In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-997V

(Not to be published)

ANNA PEREKOTIY, *on behalf of her minor child*, S.K.,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: April 20, 2020
v.	*	Ruling on Entitlement; Atopic Dermatitis; Allergic Reaction; Inactivated Polio Vaccine; Hepatitis B Vaccine; Diphtheria, Tetanus, acellular Pertussis; Significant Aggravation; *Loving* test.
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew D. Downing, Van Cott & Talamante, Phoenix, AZ, for Petitioner.

Julia Collison, U.S. Dep't of Justice, Washington, D.C., for Respondent.

DECISION ON ENTITLEMENT[1]

On August 12, 2016, Anna Perekotiy filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")[2] on behalf of her minor child, S.K., alleging that S.K. experienced a severe adverse reaction (including some developmental sequelae) to several vaccines that she received on September 18, 2013. Petition,

[1] Although this Decision has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Ruling will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. 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 Decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

filed Aug. 12, 2016 (ECF No. 1). She later amended her petition to allege solely that S.K. developed a dermatological reaction—first after receiving the Hepatitis B vaccine on August 21, 2013, and then again after the Diphtheria, Tetanus, acellular Pertussis ("DTaP") and inactivated polio ("IPV") vaccines administered on September 18, 2013. Amended Petition, filed March 6, 2017 (ECF No. 14) ("First Amended Pet.").

Having completed my review of the evidentiary record and the parties' filings, I hereby deny Petitioner's request for compensation. As discussed in more detail below, Petitioner has not preponderantly established that the Hepatitis B vaccine caused the initial onset of S.K.'s atopic dermatitis, or that the DTaP and IPV vaccines[3] S.K. received a month later significantly aggravated her then-existing dermatologic condition.[4]

I. Factual Background

A. *S.K.'s Early History*

S.K. was born on July 16, 2013, via spontaneous vaginal delivery. Ex. 14 at 9, 77. She received the first dose of the Hepatitis B vaccine the same day with no reported adverse reaction. Ex. 7 at 29, 31. On July 22, 2013, Petitioner brought S.K. to Dr. Jennifer Cropp, M.D., for her newborn visit. *Id.* at 3. No abnormalities were noted during the visit. *Id.* Petitioner brought S.K. back to Dr. Cropp at the end of July 2013 for a weight check. Ex. 7 at 7. During the visit, Petitioner reported that S.K. was exhibiting drainage from her right eye throughout the day and redness under her left armpit. *Id.* at 8–9. Dr. Cropp attributed the redness under S.K.'s armpit to moisture, and she instructed Petitioner to keep the area clean and as dry as possible. *Id.* at 10. S.K.'s eye drainage was diagnosed as Dacryostenosis[5], for which Dr. Cropp recommended warm compresses with eye massages daily. *Id.* at 10.

B. *Vaccinations at Issue and Development of Dermatologic Symptoms*

S.K. received her second dose of the Hepatitis B vaccine on August 21, 2013, during her one-month well-baby visit with Dr. Matthew Barcellona, M.D., of North Scottsdale Pediatric Associates. Ex. 7 at 11–14. No abnormalities or dermatologic concerns were noted, and no adverse reactions to the vaccine are documented in the immediate contemporaneous medical record. *Id.*

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[3] At the September 18, 2013 pediatric visit, S.K. also received the Haemophilus Influenza Type B ("Hib") and Pneumococcal vaccines. Ex. 7 at 23–24. Petitioner, however, does not allege that either of these vaccines caused or significantly aggravated S.K.'s atopic dermatitis. First Amended Pet. at 1.

[4] Atopic dermatitis is a common form of skin inflammation, often associated with allergic conditions, which leads to itching and signs of eczema. *Dorland's Illustrated Medical Dictionary* 466 (33d ed. 2020) (hereinafter *Dorland's*).

[5] Dacryostenosis is the narrowing of a tear duct. *Dorland's* at 464, 983.

The following month, on September 16, 2013, S.K. returned to North Scottsdale Pediatric Associates and was seen by Colin Petranu, M.D., for redness and rash that Petitioner reported had developed three weeks prior (or approximately six days after receiving the second Hepatitis B vaccination) with no subsequent improvement. Ex. 7 at 15. Following a physical examination, Dr. Petranu noted that S.K. exhibited flaky skin on her head, and was positive for "erythematous, raw, macerated neck folds without drainage or crusting." *Id.* at 16. She was diagnosed with intertrigo[6] and seborrhea[7], for which she was prescribed a moisturizing cream, nystatin powder, continued use of baby oil, and Ketaconazole cream. *Id.* at 17. Dr. Petranu indicated that if S.K.'s condition did not improve, he would next consider using a steroid cream. *Id.*

Two days later, on September 18, 2013, Petitioner returned to North Scottsdale Pediatric Associates for S.K.'s two-month well-baby visit with Dr. Barcellona. Ex. 7 at 19. During a physical examination of S.K.'s skin, Dr. Barcellona noted "rough patches on body, scalp flakiness, red macules in neck folds." *Id.* at 21. Again, S.K. was diagnosed with intertrigo, but her seborrhea diagnosis was changed to atopic eczema dermatitis.[8] *Id.* at 22. S.K. was prescribed hydrocortisone and moisturizer. *Id.* At the conclusion of the visit, S.K. received four vaccines: DTaP, Hib, IPV, and pneumococcal. *Id.* at 23–24. Petitioner refused the rotavirus vaccine and signed a waiver to that effect. *Id.* at 22. No adverse reactions to these vaccines were documented during the visit.

At S.K.'s four-month well-baby visit with Dr. Barcellona on November 20, 2013, Petitioner reported that S.K. had experienced a "[a] bad reaction to shots causing leg redness. [L]eg is still red and rough, but parents feel it is much better." Ex. 7 at 25. At the time, Petitioner also indicated that she was not using the prescribed steroids to treat S.K.'s dermatologic condition "because it is a steroid and steroids are 'bad.'" *Id.* S.K.'s physical exam revealed rough patches of red and scaly skin on her torso, scalp and legs. *Id.* at 27. Dr. Barcellona indicated that S.K.'s legs "have terribly controlled eczema," and it was unclear to him whether the "shot reaction was local and eczema was bigger issue, or if shot caused more reaction," but Petitioner nonetheless refused further vaccination. *Id.*

On December 9, 2013, S.K. was seen by Reena Jain, PA-C, for evaluation of a persistent rash following her vaccination on September 18, 2013. Ex. 10 at 1. A physical examination revealed dry erythematous patches on S.K.'s scalp, face, abdomen, and both lower extremities *Id.*

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[6] Intertrigo is a superficial dermatitis caused by moisture, friction, warmth, and sweat retention that is characterized by erythema, maceration, burning, itching, and sometimes erosions, fissures, exudations, and secondary infections. *Dorland's* at 939.

[7] Seborrhea is characterized by a dry, scaly dermatitis in areas of the body with sebum-producing glands, including the scalp, chest, back, axilla, and groin. *Dorland's* at 1657.

[8] An atopic eczema dermatitis is an allergic pruritic dermatitis that is characterized by erythema, edema, inflammatory infiltrates in the dermis, crusting, and scaling. *Dorland's* at 171, 586.

at 2. She was diagnosed with eczema and was prescribed Desonide lotion mixed with moisturizing cream. *Id.* at 2. Petitioner was also advised to give infant Benadryl as directed on the box to help with itching. *Id.*

Just over one month later, on January 15, 2014, Petitioner brought S.K. to Dr. Arturo Gonzales, M.D. at Scottsdale Children's Group for her six-month well-baby visit. Ex. 3 at 29–34. During the visit, Petitioner relayed a past medical history for S.K. that included a rash on both legs that had "lasted for quite some time" following administration of routine immunizations. *Id.* at 29. Petitioner also informed Dr. Gonzales of S.K.'s atopic dermatitis diagnosis, and explained that she was not applying the prescribed hydrocortisone cream because "it is a steroid." *Id.* Dr. Gonzales also noted that Petitioner was hesitant to give further immunizations until the cause of S.K.'s rash was established. *Id.* During his physical examination of S.K., Dr. Gonzales noted an eczematous rash on both legs. *Id.* at 33. At the conclusion of the visit, Dr. Gonzales requested a formal evaluation with an allergist and pediatric dermatologist to reassure Petitioner of the diagnosis and encouraged Petitioner to continue having S.K. vaccinated. *Id.* at 34. He also noted that "atopic dermatitis is not a contraindication for vaccinations." *Id.* Petitioner was to continue regularly bathing, moisturizing, and using steroid creams to treat S.K.'s symptoms. *Id.*

C. *Subsequent Allergy Testing and Treatment*

S.K. had her first appointment with Ronald Jorgensen, M.D., of the Arizona Asthma & Allergy Institute on January 22, 2014. Ex. 4 at 4. Regarding S.K.'s medical history, Dr. Jorgensen noted that "[a]fter vaccination, she had redness down the right leg that lasted for a few days…She had received several vaccinations on the same day including DTaP, IPV, Hib, pneumococcal, and rotavirus vaccines."[9] *Id.* at 13. Upon physical examination, Dr. Jorgensen noted a large dry patch of skin on S.K.'s right leg and some dry skin on her arms and legs. *Id.* at 14. Based on these findings, he instructed Petitioner to apply moisturizing products and corticosteroid cream, use laundry detergent for sensitive skin, and to give S.K. Zyrtec syrup. *Id.* at 4. He also recommended special testing to vaccines prior to their administration. *Id.* He suggested starting with the DTaP vaccine using a skin prick and intradermal test, and if those were tolerated, he suggested following up with one-tenth the dose, followed by the remainder of the dose. *Id.* at 14. Dr. Jorgensen also speculated that S.K. was likely allergic to eggs, so he told Petitioner to avoid introducing S.K. to egg products and egg-based vaccines for the time being. *Id.* He prescribed an epi-pen Jr. as a precaution *Id.* at 5.

