In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 11, 2025

KATERINA NOVITSKAYA, parent of N.G., a minor	*	
Petitioner,	*	No. 19-1214V
v.	*	Special Master Young
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.
Debra A. Filteau Begley, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On August 15, 2019, Katerina Novitskaya ("Petitioner") filed a petition in the National Vaccine Injury Compensation Program (the Program"),[2] on behalf of minor N.G., alleging that "[a]s a result of receiving the rotavirus, pneumococcal conjugate ("Prevnar 13"), and Pentacel vaccinations on June 30, 2017, N.G. suffered atopic dermatitis."[3] Pet. at 1, ECF No. 1. Respondent contested whether the vaccine caused N.G.'s injury, arguing that N.G.'s diagnosis was unclear and that she had a pre-existing topical infection which may have caused his condition. Resp't's Rept. at 7, ECF No. 16.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

[3] Atopic dermatitis is "a common, chronic type of dermatitis, thought to be hereditary, sometimes associates with other allergic conditions such as allergic rhinitis, hay fever, or asthma." *Atopic Dermatitis*, DORLAND'S ONLINE MED. DICTIONARY, https://www.dorlandsonline.com/dorland/definition?id=69246 (hereinafter, *Dorland's*).

A careful analysis and weighing of all the evidence and testimony presented in this case in accordance with the applicable legal standards[4], reveals that Petitioner has failed to provide preponderant evidence that one or more of the vaccines N.G. received on June 30, 2017, caused her to suffer from atopic dermatitis or any other condition. Accordingly, Petitioner is not entitled to an award of compensation.

I. Procedural History

Petitioner filed the petition on August 15, 2019. Pet. Petitioner filed medical records and a declaration on August 28, 2019, and additional medical records on November 25, 2019. Pet'r's Exs. 1–7, ECF No, 8; Pet'r's Exs. 8–9, ECF No. 9; Pet'r's Ex. 10, ECF No. 12. On April 27, 2020, Respondent filed his Rule 4(c) report opposing compensation. Resp't's Rept.

On March 5, 2021, Petitioner filed an expert report from Richard F. Horan, M.D. Pet'r's Ex. 11, ECF No. 25. On July 6, 2021, Respondent filed an expert report from Andrew MacGinnitie, M.D., Ph.D. Resp't's Ex. A, ECF No. 29. On March 9, 2022, Petitioner filed a supplemental expert report from Dr. Horan. Pet'r's Ex. 23, ECF No. 35.

In January 2024, the parties agreed via email communications to resolve the case with a ruling on the record in lieu of a hearing. Informal Comm., dated Jan. 24, 2024. Petitioner filed additional medical records on February 8, 2024. Pet'r's Ex. 24, ECF No. 37. On April 4, 2024, Petitioner field a motion for a ruling on the record and supporting brief. Pet'r's Mot., ECF No. 43. On June 3, 2024, Respondent filed a responsive brief. Resp't's Resp., ECF No. 45. And on July 10, 2024, Petitioner filed a reply brief. Pet'r's Reply, ECF No. 47. This matter is now ripe for consideration.

II. Factual History

A. Medical Records

1. Pre-Vaccination Medical Records

N. G. was born via cesarean section on April 27, 2017, following an uneventful pregnancy and delivery. Pet'r's Ex. 6 at 6–7. Dr. Neel Dipak Patel examined N.G. for her newborn examination at five days old and noted normal development, despite a nine percent decrease in birth weight. Pet'r's Ex. 4 at 46. N.G. was administered a hepatitis B vaccine without noted incident. *Id.* During N.G.'s one-month wellness examination on May 26, 2017, Dr. Patel diagnosed

[4] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

N.G. with baby acne and seborrhea.[5] *Id.* at 93. N.G. was unable to receive her second hepatitis B vaccination less than one month following her first, so it was postponed until her two-month wellness visit. *Id.*

2. Vaccination

On June 30, 2017, N.G. was seen for her two-month well visit. Pet'r's Ex. 4 at 109. She was assessed with cradle cap and received the Prevnar 13, rotavirus, and Pentacel (consisting of diphtheria, tetanus, acellular pertussis ("DTaP"), Haemophilus influenza B ("Hib"), inactivated poliovirus ("IPV")) vaccines during that check-up. *Id.* There were no noted adverse incidents at the time of vaccination. *Id.*

3. Post-Vaccination Medical Records

N.G. was taken to her pediatrician's office, approximately ten days later, on July 10, 2017, with a "rash on bilateral cheeks/ temples/ bilateral outer arms and extensor surfaces of legs." Pet'r's Ex. 4 at 132. N.G.'s "cradle cap on scalp" was also noted in her history of present illness. *Id.* Petitioner explained that N.G.'s rash persisted for the last four to five days but had become "more wet and oozy over the last few days." *Id.* Physical examination of N.G.'s skin revealed "bilateral cheeks with significant seb[orrheic] dermatitis rash with right upper cheek/temple [one] cm patch of crusting and serious discharge. +cradle cap on scalp. +scattered dry patches on bilateral upper outer arms and legs." *Id.* at 133. Dr. Sawsan Salman Kara assessed N.G. with seborrheic dermatitis,[6] cradle cap, and impetigo.[7] *Id.* N.G. was prescribed hydrocortisone as needed and a ten-day course of mupirocin. *Id.* Petitioner was advised to avoid scented soaps and detergents, and she was encouraged to apply thicker emollients to N.G. after baths and several times during the day. *Id.* Dr. Kara emailed Dr. Patel on the evening of July 10, 2017, to note that N.G. had "quite extensive seb[orrheic] dermatitis rash with overlying localized infection." *Id.* at 158.

