In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-1399V

Filed: 15 June 2010

KIMBERLY WARFLE, a minor, by and through her mother and next friend, MELISSA GUFFEY,	*	**PUBLISHED**
Petitioner,	*	DTaP; MMR; IPV; Chronic Urticaria; Burden Of Proof; Dermographism; Allergy; Physical Urticaria; Blotching; IgG; IgE; Anaphylactic Reaction; Wheals; Welts; Allergic Rhinitis; Pharyngitis
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Petitioner appears *Pro Se*;[1]
Melonie J. McCall, Esq., United States Department of Justice, Washington, District of Columbia, for Respondent.

PUBLISHED DECISION ON ENTITLEMENT[2]

ABELL, Special Master:

On 30 December 2005, Petitioner filed this Petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[3] alleging that, as a result of the Diphtheria-Tetanus-Acellular Pertussis (DTaP) vaccine administered to her daughter Kimberly on

[1] Until 10 November 2009, Petitioner was represented by Paul Dannenberg, Esq., of Huntington, Vermont.

[2] Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[3] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C. §300aa.

27 January 2003, Kimberly suffered from chronic urticaria[4] for a period of years, potentially leading up to the present. Transcript ("Tr.") at 11.

Eventually, the Court convened an evidentiary hearing on the ultimate issue of vaccine causation *in vivo* in Nashville, Tennessee on 18 December 2008. Tr. at 1. Wherein, the Court heard from medical expert witnesses for both parties, each of them specializing in Pediatrics and Allergy and Immunology: Dr. Oscar Frick for the Petitioner, and Dr. Shelby Josephs for the Respondent. Following those hearings, the parties filed closing briefs with the Court, and the case is now ripe for a ruling.

As a preliminary matter, the Court notes that Petitioner has, at least provisionally, satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) she is the real party at interest as legal representative[5] of her daughter Kimberly, the injured party; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 16 requirement that the Petition be timely filed have been met. Respondent did, however, challenge whether Kimberly's injury satisfied the six-month durational requirement of Section 11(c)(1)(D)(i) of the Act, a challenge that will likewise be addressed herein.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I). In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine *actually caused* an injury not so specified. § 11(c)(1)(c).

I. FACTUAL RECORD

Despite their accord on certain factual predicates contained in the filed medical records, there is, unsurprisingly, a pronounced conflict between the parties on several factual issues. Considering

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[4] Urticaria is "a vascular reaction in the upper dermis, usually transient, consisting of localized edema caused by dilation and increased capillary permeability with wheals." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1994. Chronic urticaria is classified simply as urticaria that is "continuous or persisting episodically for six weeks or more." *Id*.

[5] There was some dispute about this element up to and including the date of the Entitlement Hearing. See Respondent's Motion to Suspend Proceedings. However, Petitioner's fact witnesses averred that Petitioner and Kimberly's father had been restored custody of Kimberly, after she had been removed from their home for an interim. Tr. at 32-35, 64-66. After the Hearing, Petitioner filed court orders from the Juvenile Court of Telfair County, Georgia, which resolved the issue, indicating that custody had been returned to Kimberly's parents. Pet. Ex. 24. Respondent acknowledged in a status conference thereafter that such proof had led her to waive the objection. Therefore, the Court finds, based on the representations of the parties, that Petitioner is the proper legal representative of Kimberly.

these disputes and the Court's commission to resolve them, it behooves the Court to explain the legal standard by which factual findings are made.

It is axiomatic to say that a petitioner bears the burden of proving, by a preponderance of the evidence–which this Court has likened to fifty percent and a feather–that a particular fact occurred or circumstance obtains. Put another way, it is required that a special master, "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 [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl. Ct. 476, 486 (1984).

This Court may not rule in favor of a petitioner based on his asseverations alone. This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

Contemporaneous medical records are afforded substantial weight, as has been elucidated by this Court and by the Federal Circuit:

> Medical 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 HHS, 993 F. 2d 1525, 1528 (Fed. Cir.1993).

Medical records are more useful to the Court's analysis when considered in reference to what they include, rather than what they omit:

> [I]t must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy v. Sec'y of HHS, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F. 2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 113 S. Ct. 263 (1992) (citations omitted), citing *Clark v. Sec'y of HHS*, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

A. MEDICAL RECORDS *ET AL.*

Kimberly was born on 28 January 1999 after an uneventful pregnancy and birth. Petitioner's Exhibit (Pet. Ex.) 2 at 1; Tr. at 40-41. On 14 January 2002, Kimberly was taken to a Medical

Center's office with complaints of a 103.2° (F) fever and coughing, and was diagnosed with bilateral otitis media,[6] pharyngitis,[7] and " a viral illness [that included] viral exanthema,"[8] a skin eruption occurring in reaction to acute viral illness. Pet. Ex. 7 at 22. She was described as having a "red, flushed" face, and it was then recorded that Kimberly "breaks out [with] blotches when upset." *Id*. Shortly thereafter, on 21 February 2002, she returned for fever, nocturnal coughing and wheezing, asthma, and boggy mucosa, similarly diagnosed with bilateral otitis media, allergic rhinitis, and reactive disease with cough, as well as an unspecified viral syndrome, and she was back a week later with the same. Pet. Ex. 7 at 21. Kimberly was in good health until the following winter, when she went to the doctor's office on 13 January 2003 for a head cold accompanied by three days of fevers, which reached 102.5° (F), conjunctivitis,[9] swollen adenoids, and ear pain, all of which were diagnosed as mild sinusitis, allergic rhinitis, and purulent rhinorrhea. Pet Ex. 2 at 41. Two weeks later, on 27 January 2003, she returned to the doctor's office, that of her primary care physician Dr. Mira Juric, for a check-up, when she was noted to suffer from "allergies with significant maxillary sinusitis," enlarged adenoids and tonsils, and boggy nasal mucus, and was again diagnosed with allergic rhinitis. Pet. Ex. 7 at 18, 23. It was at this visit that she received the DTaP (her fifth), MMR (her second), and IPV (her fourth) vaccines. Pet. Ex. 6; Pet. Ex. 7 at 8. Her medical history does not report any reaction to her previously received vaccines. Pet. Ex. 7 at 23. She received the DTaP vaccination in her right deltoid. Pet. Ex. 17 at 13.