On January 29, 2014, S.K. returned to Dr. Jorgensen and was evaluated for a possible DTaP vaccine allergy. Ex. 4 at 23. Her history of present illness notes that "[h]er eczema is currently

[9] The vaccination record in this case clearly establishes that S.K. did *not* receive the rotavirus vaccine. Ex. 14 at 22. On September 18, 2013, Dr. Barcellona specifically notes that Petitioner refused the rotavirus vaccination and signed a waiver to that effect. *Id.*

flared" and her symptoms were not controlled with the medication she had previously been prescribed. *Id.* A physical exam revealed skin lesions and eczema patches on both legs, and dermatitis on her torso, arms, and face. *Id.* at 24. Dr. Jorgensen then conducted a skin prick test[10] with the DTaP vaccine, which raised a wheal 3mm by 4mm in size with 15mm by 10mm erythema flare. *Id.* at 20, 25. The result was interpreted by Dr. Jorgensen as a positive allergic reaction. *Id.* at 25. Petitioner was therefore advised to avoid Diphtheria Tetanus-containing vaccines in the future. *Id.*

On February 19, 2014, S.K. returned to Dr. Jorgensen to be evaluated for possible allergy to IPV. Ex. 4 at 27. A physical exam performed by Dr. Jorgensen was positive for skin lesions and dermatitis on both her lower extremities and face. *Id.* at 28. Unlike the DTaP test, the skin prick test with IPV showed no reaction. *Id.* at 29. When S.K. was injected with one-tenth of the dose of IPV, however, she experienced a reaction with a wheal size of 3mm by 3mm in size and an erythema flare 15mm x 9mm in size. *Id.* The challenge to polio was discontinued. *Id.* Based upon S.K.'s reaction to both the DTaP and IPV vaccines, Dr. Jorgensen concluded that she was likely allergic to both, and he advised against S.K. receiving childhood vaccinations for at least another six months, at which point he recommended individually testing each vaccine for an allergic reaction. *Id.*

On April 24, 2014, S.K. returned to Dr. Gonzales for her nine-month well-child visit. Ex. 3 at 20. The medical record from this visit reported that S.K.'s past medical conditions included atopic dermatitis and severe allergy to eggs, oats, and vaccines. *Id.* Both the review of systems and physical examination findings, however, were negative for pruritus, rash, and skin lesions. *Id.* at 21–24. Identical findings were documented during S.K.'s twelve-month well-child visit on July 29, 2014. *Id.* at 15–17. S.K. continued to be seen by a number of physicians throughout 2014 and 2015, and while some documented her history of rash post-vaccination during their review of systems or when documenting S.K.'s past medical history, no physician documented the presence of a rash or lesions during physical examination after February 19, 2014. *See* Ex. 6 at 2, 8. The subsequent medical records filed in this matter do not discuss the presence of a rash, but rather focus on S.K.'s orthopedic and cognitive impairments. *See* Ex. 8 (discussing neurological evaluations for developmental delays); Ex. 9 (discussing a consultation for S.K.'s gait abnormality).

[10] During a skin prick test, a drop of the suspected allergen is placed on the patient's skin. A needle is then used to puncture the skin through the droplet of allergen and the fluid is allowed to flow under the skin via the puncture site. After one minute, the excess fluid is wiped away and the skin is observed for fifteen minutes to see if a reaction develops. Introduction to the allergen may result in a raised bump, called a wheal, and a red inflamed area, called a flare. A reaction is positive if the wheal is three millimeters in diameter or larger and the flare diameter is ten millimeters or greater. *Mosby's Manual of Diagnostic and Laboratory Tests* 1024–27 (6th ed. 2018).

II. Expert Reports

A. *Dr. David Axelrod*

David Axelrod, M.D., provided one[11] expert report on behalf of Petitioner. Report, filed as Ex. 37 on July 11, 2017 (ECF No. 20-1) ("Axelrod Rep."). In it, Dr. Axelrod opined that S.K.'s exposure to the Hepatitis B vaccine on August 21, 2013, initiated a T_H2 immune response[12] that caused S.K.'s atopic dermatitis. *Id.* at 5. He also proposes that the vaccinations S.K. received on September 18, 2013, further encouraged the T_H2 immune response, thereby exacerbating S.K.'s atopic dermatitis. *Id.*

Dr. Axelrod is a clinical immunologist and is currently employed by a consulting firm in York, Pennsylvania. Dr. Axelrod Curriculum Vitae, filed as Ex. 16 on May 8, 2017 (ECF No. 16-2) ("Axelrod CV") at 2. He received his bachelor's degree from the University of Michigan where he also attended medical school and received both a medical and Masters degree. *Id.* at 1. Dr. Axelrod then completed his internship and his residency training at the University of Toronto and the William Beaumont Hospital-Royal Oak. *Id.* He then completed a fellowship at McGill University-Royal Victoria Hospital. *Id.* He subsequently served as a medical staff fellow at the National Institute of Health Laboratory of Clinical Immunology. *Id.* Dr. Axelrod is board certified in Internal Medicine, Rheumatology, and Allergy and Immunology, and he has authored numerous publications on those subjects. *Id.* at 3–5; Axelrod Rep. at 1. He is not board certified in dermatology.

In his report, Dr. Axelrod explained how atopic dermatitis may result from a T_H2 T cell-driven allergic reaction to certain products such as egg, latex, gelatin, and yeast—common components of vaccines. Axelrod Rep. at 2. The IgE antibody that is produced by the T_H2 reaction is implicated in immediate allergic reactions such as anaphylaxis, urticaria, angioedema, and gastrointestinal disorders. *See* E.H. Chung, *Vaccine Allergies*, 3 Clinical and Experimental Vaccine Research 50, 51 (2014), filed as Ex. 23 on May 9, 2017 (ECF No. 17-7) ("Chung"); R. Wood, *Allergic Reactions to Vaccines*, 24 Pediatric Allergy and Immunology 521, 521 (2013), filed as Ex. 26 on May 9, 2017 (ECF No. 17-10) ("Wood"). Immediate IgE-mediated reactions typically occur within minutes of exposure to an allergen, and almost always present within four hours of exposure. Chung at 51. While rare, immediate reactions have been reported at an average

[11] Petitioner filed an initial report by Dr. Axelrod on March 8, 2017 (*see* ECF No. 16), but later submitted an amended version of the report, which is the one discussed herein.

[12] T_H2 is a subset of helper T cells that produces interleukin-4 ("IL-4") and interleukin-13 ("IL-13"), which in turn is responsible for stimulating IgE and IgG antibody production and the inhibition of macrophage functions. E. Maggi, *The TH1/TH2 Paradigm in Allergy*, 3 Immunotechnology 233, 234–35 (1998), filed as Ex. 22 on May 9, 2017 (ECF No. 17-6) ("Maggi"). Individuals suffering from atopic dermatitis exhibit high proportions of T_H2-like helper T cells after contact challenge. Maggi at 236.

rate of 0.22 per 100,000 doses of vaccinations among children and adolescence, with thirty-one percent of those cases reporting an immediate reaction after receipt of the first dose. *Id.* In the absence of prior exposure to the vaccine, an immediate reaction is suggestive of either pre-sensitization to a component of the vaccine or a non-immunologically mediated response to the dose. *Id.*

Unlike immediate reactions, delayed reactions are generally not IgE-mediated, begin about forty-eight hours after exposure, and peak in severity between seventy-two and ninety-six hours after exposure. Chung at 51. Such delayed reactions are typically characterized by rashes, including urticaria and erythema multiforme. *Id.* at 51–52; Wood at 521–22. While delayed reactions may be immunologically or non-immunologically mediated, evidence suggests that they are less likely to be the result of an immunological mechanism and should therefore not be diagnosed as a vaccine allergy. *See* L. Echeverría-Zudaire et al., *Consensus Document on the Approach to Children with Allergic Reactions After Vaccination or Allergy to Vaccine Components*, 43 Allergologia et immunopathologia 304, 311 (2015), filed as Ex. 25 on May 9, 2017 (ECF No. 17-9) ("Zudaire").

While the general proposition that vaccines can cause an allergic reaction in the recipient is supported by the literature supplied in this case in connection with Dr. Axelrod's report, those same articles emphasize the importance of distinguishing between *true* allergic reactions to specific components of a vaccine versus a reaction that is merely temporally related or mediated by a non-immunological mechanism. *See* Zudaire at 308, 311–312 (noting that delayed reactions should not be diagnosed as vaccine allergies and providing examples of reactions that can simulate allergic reactions). One possible reaction that may be mischaracterized as a vaccine allergy is the appearance of a rash, which may actually correspond to the exacerbation of a preexisting condition such as atopic dermatitis. *Id.* at 312. Notably, however, neither Zudaire or Dr. Axelrod explain how the *first* exposure to a particular vaccine can exacerbate preexisting atopic dermatitis.