On July 19, 2017, Dr. Kara evaluated N.G. again for sebaceous dermatitis and a secondary infection. Pet'r's Ex. 4 at 166. Petitioner explained that she was applying mupirocin three times a day, but N.G was not improving. *Id.* She was not, however, applying the hydrocortisone cream. *Id.* N.G. was still exhibiting fluid discharge from her cheeks and golden crusting, there was a possible new patch of crusting on one shoulder, and she exhibited a newer rough rash on her legs. *Id.* On examination, the "rash" on N.G.'s legs was described as "skin colored papules." *Id.* at 167. N.G. was assessed with impetigo, and "superinfected" seborrheic dermatitis. *Id.* at 171. She was prescribed an antibiotic. *Id.*

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[5] Seborrhea is "excessive secretion of sebum." *Seborrhea*, *Dorland's*. Sebum is "the secretion of the sebaceous glands, a thick, semifluid substance composed of fat and epithelial debris from the cells of the malpighian layer." *Sebum*, *Dorland's*.

[6] Seborrheic dermatitis is "chronic dermatitis with itching, erythema, dry, moist, or greasy scaling, and yellow crusted patches on the face, scalp, or elsewhere on the body; on the scalp the patches start out small but slowly spread and may become widespread, with exfoliation of many dry scales (dandruff). The etiology of this condition is unknown." *Seborrheic Dermatitis*, *Dorland's*.

[7] Impetigo is "a contagious pyoderma, caused by direct inoculation of Staphylococcus aureus or occasionally a group A streptococcus into superficial cutaneous abrasions or compromised skin, usually on the face or a limb." *Impetigo*, *Dorland's*.

Dr. Kara provided Petitioner with patient instructions re: pediatric impetigo. Pet'r's Ex. 4 at 163. The informational sheet explained that impetigo is a skin infection that is common in babies and children and caused by two types of bacteria: Staphylococci or Streptococci. *Id.* The infection causes blisters when the bacteria gets under the surface of skin due to a cut, scrape, scratch, insect bite or other skin damage. *Id.* at 163–64. Impetigo is contagious and spreads easily in daycare or other crowded settings. *Id.* at 164. The information provided by Dr. Kara also listed signs and symptoms to include yellow discharge or pus from the site of burst blisters and swollen lymph glands. *Id.*

N.G. saw Dr. Patel on July 20, 2017, for a follow-up. Pet'r's Ex. 4 at 187. Petitioner explained that N.G.'s rash initially appeared two weeks prior on her cheeks and did not resolve when moisturizer was applied. *Id.* The rash also spread to her arms and legs and failed to improve with mupirocin and hydrocortisone creams. *Id.* Petitioner stated her hesitancy about giving N.G. antibiotics and reported that she stopped application after the first dose. *Id.* Dr. Patel obtained a skin culture and assessed infant seborrhea likely secondary to impetigo, and cradle cap. *Id.* at 188. Dr. Patel stated that antibiotics would be withheld pending a culture. *Id.* at 189. Petitioner was again encouraged to apply hydrocortisone cream to N.G.'s skin. *Id.* On July 24, 2017, Dr. Patel notified Petitioner that the culture was negative. *Id.* at 205.

On August 16, 2017, N.G.'s father called Dr. Patel's office and requested an "urgent referral" to dermatology. Pet'r's Ex. 4 at 209. A referral was provided and on August 22, 2017, N.G. was evaluated by pediatric dermatologist, Dr. Amy Gilliam. *Id.* at 220. In addition to the history previously provided, Petitioner and her husband reported that N.G. was "very itchy." *Id.* Petitioner explained that she was using organic soaps and balm, and, because she was still breastfeeding N.G., she was avoiding dairy, gluten, soy, and eggs in her diet. *Id.* She stated that she was still hesitant to use hydrocortisone cream on N.G. because she was worried it would ultimately result in a more severe skin condition. *Id.* Petitioner also expressed concern that N.G.'s eczema was triggered by her vaccinations given at two months of age. *Id.* On examination, N.G. exhibited diffuse areas of pink papules forming plaques with some erosion and crusting on her arms, legs, and trunk. *Id.* at 222. She also had weeping skin in the axillae and neck flexures. *Id.* Dr. Gilliam assessed N.G. with overlapping moderate to severe atopic and seborrheic dermatitis, impetigo, and yeast overgrowth. *Id.* Dr. Gilliam recommended apple cider vinegar baths and regular application of corticosteroids. *Id.* Dr. Gilliam also explained, "I do not believe [N.G.'s] [two-]month vaccines caused the eczema – it was probably destined to happen although vaccines and immune stimuli (i.e. illnesses) can trigger flares of eczema." *Id.*

N.G was seen by Dr. Patel for her four-month wellness visit on September 15, 2017. Pet'r's Ex. 4 at 234. Petitioner stated that she had only just started applying steroid cream to N.G. "a few days" prior to this appointment. *Id.* Petitioner recounted Dr. Gilliam's explanation that vaccines could trigger an eczema flare and refused to consent to any more vaccinations for N.G. *Id.* Dr. Patel noted that Petitioner "did not internalize that [Dr. Gilliam] also stated that she did not think it was likely that the vaccines caused the seborrhea." *Id.* During a follow-up visit with Dr. Patel on September 29, 2017, Petitioner explained that she was now supplementing N.G.'s diet with formula, and she was putting on weight. *Id.* at 248. She was also applying steroid cream with some

improvement, but she was not using the cream consistently. *Id.* Dr. Patel recommended that Petitioner apply the steroid cream more regularly. *Id.*

