At hearing he testified he first noted bumps on his chest "in May or June of 2014, [w]hen I began to develop the bumps on my face." Tr. 102; Pet. Ex. 1 at 3. Faced with these inconsistencies of his statements, he stated his testimony was more accurate than his 2017 affidavit because he could "elaborate more." He then conceded "I don't believe that it [the rash] had begun spreading that far by June. I am pretty sure it was isolated to my face at that time." Tr. 108-09. "According to me. I think I really became self aware when a swim team member had told me that, you know, there was something on my back," that was January of 2015, and "[f]or some reason I do recall that I was not entirely surprised by it." Tr. 105. Asked again when he first observed the rash on his chest, he stated, "I'm not exactly sure when I started noticing, but I'm positive that they did point it out—or that someone on my swim team did point it out in January of 2015." Tr. 109-10, 129-30; Pet. Ex. 1 at 1. When asked what his teammate told him he stated, "It's hard to recall exact words, but he did mention that I had something on my back…He was definitely referencing that my back, you know, had bumps on it…just on my back." Tr. 105-06.

Petitioner acknowledged that swim practice started after Christmas of 2014 and was in a heated outdoor pool. Tr. 98, 101. He did not wear a shirt while swimming and no one pointed out anything to him on his chest or back until a teammate did in January of 2015. Tr. 101-04. He denied seeing anything on his chest during swim season but added "I probably didn't look at myself" or "it was not of a concern to me because it had not bothered me before." Tr. 101-02. "I think I didn't notice for a while, because I am not the type of person to go look at myself in the mirror, and to like really look at my body in order to figure out what might be wrong." Tr. 104-05.

Petitioner did not recall team pictures being taken for cross country or swim team. He later stated school and team pictures were taken, but his family did not buy any, but regardless, the pictures were too small to see whether he had a rash. Tr. 95-98. According to petitioner, he and friends did not take pictures, his phone camera was not good quality, and he did not like his appearance. Tr. 95-96. At the time of the hearing, petitioner produced only five photographs stating there were no other pictures taken between August and December of 2014. *See* Pet. Ex. 6, 77, 78, 79, 86.

Petitioner affirmed it was mid-March of 2015, when his mother took a "closer look at his face" and realized the rash was not acne. That is when he told her about the rash on his back and chest. Pet. Ex. 1 at 1-2. They then looked under his shirt. Tr. 111. He was not concerned about it, but his mother was. He was "living with it and I didn't really care if it was there or not." Tr. 150.

Petitioner and his father went to Dr. Barboza on March 23, 2015, "specifically to deal with this rash." Pet. Ex. 1 at 2. They were advised it was pityriasis rosea and he was prescribed a steroid ointment. *Id*. He received the second HPV vaccination on that date. *Id*. According to petitioner, he provided the history of rash for two months to Dr. Barboza. At first, he stated, "two months" was when "it had started to spread, so it would have been on my chest and back and arms. As well as my face." Tr. 112. He then stated, "If the spreading begun there, I'm not too sure, but it was present by this time." Tr. 112. He then said January of 2015 was when the rash became itchy. Tr. 112-14. "I believe I'm talking about the fact that I had it on my chest and back and arms and it had become –it became itchy within those two months." Tr. 115. He later stated he did not recall Dr. Barboza asking him when the rash started but admitted "I-I think knowing me back then, I think I wouldn't really figure out when it started bothering me." Tr. 115, 151.

When asked to compare the "rash" in July of 2014 to the rash of March 2015, he initially responded "I don't recall them looking exactly the same." Tr. 114. However, when redirected by counsel, he stated "I believe that what started on my face is what started on my chest, yes." Tr. 114-15.

Petitioner affirmed, "Almost immediately after the second Gardasil shot, my face, chest, arms and back progressively got worse." Pet. Ex. 1 at 2. At hearing he stated, after the second HPV vaccine "… it got – it ended up getting worse. I remember like this pinkish – they became—the rash became a pinkish color, and over time there was more of them that came in." It did not involve any new parts of his body. The spots got bigger and eventually began to connect to each other. Tr. 116-17. It got worse "pretty quickly." Petitioner was unable to quantify what "pretty quickly" meant, "I am not sure on –yeah." Tr. 117.

Petitioner affirmed in June 2015, his mother contacted Dr. Barboza to inform him that the rash was worse and was told it was the natural progression of the condition and would get better but to make arrangements with a Kaiser dermatologist. Pet. Ex. 1 at 2. Petitioner saw Dr. Do on June 16, 2015, who conferred with a with a colleague, did a skin scraping, said he had a yeast infection and prescribed medication. *Id*. The medication turned the rash "pinkish red," the bumps on his skin became raised, and the rash on his face, chest, and back increased. *Id*. His mother requested a biopsy. *Id*.