The next day, on 28 January 2003, Kimberly returned to the doctor's office, after Petitioner complained that Kimberly's DTaP site was swollen and itchy; Dr. Juric observed that Kimberly's right arm was swollen, "due to allergic reaction to immunization." Pet. Ex. 7 at 15. According to the medical records, which Petitioner's fact witnesses dispute, Dr. Juric's thought was to send Kimberly home with Flonase, to return for follow-up every 24 hours, or sooner if the swelling increased, to which Kimberly's parents protested, and thus Kimberly was "admitted for observation due to parental thinking of allergic reaction to [the DTaP vaccination]." Pet. Ex. 7 at 24. When Kimberly got to the hospital, she was noted to have a high fever, an erythematous[10] body rash, and swelling and redness at the DTaP injection site. Pet. Ex. 7 at 23-24; Pet. Ex. 2 at 25. As for possible drugs that might be factors in her reaction, Kimberly was noted to be taking both Flonase for her nasal symptoms and Amoxicillin (a semisynthetic penicillin derived from ampicillin) for a sinus infection. Pet. Ex. 2 at 24. Kimberly was treated at the hospital with Benadryl and Atarax for her allergic symptoms and Acetaminophen and Ibuprofen for her fever. Pet. Ex. 2 at 14; Pet. Ex. 7 at 24.

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[6] Otitis media is "inflammation of the middle ear" which is accompanied "often with pain, fever, hearing loss, tinnitus, and vertigo." DORLAND'S, *supra*, at 1338-39.

[7] Pharyngitis is "inflammation of the pharynx." DORLAND'S, *supra*, at 1415.

[8] Exanthema is "1. a skin eruption or rash. 2. a disease in which skin eruptions or rashes are a prominent manifestation" (e.g., measles, scarlet fever, etc.). DORLAND'S, *supra*, at 651.

[9] Conjunctivitis is "inflammation of the conjunctiva, generally consisting of conjunctival hyperemia associated with a discharge." DORLAND'S, *supra*, at 409.

[10] Erythema is "redness of the skin produced by congestion of the capillaries. DORLAND'S, *supra*, at 638.

By the close of the next day, 29 January 2003, Kimberly's erythematous body rash had disappeared, and the localized swelling and redness had "remarkably" mitigated. Pet. Ex. 7 at 25. The next morning, 30 January 2003, Kimberly was reportedly pain-free, her rash was gone, and her arm swelling and redness were "markedly decreased," such that she was cleared for discharge from the hospital, from which she did depart the next afternoon, on 31 January 2003. Pet. Ex. 7 at 25; Pet. Ex. 2 at 15. One discharge summary from that visit indicated that her rash was "most possibly viral" and "probably helped" by the administration of Benadryl, and that, after she was given Benadryl upon admission, the rash had disappeared without a trace by later the same day (the date of admission). Pet. Ex. 7 at 25. A different discharge summary, which was much more brief, did not much mention her skin reaction at all, focusing instead on her persistent and at times severe fevers that marked the time of her stay in the hospital, and stating her admission and discharge diagnoses to be "febrile illness, pharyn[gitis], [and] vomiting." Pet. Ex. 2 at 30.

Kimberly was back to the doctor five days later, however, on 5 February 2003, after crying throughout the night before, when her presenting symptoms were ear pain and recurrent fevers, for which she had been taking Flonase, Amoxil, Robitussin, and Ibuprofin, and for which she was diagnosed with otitis media and pharyngotonsillitis[11] as part of an unspecified viral syndrome. Pet Ex. 7 at 14. She returned to the hospital on 12 February 2003 for recent and current pain in her throat, her stomach, and her legs, and for hives on her face and eyes. Pet. Ex. 7 at 14. The hives had appeared on 9 February, but had resolved by the next day. *Id*. She was negative for strep throat but had a very raw throat. *Id*. She was back yet again on 19 February 2003 due to a two week history of pain in her arm, legs, and back with observed swelling of her arms and legs, as well as continuing coughing, nasal congestion, and fever, although her "viral illness" seemed to be resolving, though her adenoids were still enlarged. Pet. Ex. 7 at 13. The morning of that visit, her left arm had broken out in hives, but had resolved by the time she arrived for examination by the doctor. *Id*. Her skin was described as "urticarial rash for few minutes when scratching." *Id*. Back again on 26 February 2003, her primary symptoms were not improved; she was still congested, her tonsils remained swollen, and she still had pain in her legs, although no mention was made of urticarial reactions. Pet. Ex. 7 at 12.

Returning once more on 6 March 2003, after just finishing a course of Amoxil, she had a red, itchy, blotchy rash on her arms, chest and back, as she had for the two days preceding the visit. *Id*. The rash had subsided in the morning, but had returned again at the time of the visit. *Id*. Although she had no fever, and both the nasal congestion and coughing had subsided, her body aches persisted and bothered her daily. *Id*. Nonetheless, she still suffered from allergic rhinitis. *Id*. Farther down on the same record, Kimberly's earlobes were noted to be "red," "swollen," with a "scarlatiniform[12] rash behind [her] ears." *Id*. Also noted was a "scarlatiniform rash" on her groin area. *Id*. This led to an assessment of "strep pharyngitis [with] scarlatina rash," but also "urticarial rash" that appeared "all over [Kimberly's] body." *Id*.

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[11] Pharyngotonsillitis is "inflammation of the pharynx and tonsils." DORLAND'S, *supra*, at 1416.

[12] Scarlatiniform means "resembling scarlet fever, especially the skin eruptions of scarlet fever." DORLAND'S, *supra*, at 1662.

Finally, on 17 March 2003, Kimberly was seen for an allergy consultation with Dr. Steven Tate. Pet Ex. 3.[13] At the visit, he described her rash as arising from two stimuli: A. that she "[b]roke out into a rash after receiving injection [on her] back, arms, neck, [and] torso" and B. that she "[o]ccasionally breaks out in hives when she gets upset." Pet. Ex. 3 at 1. She was listed as having no allergies to typical allergens, and both parents were listed as having no allergies or asthma, and both were noted to smoke inside the family home. *Id*. at 3. As she had not tried the allergy medication Zyrtec (*Id*. at 1), Dr. Tate thought it advisable to have her receive it (*Id*. at 7).