On October 13, 2017, Petitioner completed an online consultation at www.eczemaspecialist.com with Dr. John Van Wagner. Pet'r's Ex. 7 at 11. Petitioner submitted photographs to Dr. Van Wagner, and he responded that N.G. likely had a "very significant [S]taph aureus infection complicating the skin in addition to the uncontrolled eczema dermatitis." *Id.* He recommended a topical compound of antibiotics, steroids, and moisturizer. *Id.* Petitioner then sent that consultation to Dr. Patel who agreed that the cream recommended by Dr. Van Wagner could be helpful for N.G. Pet'r's Ex. 4 at 259.

During a return visit with Dr. Patel on November 21, 2017, N.G. was "much improved," following consistent use of the compound cream recommended by Dr. Van Wagner. Pet'r's Ex. 4 at 277. Petitioner stated her desire to delay further vaccinations until N.G.'s two-year evaluation. *Id.* However, N.G. was given her second DTaP vaccine during N.G.'s nine-month evaluation, on February 6, 2018. Pet'r's Ex. 7 at 330. On April 26, 2018, N.G. was seen for her 12-month evaluation, and her parents agreed to start administering one vaccine at a time, although she did not have any that day due to nasal congestion. Pet'r's Ex. 6 at 5–6. Petitioner did not report a flare of N.G.'s skin condition after her DTaP vaccine in February, but Dr. Patel observed "[a]topic patch at left cheek and lower extremities" during her 12-month examination. *Id.* at 9. N.G. did not present for a 15-month wellness check; but on September 25, 2018, Petitioner returned to Dr. Patel and reported that N.G.'s dermatitis was better. Pet'r's Ex. 10 at 28. On examination, N.G. did not have any skin findings. *Id.* N.G. remained on her one vaccination per visit schedule and was given a measles, mumps, and rubella ("MMR") vaccine. *Id.* at 30.

On October 13, 2018, N.G. was brought to urgent care after developing a rash over her entire body one-hour prior to arrival. Pet'r's Ex. 10 at 47. Her parents stated that her rash started abruptly one-hour after a dinner that included pecans. *Id.* On examination, N.G. was noted to have "erythematous diffuse raised itchy lesions and scattered patches of dry skin." *Id.* She was assessed with hives associated with a possible pecan allergy, treated with Benadryl, and discharged. *Id.* On May 30, 2019, N.G. was seen by Dr. Patel for a rash, cough, and nasal congestion. *Id.* at 270. Petitioner was also out of the topical cream used to manage N.G.'s skin condition. *Id.* Dr. Patel noted an atopic rash on N.G.'s chin that was possibly infected, and other areas of dermatitis on her body. *Id.* Dr. Patel also indicated that N.G. may have seasonal allergies and refilled her prescription. *Id.*

B. Petitioner's Declaration

Petitioner filed a declaration on August 28, 2019, noting that her daughter was born healthy on April 26, 2017. Pet'r's Ex. 8 at ¶ 1. Petitioner acknowledged that her daughter "developed some cradle cap and baby acne, which her pediatrician said was perfectly normal." *Id.* Petitioner described how N.G. received several vaccines on June 30, 2017, and later that day, "seemed to be in pain and was crying throughout the day." *Id.* at ¶ 2. On July 2, 2017, Petitioner "noticed [N.G.] rubbing her face," and "the next day, a red rash appeared on her cheek." *Id.* at ¶ 3. The rash spread all over N.G.'s face, "became inflamed, and began to ooze a yellowish fluid." *Id.* It continued to spread to her arms and legs. *Id.*

N.G.'s pediatrician prescribed an antibacterial ointment, which "did not seem to help" and a steroid ointment, which Petitioner did not use. Pet'r's Ex. 8 at ¶ 4. N.G.'s pediatrician then tried an oral antibiotic, but Petitioner "was uncomfortable giving her that because she was not showing signs of a bacterial infection." *Id.* at ¶ 5. Petitioner did independent research once Dr. Gilliam diagnosed N.G. with atopic and seborrheic dermatitis. *Id.* at ¶ 7. She then began to try a serious of holistic treatments. *Id.*

Eventually, Petitioner spoke with a dermatologist that recommended a treatment "of compounding steroid ointment and antibacterial ointment heavily diluted with regular cream" that she was open to trying. Pet'r's Ex. 8 at ¶ 9. The medication helped, but the dermatitis has not gone away. *Id.* at ¶¶ 9–11. N.G. scratches a lot and must "wear pants and socks no matter how hot it [i]s outside." *Id.* at ¶ 10. Petitioner explained that N.G. has developed scars on her legs from scratching and they must "continue to apply her compound cream multiple times a day on her rash areas, including her face, neck, arms, legs, chest, and stomach." *Id.* at ¶11.

III. Expert Reports

A. Expert Review

1. Petitioner's Expert, Richard F. Horan, M.D.

Dr. Horan is board certified in allergy and immunology. Pet'r's Ex. 12 at 1. He received his M.D. from Harvard Medical School and subsequently completed a residency in dermatology and a clinical fellowship in rheumatology, immunology, and dermatology. *Id.* He is currently an Assistant Clinical Professor of Dermatology at Harvard Medical School, as well as on staff at Brigham and Women's Hospital, Faulkner Hospital, and Dana Farber Cancer Institute. *Id.* at 1–2. He is also a dermatologist at Center Dermatology. *Id.* at 2. Dr. Horan has numerous publications. *Id.* at 5–8.