Petitioner agreed he provided the history of rash for six months to Dr. Do but was referring to the fact "that it was—it has been itchy from that standpoint of January where it began to start—it began to bother me." Before that, it had not hindered "my physical abilities", but "itchiness kind of takes you away from the task. So it was – it was visible, but it would be nothing different from like a skin tag is, and did not bother me." Tr. 120-21. However, later when questioned about his feelings regarding the worsening of the rash, he stated, "It was always, even still now, it has always been my mindset that yes, it is a visual thing, but if it doesn't hinder my ability to do something or do like anything, why does it matter, because I can still do everything I want to." Tr. 151.

Petitioner affirmed his receipt of the third HPV vaccination on August 11, 2015. Pet. Ex. 1 at 2. He was informed on August 24, 2015, of the biopsy results showing dermal mucinosis. Pet. Ex. 1 at 2. Dr. Do prescribed an ointment, but his skin did not get better. *Id*. In mid- October 2015, Dr. Beets-Shay did another biopsy and he was diagnosed with tumid lupus. *Id*. The medications prescribed gave him headaches, nausea and diarrhea. *Id*. There is no mention of the rash getting worse after the August 11, 2015 HPV vaccination in petitioner's affidavit or testimony.

Petitioner was presented with a photograph from November of 2015 which showed extensive rash on his chest, back and arms. Tr. 118; Pet. Ex. 6. When asked how long the rash looked as it did in that photograph, he responded "It had been definitely – it had been for a while. In order to get to this size, it takes quite a long time. I'm thinking like maybe – it definitely goes back to – I would say it has to go back to that very first summer in 2014." Tr. 118. Corrected by counsel, petitioner asked, "When you mean 'looked like this' in this exact photo or it had started to, you know, begin on my chest?" Tr. 118. After being told to focus on the photo, petitioner stated, "Probably a month before it started to change, because it was – at that point, it was starting to grow." Tr. 119; Pet. Ex. 6 at 1-3. Asked when the rash started on his arms as shown in the photograph, petitioner was unsure but believed the rash on his arms started later, after he had the rash on his chest and back. Tr. 119; Pet. Ex. 6 at 4. Petitioner recalled "the rash had come down all the way and crossed my forehead. So I had almost like a butterfly looking rash." Tr. 122. He conceded after November of 2015, the rash got much worse "like one entire big rash." It was still growing. I believe it looked different." Tr. 122, 152-53. Petitioner stated now "You can see the remnants of it, but it has begun to start healing itself." Tr. 122.

Having confirmed that the rash changed during the month prior to the November 2015 photograph, I asked petitioner to describe the difference in the appearance of his skin in April and November of 2015; he did not understand my question. Tr. 153. He then stated, "From the very beginning it has changed." Tr. 154. He finally admitted "Okay, there was no—that's—in April is different from what's in this picture. My bad." Tr. 154. He then described the difference between April and November of 2015, "There are less of the bumps, and each of these were smaller…Probably not significantly, but if you compared two pictures, you would be able to tell. Except you don't have that picture," referring to a photograph from April 2015. Tr. 154. He added, "I think it was December or January of 20—or December of 2014 and January 2015 is when I really started to notice it, because someone told me about it that it had already been really apparent that it was there." Tr. 155. I asked petitioner to describe the progression between January 2015 through November 2015:

Q: …Was it pretty consistent, was it slowly getting worse, was it different parts of your body at some point? At what point did it evolve to [what is seen in the November 2015 photographs]?

A: I believe it was the second HPV shot that, you know, really –

Q: And when was that?

A: That was March.

Q: Okay. And then it looked like this (referring to the November 2015 photograph)?

A: Not immediately. It had to progress to it.

Q: Okay, but you said it looked like this a month before this picture was taken. What I'm trying to get to is now you've pinpointed March. Between March and November when it looked like that [in the photograph], what was going on? What was the evolution?

A: It was there's (sic) just every day or like you can tell almost every month there would a be a new addition to the rash, and each of the individual ones would be expanding, and month by month you could see all – it's hard for me to see because I – I don't really look that often, but –

Q: So how do you think it was significantly different after the second vaccine?

A: To my parents, they could tell that they looked at me that one month and then I didn't see them for a couple of months, and then they come back and like, wow, it got a lot worse.