B. *Dr. Schield Wikas*

Schield Wikas, D.O., provided one expert report on behalf of Petitioner. Report, filed as Ex. 38 on Dec. 19, 2017 (ECF No. 26-1) ("Wikas Rep."). In his report, Dr. Wikas opines that S.K.'s exposure to latex and yeast components in the Hepatitis B vaccines she received elicited a primary adaptive immune response to those components. *Id.* at 6. Her subsequent exposure to the DTaP and IPV vaccines then incited "an adaptive, secondary, memory immune response" to the latex and yeast components of those vaccines, resulting in exacerbation of atopic dermatitis. *Id.*

Dr. Wikas is a board-certified dermatologist with specialties in medical dermatology, dermatologic surgery, sclerotherapy, and hair transplantation and restoration. Dr. Wikas Curriculum Vitae, filed as Ex. 39 on Dec. 19, 2017 (ECF No. 26-2). He does not hold any

certifications in immunology. Dr. Wikas received his bachelors and Masters degrees from the University of Cincinnati College of Pharmacy before obtaining his Doctor of Osteopathic Medicine degree from the Kansas City University of Medicine and Biosciences. *Id.* Dr. Wikas then completed his internship at Cuyahoga Falls General Hospital and his Residency in dermatology at Cleveland Clinic Foundation. *Id.* Since 1984, Dr. Wikas has worked for Tri-County Dermatology where he serves as the director of the dermatology residency program. *Id.* at 7. Additionally, he has published several articles on topics within the field of dermatology and serves as a clinical instructor for medical students and residents. *Id.*

As Dr. Wikas noted in his report, atopic dermatitis is a common skin disease that typically affects children under the age of five. Wikas Rep. at 4. In its early acute stage, T_H2 cells are present in abundance, and they promote the production of cytokines like IL-4 and IL-13, which in turn result in the production of IgE antibody. *Id.* In the subsequent chronic stage of the disease process, both T_H1 (which is responsible for initiating phagocytosis through the production of interleukin-2, interferon gamma, and tumor necrosis factor) and T_H2 cells are present. *Id.* (citing Maggi at 234). During this phase, production of the cytokine interleukin-5 ("IL-5") leads to an increase in eosinophils—white blood cells that are involved in the pathogenesis of allergic reactions and inflammation. *Id.* (citing Maggi at 234).

The resulting inflammation causes dry skin prone to cracking and which subsequently cannot serve as an effective barrier against pathogens and other irritants. Wikas Rep. at 4; *see* S. Weidinger et al., *Atopic Dermatitis*, 387 Lancet 1109, 1115–16 (2016), filed as Ex. C, Tab 8 on Feb. 25, 2019 (ECF No. 41-10) ("Weidinger"). Infiltration of the compromised barrier allows further stimulation of the T_H2/T_H1 cycle, encouraging a chronic, relapsing pattern. Wikas Rep. at 4; *see also* L. Schneider et al., *Atopic Dermatitis: A Practice Parameter Update 2012,* 131 J. Allergy Clinical Immunology 295, 296 (2012), filed as Ex. C, Tab 3 on Feb. 25, 2019 (ECF No. 41-5) ("Schneider"). This reaction, according to Dr. Wikas, can not only be *initiated* by exposure to components of vaccines, but the same exposure can *exacerbate* an existing case. Wikas Rep. at 4–5 (citing Zudaire at 312; N. Saulnier et al., *Gene Expression Profiling of Patients with Latex and/or Vegetable Food Allergy*, 16 Eur. Rev. for Med. and Pharmacological Sci. 1197, 1207 (2012), filed as Ex. 27 on May 9, 2017 (ECF No. 18-1) ("Saulnier")).[13]

Relying on Dr. Axelrod's report and the accompanying literature, Dr. Wikas attributed S.K.'s atopic dermatitis exacerbation to an allergic reaction to the latex and yeast components of the vaccines she received in September 2013. Wikas Rep. at 6. He did not address the absence of record evidence that S.K. had ever *previously* experienced latex and yeast allergies, however. He otherwise noted the temporal relationship between S.K.'s atopic dermatitis flare and the receipt of

[13] Despite Dr. Wikas being board certified in dermatology, most of Dr. Wikas' report mimics that of Dr. Axelrod—an immunologist—and it is also evident that Dr. Wikas relied heavily if not exclusively on the literature previously submitted by Dr. Axelrod. *See generally* Axelrod Rep.; Wikas Rep.

her September 18, 2013[14] vaccinations, which he considered direct evidence of a causal association. *Id.*

C. *Dr. Francis Lobo*

Francis Lobo, M.D., a clinical immunologist, provided one expert report on behalf of Respondent in this matter. Dr. Lobo Report, filed as Ex. A on Sept. 7, 2017 (ECF No. 22-1) ("Lobo Rep."). Dr. Lobo opined that S.K. did not experience an allergic reaction leading to the development and subsequent exacerbation of atopic dermatitis, but rather a mild, transient infantile atopic dermatitis most likely unrelated to vaccine administration. *Id.* at 8.

Dr. Lobo is currently employed as a clinician at Yale University School of Medicine Department of Internal Medicine in the Allergy and Clinical Immunology section. Dr. Lobo Curriculum Vitae, filed as Ex. B on Sept. 7, 2017 (ECF No. 22-6) ("Lobo CV"). He received his bachelor's degree in biology from the University of Pennsylvania before receiving a Masters degree in the history of medicine from the University of Cambridge. *Id.* at 1. He then obtained his medical degree from Yale University School of Medicine. *Id.* Dr. Lobo then completed his residency in internal medicine as well as a post-doctoral fellowship in allergy and immunology at Yale-New Haven Hospital. *Id.* He is board certified in allergy and immunology. *Id.* at 2.

Dr. Lobo's clinical duties include seeing approximately seventy-five patients a week, including both pediatric and adult patients. Lobo Rep. at 2. He also serves as a faculty member and instructor at Yale University, where he teaches basic and clinical immunology to medical students, residents, and fellows. *Id.* Additionally, Dr. Lobo has written and published several articles on topics within the field of allergy and immunology. Lobo CV at 3–4.

In his report, Dr. Lobo first noted that the temporal relationship between S.K.'s August 2013 vaccination and development of atopic dermatitis thereafter was too attenuated to establish a causal connection. Lobo Rep.at 4–5. He emphasized that acute allergic reactions such as urticaria, swelling, wheezing, hypotension, and anaphylaxis are generally short-lived, presenting and resolving within twenty-four hours of exposure. *Id.* Therefore, onset of atopic dermatitis six or seven days *after* vaccination was inconsistent with an allergic reaction. *Id.*

Dr. Lobo also challenged Petitioner's contention that S.K. likely had an allergy to latex, yeast, DTaP, or IPV. He first emphasized the fact that S.K. could not exhibit an allergic reaction to microbial components of the vaccines she had never encountered before September 18, 2013. Lobo Rep. at 5. Without prior exposure, it would be impossible for her to have developed the

[14] Dr. Wikas incorrectly noted that S.K. received the DTaP, Hib, IPV, and pneumococcal vaccines on September 16, 2013, and his opinion reflects this mistake when he opines on the timing of secondary adaptive immune responses. Wikas Rep. at 6. Like Dr. Axelrod, Dr. Wikas also mistakenly reports that S.K. received the Rotavirus vaccine. *Id.*

antibodies required to mount an adaptive immune response and mediate an allergic reaction. *Id.* Additionally, Dr. Lobo opined that the skin testing S.K. subsequently underwent had not been interpreted in a manner consistent with diagnostic protocol. *Id.* at 6. In his understanding, a positive response to a skin prick test requires a wheal three millimeters *greater* than the control. *Id.* S.K.'s treating allergist, however, interpreted the results of her DTaP skin prick test as positive, despite exhibiting a wheal size only two millimeters larger than the saline control.[15] Though Dr. Lobo conceded that S.K. did through testing demonstrate an erythematous reaction to IPV, that reaction occurred only after S.K. was injected intramuscularly, and was limited to a localized erythema rather than the systemic reaction he would expect to see when a true allergen is rapidly disseminated throughout the body. *Id.* This distinction, according to Dr. Lobo, implied that the erythema S.K. exhibited following the IPV injection by Dr. Jorgensen was not evidence of an allergic reaction, but rather a "miniscule effect of the trauma of the injection." *Id.*

Even if S.K. *did* have a true allergy to latex—a non-microbial component of certain vaccines—Dr. Lobo emphasized that it is unlikely S.K. received a vaccine containing latex on September 18, 2013. Lobo Rep. at 5 ("[l]atex is not present in [the pneumococcal vaccine] or IPV, is present in only one of three available DTaP preparations, and is present in one of the two Hib vaccines from Sanofi Pasteur."); *see also* Centers for Disease Control, *Latex in Vaccine Packaging*, filed as Ex. A, Tab 1 (ECF No. 22-2).

D. *Dr. Jonathan Spergel*

Jonathan Spergel, M.D., PhD, a board-certified allergist and immunologist, provided one expert report on behalf of Respondent. Spergel Report, filed as Ex. C on Feb. 25, 2019 (ECF No. 41-1) ("Spergel Rep."). In it, Dr. Spergel opined that there was no evidence of a causal relationship between vaccines and the initiation or exacerbation of atopic dermatitis. *Id.* at 4. Additionally, he proposed that the reactions S.K. experienced are better classified as irritant reactions rather than allergic reactions. *Id.* at 3.

Dr. Spergel is currently employed as a physician and chief of the allergy and immunology division at the Children's Hospital of Philadelphia. Spergel Curriculum Vitae, filed as Ex. D on Feb. 25, 2019 (ECF No. 41-2) ("Spergel CV"). He received his bachelor's degree in chemistry from Princeton University, and then he obtained his medical degree and PhD from the Mt. Sinai School of Medicine. *Id.* at 1. Dr. Spergel thereafter completed an internship and residency in pediatrics at Yale-New Haven Hospital, followed by a fellowship in allergy and immunology at Children's Hospital in Boston, Massachusetts. *Id.* Besides his clinical duties, Dr. Spergel serves as an instructor in pediatric allergy and immunology at the Perelman School of Medicine at the University of Pennsylvania, where he is also a faculty member of the Skin Disease Research Core

[15] Dr. Lobo noted also that S.K.'s saline control exhibited erythema, which is indicative of dermatographism—a type of urticaria that results from firm stroking or scratching the skin. Lobo Rep. at 6; *see also Dorland's* at 490, 492.

Center. *Id.* Though he is not board certified in dermatology, Dr. Spergel has significant experience studying atopic dermatitis and other immunologically-mediated dermatological disorders, and he has served on several committees dedicated to atopic dermatitis and eczema. *Id.* at 3–4. Dr. Spergel has also published numerous articles and presented on the topics of allergy, immunology, and atopic dermatitis. *Id.* at 5–32.