2. Respondent's Expert, Andrew MacGinnitie, M.D., Ph.D.

Dr. MacGinnitie is board certified in allergy and immunology as well as in pediatrics. Resp't's Ex. A at 2. He received his Ph.D. in pathology and his M.D. from the University of Chicago. Resp't's Ex. B at 1. He subsequently completed a residency in pediatrics and fellowships in allergy/immunology and pediatrics. *Id.* He is currently an Associate Professor of Pediatrics at Harvard Medical School and Attending Physician well as the Clinical Chief for the Division of Immunology at Boston Children's Hospital. Resp't's Ex. A at 1. In his active practice, he sees more than 1,600 patients annually and routinely treats patients with atopic dermatitis, including infants. *Id.* at 2. He also occasionally supervises the Atopic Dermatitis Center "which provides comprehensive care for infants and children with severe atopic dermatitis." *Id.* Dr. MacGinnitie has published numerous articles. Resp't's Ex. B at 12–16.

B. Expert Reports

1. Petitioner's Expert, Dr. Horan

Dr. Horan noted that prior to the vaccinations at issue in this case, N.G. suffered from seborrhea of infancy and baby acne. Pet'r's Ex. 11 at 1. Post vaccination, in July of 2017, N.G. developed a rash on her arms and legs "consistent with atopic dermatitis and inconsistent with seborrheic dermatitis, which would be confined to her scalp and face." *Id.* According to Dr. Horan, infantile acne is common and is unrelated to the atopic dermatitis that manifested in this case as "extensive eczema on the arms, legs, and trunk." Pet'r's Ex. 23 at 3. Dr. Horan further explained that N.G.'s dermatitis likely "developed before any infection." Pet'r's Ex. 11 at 1.

Dr. Horan agreed with N.G.'s treaters on her diagnosis and stated that the dispute in this case centered on the cause of her condition. Pet'r's Ex. 11 at 2. He noted that "the epidemiologic literature on this point does not identify a causal relationship between vaccinations and atopic dermatitis." *Id.* at 4. Dr. Horan also agreed with N.G.'s pediatrician that "a variety of intercurrent environmental processes [] can trigger atopic dermatitis." *Id.* However, he noted "there has been suggestion that later rather than earlier administration of DTaP immunization to infants may be associated with some decreased risk of atopic dermatitis." *Id.*

In support of this contention, Dr. Horan cited the Gehrt et al.[8] article which recorded "a 6% lower risk of developing new cases of more severe atopic dermatitis between age [four] months and age [one] year in a cohort of nearly 900,000 Danish children," that received their first dose of DTaP vaccine on a schedule delayed by at least one month. Pet'r's Ex. 14 at 1. By way of introduction, the article noted that 25% of children in "high income countries" suffer from atopic dermatitis, with "up to 90% of cases [occurring] within the child's first year of life." *Id.* at 2. The authors conceded that the etiology is unknown, but asserted that "skin barrier dysfunction, heritable and environmental factors, and activation of immune responses" are involved. *Id.* There was acknowledgment of potential bias within the study related to ascertainment, i.e., "families who consult their physician less often would be less likely to get their children vaccinated on time and less likely to present their child with [atopic dermatitis] symptoms." *Id.* at 7. However, if this health care-seeking behavior resulted in bias, the expectation would be "higher rates of timely vaccination among children who are diagnosed with [atopic dermatitis] before the date of recommended vaccination." *Id.* However, there was not evidence of this. *See id.* The authors cautioned that "because all children eventually receive the vaccine, the results of the analyses only pertain to the modifying effect of timing of vaccination, and it is not possible to attribute any risk of [atopic dermatitis] to vaccination with DTaP vaccine alone." *Id.* at 8.

While acknowledging the mechanism of vaccine-induced dermatitis is unknown, Dr. Horan asserted that "TH2 cytokines are considered to play a role in the pathogenesis of atopic dermatitis." Pet'r's Ex. 11 at 4. Likewise, "[e]levated TH2 cytokine levels have been associated

[8] Lise Gehrt et al., *Timeliness of DTaP-IPV-Hib Vaccination and Development of Atopic Dermatitis Between 4 Months and 1 Year of Age—Register-Based Cohort Study*, 9 J. ALLERGY & CLINICAL IMMUNOLOGY PRACTICE 1520 (2010).

with immunization." *Id.* The Berger[9] Science Commentary article was filed by Dr. Horan and generally discussed the role of Th2 cytokines in the immune system. Pet'r's Ex. 16 at 1. Cytokines are defined as "the hormonal messengers responsible for most of the biological effects in the immune system." *Id.* Th2 cytokines are produced by T lymphocytes that "bear antigen specific receptors on their cell surface to allow recognition of foreign pathogens." *Id.* Specifically, Th2 cytokines can act as a balance to Th1 cytokines and have an anti-inflammatory effect. *Id.* The article noted, "[s]ome people have suggested that immunisation programmes (and the subsequent reduction in microbiological exposure) are responsible for the increasing incidence of atopy. There is, however, no evidence that immunisation causes atopy." *Id.* Brandt & Sivaprasad[10] also suggested further research into "the role of Th2 cytokines in [atopic dermatitis]." Pet'r's Ex. 17 at 8. "Given the complex nature of [atopic dermatitis] – with genetic, and environmental risk factors – resulting in either defective skin barrier function, or altered immune function, a great deal of work remains to be done to delineate the components that contribute to [atopic dermatitis], both in maintaining skin barrier integrity, and modulation of immune responses." *Id.*