Q (By respondent's counsel): Okay, so when they didn't see it for a couple of months, how many months would it be before they saw it?

A: At this time period, they probably checked a lot more often.

Q: Okay. So –

A: Maybe a couple of months wasn't the right terminology.

Tr. 156-57. "I think there was a point that it did accelerate – like the growth was faster during that time period, like after March. And so there was a progression up until 2017 that, you know, it just kept growing and growing and growing." Tr. 158-59.

Petitioner confirmed that, from January of 2015 into the spring of 2015, he was on the swim team, without a shirt on. Other than on teammate's comment in January of 2015 about something on his back, no one commented thereafter about seeing anything on his body. Tr. 159.

Petitioner saw Dr. Teng at Stanford who agreed that he had subacute cutaneous lupus erythematosus. Pet. Ex. 1 at 3. "I was told that, since my condition was possibly a result of photosensitivity, I needed to remain vigilant about my sun exposure." *Id*.

D. Documents Produced after the Hearing

Following the hearing, the photographs produced prior to and referred to during the hearing were refiled with the associated metadata: Pet. Ex. 82 with metadata for Pet. Ex. 6, photographs from November 10, 2015 of petitioner's forehead, chest, back and arms taken on an iPhone 5; Pet. Ex. 83 with the metadata for Pet. Ex. 77, a photograph of petitioner at his piano recital, dated November 9, 2013 and taken with a Nikon camera; Pet. Ex. 84, with metadata for Pet. Ex. 78, a photograph of petitioner with his mother dated June 15, 2014 and taken with a Nikon camera; Pet. Ex. 85, with the metadata for Pet. Ex. 79, a photograph of petitioner dated July 19, 2014 taken with an iPhone 5; and Pet. Ex. 86, with metadata, a photograph of petitioner dated April 20, 2014 taken with a Nikon camera. Petitioner appears to have clear skin in the photos taken in November of 2013 and April and June of 2014. He appears to have small bumps on his forehead in the photo taken in July of 2014. The photos from November of 2015 were taken at a doctor's visit and show an extensive rash on petitioner's face, chest, back, and arms.

Also filed were 39 photographs from 2013 through 2017, including photographs dated March 31, 2013; April 7, 2013; July 3, 2013; and September 14, 2013. *See* Pet. Ex. 87 at 1-4. The March 31, 2013 photograph is of petitioner taken at a school with an iPhone 5s. *Id*. at 1. The April 7, 2013 photograph of petitioner was taken with a Nikon camera. *Id*. at 2. The July 3, 2013 photograph is of petitioner taken with a Nikon camera, and the September 14, 2013 photograph is of petitioner in his track uniform, taken with an iPhone. *Id*. at 3-4. In the photographs taken in March and April of 2013 a year prior to his HPV vaccination, petitioner appears to have pimples on his forehead. In the photographs taken in July and September of 2013, petitioner appears to have clear skin. Petitioner exhibit 88 included 12 photographs dated April 20, 2014, taken with a Nikon camera; a photograph dated May 29, 2014, taken with an iPhone; four photographs dated June 15, 2014, taken with a Nikon camera; a photograph dated July 15, 2015, taken with a Nikon camera; two photographs dated July 17, 2014, one taken with a Canon camera and one with a Nikon camera; and three photographs dated July 20, 2014, two taken with a Canon camera, and one taken with a Nikon camera. Petitioner appears to have clear skin in all 12 photographs.

Petitioner filed Pet. Ex. 89, which included seven photographs. A photograph dated January 8, 2015, was petitioner's 16th birthday, his face appears clear. Pet. Ex. 89 at 1. A photograph dated May 8, 2015 taken with an iPhone 5 shows petitioner holding an award. *Id.* at 2. The picture shows a rash on his forehead that does not resemble acne but is flatter and more plaque-like. *Id*. A photograph taken May 11, 2015 on an iPhone 5 is of petitioner's father's birthday and shows clusters of plaque-like areas. *Id*. at 3. A photograph dated July 18, 2015 taken with an iPhone 5 shows a cluster of plaque-like areas on petitioner's forehead and cheek. *Id*. at 4. Two photos dated August 4, 2015 taken with an iPhone 5 show plaque-like papules on petitioner's shoulder and stitches to a biopsy site. *Id*. at 5-6. The final photo, taken on August 18, 2015, shows an infection at the biopsy site. *Id*. at 7.

Petitioner filed Pet. Ex. 90, containing 13 photographs. In some of the photos, it is difficult to tell whether petitioner has a rash on his face; the rest of his body cannot be seen. *See* Pet. Ex.