Dr. Spergel's report began by examining some of the common causes of atopic dermatitis that might better explain S.K.'s development of the disease and/or its subsequent exacerbation. Atopic dermatitis is the most common pediatric skin disorder, affecting approximately ten to twenty percent of all children. Spergel Rep. at 2; C. Flohr et al., *Atopic Dermatitis and the Hygiene Hypothesis Revisited*, 41 Current Problems in Dermatology 1, 1 (2011), filed as Ex. C, Tab 9 on Feb. 25, 2019 (ECF No. 41-11) ("Flohr"). Dr. Spergel agreed with Petitioner's experts that the mechanism through which atopic dermatitis is initiated and perpetuated involves a T_H2 T cell-driven inflammation during the acute phase, and a subsequent T_H2/T_H1 T cell-mediated chronic phase. Spergel Rep. at 2–3.

Common triggers for atopic dermatitis include "viral infections, bacterial infections, aeroallergens (including animal dander), food allergies and poor skin care." Spergel Rep. at 3 (citing P. Arkwright et al., *Management of Difficult-to-Treat Atopic Dermatitis*, 1 J. Allergy Clinical Immunology: In Practice 142, 143–44 (2013), filed as Ex. C, Tab 1 on Feb. 25, 2019 (ECF No. 41-3)). Dr. Spergel did not, however, accept vaccines as a potentially causal or aggravating agent of atopic dermatitis, citing literature that he maintained cast doubt on that proposal. Spergel Rep. at 4 (citing Chung at 51); *see also* Flohr at 21–26, 28; C. Grüber, *Early Atopic Disease and Early Childhood Immunization – Is There a Link?*, 63 Allergy 1464, 1464 (2008), filed as Ex. C, Tab 10 on Feb. 25, 2019 (ECF No. 41-12) ("Grüber").

Dr. Spergel emphasized two important points about the development of any allergy. First, he noted that T_H2 responses are antigen-specific—they require a prior exposure to the allergen and sensitization to it thereafter. Second, he stressed that IgE antibodies normally increase during the first few years of life, thereby making pediatric allergies inevitably more common during this stage of development regardless of antigen exposure. Spergel Rep. at 5–6; *see also* R. Nickel et al., *Variability of Total Serum Immunoglobulin E levels from birth to the Age of 10 Years. A Prospective Evaluation in a Large Birth Cohort (German Multicenter Allergy Study)*, 35 Clinical and Experimental Allergy 619, 619 (2005), filed as Ex. C, Tab 12 on Feb. 25, 2019 (ECF No. 41-14) ("Nickel").

Regarding antigen specificity, Dr. Spergel explained that it is only after an individual is initially exposed to the allergen and then undergoes the sensitization process will they experience a T_H2-mediated allergic response upon subsequent exposures to that allergen. Spergel Rep. at 5–6. He opined that such allergen sensitization is not associated with general sensitization, and thus

an individual would not automatically develop additional allergies to other substances. *Id.* at 6. Rather, the development of additional allergies may instead be attributable to the naturally-increasing levels of IgE occurring during early childhood development. *Id.* (citing Nickel at 619). This contention was undercut, however, by another piece of literature offered on behalf of Respondent, in which the authors observed that "[i]ncreases in [total] IgE levels were temporally related to the onset of respiratory allergies *and of specific sensitization*." P. Matricardi et al., *Longitudinal Trends of Total and Allergen-Specific IgE Throughout Childhood*, 64 Allergy 1093, 1097 (2009), filed as Ex. C, Tab 13 on Feb. 25, 2019 (ECF No. 41-15) ("Matricardi") (emphasis added). Matricardi concluded that both specific IgE and total IgE levels increased whenever a child experienced an allergen-specific response. *Id.* at 1097.

Despite the findings of Matricardi, Dr. Spergel's report and other pieces of accompanying literature emphasized the importance of identifying specific allergens that may lead to an adverse reaction such as atopic dermatitis. Spergel Rep. at 3–5; S. Dreskin et al., *International Concensus (ICON):Allergic Reactions to Vaccines*, 9:32 World Allergy J. 1, 9–16 (2016), filed as Ex. C, Tab 5 on Feb. 25, 2019 (ECF No. 41-7) ("Dreskin"). Consistent with the opinions of Drs. Axelrod and Wikas, Dreskin notes that people rarely experience allergic reactions to vaccine antigens, but there is some evidence suggesting that certain vaccine components (i.e., gelatin, egg, yeast, and latex) may cause allergic reactions in a small proportion of the population. Dreskin at 9. Even people with allergies to these components are typically able to receive vaccinations as usual because the components are present in such small amounts that they are unable to produce adverse reactions. *Id.* In individuals with unusually high levels of IgE antibody, however, these components may induce severe reactions. *Id.* Therefore, practitioners employ skin testing against both the vaccine itself, as well as those specific components most likely to induce an allergic reaction. *Id.* at 12. Dreskin cautions that these tests, however, must be interpreted carefully because false positives may result due to irrelevant IgE responses or irritant effects of the vaccine. *Id.*

While he agreed with S.K.'s egg allergy diagnosis, Dr. Spergel contended that the positive skin prick test results for IPV and DTaP were likely false positives. Spergel Rep. at 3. He noted that individuals with atopic dermatitis experience very high rates of false positives during skin prick tests, and there is evidence that individuals with atopic dermatitis experience higher rates of sensitizations (including food allergies) and other immune-mediated inflammatory diseases. *Id.* (citing D. Fleischer et al., *Oral Food Challenges in Children with a Diagnosis of Food Allergy*, 158 J. Pediatrics 578, 581 (2011), filed as Ex. C, Tab 2 on Feb. 25, 2019 (ECF No. 41-4) ("Fleischer")); *see also* Weidinger at 1109–11; Dreskin at 12.

Given this predisposition, along with S.K.'s erythematous reaction to the saline control, Dr. Spergel reasoned that S.K.'s skin prick test result could not be reliably interpreted as a truly positive allergic reaction, and it was more likely than not evidence of an irritant reaction. Spergel Rep. at 3. Dr. Spergel found further support for this conclusion from the fact that S.K. experienced

mainly an erythematous reaction, rather than anaphylaxis—the type of IgE-mediated reaction one would expect to see when an allergic individual is exposed to the target allergen. *Id.* At the same time, however, literature establishes that other forms of allergic reaction less severe than anaphylaxis (e.g., erythema, pruritus, urticaria, and angioedema) are also mediated by IgE production. Dreskin at 2; Zudaire at 310.

The record in this case shows that S.K. did receive skin prick testing against IPV and DTaP—though Dr. Spergel questioned the reliability of the test given S.K.'s erythematous reaction to the saline control—but did not undergo the same testing for other specific vaccine components such as yeast and latex. Ex. 4 at 20, 25, 29. Thus, according to Dr. Spergel, there was no evidence that S.K. ever suffered from allergies to either latex or yeast, and her development and subsequent exacerbation of atopic dermatitis cannot be attributed to an allergic reaction to those kinds of components. Spergel Rep. at 5–6. In furtherance of that opinion, Dr. Spergel pointed out that even if S.K. did have an allergy to the vaccines she received on September 18, 2013, she could not have experienced any reaction within minutes of vaccine administration because she had not been previously exposed to the vaccines, and she could not have developed sensitization to them. *Id.* at 4.

Dr. Spergel did provide some alternative explanations for S.K.'s atopic dermatitis and its exacerbation. Such factors include exposure to cat dander from the family's pet, exposure to egg—a food allergy S.K. was known to have—via breastmilk, poor skin care and refusal to use topical medications, use of irritating soaps and detergents, bacterial, viral, and fungal infections, and rubbing already aggravated skin. Spergel Rep. at 4.

III. Procedural Background

As noted above, this case was initiated on August 12, 2016. Medical records were filed between August 16-17, 2016, and Respondent filed his Rule 4(c) Report responding to those filings on February 7, 2017. Respondent's Report, filed Feb. 7, 2017 (ECF No. 10). On March 6, 2017, Petitioner filed her first amended petition, in which she limited her claim solely to atopic dermatitis as the alleged injury. Both parties then submitted the aforementioned expert reports. On July 19, 2017, Petitioner filed her second amended petition. Amended Petition, filed July 19, 2017 (ECF No. 21) (Second Amended Pet.").

On February 2, 2018, I issued a pre-hearing order setting the entitlement hearing in this case for April 2, 2019. Prehearing Order, filed Feb. 2, 2018 (ECF No. 31). On September 20, 2018, however, Respondent filed a motion to dismiss, to which Petitioner filed her opposition on September 28, 2018. Motion to Dismiss, filed Sept. 20, 2018 (ECF No. 35) ("Mot. to Dismiss"); Response to Mot. to Dismiss, filed Sept. 28, 2018 (ECF No. 36) ("Resp. to Mot. to Dismiss"). Respondent's Reply was filed October 2, 2018. Respondent's Reply to Resp. to Mot. to Dismiss,

filed Oct. 2, 2018 (ECF No. 37).

In reaction to these filings, on March 14, 2019, I issued a scheduling order offering Petitioner the opportunity to request a ruling on the record rather than proceed to hearing. Petitioner opted to do so by filing dated May 16, 2019. Motion for Decision on the Record, filed May 16, 2019 (ECF No. 45) ("Mot. for Ruling"). Respondent filed his opposition on July 11, 2019, and Petitioner filed her Reply on August 14, 2019. Response to Mot. for Ruling, filed July 11, 2019 (ECF No. 47) ("Resp. to Mot. for Ruling"); Reply, filed Aug. 14, 2019 (ECF No. 48) ("Reply for Ruling").

IV. Parties' Respective Arguments

A. *Petitioner's Motion*

Petitioner argues that S.K. experienced a severe dermatological reaction after receiving the Hepatitis B vaccine on August 21, 2013, and that this reaction was then exacerbated by the IPV and DTaP vaccines administered on September 18, 2013. Mot. for Ruling at 10. Relying on the reports of Drs. Axelrod and Wikas, as well as the medical literature filed in the matter, Petitioner posits that components contained within the Hepatitis B vaccine S.K. received—namely latex and yeast—initiated a delayed IgE-mediated response, leading to an increased production of inflammatory eosinophils, thereby resulting in an acute onset of atopic dermatitis. *Id.* at 10–12. The subsequent receipt of the IPV and DTaP vaccines then significantly aggravated her condition by initiating an immediate IgE-mediated response. *Id.* Her condition then entered the chronic phase where both T_H1 and T_H2 are present, causing persistent dry, cracked skin that fails to barricade against other allergens and irritants that can perpetuate inflammation. *Id.* at 13.