The Rowe et al.[11] article noted that as of 2005, the DTaP vaccine "ha[d] an improved safety profile in infants, but little information [wa]s available concerning the nature of the ensuing immunological memory in older children." Pet'r's Ex. 18 at 1. As a result, the researchers sought to access "vaccine antigen-specific humoral and cellular responses to boosting with DTaP in 4- to 6-year-old children primed during infancy." *Id.* The authors found large local reactions in 43% of children following the booster that "were associated with vigorous T helper 2 (Th2)-polarized memory responses to vaccine antigen." *Id.* The study results "suggest[ed] that the underlying mechanism involves reactivation of Th2-polarized cellular immune memory." *Id.* Rowe et al. also included a "post hoc analysis of immunological data collected on . . . the reactogenicity of DTaP-IPV vaccine." *Id.* at 4. Analysis "suggest[ed] the possibility that reactivation of Th1-polarized poliovirus-specific memory cells by IPV may provide "bystander" feedback inhibition of the Th2 component of DTaP-specific memory, both locally and in the draining lymph node." *Id.* at 5.

Dr. Horan noted that while seborrheic dermatitis and infantile acne are very common in babies, "significant atopic dermatitis on the arms, legs, and trunk is not [a] common progression," of either of those conditions. Pet'r's Ex. 11 at 4. However, the timing of the dermatitis following N.G.'s series of vaccines is suggestive of a relationship, and Dr. Horan identified "the transient promotion of a TH2 immune response to the two-month vaccines as the causal mechanism. *Id.* Dr. Horan argued that the "[t]he lack of defined and precise immunochemical model for the inflammatory response in this patient is not an impediment to seeing cause and effect." Pet'r's Ex. 23 at 1. He continued that in most clinical entities, "a precise model with sequential step-by-step descriptions of what occurs during a complex immune response" is lacking. *Id.*

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[9] Abi Berger, *Science Commentary: Th1 and Th2 Responses: What Are They?*, 321 BMJ 424 (2000).
[10] Eric B. Brandt & Umasundari Sivaprasad, *Th2 Cytokines and Atopic Dermatitis*, 2 J. CLINICAL CELLULAR IMMUNOLOGY 110 (2011).
[11] Julie Rowe et al., *Th2-Associated Local Reactions to the Acellular Diphtheria-Tetanus-Pertussis Vaccine in 4- to 6-Year-Old Children*, 73 INFECTION & IMMUNITY 8130 (2005).

Dalton et al.[12] recorded two cases studies that focused on exacerbation of atopic dermatitis following bacillus Calmette-Guerin [("bCG")] vaccination. Pet'r's Ex. 20 at 1. The studies involved an 11-year-old boy and a 12-year-old girl who suffered from atopic dermatitis since infancy and experienced severe flares one week and two days post vaccination, respectively. *Id.* The authors acknowledged that "[c]ause and effect cannot be proved in these two cases." *Id.* at 2. However, they hypothesized that the bCG vaccine initiates a process that leads to production of Th2 cytokines "thus stimulating B cells, eosinophils and mast cells-responses . . . thought to mediate the tissue damage seen in patients with atopic dermatitis. *Id* The theory begins with a genetic susceptibility that leads to the migration of activated lymphocytes and increased cytokine production at a site already inflamed due to pre-existing atopic dermatitis. *Id.* The bCG vaccine acts "as a superantigen, [and] may induce expression of cutaneous lymphocyte associated (CLA) antigen on T cells, with such CLA+ cells preferentially accumulating in inflamed skin." *Id.*

Dr. Horan explained that in the present case, "a bacterial infection would not be the cause of the condition, but can often cause a widespread flareup of an existing atopic dermatitis." Pet'r's Ex. 11 at 3. Noting that the culture from N.G.'s sample was negative, Dr. Horan cautioned that "a negative culture does not exclude the possibility of localized Staph aureus causing a diffuse flare." *Id.* In sum, Dr. Horan stated that "the occurrence of atopic dermatitis after vaccination is consistent with the immunobiology, physiology, and time course in relation to the vaccinations." Pet'r's Ex. 23 at 1. In this specific case, "[t]he issue of causation relates to the specific flare and associated symptoms and discomfort in this child." *Id.*

Petitioner also filed the Wood et al.[13] article that discussed vaccine allergies and noted that eczema is a type of T-cell mediated allergy that can occur following vaccination. Pet'r's Ex. 19 at 2. The article noted that onset for these type III hypersensitivity reactions are delayed and "usually manifest in the form of local eczema, starting from [two to] 8 hours up to [two] days after vaccination. Sometimes the reaction may extend beyond the injection area and may even become generalized." *Id.* at 3.