90 at 1, 3, 10, 13. A photograph dated February 11, 2106 taken with an iPhone 6s Plus shows the plaque like rash on the side of petitioner's face. *Id*. at 2. The remaining photos are close-ups of petitioner's rash. Four photos dated February 22, 2016, show extensive pink plaque-like papules. *Id*. at 4-7. In a photograph dated March 4, 2016, the rash looks flatter and lighter. *Id*. at 8. A photograph dated March 9, 2016, shows what appears to be petitioner's shoulder, with raised pink plaque-like papules. *Id*. at 9. In two photos dated June 9, 2016, the rash appears much lighter and drier. *Id*. at 11-12.

Petitioner filed Pet. Ex. 91, containing three photographs: a photo dated January 9, 2017 taken with an iPhone 6s Plus of petitioner's birthday, and two photographs dated December 28, 2017 taken with an iPhone 6s show extensive rash on petitioner's back.

Petitioner filed Pet. Ex. 95 containing his medical records prior to 2013. As more specifically set forth in the medical history, infra, petitioner had a history of elevated CPK and abnormal liver function tests and protein in his urine. This record as previously noted is incomplete.

IV. Findings of Fact

In order to overcome the presumption that contemporaneous written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling." *Blutstein*, 1998 WL 408611, at *5. Petitioner's affidavit and his hearing testimony are inconsistent with the contemporaneous medical records. The facts contained in his affidavit are inconsistent with his testimony at hearing. Confounding those inconsistencies was the testimony and affidavit of petitioner's mother, Mrs. Leong.

Usually, a lapse of time is associated with a decline in memory; however, for petitioner and Mrs. Leong, time seemed to have improved their abilities of recall but only as to details beneficial to the case.

The only issue to be determined here is the onset of petitioner's rash. Based on the medical records, affidavits, testimony and photographs, the onset of petitioner's rash was in January of 2015. I find the following facts established by a preponderance of the evidence.

1. Petitioner experienced minor flares of acne prior to and after February of 2014. Tr. 89-92, 142-43. He received an HPV vaccination on February 14, 2014. Pet. Ex. 4 at 1; Pet. Ex. 1 at 1.

2. In July of 2014, petitioner suffered a respiratory illness, suspected pneumonia, and a high fever for which he was prescribed Zithromax. Pet. Ex. 2 at 62. An examination conducted by Dr. Barboza specifically documented "no rash." *Id*. at 63.

3. Between July of 2014 through March 23, 2015, petitioner did not see a doctor or complain to anyone of any health/skin issues or concerns. *See* Pet. Ex. 2; Tr. 103, 144.

4. In the fall, winter, and spring of 2014 to 2015, petitioner participated in cross country for his high school followed by swim team, which started after Christmas of 2014. Tr. 98-101. Both sports were conducted outside. Tr. 73. During swim season, petitioner's body, specifically his chest, back, and arms, were exposed. Tr. 104. During swim season, he did not recall seeing anything on his chest. Tr. 101-02.

5. In January of 2015, a teammate advised petitioner of a bump on his back. Tr. 108-09. There was no affidavit or testimony provided from this person. Petitioner never mentioned it to his parents because it did not bother him, nor did he care. Tr. 102, 103, 121, 144, 150-51; Pet. Ex. 1 at 1. The contemporaneous medical records consistently document onset as January of 2015 until October of 2015 when Mrs. Leong suspected the HPV vaccines. Pet. Ex. 2 at 94, 139, 149, 358, 368, 430.

6. In March of 2015, Mrs. Leong noted a rash on petitioner's face that did not resemble acne. Pet. Ex. 1 at 1-2. Petitioner then told her a friend pointed out something on his back in January of 2015. Pet. Ex. 1 at 1-2; Tr. 111. Mrs. Leong looked under petitioner's shirt and immediately made an appointment with Dr. Barboza. Pet. Ex. 76 at 1; Tr. 17-18, 67-68.

7. Petitioner presented to Dr. Barboza on March 23, 2015 and reported a rash for two months. Pet. Ex. 2 at 94. Petitioner was diagnosed with PR, which he was advised would resolve within three months. *Id*. at 93-94. Petitioner received HPV and hepatitis A vaccinations on that date. *Id*. at 97. He was prescribed a topical medication for itching; the prescription was not picked up because it was not itchy. Pet. Ex. 2 at 97; 113. A notation in the medical record advised petitioner to follow up with a dermatologist in four weeks if there was no improvement. *Id*. at 94.