Petitioner contends that this perpetuating "inflammatory milieu" began around August 27, 2013—six days after S.K. received the second dose of the Hepatitis B vaccine. Mot. for Ruling at 14; Ex. 7 at 15 (noting "redness and rash on neck x3 weeks"). A few weeks later, on September 18, 2013, Dr. Barcellona again noted rough dry patches of skin on S.K.'s body, and he diagnosed her with atopic dermatitis. Ex. 7 at 21–22. During the same visit, he administered IPV and pneumococcal vaccines into S.K.'s left leg and the DTaP vaccine into her right leg. *Id.* at 23–24. According to Ms. Perekotiy, S.K. immediately exhibited symptoms of a reaction to the vaccines—her daughter's legs turned purple. Statement of Anna Perekotiy, filed as Ex. 1 on Aug. 16, 2016 (ECF No. 4-1) at ¶ 5. In the months following, S.K.'s legs remained red, and she continued to scratch and cry in pain. *Id.* at ¶ 7; Ex. 58 (photograph dated Nov. 1, 2013 displaying rash on legs and torso). Petitioner contends that this condition persisted for over a year—citing to medical records where Ms. Perekotiy reported her daughter's rash had been present for over a year, as well as a photograph that depicts S.K.'s rash on March 29, 2014 (just over six months from the time of her September 18, 2013 vaccinations). Ex. 1 at 24; Ex. 12 at 3; Ex. 59.

Between September 18, 2013 and February 19, 2014, S.K. was evaluated by pediatricians, dermatologists, and an allergist for her atopic dermatitis. During these visits, the physical examinations revealed a persistent rash on her legs, torso, face, and arms. Ex. 3 at 33; Ex. 4 at 14, 24, 28; Ex. 7 at 27; Ex. 10 at 2. Her clinical presentation led some treaters to question whether the vaccines she received contributed to her condition. Ex. 7 at 27 (noting that it is "unclear if shot reaction was local and eczema was bigger issue, or if [the] shot caused more reaction"). Another treater, Dr. Jorgensen, concluded that S.K. had experienced an allergic drug reaction to IPV and DTaP. Ex. 4 at 28. This opinion was supported by skin prick tests and low dose introductions of IPV and DTaP that Dr. Jorgensen interpreted as positive for T_H2-mediated erythematous reactions. *Id.* at 25, 29; Mot. for Ruling at 15 (citing Letter from Treating Immunologist, Ronald Jorgensen, M.D., filed as Ex. 55 on Feb. 2, 2018 (ECF No. 33-1)).

B. *Respondent's Opposition*

Respondent first argues that Petitioner has not established that the Hepatitis B vaccine S.K. received on August 21, 2013, caused her initial onset of atopic dermatitis. Resp. to Mot. for Ruling at 12. In support of his position, Respondent points out that Petitioner's experts discussed examples of an immediate IgE-mediated anaphylactic responses to allergens, such as latex, but the record does not support a finding that S.K. ever experienced such a reaction. *Id.* Additionally, epidemiological studies have found no link between immunization and the initiation *or* exacerbation of atopic dermatitis. *Id.*; *see* Flohr at 1; Grüber at 1464. And even if Petitioner's theory of causation was medically reliable, there is no evidence to support a logical sequence of cause and effect—namely because the record (as reflected in subsequent testing) does not support a finding that S.K. suffered from latex and/or yeast allergies. Resp. to Mot. for Ruling at 13. Nor did Petitioner adequately explain how an IgE-mediated reaction based upon such an allergy—a response that generally appears and resolves within twenty-four hours—could thereafter lead into a chronic disease process six days after exposure. Resp. to Mot. for Ruling at 14.

Respondent also disputes Petitioner's success in establishing that the IPV and DTaP vaccines S.K. received on September 18, 2013, could have significantly aggravated her atopic dermatitis (which Respondent allows existed as of that date, even if it had not been initially caused by the Hepatitis B vaccine). Resp. to Mot. for Ruling at 14. Focusing on the record at the outset, Respondent observes that although Ms. Perekotiy claims that S.K. experienced an immediate reaction to the IPV and DTaP vaccines, the medical record does not reflect any phone calls or doctor visits for two months following the vaccination. *Id.* Additionally, the record itself is vague in its description of S.K.'s dermatologic condition, and it is not immediately clear that her clinical course was affected by the vaccinations that she received. *Id.* at 14–15.

Regarding Petitioner's proposed mechanism of causation, Respondent argues once again

that there is no evidence that S.K. experienced any kind of immediate, IgE-mediated reaction of the sort typically associated with latex and yeast allergies. Resp. to Mot. for Ruling at 15. This, in combination with literature finding no link between vaccination and atopic dermatitis generally, rebuts Petitioner's proposed theory of causation. *Id.*; *see* Flohr at 1; Grüber at 1464. Additionally, Respondent highlights the fact that T_H2 responses are antigen-specific, and therefore require sensitization to a specific allergen before a response will occur. Resp. to Mot. for Ruling at 15. But this sensitization would not have occurred, since S.K. had never been exposed to the IPV and DTaP vaccines prior to the first doses she received on September 18, 2013. *Id.* As a result, the initial receipt of a vaccine could not inherently make an individual more allergic. *Id.* at 16. Instead, Respondent proposes that S.K.'s atopic dermatitis was more likely the result of a known food allergy to egg. *Id.* at 16–17. While none of the vaccines S.K. received contain egg-product, S.K. was likely exposed to egg via breastmilk. *Id.* at 17.

C. *Petitioner's Reply*

In her Reply, Petitioner emphasizes that S.K. *did* undergo allergy testing, and that the results of those tests were interpreted by a treating physician as positive reactions. Reply for Ruling at 2. That same treating physician recommended that S.K. not receive any more vaccinations unless subsequent allergy testing was negative. *Id.* (citing Ex. 55 at 1). This evidence, according to Petitioner, offers significant support for her claim, and such evidence is not easily minimized by Respondent. Much of the Reply then focuses on bolstering the credentials of Drs. Axelrod and Wikas. Reply for Ruling at 3–6. Lastly, Petitioner argues that S.K. did meet the six-month severity requirement based upon medical records documenting a past medical history of rash lasting for more than a year, as well as photographs provided by S.K.'s mother—the latest of which is dated approximately six months after S.K. received her September 2013 vaccinations. *Id.* at 6–7.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[16] In this case, Petitioner does not assert a Table claim.

[16] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

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

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant

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concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). *Tarsell v. United States,* 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner's overall burden); *see also Contreras,* 121 Fed. Cl. at 245; *Andreu*, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. *See, e.g.*, *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010) (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' *sufficient to prove by a preponderance of the evidence a medical theory* linking the [relevant vaccine to relevant injury]."") (emphasis added). Regardless, one thing remains: petitioners always have the ultimate burden of establishing their Vaccine Act claim *overall* with preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell*, 133 Fed. Cl. at 793 (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates

that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Standards Applicable to Significant Aggravation Claim*

Where a petitioner so alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

Subsumed within the *Loving* analysis is the requirement to evaluate the likely natural course of an injured party's preexisting disease, in order to determine whether the vaccine made the petitioner worse than he would have been but for the vaccination. *Locane v. Sec'y of Health & Human Servs.,* 685 F.3d 1375, 1381–82 (Fed. Cir. 2012) (upholding special master's determination that petitioner had failed to carry her burden of proof in establishing that her preexisting injury was worsened by the relevant vaccine); *Hennessey v. Sec'y of Health & Human Servs.*, No. 01-190V, 2009 WL 1709053, at *41–42 (Fed. Cl. Spec. Mstr. May 29, 2009), *mot. for review denied*, 91 Fed. Cl. 126 (2010). The critical point of examination is thus "whether the change for the worse in [petitioner's] clinical presentation was aggravation or a natural progression" of the underlying condition. *Hennessey,* 2009 WL 1709053, at *42.[17] The Federal Circuit has upheld the determinations of special masters that worsening was not demonstrated in connection with establishing a petitioner's overall preponderant burden of proof for a non-Table causation-in-fact claim. *See, e.g., Snyder/Harris v. Sec'y of Health & Human Servs.*, 553 F. Appx. 994, 999–1000 (Fed. Cir. 2014); *Locane,* 685 F.3d at 1381–82.[18]

C. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then

[17] The legislative history of the Vaccine Act strongly supports interpreting "significant aggravation" as requiring a claimant to establish that a vaccine rendered a preexisting condition qualitatively worse than it would have been otherwise—not simply that the affected individual experienced a post-vaccination symptom that contrasts with the individual's comparatively better pre-vaccination health. *See* H.R. Rep. No. 99-908, at 15 (1986) ("This [significant aggravation] provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis" (emphasis added)).

[18] This is consistent with the fact (well recognized by controlling precedent) that evidence of "worsening" relevant to Respondent's alternative cause burden may reasonably by evaluated by a special master in determining the success of a petitioner's prima facie showing. *Snyder/Harris*, 553 F. Appx. at 1000 ("'[N]o evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute.'" (*quoting Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012))); *see also de Bazan* at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.").

required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

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

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

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent'") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a

determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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

D. *Analysis of Expert Testimony*

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

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have

been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Human Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

E. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are

central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

F. *Resolution of Case Via Ruling on Record*

The parties have requested that I resolve this matter on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Kreizenbeck v. Sec'y of Health & Human Servs.*, No. 08-209V, slip op. at 8 (Fed. Cir. Jan. 6, 2020); *Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy* 23 Cl. Ct. at 730–31.