2. Respondent's Expert, Dr. MacGinnitie

Dr. MacGinnitie, briefly summarized Petitioner's medical records and provided definitions of relevant conditions. Resp't's Ex. A at 3–7. He agreed with Dr. Horan's explanation of eczema, noting that although the technical definition refers to a specific type of rash, "in practice, pediatricians, allergists and dermatologists often use eczema interchangeably with atopic dermatitis, a practice which has also been noted in the literature." *Id.* at 6–7. Atopic dermatitis, he also described as a specific type of rash, this one usually seen in young children "start[ing] about [two to six] months of age." *Id.* at 7. He noted that atopic dermatitis "is characterized by both decreased barrier function of the skin and immune mediated inflammation." *Id.* Dr. MacGinnitie explained that "[s]cratching is thought to play a key role in the pathophysiology, which in turn, "help[s] trigger inflammation." *Id.* Lastly, Dr. MacGinnitie defined seborrheic dermatitis as "a rash often seen in neonates, typically on the scalp with thick, greasy scales." *Id.*

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[12] S.J. Dalton et al., *Exacerbation of Atopic Dermatitis After Bacillus Calmette-Guérin Vaccination*, 91 J. ROYAL SOC'Y MED. 133 (1998).

[13] Nicholas Wood et al., *Antibody and Cell-Mediated Immunity to Pertussis 4 Years After Monovalent Acellular Pertussis Vaccine at Birth*, PEDIATRIC INFECTIOUS DISEASE J. 33 J. 511 (2014).

Dr. MacGinnitie stated that he "did not take from Dr. Horan's report a coherent, step-by-step theory by which vaccination triggered N.G.'s eczema." Resp't's Ex. A at 7. He understood Dr. Horan's theory to involve the vaccine-induced "production of Th2 cytokines which are also involved in atopic dermatitis." *Id.* Dr. MacGinnitie asserted that "Dr. Horan does not provide any details of which cytokines were involved, describe a pathway by which vaccination might have triggered onset . . . , or offer any explanation how his theory would support an onset five or six days after vaccination." *Id.*

Warning that 15-20% of children will suffer from atopic dermatitis at some point between two and six months of age, Dr. MacGinnitie noted that many vaccinations occur during this time and asserted that "[i]t is important not to confuse temporal correlation with causality." Resp't's Ex. A at 7–8. Instead, Dr. MacGinnitie argued that many patients who suffer from seborrheic dermatitis go on to suffer from atopic dermatitis. *Id.* at 8. He asserted that "although the pathophysiology of [seborrheic dermatitis] is not well understood, recent data suggest that skin barrier dysfunction and colonization with bacteria including Staphylococcus aureus are important predisposing factors for both." *Id.* This progression is supported by N.G.'s presentation and "the fact that Dr. Gillam, the pediatric dermatologist who cared for N.G., diagnosed her with seborrheic dermatitis/atopic dermatitis overlap." *Id.* (citing Pet'r's Ex. 4 at 220–23). Dr. MacGinnitie opined that N.G.'s seborrheic and atopic dermatitis "most likely represent overlapping manifestations of the same underlying skin disorder. As her [seborrheic dermatitis] was present *prior* to her [two]-month vaccinations cannot have triggered the onset of her skin disorder." *Id.* (emphasis in original). In support of this contention, Dr. MacGinnitie relied on the Mimouni et al.[14] article which focused on 191 children, aged four to 13 years, that were diagnosed with infantile seborrheic dermatitis. Resp't's Ex. A, Tab 5 at 1. A follow-up with 88 of the children 9.6 years (median) later, revealed five with atopic dermatitis. *Id.* at 2. The authors stated, "[t]he finding that 6% of our patients had atopic dermatitis suggests that in a minority of patients infantile seborrheic dermatitis may be indistinguishable from atopic dermatitis, even when strict clinical diagnostic criteria are used." *Id.* A second article, published in 1986 by Podmore et al.[15] compared a "group of 76 children diagnosed as having seborrheic eczema and a group of 62 children seen over the same time period at the same clinic and diagnosed as having atopic eczema." Resp't's Ex. A, Tab 6 at 1. The authors found that "although seborrheic eczema and atopic eczema in infancy have a higher than normal incidence of atopic manifestations in later childhood and thus seborrheic eczema may be part of the spectrum of atopic disease with resultant prognostic implications." *Id.* at 9.

Dr. MacGinnitie also submitted the Chadha & Jahnke[16] article discussing common neonatal rashes. Resp't's Ex. A, Tab 2 at 1. Chadha & Jahnke noted that atopic and seborrheic dermatitis are similar in their sites of involvement (face, ears, and trunk) and often initially overlap. *Id.* at 5. However, seborrheic dermatitis "usually resolves spontaneously around age [six] months," and is not indicated by symptoms of pruritus and oozing. *Id.* at 24. By comparison, atopic dermatitis "commonly develops between ages [three] and [six] months." *Id.* Symptoms include "erythema, edema, papules, vesicles, oozing, and crusting. Pruritus is a hallmark feature." *Id.* The

[14] Karin Mimouni et el., *Prognosis of Infantile Seborrheic Dermatitis*, 127 J. PEDIATRICS 744 (1995).
[15] P. Podmore et al., *Seborrheic Eczema—A Disease Entity Or A Clinical Variant of Atopic Eczema?*, 115 BRIT. J. DERMATOLOGY 341 (1986).
[16] Angad Chadha & Marla Jahnke, *Common Neonatal Rashes*, 48 Pediatric Annals e16 (2019).

authors noted "[e]pidermal barrier dysfunction, immune dysregulation, and environmental exposures play a role in the pathogenesis." *Id.*