Kimberly returned to Dr. Tate's office two days later, on 19 March 2003. Pet. Ex. 3 at 5. Her "chief complaints" are listed as:

> [The patient] had [a] reaction to DTaP injection on [29 January 2003] and has been on Benadryl ever since. She was and still is hiving every afternoon. Mom stopped Atarax and Benedryl and started Zyrtec. Before visit, [the patient] was off med[ication]s for 1 week. Mom noticed it was fading and eventually faded before the appointment. After giving Zyrtec, she is hiving again. Pharmacist suggested that she is allergic to the antihistimine??? Mom says she has a runny nose and she hates to stop everything...

Pet. Ex. 3 at 5 (ellipsis in original). She stopped taking the Zyrtec. *Id*. at 10.

On 25 March 2003, Dr. Tate wrote an assessment of Kimberly's allergic condition, and diagnosed "chronic urticaria." *Id*. at 9. He requested her return for skin testing in eight weeks. *Id*.

On 21 November 2005, Kimberly was seen at a different doctor's office for a fever over 102° (F), a cough, an earache, a runny nose, and a stomachache. Pet. Ex. 7 at 2. On a review of systems on the progress note, under the category of dermatological symptoms, no symptoms were noted; however, under the physical examination section of the same form, her skin was noted to be abnormal, and she was listed in the affirmative for both lesions and rash. *Id*.

When Kimberly was in Georgia, she was seen by a doctor on 31 January 2007 complaining of "severe abdominal pain." Pet. Ex. 17 at 34. She had been experiencing cold symptoms and a wet cough for two days, and aches in her head and body that had arisen about 24 hours previous. *Id*. Her temperature rose to 102° (F) the day of the visit. She was not reported to have been suffering from any "significant past illness," but yet "had varicella[14] [the previous] week." *Id*. Her skin was "[r]emarkable for large blacheable macules[15] all over [her] back involving a large area of the back over the scapular area and infrascapular area and a few blotchy red macules noted on the face and

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[13] Only after the Entitlement Hearing did Petitioner acquire and file a missing part of the medical record from the visit with Dr. Tate, wherein someone took a "Physical Examination" of Kimberly. Pet. Ex. 23, filed 12 March 2009. Of note, Kimberly was recorded as having unremarkable presentation of the Mouth, Throat, Lymph Nodes, and Chest. Pet. Ex. 23 at 1. Under "Skin Examination" was written "Mild hiving seen on chin and neck." *Id*.

[14] Varicella is chickenpox. DORLAND'S, *supra*, at 2008.

[15] Blancheable means able or capable of turning white. A macule is "a discolored lesion on the skin that is not elevated above the surface." DORLAND'S, *supra*, at 1086.

on the trunk." *Id*. However, no petechia,[16] purpura,[17] or wheals[18] were noted. *Id*. The doctor prescribed treatments to address her flu-like symptoms, but but did not order treatments for the skin condition noted. *Id*. at 35.

B. Testimony Bearing on Entitlement

The Court heard from Kimberly's parents as providers of fact witness testimony, and from experts Dr. Oscar Frick for the Petitioner, and Dr. Shelby Josephs for the Respondent.

1. Blane Warfle

Kimberly's father Blane Warfle was first to testify at the hearing. He testified that Kimberly "was a typical, normal, young kid that would get a cold now and then," but that "basically she was a healthy child." Tr. at 16. He recalled that Kimberly had a "little minor cold" prior to her vaccination. Tr. at 17. He agreed that Kimberly had been taking antibiotics when she received the vaccination. Tr. at 28. He thought that Kimberly might have gotten all the vaccination in the same arm, but was not sure. Tr. at 21. He said it was only about half an hour after arriving home that Kimberly "was getting really flush and started welting up." Tr. at 18. Mr. Warfle recounted that, in his recollection, when he and Kimberly's mother took her back to Dr. Juric, the good doctor immediately urged them to admit her into the hospital, which they did. Tr. at 19-20.

Mr. Warfle stated that he had never seen Kimberly experience "the blotches on her skin" that she manifested the day of the vaccination. Tr. at 19. He remembered that Kimberly was not only experiencing swelling at her vaccination site, but that there was other swelling "all over her body." Tr. at 20. Mr. Warfle described Kimberly's heath in the days after she returned home with her parents as having "good days and bad days," the latter of which were characterized as including "runny noses [and] blotching" with the occasional fever. Tr. at 21. He later added to these symptoms his recollection that he and Kimberly's mother "spent ... a lot of nights with [Kimberly] being irritable and [her joints] aching." Tr. at 26.

Mr. Warfle stated that Kimberly continued to experience those same symptoms unto the present, for which she is given over-the-counter allergy medicine "every morning." Tr. at 23-24. He indicated that the treatment currently given to Kimberly was one pill a day for "cold symptoms."

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[16] Petechia are "a pinpoint, nonraised, perfectly round, purplish red spot caused by intradermal or submucous hemorrhage." DORLAND'S, *supra*, at 1411.

[17] Purpura are "1. any of a group of conditions characterized by ecchymoses or other small hemorrhages in the skin, mucous membranes, or serosal surfaces; possible causes include blood disorders, vascular abnormalities, and trauma. 2. any of several conditions similar to the traditional purpura group, which may be caused by decreased platelet counts, platelet abnormalities, vascular defects, or reactions to drugs." DORLAND'S, *supra*, at 1547.

[18] A wheal is "a smooth, slightly elevated area on the body surface, which is redder or paler than the surrounding skin; it is often accompanied by severe itching and is usually evanescent, changing its size or shape or disappearing within a few hours. It is the typical lesion of urticaria, the dermal evidence of allergy, and in sensitive persons may be provoked by mechanical irritation of the skin. Called also *hive* and *welt*." DORLAND'S, *supra*, at 2063.

Tr. at 29. He stated that if Kimberly does not take such medicine daily, "she gets sick ... she gets blotchy." Tr. at 24. He explained later what he meant by that description, adding "she breaks out in hives, looks like hives, big blotchy hives on her" that surface "everywhere" on her body, and the hives are "red spots, big red spots," of differing size. Tr. at 30. When asked if that treatment regimen is ever ineffective, he said "Not really ... she still has fevers and stuff like that, but her mother pretty much gets it down." Tr. at 26.