ANALYSIS

Petitioner has two associated, non-Table claims: one alleging that the Hepatitis B vaccine directly caused S.K.'s atopic dermatitis, and a significant aggravation claim based on two vaccines she received approximately one month later. Both claims must be established by a preponderance of the evidence, though the specific factors that must be proven differ between the claims. As set forth below, I find that although Petitioner offers several items of reliable evidence, she has not preponderantly established either claim.

I. Overview of Atopic Dermatitis

The experts largely agreed on the characteristics of atopic dermatitis, but a few additional points are in order. Atopic dermatitis is a complex skin allergy disease that most often manifests in young children, and is generally characterized by skin irritation, dryness, sweating, and itching. A. Cantani, *Pediatric Allergy, Asthma and Immunology* 473 (U. Heilmann ed., 2008)

("Cantani").[19] As discussed by both parties' experts, the pathogenesis of atopic dermatitis involves the production of a specific antibody, IgE, and the corresponding/subsequent stimulation of the skin's inflammatory response. *See* Axelrod Rep. at 2; Spergel Rep. at 2–3. Foreign antigens that are introduced to the body are captured by Langerhans cells[20], which reside in the epidermis layer of the skin and carry IgE antibodies on their cell membranes. Cantani at 478. The Langerhans cells then migrate and interact with T-cells, such as memory T_H2 cells, and mast cells. *Id.* at 478, 484; Maggi at 236.

Activated T_H2 cells subsequently support the proliferation and release of interleukins while mast cells initiate the release of histamines—key mediators of an inflammatory response. Cantani at 478, 484. Significantly, skin mast cells can also be activated by nonimmunological stimuli, including viral proteins and components of bacterial membranes. *Id.* at 484. Following the initial release of histamine, an individual may experience signs of a Type I hypersensitivity, such as pruritic, erythematous, or macular rashes as well as vasodilation.[21] *Id.* In a second phase, T_H1 cells—characteristic of delayed-type hypersensitivity reactions—predominate and play a key role in producing skin lesions. *Id.* at 489–90. As T_H2 gives way to T_H1 proliferation, the individual may experience worsening inflammation. *Id.* at 490; *see also* Spergel Rep. at 2–3.

Clinical presentation of atopic dermatitis in infants generally presents as an erythematous rash on the face. Cantani at 501. Scratching and itching may worsen the disease, as well as exposure to additional allergens and irritants after the condition's symptomatic manifestation. *Id.* at 497–500. Because individuals with atopic dermatitis are more likely to also experience sensitizations, identification and removal of food allergens from an individual's diet plays a significant role in the management and treatment of the condition. *Id.* at 497, 512; *see also* Fleischer at 581; Weidinger at 1110.

II. Petitioner Has Not Preponderantly Established that the Hepatitis B Vaccine Did Cause S.K.'s Initial Presentation of Atopic Dermatitis

There is no dispute in this case about the administration of the vaccines in question, S.K.'s diagnoses, or the date S.K. most likely experienced onset (around August 27, 2013). Thus, Petitioner's claim regarding initiation of S.K.'s atopic dermatitis turns on whether the Hepatitis B

[19] Cantani is a medical treatise on the topic of pediatric allergy and immunology. It is not being filed in this matter because it is not controversial, nor contrary to the testimony provided by the parties' experts, and my determination of entitlement does not turn on my general reference to it. I cite to it merely because it provides supplemental information and context absent from the parties' existing literature filings.

[20] Langerhans cells are predominantly located in the skin but can also be found in the lungs, lymph nodes, spleen, and thymus. They are antigen-presenting cells, and they are most commonly implicated in the mediation of allergic reactions. *Dorland's* at 315.

[21] Vasodilation describes the dilation of blood vessels leading to increased blood flow. *Dorland's* at 1996.

vaccine could cause atopic dermatitis in the manner proposed, whether it did so here, and whether S.K.'s onset was within a medically acceptable timeframe. I find that Petitioner has not preponderantly satisfied any of the *Althen* prongs for this claim.

The first *Althen* prong requires petitioners to establish a "reputable medical theory" demonstrating that the vaccine received *can cause* the type of injury alleged. Here, both parties agree that atopic dermatitis, like other types of allergic reactions, is immunologically mediated by IgE generated in response to increased T cell and cytokine activity. *See* Axelrod Rep. at 2; Wikas Rep. at 4; Spergel Rep. at 2–3. Individuals suffering from atopic dermatitis also tend to exhibit higher rates of sensitization, such as food allergies and other immune-mediated inflammatory diseases. Fleischer at 581. Thus, the immune character of the condition has been established—opening the door to a conclusion that a vaccine *might* be associated with that condition.

In addition, I find that preponderant evidence (particularly some of the literature filed in this case) supports the conclusion that exposure to potentially allergenic vaccine components could trigger the kind of immunologic reaction necessary to produce an IgE-mediated allergic reaction. *See*, *e.g.*, Chung at 50; Dreskin at 9–16 (emphasizing that although vaccine antigens themselves rarely cause allergic reactions, *other* vaccine components may induce an allergic response and should be identified so as to modify vaccine administration if necessary); Spergel Rep. at 5–6. But this alone is insufficient to support finding that vaccines can also cause atopic dermatitis—a condition that much of the literature distinguishes from a true allergic reaction. *See, e.g.*, Zudaire at 311–12.

On that specific subject, Respondent offered certain items of literature aimed at rebutting Petitioner's points regarding the capacity of a vaccine to cause atopic dermatitis—although not all were equally persuasive. For example, Flohr, a review article, considered numerous studies on different aspects of atopic dermatitis, including studies evaluating the effects of vaccination on the development and exacerbation of the condition. Flohr at 21. Some of the studies Flohr considered found that there was an *increased* risk for atopic dermatitis following vaccination, but Flohr identified sources of error in those studies and therefore rejected their conclusions. *Id.* (discussing a Danish cross-sectional study that found a twofold increase in atopic dermatitis risk in children following receipt of the measles, mumps, and rubella vaccine, and two UK studies that found increased risk of atopic dermatitis in children following receipt of diphtheria/tetanus and polio containing vaccines).

Though not insignificant, the weight I give to literature reviews is less than what I would give to other forms of more direct evidence, such as epidemiological studies and research studies centering on some aspect of the relevant condition. Flohr's conclusions are further diminished by the lack of follow-up studies addressing the sources of error alleged by Flohr. Without subsequent studies, there exists merely a handful of studies—some of which *do* find a causal relationship

between vaccines and atopic dermatitis—along with a single review of those studies that alleges unverified sources of error and therefore arrives at the opposite conclusion. Thus, Flohr alone is not sufficient to overcome Petitioner's showing.

But Respondent also offered a 2008 epidemiological study, Grüber, involving over 2,000 children. Grüber focused on children who were at a high risk of developing atopic dermatitis, versus children already suffering from it, to see if childhood vaccinations had any effect on the initiation or exacerbation of atopic dermatitis. Grüber at 1464. Ultimately, Grüber concluded that vaccination did not pose an increased risk for either the development or exacerbation of atopic dermatitis. Grüber at 1469. This is a very persuasive study worthy of substantial weight, and it was not rebutted by Petitioner. This study, along with the findings of Flohr, sufficiently rebut Petitioner's arguments, thereby making Petitioner's overall showing insufficient to establish an entitlement award.

Petitioner also failed to offer preponderant evidence to support the second *Althen* prong, which requires establishing a logical sequence of cause and effect between the alleged injury and the vaccine received. The medical record reveals that prior to receiving the Hepatitis B vaccine on August 21, 2013, S.K. (who had previously received the same vaccine at birth, one month before, but with no reaction) had not exhibited any dermatologic symptoms consistent with atopic dermatitis. Ex. 7 at 11–14 (discussing physical examination findings on August 21, 2013, which were negative for any dermatologic concerns). Only six days later (as reported to treaters by Ms. Perekotiy) did S.K. begin exhibiting dermatologic symptoms, which were thereafter diagnosed as atopic dermatitis the following month. *Id.* at 15, 21–22 (noting that S.K.'s symptoms began approximately three weeks prior).

Petitioner maintains that S.K.'s atopic dermatitis was the result of a delayed IgE-mediated allergic response to the latex and yeast components of the Hepatitis B vaccine. Mot. for Ruling at 12. But Respondent points out that such delayed reactions (occurring within forty-eight hours of allergen expose, and then peaking within seventy-two to ninety-six hours post-exposure (three to four days later) are *not* usually IgE-mediated. Chung at 51; Wood at 521–22. In fact, as Zudaire emphasizes, such reactions merely *simulate* an allergic response, and should therefore not be diagnosed as a true vaccine allergy. Zudaire at 311–12. Additionally, no allergy testing was conducted against the Hepatitis B vaccine or any of its alleged components (latex and yeast). *See* Ex. 4 at 25, 29 (discussing allergy test results for Diphtheria/Tetanus and IPV vaccines). Without positive allergy test results, there is insufficient evidence that S.K. was allergic to any component of the Hepatitis B vaccine. For these reasons, I find that Petitioner has not satisfied her burden under *Althen* prong two.

Petitioner's showing under the third *Althen* prong is similarly flawed—and would compel dismissal of this claim *even if* she had met the first two prongs. Respondent's experts, along with

much of the literature submitted in this matter, proposed that the onset of delayed allergic reactions will occur *at least* within forty-eight hours of allergen exposure, peaking three to four days post-exposure. Chung at 51; Wood at 521–22. But the medical records in this case suggest that S.K. did not display symptoms of atopic dermatitis until August 27, 2013—*six days* post-vaccination. Ex. 7 at 15. Thus, the medical record establishing S.K.'s onset is inconsistent with the most scientifically reliable/medically acceptable timeframe.