The Stander[17] article focused on atopic dermatitis and listed common coexisting conditions in patients, "including food allergies (especially in children), allergic rhinitis, rhinoconjunctivitis, and asthma." Resp't's Ex. A, Tab 3 at 4. There was also an increased "risk for the development of bacterial, viral, or fungal skin infections due to skin barrier defects, bacterial skin colonization (especially by Staphylococcus aureus), and an altered skin microbiome." *Id.* The author identified "[t]he proximate mechanism for eczematous lesions [as] inflammation related to dysregulation of Th2 cells." *Id.* at 31. She explained that the inflammation is thought to be initiated by disruption of the epidermal barrier and activation of epidermal inflammatory dendritic and innate lymphoid cells, which attract and interact with invading Th2 cells." *Id.*

Dr. MacGinnitie also discounted any possibility that N.G.'s subsequent vaccinations exacerbated her atopic dermatitis. Resp't's Ex. A at 8–9. He noted that assuming Dr. Horan's causation theory is applicable, "one would expect subsequent vaccinations to trigger [production of Th2 cytokines that result in] flares of N.G.'s [atopic dermatitis], but this was not observed." *Id.* Specifically, N.G.'s second DTaP vaccination did not result in a flare of her dermatitis, and "she was not brought back for treatment until almost 60 days later, on April 26, 2018." *Id.* at 8.

Both experts agreed that "the epidemiologic literature on this point does not identify a causal relationship between vaccinations and atopic dermatitis." Pet'r's Ex. 11 at 4; Resp't's Ex. A at 9. Dr. MacGinnitie supported this contention with the Ayasse[18] article that concluded, "[n]o vaccine regimen was consistently associated with developing [atopic dermatisis]." Resp't's Ex. A, Tab 9 at 2. The authors considered 6,515 articles, published from 1997 to 2018, to identify relevant articles "with primary epidemiologic data reporting the prevalence of [atopic dermatitis] in patients receiving a vaccination or related vaccination adjuvant." *Id.* Ultimately, the review included "44 studies and meta-analysis of 37 studies [and] found no consistent associations of vaccination by any regimen, and particularly BCG, pertussis, or multiple vaccines with [atopic dermatitis] in pooled meta-analysis." *Id.* at 6. The authors noted "there were no randomized control trials comparing development of [atopic dermatitis] in children who were vs. were not vaccinated." *Id.*

Dr. MacGinnitie also responded to the literature that Dr. Horan submitted in support of causation. Resp't's Ex. A at 9. Dr. MacGinnitie argued that the results from the Rowe et al. article were inapplicable to N.G.'s case because the study related to booster shots and identified "large localized reactions to DTaP of redness and swelling at the injection site of vaccination in [four to six] year old children, not [atopic dermatitis, seborrheic dermatitis], or eczema." *Id.* (citing Pet'r's Ex. 18). Dr. MacGinnitie further noted that the Dalton et al. case studies were irrelevant because N.G. was not comparable in age to these subjects, had not received a booster at the time of her dermatitis onset, and did not exhibit "redness and swelling at the site of vaccination." *Id.* (citing Pet'r's Ex. 20).

[17] Sonja Stander, *Atopic Dermatitis*, 384 NEJM 1136 (2021).
[18] Marissa Ayasse et al., *Vaccines Do Not Cause Atopic Dermatitis: A Systematic Review and Meta-Analysis*, 39 VACCINE 1805 (2021).

IV. Applicable Legal Standards

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as modified by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. den'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a

'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322 and *LaLonde*, 746 F.3d at 1339). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357,1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* requires that courts determine the reliability of an expert opinion before it may be considered as evidence. 509 U.S. 579 (1993). However, in the Vaccine Program, the *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely 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."); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). Under *Daubert*, the

> 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 are "meant to be helpful, not definitive." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999). The factors do not "constitute 'a definitive checklist or test'" and may be applied differently depending on the facts of a particular case. *Id.* at 150 (quoting *Daubert*, 509 U.S. at 593).

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. 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 v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. 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; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "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.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record." *Id.*

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must also show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547. In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen*, 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" § 13(a)(2); *see also Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

V. Discussion

A. *Althen* Prong One

Petitioner's expert Dr. Horan argued in favor of vaccine-caused atopic dermatitis based on a belief in the medical community that Th2 cytokines play a large role in the immune cell-mediated condition and studies that have revealed elevated Th2 cytokine levels post immunization. Indeed,

there are several articles filed by Petitioner and Respondent that illustrate the paramount role of Th2 cytokines in the immune system generally. Furthermore, the nature of a patient's immune system response to a foreign antigen is central to vaccine efficacy, as well as the development of an allergic dermatological condition. However, as Respondent's expert Dr. MacGinnitie noted, Dr. Horan did not present any support for his contention that the elevated levels of Th2 cytokines that develop post vaccination result in the diffuse inflammation and epidermal barrier dysfunction that is the hallmark of atopic dermatitis. In plainer language, there is no link between the presence of Th2 cytokines due to vaccination and pathogenesis. Th2 cytokines are key proteins used by the immune system's early line of defense against invaders. It may be just as well that elevated Th2 cytokines may be a component of an adaptive immune response and not the impetus for one.

The Berger article filed by Petitioner noted that despite suggestions of a possible relationship, there is "no evidence of that immunsation causes atopy." Pet'r's Ex. 16 at 1. A second article, Dalton et al., cautioned that even pursuant to a hypothesis that a vaccine can exacerbate atopic dermatitis, "[c]ause and effect cannot be proven." Pet'r's Ex. 20 at 2. Furthermore, unlike in the current case, the theory presented by Dalton et al. applies to pre-existing atopic dermatitis that is worsened by the live bCG vaccine. Notably, Dr. Horan focused on N.G.'s DTaP vaccine for his causation theory and not the live rotavirus that N.G. received. Petitioners are not required to present evidence of proven cause and effect. However, the theory presented must be sound and reliable. It is not enough to identity a component of the immune system without explaining how said component's upregulation is indicia of but-for or substantial factor causation.