Mr. Warfle indicated that the red splotching on Kimberly's skin appeared the day of the vaccination–that day was "when it pretty much started," and that "it started on her arm first," specifically her deltoid, although he was unsure as to which arm it was. Tr. at 30. Further, "it started in her arm and then it just started covering her, covering her body." *Id*. He averred Kimberly had not manifested "any of those splotches, blotches, [or] hives before the 27th of January 2003," and did not recall his wife mentioning having seen them either. Tr. at 31. Regarding whether any treating physicians had observed or recorded those dermatological symptoms, the following interchange occurred during re-direct examination:

> Q Do you recall at one point that Dr. Juric described Kimberly as having some kind of blotching when she got upset prior to the vaccination?
>
> A No, sir.
>
> Q Did she ever do that from what you could see?
>
> A No, sir.
>
> THE COURT: If there's an indication in the medical records to that effect, do you have any explanation for that?
>
> THE WITNESS: No, sir. Unless Dr. Juric wrote something in there that wasn't, you know, shouldn't have been there. Like I say, I've been around Kimberly, you know, all the time ever since she was a baby, until that little time she was taken away from us, until this shot I never noticed any blotching on her or anything like that.
>
> THE COURT: Prior to the vaccination?
>
> THE WITNESS: Yeah.

Tr. at 37-38.

2. Melissa Guffey

The other fact witness offered was Petitioner herself, Melissa Guffey, Kimberly's mother. By her recollection, Kimberly had been healthy at all of her well child check-ups. Tr. at 42. She recounted that the visit to Dr. Juric on 27 January 2003 was a school physical in preparation for Kimberly to begin preschool. *Id*. She recollected that, of the three vaccinations Kimberly received that day, one was administered in each arm, and one was administered in her leg, each in separate locations. Tr. at 43.

Petitioner indicated that Kimberly had not "ever had any problem with rashes or allergies" prior to 27 January 2003, and that she could not "recall her getting rashes when she was upset." Tr.

at 43. She could not call to mind any reason why Dr. Juric would have recorded on 14 January 2002 (a year before the vaccination at issue) that Kimberly's face was red and flushed and that her skin "[broke] out in blotches when upset." Tr. at 44. Petitioner insisted that she did not ever tell Dr. Juric that Melissa broke out in a rash when she became upset. Tr. at 44-45.

Describing the day of Kimberly's vaccination, Petitioner recounted:

> We got home. Kimberly was very whiny and upset and [had] a fever, and I give her the Tylenol as the doctor had told me to do, and she just kept getting worse and worse until the doctor told me to bring her in. ... She was getting big rashy welts all over her whole body. ... Her arm was the worst spot on the right arm. It was the reddest and it was real hot to the touch but she had welts and rash all over.

Tr. at 45. By the time she checked into the hospital later that day, Petitioner remembered that Kimberly was "rashy and feverish, vomiting." Tr. at 47. Even when Kimberly was discharged from the hospital, Petitioner remembered that she "was still rashy." *Id*. Thereafter, said Petitioner, Kimberly "[was not] the same," as she "stayed sick a lot with fevers, sore throat, headaches, rashes, aches and pains," became "a lot more clums[y]," losing her balance and falling at times, and was "up many nights crying with pain." Tr. at 47-48. When the Court requested Petitioner to explicate further the "difficulty walking," Petitioner stated merely that "She said her legs hurt all the time," and that pain in her lower legs persisted "for months after." Tr. at 50.

Petitioner recounted the drug reaction Kimberly experienced when she began to take Zyrtec, and clarified that Kimberly never did undergo a skin test for allergies, but that she knows that Kimberly is not allergic to "cats, dogs, ragweed *et cetera*." Tr. at 51-52. Petitioner described Kimberly's current treatment regimen as over the counter medicine for multi-cold symptoms. Tr. at 51. This treatment, which Kimberly's physician did not recommend but is aware that she follows, purportedly "controls her congestion," such that if she does not take the medicine on a given day, Kimberly "gets really congested." Tr. at 52-53. After significant testimony about this treatment regimen, Petitioner divulged that the medication is for her congestion, and does not affect her skin condition at all. Tr. at 54. Even so, Petitioner summarized that Kimberly usually manifests the rash daily, although she said that frequency "depends" and that it "varies" as to what time of the day it manifests. *Id*. Her rash outbreaks are also sensitive to heat. Tr. at 55. Beyond actual hot temperature, Petitioner testified that Kimberly has often indicated that she is hot when the ambient temperature is not uncomfortably hot to others, and that at those times, even though Kimberly might not have a fever, she will nevertheless manifest a rash. Tr. at 57. Petitioner reiterated that Kimberly "never had any type of these problems before the vaccination." *Id*.

The Court questioned Petitioner's testimony that Kimberly "takes no medications for [her rash] and [has] never had a diagnosis for what it is," and yet has suffered from the condition consistently since 2003. Tr. at 55. Petitioner stated that Kimberly experiences the rash "[l]iterally every day." *Id*. When the Court asked Petitioner whether Kimberly's "doctors ever comment [or] say anything ... about [the red blotches, hives, or rash]," to which Petitioner responded that they did not, though they had knowledge of same. Tr. at 56. Petitioner also stated that the over the counter cold symptoms medication she administers to Kimberly is effective only for her rhinitis, rhinorrhea

and sinusitis, and that Kimberly does not take any medication for her rashes; Petitioner "just keep[s] her cool," which keeps the rashes "under control." Tr. at 57.

On cross examination, Petitioner testified that, to her knowledge, Kimberly was never tested for "any potential allergic condition to the antibiotics that she was taking," or to any one "of the drugs that she was taking," and did not recall Kimberly having allergic reactions to any of the medications she had been administered over the course of her life. Tr. at 62.