Petitioner argues for a longer timeframe, with Dr. Axelrod opining that adaptive immune responses to an allergen can occur up to twenty-five days after exposure. Axelrod Rep. at 4. In support of this contention, Petitioner cited two articles, only one of which was filed in this matter.[22] *See* A. Abbas et al., *Cellular and Molecular Immunology* 10 (8th ed. 2015) ("Abbas"). Her reliance on Abbas, however, is misplaced. Abbas demonstrates only that the secondary immune response (primarily mediated by memory B cells) is as a general rule more robust than the primary response to a specific antigen. *Id.* But even though it is true that S.K. had been administered the Hepatitis B vaccine once prior (thus suggesting the second dose would prompt a more robust reaction), it is not apparent how the findings of Abbas translate into response times for *initial*, IgE-mediated allergic reactions. Abbas also notes that memory T cells react "much more rapidly and vigorously" during a secondary immune response than during the primary response—consistent with the other literature suggesting that an allergic response would be far more immediate. *Id.* This further undercuts Petitioner's argument that longer, delayed response times are typical of secondary immune responses. I therefore find that Petitioner has failed to meet her burden in establishing the third *Althen* prong with respect to her Hepatitis B-oriented claim.

III. Petitioner Has Not Preponderantly Established that the DTaP and IPV Vaccines Significantly Aggravated S.K.'s Preexisting Atopic Dermatitis

The parties agree that S.K. was already experiencing atopic dermatitis when she received the DTaP and IPV vaccines in mid-September 2018, and thereafter experienced symptoms for some period of time (although Respondent contests that this period was sufficiently severe to meet a core claim requirement). This leaves three primary issues to be resolved: (a) could these vaccines aggravate atopic dermatitis, (b) did they do so in this case, and (c) was the aggravation worse than what otherwise would be expected for a child already suffering from this condition. I find that Petitioner has not satisfied these elements.

[22] The second article Petitioner cited to in support of this proposition in Dr. Axelrod's report was not filed in this case. Axelrod Rep. at 4, 6. Instead, Petitioner filed an article from 1949 discussing the speed of secondary immune responses to various forms of tetanus toxoid (none of which are the same as the vaccines administered to S.K.). J. Miller et al., *The Speed of the Secondary Immune Response to Tetanus Toxoid with a Review of War Reports and Observations on Simultaneous Injection of Toxoid and Antitoxin*, 3 Pediatrics 64 (1949), filed as Ex. 31 on May 9, 2017 (ECF No. 18-5). I give this second article very little weight due to its age, as well as the fact that the study did not consider any of the vaccines at issue in this matter.

A. Petitioner has not Provided a Reliable Theory of Causation (Loving Factor Four)

The Fourth *Loving* factor largely tracks the first *Althen* prong, asking whether a petitioner has established a scientifically/medically reliable theory that the vaccine in question "could cause" aggravation of the alleged preexisting condition. *Loving*, 86 Fed. Cl. at 144. Here, Petitioner was unable to preponderantly establish that the vaccines S.K. received in September 2013 could trigger further adverse events in a person already suffering from atopic dermatitis.

The literature filed in this matter establishes that individuals already suffering from atopic dermatitis will likely display future additional sensitivity to *any* stimuli, vaccine or not, rendering them more disposed to experience other IgE-mediated inflammatory reactions. Fleischer at 581; *see* Weidinger at 1110 (noting that two-thirds of infants with moderate atopic dermatitis exhibit sensitization to food allergens). In large part, this may be due to the propensity of atopic individuals to overproduce IgE, and may also be attributed to the defective skin barrier caused by the ongoing inflammatory T_H2/T_H1 cycle and the damage it causes. *See* Wikas Rep. at 4; Schneider at 296.

As a result, allergens different from the initial dermatitis-causing exposure could exacerbate existing symptoms. Weidinger, for example, found that among children with moderate existing atopic dermatitis, exposure to food allergens sometimes resulted in IgE-mediated immediate reactions, such as pruritis, urticaria, and flushing. Weidinger at 1110. In some instances, that immediate reaction was later followed by worsening eczema and atopic dermatitis. *Id.* This sensitivity explains why skin prick tests in individuals with atopic dermatitis have higher rates of false positives, and why such an individual may experience an erythematous reaction even to saline controls. Weidinger at 1110. And as discussed by Respondent's expert, Dr. Spergel, the literature recognizes that irritant reactions resulting in erythema and exacerbated atopic dermatitis may also occur in atopic individuals following vaccination. *Id.* at 1109–11; Dreskin at 12; Zudaire at 312; Spergel Rep. at 3. Thus, Petitioner has offered *some* reliable evidence in favor of the conclusion that the IPV or DTaP vaccines could similarly aggravate existing atopic dermatitis (at least transiently).

In opposition to these arguments, Respondent again relies on the findings of Flohr and Grüber, which dealt specifically with the propensity of vaccines to cause or exacerbate atopic dermatitis—and they are equally persuasive in rebutting the significant aggravation claim. Grüber is especially difficult for Petitioner to overcome. Although she has cited some reliable subsequent review articles that support her contention that vaccines might exacerbate an existing case of atopic dermatitis (*see, e.g.*, Zudaire at 312), Petitioner has not rebutted Grüber, an epidemiologic study that goes directly to her central contentions in this case. As I have often noted, while petitioners need not *offer* epidemiologic evidence to prevail, I may consider those relevant studies that bear on a claim, and reliable studies are entitled to evidentiary weight. *McCollum v. Sec'y of Health & Human Servs.*, No. 14-790V, 2017 WL 5386613, at *17–18 (Fed. Cl. Spec. Mstr. Sept. 15, 2017),

mot. for review den'd, 135 Fed. Cl. 735 (2017), *aff'd*, 760 Fed. Appx. 1003 (Fed. Cir. 2019).

Overall, Petitioner's showing on this *Loving* element was not ultimately persuasive and was not aided by her expert showing. Respondent, on the other hand, offered credible and persuasive expert testimony that (coupled with the filed literature) substantially detracted from Petitioner's proffered theory. Because of the foregoing, my weighing process did not produce a finding in Petitioner's favor on the fourth *Loving* factor, despite the fact that Petitioner offered some reliable evidence. As science advances, and/or this issue is subject to further (or updated) study, more evidence may be developed that supports the kind of claim asserted herein. But it does not exist today. Under the legal standards I must apply, the evidence in this case does not support a finding that the DTaP and IPV vaccines can likely produce atopic dermatitis exacerbations.

B. Petitioner has Established a Worsening of S.K.'s Condition, but not a Causal Relationship Between Vaccination and the Exacerbation (Loving Factors Three and Five)

Petitioner has successfully demonstrated that S.K.'s atopic dermatitis worsened following vaccination, but she has failed to establish that the worsening was *due to* vaccination. *See Hennessey,* 2009 WL 1709053, at *42. Here, S.K.'s medical record, when amplified by Ms. Perekotiy's testimony and photographs, maps S.K.'s clinical course from onset to resolution of her atopic dermatitis. This evidence persuasively establishes that S.K.'s post-vaccination condition differed from her pre-vaccination condition in general severity. But for the reasons mentioned above, the relationship between S.K.'s worsening condition and the vaccines she received was most likely merely temporal—not causal.

On September 16, 2013—two days *prior* to receiving the two vaccines relevant to the significant aggravation claim—S.K. was evaluated by Dr. Petranu for redness and a rash. Ex. 7 at 15. His physical evaluation revealed that S.K. had flaky skin on her head and was positive for "erythematous, raw, macerated neck folds without drainage or crusting." *Id.* at 16. Even on the day of vaccination, S.K. displayed rough patches on her body, scalp flakiness, and red macules in her neck folds. *Id.* at 21. Thus, there was no evident change in S.K.'s condition, and no lower extremity involvement was noted during either of these visits.

The subsequent record is silent on an immediate reaction but is supplemented by Ms. Perekotiy's unrebutted contention that within minutes of the DTaP and IPV vaccines being administered, S.K.'s legs (the situs of administration) became purple. Statement of Anna Perekotiy at ¶ 5. Then, on October 27, 2013, Petitioner took a picture of S.K. where her legs appear to be covered in red splotches—a condition that was not previously noted in the medical record. Ex. 57. A second picture taken on November 1, 2013 again demonstrates extensive redness on S.K.'s legs, lower torso, and head. Ex. 58. These closer-in-time alleged reactions are corroborated by subsequent statements made to treaters about S.K.'s worsening condition. *See* Ex. 4 at 13; Ex. 10

at 1.[23]

As the overall record demonstrates, S.K.'s condition prior to her receipt of the September 2013 vaccinations did not involve her lower extremities and appeared limited to her scalp and neck. Ex. 7 at 16, 21. Thus, S.K.'s development of atopic dermatitis symptoms in her legs, where she had previously had no signs of the disease, establish the worsening of her pre-vaccination condition. But the record only supports a temporal association between the vaccination and subsequent leg rash—not that the vaccines themselves "more likely than not" caused a reaction thereby inducing the rash and subsequent exacerbation of atopic dermatitis.

First, as noted above, there is thin evidence suggesting that vaccines can cause or exacerbate atopic dermatitis generally. *See* Grüber at 1469. Petitioner's overreliance on the temporal association between S.K.'s exacerbation and vaccination is insufficient to sustain her claim in the face of scientific and epidemiological evidence to the contrary. *See Moberly*, 592 F.3d at 1323–24. Not all adverse post-vaccination events are caused by vaccination (since, were that the case, all a claimant would need to do to prevail in *any* Vaccine Act case would be to show onset of injury after vaccination).[24]

Second, the record does not otherwise persuasively link the DTaP or IPV vaccines to S.K.'s worsening. At best, Petitioner can point to the skin-prick testing performed by Dr. Jorgensen in the winter of 2014 as supporting the conclusion that S.K. was allergic to either the antigenic components of these two vaccines or their ingredients. Ex. 4 at 20, 25, 29. However (and as discussed above), S.K. could *not* have been predisposed to a response to these vaccines (whether antigenically-specific or to other components) before first receiving them in September 2018, and because she unquestionably was displaying symptoms of atopic dermatitis by this time, any post-vaccination reaction is equally if not more likely attributable to the general sensitivity a person with atopic dermatitis would display to any stimuli. Fleischer at 581; *see* Weidinger at 1110. In addition, Drs. Lobo and Spergel raised reasonable points about the reliability of Dr. Jorgensen's testing results, and they persuasively noted that there is no evidence in this case that S.K. did possess an allergy to latex or yeast. Dr. Lobo Rep. at 6; Spergel Rep. at 3; *see* Ex. 4 at 20, 25, 29 (discussing skin prick tests against IPV and DTaP generally, but also showing a failure to test against yeast and latex).