8. Neither petitioner nor Mrs. Leong contacted any medical provider until June 3, 2015, when Mrs. Leong emailed Dr. Barboza to advise petitioner's rash seemed worse with more on his back and arm, but not much itchiness. Pet. Ex. 2 at 115. Dr. Barboza responded she had advised petitioner and his father the rash would progress and there was no treatment. *Id.* at 114. Mrs. Leong responded they were unsure when the rash started but were sure it was more than five months and she was worried. *Id*. at 113. They were referred to a skin specialist. *Id*.

9. On June 6, 2015, petitioner presented to Dr. Do and reported rash for six months. Pet. Ex. 2 at 139. Examination revealed scattered tan to light pink papules predominantly on the face, shoulders, outer arms, chest, and back. *Id*. at 141. A skin scraping revealed "yeast infection." *Id*. Oral fluconazole and topical hydrocortisone were prescribed. *Id*.

10. Both petitioner and Mrs. Leong described petitioner's rash as worse after June 16, 2015, attributing the worsening to the medication for the yeast infection. Both described the rash after the use of the medication as turning pinkish red, the bumps became raised, and the rash on his face, chest, and back increased. Pet. Ex 76 at 2; Tr. 22-23,78; Pet. Ex. 1 at 2; Pet. Ex. 2 at 141, 358, 485.

11. On August 4, 2015, Dr. Do documented rash beginning at the beginning of 2015 and lasting for seven months. Pet. Ex. 2 at 149. The rash was still described in the record as mild with scattered tan to light pink papules predominantly on his face, upper shoulders, outer arms, chest, and back. *Id*. at 151. A biopsy was done on petitioner's upper arm. *Id*.

12. On August 11, 2015, petitioner was administered a third HPV and Menactra vaccinations. Pet. Ex. 2 at 173-74; 176; 187; 204-05.

13. The following day, Mrs. Leong sent an email about an infection at the biopsy site. Pet. Ex. 2 at 228. A visit on August 13, 2015 confirmed cellulitis. *Id*. at 236. Keflex and Mupirocin topical medication were prescribed. *Id*. at 239.

14. On August 28, 2015, Mrs. Leong and Dr. Do discussed petitioner's condition and the need for another biopsy. Pet. Ex. 2 at 287. There was no complaint that the rash had worsen after the August 11, 2015 vaccinations.

15. On September 14, 2015, Dr. Do and Mrs. Leong had an email exchange to discuss a trial of Lidex cream on one area to see if it helped. Pet. Ex. 2 at 324. There was no mention of the rash being any worse.

16. On September 16, 2015, Mrs. Leong emailed Dr. Barboza about petitioner's test result from his physical. She raised no concern about the rash being worse. Pet. Ex. 2 at 342.

17. At his October 9, 2015, visit with Dr. Do, petitioner reported the topical medication did not work. Pet. Ex. 2 at 358. Mrs. Leong reported the rash looked flatter, but more red. *Id.* Examination revealed "lesions were flatter and more pink on that date with no overlying scales." *Id*. at 360. Plaquenil was recommended. *Id*. Mrs. Leong opted for a second opinion. *Id*. A flu vaccine was administered. *Id*. at 365.

18. An examination by Dr. Beet-Shay on October 16, 2015, documented pink papules of the face, arms, upper back, and chest that started about December of 2014. Pet. Ex. 2 at 368. The rash was described as multiple pink follicular papules on both upper arms, multiple one cm or less round pink papules on the upper and lower back, some scales on the lower back, small pink papules on the upper chest, and pink patches and some plaques on the face and behind the ears. *Id*. at 369.

19. On November 6, 2015, Dr. Do documented petitioner's diagnosis as tumid lupus/cutaneous lupus erythematosus that started at the beginning of 2015, with a duration of nine to ten months. Pet. Ex. 2 at 479.

20. Photographs produced from November of 2015 showed extensive rash on petitioner's back, chest, arms, face and ears. Pet. Ex. 6 at 1-3. Petitioner explained over the month prior to the November of 2015 photograph, the rash increased and became more widespread. Tr. 118-19, 152-53; Pet. Ex. 6 at 1-3. The rash came down across his forehead and looked like a butterfly rash on his face. Tr. 122.

21. On November 20, 2015, Dr. Beets-Shay noted that the rash had spread. Pet. Ex. 2 at 576-78.

22. On November 25, 2015, Mrs. Leong provided a history of rash for 1 to 1 ½ years on petitioner's face, chest, back and arms during a telephone conference with Dr. Mombourquette. Pet. Ex. 2 at 600. She reported HPV vaccinations starting in the spring of 2014 and finishing in 2015, and her belief the HPV vaccination was the cause. *Id*.