3. Oscar Frick, MD

At the hearing, Dr. Frick began be recounting his background and education:

> My education was that I graduated from High School in New Jersey in 1940. I went to Cornell University, Arts and Sciences, in Ithaca, New York, and graduated with an ABOUT in 1944. Attended Cornell Medical College in New York City with an M.D. in 1946, and I served in the Navy for two years. And then upon discharge I went to the University of Pennsylvania, Post-Graduate School of Medicine in Pediatrics, and received a Master of Medical Sciences degree in 1960, and then I went into private practice in pediatrics in Huntington, Long Island, for eight years, and then went to Stanford University School of Medicine and Immunology at Stanford, California, got a Ph.D. in 1964.
>
> And then I had several post-doctoral fellowships. I interned at Davies Hospital in Columbia College in New York from 1946 to '47. Residency in Children's Hospital in Buffalo, New York, 1950-51, and then post-doctorate fellow at allergy and immunology at the World Victoria Hospital, Magilian University, Montreal, Canada, 1958-59.
>
> And then post-doctoral fellow pediatrics, allergy immunology, University of California, San Francisco, '59 to '60, and then -- M-a-i-a-d, post-doctoral fellowship in allergy and immunology in the Center of Immunology in Hospital Brusite, Paris, France, 1960-62, and then NIAID, NIH post-doctoral fellowship in immunology at Stanford University from '62 to '64.
>
> ...[A]fter two years in the Navy at U.S. Naval Hospital in Quantico, Virginia, then I was in private practice, pediatrics, at North Shore Medical Group in Huntington, Long Island, '61 to '68. And then in 1964 I joined the faculty at the University of California, San Francisco, as an assistant professor of medicine, of pediatrics, and then moved up the professorial rank to associate professor in '67, and then to full professor in '72. And then became emeritus in 1996 until the present. And I'm still the head of the allergy training program in pediatric allergy at the University of California, San Francisco.
>
> ...I'm Board certified by the American Board of Pediatrics in 1952 and in 1960 certified in American Board of Peds, Sub--Board in allergy. 1973 certified by the American Board of Allergy and Immunology, of which I was also one of the founding members. In 1978 I was recertified by the American Board of Allergy and Immunology.

Tr. at 71-73.[19]

Dr. Frick summarized Kimberly's prevaccinal course as having "allergic rhinitis and apparently some sinusitis episodes," but thought generally speaking that "she was a pretty healthy child." Tr. at 74. He understood her allergic rhinitis to have consisted since that time, continuing to contemporaneity. *Id*. He also discussed her possible predisposition (though not discussed by treating doctors in the medical records) toward skin reactivity: "Apparently she has sort of a labile skin, so when she does get upset apparently she does get some blotches, which is not uncommon in children." Tr. at 75. He agreed with the summarization that "the DTaP is in the right arm and the other two vaccinations were not in the right arm." Tr. at 76.

Dr. Frick summarized her initial reaction to the vaccination thusly:

> Within apparently several hours the arm, the right arm, became swollen and hot and red, and then she broke out in a rash, which persisted. She also became very irritable. Then she was taken to the --- she was seen again I guess by Dr. Juric two days later and she had a fever and rash, swelling of the face and throat at that time. And Dr. Juric said that she should be admitted to the hospital, which was done, and she had a diagnosis then of maxillary sinusitis and pharyngitis and the rash.
>
> The rash had spread over the trunk and the arms and gradually subsided with various --- with heat --- with compresses and antihistamines and analgesic medication, and gradually that reaction subsided over the next two days and she was discharged on January 31st.

Tr. at 76-77.

Dr. Frick discussed with the Court the progression of Kimberly's skin condition to urticaria in full bloom:

> [S]he continued apparently to have the rash, which came and went and the rash actually became urticarial, which means that there were actually swellings in the skin,

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[19] It is quite possible that Respondent effected a waiver to her previously-raised *Daubert* challenge to Dr. Frick's admissibility, in the following interchange:

> MR. DANNENBERG: I'd like to present Dr. Frick as a witness in this matter.
>
> THE COURT: I'm presuming, Ms. McCall, that you may have queries but nothing to go to the heart of his ability to testify?
>
> MS. McCALL: That's correct.
>
> THE COURT: He's accepted.
>
> MR. DANNENBERG: Thank you, sir.

Tr. at 73-74.

as well as the blotching that she had further and apparently that whole situation was revved up by the injection.[20]

THE COURT: Was the urticaria within several days of that initial time or does that not show up for some period later?

THE WITNESS: From what I understand it was right at that first day, because she had this swelling in the face and throat as well, which indicates some angiodema[21] as well as urticaria.

THE COURT: Okay. Does that continue or is it intermittent or is there a differential in the quality of what that is, or is it the same over the period of a year or two years?

THE WITNESS: No, that continued and the urticaria apparently has continued even up until the present day, from what I understand.

Tr. at 77. Despite the exact differences between the phenomena manifested, Dr. Frick believed that they were all manifestations of the same condition, whatever the underlying core might have been. Tr. at 78-79. He believes urticaria is the diagnosis of this core, underlying pathology. Tr. at 79. Dr. Frick did not believe that Kimberly suffered from urticaria prior to her vaccination, but that she merely "had somewhat hyperactive skin from what I understand, which she gets this blotching when she cried or got upset but that's different from urticaria." Tr. at 80. He further distinguished Kimberly's condition before the vaccination with her condition thereafter:

> I think she had somewhat reactive skin beforehand, and then she did have the DTaP injection and a reaction to that, and I think that just revved up the whole skin that she had, so that she continued to have --- well, then she developed urticaria and this lasted over six weeks, of which the definition is that it becomes chronic urticaria, and that was the time that Dr. Tate saw her, and that condition has continued. So I think the whole skin was revved up by that vaccination.

Tr. at 82-83. Such "revving up," Dr. Frick later explained, "can last months or it can last sometimes even years actually, but generally it's more in the area of months." Tr. at 84. Dr. Frick concluded that Kimberly's vaccine-related chronic urticaria lasted from the point of vaccination in January 2003 until "at least" 2005, and potentially continuing until what was then the present day. Tr. at 85.

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[20] At the Court's request, Dr. Frick explicated his understanding of the different dermatological phenomena encountered in this case, and the sequence of their respective manifestation:

> [M]aculars is a flat area of the redness area of the skin, and blotching is in my definition [] the same thing. Urticaria is an actual swelling of the skin in what we generally know as hives. And then these little swellings are called wheals, and this results from the capillaries leaking fluid from the blood into the soft tissues, and that's different from the blotching that she had earlier.

Tr. at 78-79.