Lastly, Petitioners are not required to present epidemiological studies in support of their claims. Indeed, the Federal Circuit has explicitly identified the types and uses of many different types of medical evidence that can be used to constitute preponderant evidence of causation, solely or in the aggregate. *See Broekelschen*, 618 F.3d 1339; *Knudsen*, 35 F.3d 543. In cases where large scale studies have been done however, they are certainly persuasive evidence to be considered on behalf of the submitting party. In this case, Dr. MacGinnitie filed the Ayasse et al. article "with primary epidemiologic data" which "found no consistent associations of vaccination by any regimen . . . with [atopic dermatitis] in pooled meta-analysis." Resp't's Ex. A, Tab 9 at 2. While not dispositive, this certainly qualifies as strong evidence that was not adequately addressed by Dr. Horan. In sum, Petitioner did not provide preponderant evidence that one or more of the vaccines she received, rotavirus, Prevnar 13, or Pentacel, can cause atopic dermatitis.

B. *Althen* Prong Two

Without the articulation of a sound and reasonable theory pursuant to *Althen* prong one, it is impractical to conduct the prong two analysis. Using aspects of the medical literature that Dr. Horan filed, the absence of an initial localized hypersensitivity would weigh against an atopic dermatological reaction in response to an injection. Additionally, the clinical presentation, progression, and exacerbation of N.G.'s atopic dermatitis is consistent with her prior history of infant seborrheic dermatitis, her age at onset, and the presumed presence by her treaters of the Staphylococcus aureus that is described in the literature as common with this condition. It is also notable that N.G.'s second DTaP vaccination did not result in an atopic dermatitis flare. Dr. MacGinnitie raised this point, and Dr. Horan did not respond. It remains inconsistent with Dr. Horan's proposed theory that vaccines generally, and DTaP specifically, triggered Th2 cytokine

productivity resulting in N.G.'s initial atopic dermatitis flare. Indeed, N.G. is not similarly situated to the children identified in the case studies, in age, location of initial rash, or type of vaccine. She was younger, with multiple initial rashes on various sites on her body, and in response to an initial vaccine (not a booster). Petitioner has not presented preponderant evidence of vaccine causation in N.G.'s case.

C. *Althen* Prong Three

The parties do not dispute that N.G. suffered from atopic dermatitis. Petitioner contends that N.G.'s atopic dermatitis developed independently of her seborrheic dermatitis, post vaccination. Respondent contends that N.G.'s atopic and seborrheic dermatitis were overlapping manifestations of the same disorder; therefore, the initial symptoms of N.G.'s condition developed pre vaccination. The medical literature filed partly supports the contentions of both parties. The Chadha & Jahnke article noted that while seborrheic and atopic dermatitis are similar conditions that can overlap, there are distinctions, including location and presentation, that can be used for differential diagnosis. Notably, the authors did not state the former and the latter are manifestations of the same condition. Further, the Podmore et al. article noted that the relationship between the two conditions is an increased risk of atopic dermatitis in patients that suffer from infantile seborrheic dermatitis. Within the medical literature is preponderant evidence that these two conditions, while similar in nature, are not the same. It follows that the manifestation of N.G.'s atopic dermatitis is evidenced by the distinct symptom of a wet and oozing rash that extended to her outer arms and legs for several days prior to the first reporting on July 10, 2017, ten days post vaccination. That would place the onset at approximately five-to-seven days post vaccination.

Dr. Horan cited the Wood et al. article that described eczema as a type III hypersensitivity, manifesting locally at the site of antigen interaction, starting from two to eight hours up to two days after vaccination. It does not appear that N.G.'s atopic symptoms occurred within this timeframe. It also does not appear that N.G.'s symptoms originally appeared at the site of injection in her arm and spread outward. Dr. Horan does not specifically outline what an appropriate timeframe for post-vaccination atopic dermatitis onset would be; but the two case studies that Dr. Horan referenced involve onset of two days and one week. The timeframe in this case would seem to be more consistent with those examples, although the vaccine at issue in those cases was not administered to N.G. The record does not contain preponderant evidence of an articulated temporal relationship between one or more of the vaccines N.G. received and her atopic dermatitis. While the cases studies in the filed literature identify a potential proximate temporal relationship between the bCG vaccine and the development of eczema, Dr. Horan does not present preponderant evidence of the similarities between those cases and the present one. After a consideration of the evidence filed and the arguments presented, Petitioner has not presented preponderant evidence of an appropriate temporal relationship for general vaccine causation that can be applied here. Petitioner has not met her burden pursuant to *Althen* prong three.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that N.G.'s atopic dermatitis was caused-in-fact by one or more of her June 30, 2017 vaccinations. While the record does contain preponderant evidence that her relevant symptoms developed post

vaccination, given the age of onset for most children that suffer from atopic dermatitis, (two to six months), the temporal relationship would suggest vaccine causation for every child that has adhered to the CDC's suggested vaccination schedule to date. That alone is not sufficient to meet Petitioner burden. Accordingly, Petitioner's claim is **DENIED**. Absent a timely motion for review, the Clerk is directed to enter judgment dismissing this case for insufficient proof in accordance with Vaccine Rule 11(a).[19]

IT IS SO ORDERED.

s/Herbrina D.S. Young
Herbrina DS Young
Special Master

[19] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.