23. On December 14, 2015, the family reported petitioner had stopped all medications. Pet. Ex. 2 at 654. The rash was spreading and becoming worse. *Id*. Examination revealed more extensive lesions grayish in color and almost scaly. *Id*. at 655.

24. Petitioner presented to Dr. Teng at Stanford on February 15, 2016, who noted photosensitive connective tissue disease. Pet. Ex. 3 at 2, 17. The rash was documented as pink papules and plaques on his face, ears, nose, upper chest, upper back and now peri-inguinal dilated papules on all 10 digits. *Id*. at 3. Dr. Teng agreed the diagnosis was SCLE. *Id*. at 34. There were no signs of systemic autoimmune disease. Pet. Ex. 2 at 607. Dr. Teng noted that petitioner did not use the topical steroid as prescribed and did not use sunscreen. Pet. Ex. 3 at 31, 34. It was questionable whether topical medication failed or did not work due to non-compliance. *Id*. at 50.

25. Both petitioner and Mrs. Leong reported that the rash progressed after March of 2015 onward, "it just kept growing and growing and growing," and "continued to progress up until 2017". It "continued to get worse gradually." Tr. 116, 152-54, 156-57, 158-59; Pet. Ex. 76 at 2; Pet. Ex. 2 at 707; Pet. Ex. 3 at 47, 49, 73; Pet. Ex. 5 at 19; Pet, Ex 6 1-3.

26. Between February 14, 2014 and October 9, 2015, petitioner received an HPV vaccination on February 14, 2014, HPV and hepatitis A vaccinations on March 23, 2015, HPV and Menactra vaccinations on August 11, 2015 and flu vaccine on October 9, 2015. Pet. Ex. 4 at 1; Pet. Ex. 2 at 97, 174, 204-05, 365.

In reaching the above conclusions, I assigned greater weight to the contemporaneous medical records than to the affidavits and testimony elicited at hearing. My decision to assign less weight to the affidavits and hearing testimony was based primarily on the lack of corroboration by the medical records and the inconsistencies of the testimony of the petitioner and Mrs. Leong with themselves and each other. The contemporaneous medical records and histories provided by petitioner and Mrs. Leong when seeking medical treatment are far more reliable than the evidence prepared in anticipation of and/or presented after litigation commenced. This is particularly because the reported onset changed when Mrs. Leong started researching HPV vaccination and lupus and became convinced that the HPV vaccination was the cause of petitioner's condition. From there, the family created a timeline with little, if any corroborating evidence to support it. I find that petitioner's statements made contemporaneously to his medical providers when seeking medical treatment retain an appreciably higher indicia of reliability than the inconsistent statements contained in the affidavits and the hearing testimony. Additionally, the medical records from multiple providers document onset in or around January of 2015. Petitioner's skin condition slowly progressed and evolved, with what appeared to be a more pervasive spread of the rash on

his back, chest, arms, face then his ears and all ten digits between November of 2015 through February of 2016. The spread between November of 2015 through February of 2016 is illustrated in photographs and the examinations detailed in the medical records for that time period, with no HPV vaccination or other vaccination temporarily associated with it.

Other factors that weighed heavily in my decision are as follows: The Petition filed in this matter contains facts presumably provided by the petitioner and Mrs. Leong when they retained counsel one month prior to the statute of limitations in 2018. The Petition alleges onset of rash on petitioner's body in early 2015. Pet. at ¶4. The rest of what is contained in the petition was contradicted by petitioner and his mother during the hearing when they attempted to place onset in spring/summer, May, June or July of 2014.

Petitioner and Mrs. Leong came to the hearing having produced a handful of photographs to their counsel, one taken in November of 2013 and several in June and July of 2014. They represented these were the only photographs that existed each testifying to all the reasons the family was not together for an eight-month period between July of 2014 and late March of 2015 and why no photographs were taken during that time. They coordinated a series of events to place onset in the spring and/or summer of 2014 based on these photographs produced prior to hearing. However, being sequestered during testimony, the witnesses story unraveled. I am convinced that if counsel had been given accurate facts and truthful information all of which was ultimately produced after hearing, this case would have taken a different course. The following are some of the credibility issues considered in this ruling but not all.