[21] Angioedema is "a vascular reaction involving the deep dermis or subcutaneous or submucosal tissues, representing localized edema caused by dilation and increased permeability of capillaries, and characterized by development of giant wheals. *Urticaria* is the same physiologic reaction occurring in the superficial portions of the dermis." DORLAND'S, *supra*, at 83.

The Court queried Dr. Frick on the medically appropriate time interval for onset of symptoms, were Kimberly's chronic urticaria to have been caused or otherwise triggered by her DTaP vaccination, given that Petitioner first testified that symptoms manifested within four hours and later testified (at trial) that the interval was 30-60 minutes; Dr. Frick thought that, regardless, it was within the acceptable time frame. Tr. at 80. He explained:

> Well, the chemicals that are released from an allergic reaction[–]histamine is one of the main ones, and that's released very quickly, within a matter of minutes, and then there are other ones that are released, something called the leukotrienes[22] or they used to be known as slow-reacting substance, so it took several hours for those to manifest themselves, so that the whole reaction takes over a period of several hours to become full blown, and that's apparently what happened in this case after the [DTaP] vaccination.

Tr. at 80-81.

At the Court's urging, Dr. Frick explained his theory of how Kimberly's DTaP vaccination caused her to develop chronic urticaria as follows:

[The chronic urticaria is] a reaction to the DTaP injection itself, either the actual diphtheria toxin or the tetanus toxin in the vaccine, or perhaps some stabilizing agent in the vaccine, because at least they used to have gelatin in the vaccine and also there are cultures of fetal calf serum, which they grow the organisms on, and fetal calf serum has bovine serum and albumin, so that could be a possible allergen, as well, in the injection.

Tr. at 82-83. Dr. Frick analogized Kimberly's condition to anaphylactic reaction, for which there is support in the medical literature for a relationship with the DTaP vaccine, while cautioning that Kimberly's reaction did not rise to the level of anaphylaxis. Tr. at 83-84. When asked, however, Dr. Frick conceded that he was "not able to find" supportive medical literature to implicate the DTaP vaccine in causing chronic urticaria. Tr. at 84.

Dr. Frick believed that either of the diphtheria or tetanus toxins could have caused the injury, as could also other protein elements added to the vaccine to manufacture it or to increase its efficacy:

> In addition to the diphtheria toxin and the tetanus toxin, any sort of other foreign protein that might have been used in the culture of those bacteria, or peptones also, which might be in the culture medium. Those are foreign proteins and they also could be possibly responsible.
>
> Q And then the diphtheria or tetanus toxins themselves could have also caused it?

---

[22] A leukotriene is "any of a group of biologically active compounds consisting of straight chain, 20-carbon carboxylic acids with one or two oxygen substituents and three or more conjugated double bonds. They are formed from arachidonic acid by the lipoxygenase pathway and function as regulators of allergic and inflammatory reactions.... Some ... stimulate the movement of leukocytes; three others ... together constitute slow-reacting substance of anaphylaxis, which causes bronchial constriction and other allergic reactions." DORLAND'S, *supra*, at 1023.

A That's right, and that was the citation on the anaphylaxis paper that I highlighted.

Tr. at 87-88.

Dr. Frick explained the mechanism of his theory whereby Kimberly's DTaP vaccination caused her chronic urticaria:

> What happens is that the body recognizes antibodies, presumably what we call IgE or allergic antibodies, which were raised presumably from the previous injections that she had the earlier DTaP injections, because this was the fifth one, I understand. And so she became sensitized and as a result the IgE antibodies react with mast cells, which are the emergency cells in the skin and mucus membranes, and these then release as a result of that IgE antibody and the diphtheria tetanus antigens reacting together caused the release of chemicals in the mast cells in the skin. And these then release histamine and histamine causes a swelling of the capillaries and this opens up little pores in the capillaries that pours fluid from the bloodstream plasma, from the bloodstream out into the tissues, which is then known as edema or --- and it also itches strongly, and that itching means urticaria, and that's the condition that we generally know as hives.
>
> There's also a further swelling sometimes which is called angioedema, which is just a very much larger form of the same thing, but the angioedema doesn't actually itch. Then I think there was also, perhaps also an IgG, which is the other major immunoglobulin that we have, and those that form immune complexes with the antigens, and this then can cause something called serum sickness. And serum sickness is a condition that can last again sometimes weeks or sometimes even months, and this causes things like joint pains and central nervous system problems, possibly the falling down that she had. Can't say for sure. Perhaps the pain in the legs that the mother talked about. So these conditions may be related to the serum sickness type reactions.

Tr. at 88-89.

Concerning potential other causes of Kimberly's chronic urticaria, Dr. Frick thought it might be "possible that antibiotics could have done something as well," but found the temporal association between vaccination and reaction to be decisive: "the fact that it occurred within hours after the injection site, I think implicates that it was the DTAP vaccine that did it." Tr. at 86. He also thought that the other vaccines Kimberly received on 27 January 2003 were "less likely" as independent or concurrent causes, although he noted that "there have been reactions to measles-mumps-rubella vaccine also," and he mentioned some older and more dated medical literature in support of that possibility. *Id*. Dr. Frick did not believe to a preponderance that the MMR vaccine could be implicated in Kimberly's case. Tr. at 87. He believed that only the DTaP vaccine was causative, "because the other sites, the other two injection sites were not involved," as "[t]he only one that caused any swelling was the DTAP vaccine." *Id*.

Given this analysis of cause and effect, Dr. Frick concluded that Kimberly's "vaccinations of 2003 were a substantial factor in the development of the chronic urticaria," and that "but for the vaccination she would not have developed chronic urticaria at that time," although he conceded that she might have developed chronic urticaria regardless of the vaccine if some other trigger had prevailed upon her irrespective of the vaccine. Tr. at 90.