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[23] Although contemporaneous medical records are presumptively correct and are usually the best evidence of a particular contention like the date of occurrence of a symptom, subsequent records that consistently corroborate the symptom's occurrence at a particular time can preponderantly establish that as a fact, even if earlier records do not exist. *See, e.g.*, *Cooper v. Sec'y of Health & Human Servs.*, No. 16-1387V, 2018 WL 1835179, at *6–7 (Fed. Cl. Spec. Mstr. Jan. 18, 2018).

[24] The record also hints in places that Petitioner's reluctance to treat S.K. with prescribed steroidal topical creams or other medications may well *also* have been a factor in any worsening of the atopic dermatitis (or at least its failure to improve). *See, e.g.*, Ex. 7 at 25 (Dr. Barcellona noting that Petitioner was not using the prescribed steroids to treat S.K.'s dermatologic condition "because it is a steroid and steroids are 'bad.'"). This Decision, however, does not turn on the finding of such an alternative explanation.

Accordingly, even though Petitioner has preponderantly established that S.K.'s course worsened post-vaccination, she has not *also* shown that such worsening can be reliably vaccine-attributed. Petitioner relies too much on the obvious temporal relationship between vaccination and her subsequent symptoms. This is an insufficient basis for the conclusion that the DTaP and IPV vaccines caused S.K.'s atopic dermatitis exacerbation.

C. *Other Loving Factors*

The sixth and final *Loving* factor requires petitioners to establish a proximate temporal relationship between the significant aggravation of their condition and the received vaccine. *Loving*, 86 Fed. Cl. at 144. Petitioner maintains that S.K. experienced significant aggravation of her atopic dermatitis within minutes of receiving the IPV and DTaP vaccinations in both legs. Mot. for Ruling at 2 (citing Statement of Anna Perekotiy at ¶ 5).

Respondent correctly notes that the medical record from that September 2013 visit do not document any adverse reactions. Response to Mot. for Ruling at 3–4; Ex. 7 at 23–24. However, subsequent contemporaneous medical records pre-dating the initiation of this litigation are consistent with Petitioner's allegations. For example, a letter written by Dr. Jorgensen dated January 28, 2014 provides a medical history in which Petitioner reported S.K. developed redness in her legs the day she received the DTaP and IPV vaccinations. Ex. 4 at 13. In addition, and although not as persuasive as contemporaneous records, Petitioner's testimony and the consistency of her reporting in subsequent medical records preponderates in her favor. Thus, Petitioner has met her burden under the sixth *Loving* factor.

I will not provide a lengthy analysis of *Loving* factors one (establishing a petitioner's pre-vaccination condition) and two (establishing a petitioner's post-vaccination condition), because both parties appear to agree that S.K. experienced atopic dermatitis prior to and following her September 18, 2013 vaccinations. Mot. for Ruling at 2 (citing Ex. 7 at 22); Response to Mot. for Ruling at 14–15 (discussing the overall course of S.K.'s atopic dermatitis both before and after vaccination).

But despite these findings, Petitioner has not provided sufficient evidence to carry her burden; especially when rebutted with the epidemiological evidence offered by Respondent in this matter. Specifically, Petitioner's literature offered in support of her proposed theory, while appearing to be viable at first glance, was substantially outweighed by the Grüber epidemiological study, which found no causal connection between childhood vaccination and the development or exacerbation of atopic dermatitis. Similarly, Petitioner's experts failed to provide adequate support for the proposed theory. Though qualified to offer an opinion in the matter, Drs. Axelrod and Wikas were less credible overall in the opinions they offered when compared to Respondent's

expert, Dr. Spergel. Thus, I find that Petitioner has failed to meet her overall burden under *Loving.*

IV. Petitioner Has Met the Six-Month Severity Requirement

Besides contending that Ms. Perekotiy has not met her primary *Althen* or *Loving* evidentiary burdens, Respondent argues that S.K.'s atopic dermatitis course post-vaccination did not meet the six-month severity requirement set forth in Section 11 of the Vaccine Act. Response to Mot. for Ruling at 5–6. This argument was also the subject of Respondent's Motion to Dismiss. *See generally* Mot. to Dismiss.

According to Respondent, S.K. exhibited symptoms of atopic dermatitis between approximately August 27, 2013 and February 19, 2014, as noted by her treating physicians during physical examination. Response to Mot. for Ruling at 5–6; Ex. 7 at 15–19; Ex. 4 at 28. Physical examinations after February 19, 2014, however, were negative for dermatologic symptoms. Response to Mot. for Ruling at 5. Thus, Respondent contends, Petitioner cannot establish sufficient severity, since S.K.'s course of aggravated dermatitis was over within five months of vaccination.

Petitioner argues in response that subsequent records do in fact reference S.K.'s atopic dermatitis, describing a disease course of at least six months. *See, e.g.*, Ex. 6 at 8 (review of systems documenting a "present rash" as of June 16, 2015); Ex. 9 at 12 (Petitioner reported on September 16, 2015 a rash that lasted for one year); Ex. 12 at 3 (history of present illness prepared on September 15, 2015 describing Petitioner report of a rash that lasted for over a year). Petitioner also submitted a photograph of S.K. that was taken on March 29, 2014 (six months post-vaccination), in which S.K. still appears to have red, cracked skin on her lower extremities. Ex. 59.

I find that Petitioner has provided just enough evidence to preponderantly establish the six-month severity requirement. This determination does not arise solely from the medical record. While some of the medical records dated after February 2014 contain references to a rash lasting longer than six months, all of those references are contained in either the review of systems or past medical history sections—portions of the medical record that rely on patient reporting and are therefore subject to biases and mistaken memory. In addition, none of S.K.'s treating physicians documented present dermatologic symptoms during physical examination after February 2014. There is overall thin evidence to be found in the record that S.K.'s atopic dermatitis persisted for long as a concern.

Nonetheless, other corroborative evidence helps satisfy this core vaccine injury claim requirement. The March 29, 2014 photograph of S.K. (in which she displays a red, splotchy rash and cracked skin on her lower extremities) is particular trustworthy, probative evidence that S.K. did in fact continue to experience residual symptoms of her atopic dermatitis. I also give some

weight to the statements of Petitioner that S.K.'s dermatitis did not immediately subside despite the contrary suggestions of the medical record. These items of evidence, when weighed in light of the leniency and disposition toward generosity that the Program mandates petitioners are to receive, are enough to satisfy severity in this case, even if the evidence on this issue is close. *See, e.g.*, *Wright v. Sec'y of Health & Human Servs.*, 146 Fed. Cl. 608, 614 (2019) (emphasizing the need to keep in mind Program policy goals when evaluating severity); *see also Purtill v. Sec'y of Health & Human Servs.*, No. 18-832V, 2019 WL 7212162, at *6 (Fed. Cl. Spec. Mstr. Nov. 12, 2019) (close calls on elements of entitlement claims should be decided in a petitioner's favor), *citing Roberts v. Sec'y of Health & Human Servs.*, No. 09-427V, 2013 WL 5314698, at *10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013).

V. Respondent Has Established an Alternative Cause for S.K.'s Atopic Dermatitis

I also find that even if the Petitioner had met her primary burden of proof, Respondent would have met his shifted burden, because he has offered preponderantly-supported alternative causes for the exacerbation of S.K.'s atopic dermatitis. *See Althen*, 418 F.3d at 1278 (citing *Knudsen*, 35 F.3d at 547).

Specifically, Dr. Spergel proposed that S.K.'s exposure to egg via the breastmilk she was consuming could explain the exacerbation of her condition. Spergel Rep. at 5. Much of the literature in this matter supports the proposition that exposure to food allergens frequently exacerbates atopic dermatitis. *See, e.g.*, Weidinger at 1116 (emphasizing the importance of avoiding food allergens in children with atopic dermatitis). There is no dispute that S.K. was being breast-fed throughout this period. *See, e.g.*, Ex. 7 at 11, 19.

Petitioner's claim was undercut further by the fact that atopic dermatitis is understood to be *self-perpetuating*, independent of intervening factors. Once the skin barrier is compromised, more irritants may easily enter the body, refueling the T_H2/T_H1 cycle. Wikas Rep. at 4. Additionally, the itchy sensation produced by atopic dermatitis often leads to scratching and rubbing, which similarly perpetuates inflammation. K. Malik et al., *An Update on the Pathophysiology of Atopic Dermatitis*, 35 Dermatologic Clinics 317, 322–23 (2017), filed as Ex. C, Tab 4 on Feb. 25, 2019 (ECF No. 41-6). I find that these baseline aspects of the conditions all better explain any exacerbation experienced herein than the September 2018 vaccines.

CONCLUSION

This was a *difficult* case. I take S.K.'s condition seriously and the negative impact that it had on her life and those of her parents. Petitioner's good faith arguments were backed by many solid items of proof. But on the fundamental point of causation, it was not a *close* case. The Vaccine Act permits me to award compensation to a petitioner alleging a "non-Table Injury" only

if she can show by medical records or competent medical opinion that the injury was more likely than not vaccine-caused. The evidence in the record did not ultimately preponderate in a favorable ruling.

Accordingly, and for the aforementioned reasons, I DENY entitlement in this case. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMEN**T in accordance with the terms of this Decision.[25]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[25] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment it (jointly or separately) they file notices renouncing their right to seek review.