1. Petitioner affirmed in early 2015 not only was his face not getting better, but he also noticed bumps on his chest. Pet. Ex. 1 at 1, 2. However, he testified that after July of 2014, the bumps on his face "got bigger and they started spreading to my chest and my back. And my arms." Tr. 99. He then stated the bumps were on his chest in May or June of 2014 "when I began to develop the bumps on my face." Tr. 102. He then said "I don't believe that it had begun spreading that far by June. I am pretty sure it was isolated to my face at that time." Tr. 108-09. He denied the "rash" on his face during the summer of 2014 was the same as the "rash" on his chest and back, then corrected that stating what started on my face was the same as what started on my body. Tr. 114-15. Petitioner suggested the July 2014 photographs did not show the rash on his body because it was under his shirt. Tr. 139-40; Pet. Ex. 79. He then denied seeing anything on his chest during the 2014/2015 swim season, but probably because he did to look at himself or it didn't concern him. Tr. 101-02. Later when asked about when the rash appeared on his body, he was not "exactly sure when I started noticing, but I'm positive that they did point it out—or that someone on my swim team did point it out in January of 2015." Tr. 109-10, 129-30; Pet. Ex. 1 at 1. He finally admitted, "I think it was December or January of 20—or December of 2014 and January 2015 is when I really started to notice it, because someone told me about it that it had already been really apparent that it was there." Tr. 155.

2. Petitioner stated he provided a two month history of rash to Dr. Barboza on March 23, 2015 but meant it had been two months since "it had started to spread, so it would have been on my chest and back and arms. As well as my face." Tr. 112. Petitioner stated he provided the six month history of rash to Dr. Do in June of 2015 but meant it was six months since

the rash became itchy in January and "it began to bother me." Tr. 120. He stated prior to January of 2015, "it was visible, but it would be nothing different from like a skin tag is, and did not bother me". Tr. 112-14, 115, 120-21. However, he later stated that he did not know if or when the rash bothered him, that "it has always been my mind set that yes, it is a visual thing, but if it doesn't hinder my ability to do something or do like anything, why does it matter, because I can still do everything I want to." Tr. 151.

3. Mrs. Leong had no idea when petitioner's rash began or when his vaccines were received. She reported a variety of vaccination dates and onset dates. *See* Pet. Ex. 2 at 421-22; Pet. Ex. 3 at 31, 47. At hearing, she stated onset was the spring, summer, May, June, and July. Pet. Ex. 76 at 1-2; Tr. 13-15, 17-19, 28-29, 35-36, 52-54, 67-68. She admitted not knowing when petitioner first noticed "bumps" on his chest; but a swim team friend told him he had something on his back in "late 2014 or January of 2015." Pet. Ex. 76 at 1.

4. Mrs. Leong affirmed that she did not learn of the bumps on his chest or back until February of 2015 at dinner. Pet. Ex. 76 at 1-2; Tr. 17-18. She testified to being too busy to take a close look at petitioner's face from July of 2014 until February of 2015 when she noticed petitioner's face was worse, like a mask. Tr. 17-18, 30-32. However, at another time during the hearing, she stated his skin problems were noticeably worse and the bumps on his face became "more recognizable" between July and December of 2014. Tr. 67-68.

5. Mrs. Leong avidly emailed medical providers through the Kaiser electronic system. Had Mrs. Leong seen anything on petitioner that could be described as scaly annular pink papules and plaques rather than acne on his forehead and face before March of 2015 as she suggested, she likely would have immediately contacted Kaiser and/or Dr. Barboza. From the time Kaiser undertook petitioner's care in 2013, Mrs. Leong routinely emailed petitioner's providers for everything from wart treatments to google searches. Pet. Ex. 2 at 6, 39, 41-43, 45, 69, 76-79, 93, 113-15, 141, 170, 318, 342, 394, 412, 418, 421, 468, 472, 485, 637, 707.

6. Petitioner relied on photographs from November of 2015 to show the extent and gravity of the progression of his rash. *See* Pet. Ex. 6. When initially asked how long the rash had looked like that, petitioner stated since the summer of 2014. Tr. 118. He then stated the rash became that severe in March 2015, after the second HPV vaccine. He then stated "Not immediately. It had to progress to it." Tr. 156. He finally admitted "probably a month before [the photo] it started to change, because it was – at that point, it was starting to grow." Tr. 118-19, 152-53; Pet. Ex. 6 at 1-3. He also stated he was unsure when the rash started on his arms but believed it started later, after the chest and back. Tr. 119; Pet. Ex. 6 at 4.