Dr. Frick reviewed with the Court the medical literature he had included in support of his expert medical opinion. Most of it was general in nature, and described either urticaria or adverse reactions to the DTaP vaccine, but not both. Tr. at 91-96. One reference that did discuss urticaria in reaction to the DTaP vaccine was the 2006 Report of the Committee on Infectious Diseases of the American Academy of Pediatrics, the 27th edition of the "Redbook," which stated as follows:

> **Allergic reactions**. The rate of anaphylaxis to DTP vaccine was estimated to be approximately 2 cases per 100,000 injections; the incidence of allergic reactions after immunization with DTaP vaccine is unknown. Severe anaphylactic reactions and resulting deaths, if any, are rare after pertussis immunization. *Transient urticarial rashes* that occasionally occur after pertussis immunization, unless appearing immediately (ie, within minutes), are *unlikely to be anaphylactic (IgE-mediated) in origin*. These rashes probably represent a reaction caused by circulating antigen-antibody complexes formed from antigens in pertussis vaccine and corresponding antibody acquired from an earlier dose or transplacentally. Because formation of such complexes depends on a precise balance between concentrations of circulating antigen and antibody, *such reactions are unlikely to recur* after a subsequent dose and are not contraindications for further doses.

Pet. Ex. 16, un-numbered attachment thereto, with no full citation provided, at 509 (italics added).

Another reference was to the sixth edition of MIDDLETON'S ALLERGY: PRINCIPLES & PRACTICE (second volume, chapter 91),[23] which discusses two cases of "generalized urticaria" in reaction to diphtheria proteins. Pet. Ex. 16, un-numbered attachment thereto, at 1668. Pertussis, says the same source, does lead to IgE production in the body, but the resultant increase in antibodies was seen to be "unrelated to atopic status (i.e., having asthma, allergic rhinitis, eczema, or food allergy ... IgE antibodies may predispose to local reactions to subsequent doses of the vaccine, [but] they have not generally predisposed to systemic reactions)." *Id*.[24]

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[23] N. Franklin Adkinson, Jr. *et al*. (eds.), 2 MIDDLETON'S ALLERGY: PRINCIPLES & PRACTICE 1668 (6th ed. 2003) (Mosby).

[24] Petitioner did not discuss that source's treatment of tetanus, which states, in part:

> A small number of reports of apparent anaphylaxis, including fatalities, have been reported after tetanus toxoid administration but few have included assessment for IgE antibody. In a single case report, a 5-year-old is described with generalized urticaria and angioedema after his fourth dose of DPT. Subsequent skin testing revealed a positive response to tetanus toxoid. He subsequently received a dose of the vaccine uneventfully by graded dosing.

Pet. Ex. 16, un-numbered attachment thereto, at 1669.

This reference, when mentioned, prompted the Court to question how long the "generalized urticaria" in the study could be expected to have lasted, given that such durational time frame was not stated therein. Tr. at 98. The Court asked Dr. Frick whether the reference in that article of medical literature supported Petitioner's claim that Kimberly's vaccine-related urticaria persisted for months and even years. *Id*. Dr. Frick responded that, although the authors did not state a duration for the "general" urticaria, it is generally known that "with chronic[25] urticaria it does take sometimes months or sometimes even years for it finally to subside." Tr. at 98-99.

The next article discussed was one written by Dr. Frick on allergic response in dogs, which Dr. Frick explained thusly:

> Well, this is a dog model but dogs also have problems --- allergic problems and they're probably the nearest animal to humans in terms of developing allergies except for primates, monkeys, and we've used the allergic dog for studying these reactions for over 20 years, and it's a very useful model for allergic reactions....
>
> THE COURT: Okay. Now, how is this particular article specifically on point?
>
> THE WITNESS: Yeah, because the reason I brought that particular article up was that they investigated what the allergens might be in that and in that they found that seven out of eight dogs who had allergic reactions after the vaccine --- I guess this was the distemper --- rabies vaccine, that they had allergy to the bovine serum albumin and that was in the fetal calf serum. That's the reason I brought it up, because some of these vaccines do contain those materials as well as the actual diphtheria tetanus.
>
> Q And to your knowledge the current DTaP is made with the same [medium]?
>
> A I believe it does, yes.

Tr. at 101, discussing Pet. Ex. 18, Oscar L. Frick, M.D. *et al.*, *Immunoglobulin E. Antibodies to Pollen Augmented in Dogs by Virus Vaccines*, 44 (3) AMERICAN JOURNAL OF VETERINARY RESEARCH 440-445 (March 1983).

The next article discussed the attributes of pertactin, a portion of the pertussis toxin used in acellular pertussis vaccine, and particularly those types of the vaccine that use genetic deletion in their manufacture. Dr. Frick testified that the article's mention of allergic reactions to pertactin (or the bovine protein medium in the vaccine) meant such a reaction could result in the chronic urticaria complained of. Tr. at 102, discussing Marcel Hijnen *et al.*, *Antibody responses to defined regions of the* Bordetella pertussis *virulence factor pertactin*, 40 SCANDINAVIAN JOURNAL OF INFECTIOUS DISEASES 94-104 (2008). No specific reference was provided, however, and the Court's review of that article did not reveal any support for the contention that the DTaP vaccine can cause chronic urticaria. If Dr. Frick's point was that the acellular Pertussis component of the DTaP vaccine can

[25] Actually, Dr. Frick's answer did not respond to the Court's question regarding the duration of "general urticaria" by discussing "chronic urticaria." The study under discussion did not mention chronic urticaria, and by its definition, chronic urticaria is urticaria of a longer duration than other forms.

cause allergic reactions, that still does little to prove to a preponderance that the vaccine can cause *chronic* urticaria.

Lastly, on direct examination, Dr. Frick discussed his disagreement with the explanation given by Respondent's expert, Dr. Josephs:

> Q And I think [Dr. Josephs'] opinion was that it was derm[o]graphia. Do you have any comment on that?
>
> A Yes. I think she did have this flushing or this, as they say, redness of the skin before --- in 2002, so that indicates that she has a somewhat labile skin, and that was then I think aggravated by the DTAP injection.
>
> Q And isn't derm[o]graphia more of when someone scratches their skin and then it turns red, rather than a drug reaction? ... How do you describe the definition of urticaria? Is it just simply happens when someone scratches their skin?
>
> A No, you have --- generally you have to have some sort of a reaction, an antibody reaction. There are some people, yes, that do have what they call physical urticaria, which happens with sun sometimes or sometimes cold, there's something called cold urticaria. People jump into a swimming pool and have anaphylaxis from that, from generalized urticaria, but those are different conditions than this.
>
> ...Q His opinion did not address the urticaria; is that correct?
>
> A I think he thinks that the condition was all --- just a reactive skin that happens from --- that's just part of our makeup that she has a reactive skin.
>
> Q In your opinion it's much more involved than that?
>
> A I think so, yes.
>
> Q And resulting from her vaccination?
>
> A That's right, that it was revved up by the vaccination.