7. Glaringly missing in this case are any facts, testimony, or corroborating evidence about the "rash" between July of 2014 and March of 2015, other than petitioner's swim teammate mentioning a bump on his back in January of 2015. The explanation by both petitioner and Mrs. Leong that the family was not together between July of 2014 and March of 2015, so no one noticed the "rash" until March of 2015 was simply incredible. Tr. 22, 30-33, 47-49, 51, 67, 72-73, 95-98, 100-01, 103, 105, 127-30, 133-37, 145; Pet. Ex. 1 at 1; Pet. Ex. 6, 77,

> 78, 79, 86. If I was to accept this testimony as true then I would have to accept that Mrs. Leong and all those involved in petitioner's life, including petitioner himself, provided no care to a 15 year old for an eight month period. I would also have to believe that petitioner's body and face were covered in plaques and no one at school or at practice, cared to mention anything about it.

While little inconsistencies can be overlooked, are expected, and can be attributed to faulty memory, continuous unsupported and contradictory statements cannot. Petitioner and Mrs. Leong were not persuasive in their testimony. The medical records and what they reported to medical personnel was far more persuasive and consistent. Petitioner may have had acne in the spring and summer of 2014, but the onset of a significantly different appearing rash began with "something" on his back in January of 2015, as pointed out by a teammate. From that point, petitioner's rash gradually progressed, with a dramatic change in November of 2015, when it became more pervasive, until it began to "self-heal" in 2017.

If one culls through the contemporaneous medical records, and winnows fact from fiction, what is left is the following summary: Petitioner has a history of abnormal blood work, urine testing and received all his vaccinations without event. On February 14, 2014, petitioner received an HPV vaccination without event. He was a teenager in high school who experienced mild acne at times. He had an upper respiratory infection in July of 2014, with a high fever, cough, and weakness, was diagnosed with suspected pneumonia and prescribed Zithromax. The cough continued for some time thereafter. He was otherwise "healthy," and participated in cross country and swim team during the 2014-15 school year. From December of 2014 through March 23, 2015, petitioner was routinely at swim practice and meets without a shirt on. At some point in January of 2015, one of petitioner's swim teammates mentioned "something" on petitioner's back. Petitioner did not mention his teammates' comment to anyone because it did not bother him. In or around March 2015, Mrs. Leong noted a rash on petitioner's face that did not resemble acne. Petitioner told her he had something on his back and took his shirt off. Seeing the rash, Mrs. Leong immediately contacted the doctor. At petitioner's appointment for the rash on March 23, 2015, petitioner reported rash for two months. He received HPV and hepatitis A vaccinations. Assured the rash was benign and would go away, and noting that it did not itch, a prescription provided for itching was not filled. Petitioner was advised to contact the doctor if the rash worsened. There was no follow up until June 3, 2015, when Mrs. Leong emailed Dr. Barboza and said that the rash did not go away, looked like it spread, and had been there for five months. Petitioner was examined by Dr. Do on June 16, 2015, determined to have a yeast infection on his skin and was prescribed medication which both petitioner and Mrs. Leong recounted made the rash look worse, raised and spreading. Petitioner returned to Dr. Do in August, reporting no change. The third HPV vaccine and a Menactra vaccine were given on August 11, 2015. Little was reported thereafter until petitioner was diagnosed in October of 2015 with SCLE. Photographs taken in November of 2015 showed a dramatic change in the quality and the amount of the rash which petitioner testified had occurred over the month prior to the photograph. The rash progressed and worsened into February of 2016, spreading to his hands, lower back, face, ears and all ten digits. The rash has since dissipated, leaving behind some scarring.

After careful consideration and based on the record as a whole the rash petitioner alleges resulted from the HPV vaccination(s) began in January of 2015 when petitioner's friend purportedly advised him of something on his back in January of 2015.

V. Conclusion

I find that the onset of petitioner's rash to be January of 2015, 11 months after the receipt of his first HPV vaccination. Petitioner is **ordered** to provide a copy of this fact ruling to his expert witnesses. Petitioner's experts **must rely on the facts as I have found them in this Ruling.** If petitioner's chosen expert witness disagrees with any of my factual findings, he or she must state why with specificity and provide citations to petitioner's medical records that support his or her interpretation. **Under no circumstances should the expert witness rely upon the facts as described in any of the affidavits filed in this case.**

The following is therefore ORDERED:

By no later than October 30, 2020, petitioner must file a status report updating the court on his progress in filing expert report(s) based on the facts as I have found them and provide the date upon which he expects to file his expert report(s). If petitioner is unable secure reports from his expert(s), he must file either a motion to dismiss or a motion for a ruling on the record, both of which will result in the dismissal of his claim.

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master