Tr. at 104-105.

On cross-examination, Dr. Frick stipulated that urticaria can be caused by viral infections as well as medications, such as antibiotics. Tr. at 106-107. He acknowledged that "most cases [of urticaria] are idiopathic and the cause isn't really known." Tr. at 110. He conceded that he had not reviewed any medical records engendered between Kimberly's birth in 1999 and January 2002, to be able to know if she experienced any skin conditions during that time. Tr. at 108, 113.

Respondent queried Dr. Frick regarding the notation of Kimberly's teacher from 2005, which Dr. Frick relied upon to conclude that Kimberly still suffered from chronic urticaria at that time, to which Dr. Frick responded that "Ms. Reid mentioned that she had bumps, I think. ... And she would itch them, and itching also comes with urticaria, but not with blotchy bumps, with blotches or with macules. Macules don't itch." Tr. at 109. Dr. Frick conceded that the description of "red, blotchy lumps was "a layperson's description," that "no medical record describ[ed] this reaction in 2005," and that "there aren't any records from 2005 on another date close in that time period that describes

any kind of skin problems that Kimberly had." *Id*. However, he later agreed on redirect examination that one need not "be a doctor in order to recognize a lump." Tr.at 113-14.

> After Respondent's expert had testified, Dr. Frick had this to say on rebuttal:
>
> I think in terms of the chronicity of the condition, and I think the only record we have is the schoolteacher's notation in the fall of 2005 that the spots were red blotchy bumps, which indicates that there was swelling, and that they itched, and I think we haven't made enough point about the itching, because the itching is caused by histamine primarily, and so to state the fact that they itched and they were bumps indicates that this was actually urticaria and chronic urticaria.
>
> And then one of the reasons for my bringing up that most recent dog article from Japan where they found that the dogs at least after the immunizations had fetal calf serum, which contained bovine serum albumin in it, that could actually have been the allergen. And the fact that the child eats beef over the next few years after the initial thing, could actually keep the hives going, because it would be contained to supply allergen, because beef does contain bovine serum albumin, which is the blood in the beef. So it's a theory. It may seem sort of far fetched, but at least it could explain why the situation is chronically continuing.

Tr. at 175-176. Respondent then cross-examined Dr. Frick regarding "whether or not [he had] ever had occasion in his career of treating patients that had chronic urticaria following DTAP vaccine," and whether "any case reports or case studies [indicated] DTAP vaccine caused chronic urticaria. Tr. at 177. Dr. Frick replied that, "I have not seen that in the literature and I have not seen it personally, no." *Id*.

4. Shelby Josephs, MD

At the hearing, Dr. Josephs began by reciting his education and experience as an offer of expertise:

> I obtained my college degree at the University of Pennsylvania, and graduated 1971. I attended Duke University Medical School and graduated 1975. I did my internship and residency at St. Louis Children's Hospital until 1977, and then returned to Duke University for my fellowship in allergy, immunology and pulmonary disease, finishing in 1979.... [In 1979] I then went to the Children's Hospital in Washington, D.C., where I stayed until 1990, and then I went into private practice, where I remain today.
>
> ...I see adults and children. I would say it's more children than adults, but we see both.... I'm certified by the American Board of Pediatrics. That was in 1979, and then the American Board of Allergy and Immunology, which is a conjoint board between the American Board of Pediatrics and the American Board of Internal Medicine, so that certification was in 1979 and recertified in 1986.

Tr. at 116-17. He "treat[s] patients that have urticaria." Tr. at 117-18. The Court accepted Dr. Josephs as an expert in the field of allergy and immunology without objection from Petitioner. Tr. at 118.

Dr. Josephs did not believe Kimberly's ensuing long-term medical course was a result of her DTaP vaccination, although he agreed that "she [did] have some kind of reaction due to the DTaP." Tr. at 118. He identified the points of disagreement between his view of Kimberly's case and the one offered be Petitioner:

> [Dr. Frick's] contention was that she has an ongoing problem with skin rashes, which have been called chronic urticaria today, and that I did not think that the record showed that the ... DTAP immunization was the cause of that persistence or continuing nature of skin rashes.... I thought that there was another explanation for her reaction that occurred within the day of getting immunization. I thought there was evidence that she had rashes prior to the immunization and I thought that there was another diagnosis which would explain both the preceding and continuing problems with the skin rashes that does not need to invoke the [DTaP] immunization. And for that reason I thought the [DTaP vaccination was] not likely to be the cause of her disability.

Tr. at 119.

Going into greater detail, Dr. Josephs first clarified the categories of symptoms seen in Kimberly's history:

> I think that part of the difficulty in trying to understand --- or come to conclusions in the case have in part something to do with semantics, that is, the use of terminology perhaps somewhat loosely. Specifically, we've had rashes described as blanching, macules, blotches, hives, wheals, welts, urticaria, [scarlatiniform], [erythematous] and lumps, and while it's true that those may or may not be accurate descriptions, I'm not entirely certain that everybody is using the terms in the way they're defined in Stedman's Textbook.
>
> I think we'll all agree that macules --- macular is a medical term for a flat rash, and that hive, urticaria, wheal, spelled with an A, and welt, would be raised rashes that are most often transient. They come and go, come and go. But what's not certain to me is that when a given doctor in the record says there's blanching or in one case they called it fainty rash or blotchy, I'm not entirely certain we can tell what that was really referring to. We do know that there was at least on one occasion mention by Dr. Juric, who was seeing Kimberly for another reason, that she had a rash that came on sort of suddenly while she was there being examined, while she was upset.

Tr. at 121-22.

Dr. Josephs next discussed his opinion of her initial reaction in the days following vaccination, and why that reaction did not extend to cause the urticarial symptoms that followed thereafter:

I thought that Kimberly did have a reaction to the vaccine manifested by the kinds of symptoms that were described in the complaint, but I thought that that reaction was a rather typical or relatively common type of reaction.

...In the *Redbook* there's a quite accurate --- the description of the type of reaction that I believe that Kimberly had after her [DTaP] vaccine. And I'll just quote here, "The pathogenesis and frequency of substantial reactions and limb swelling is not known but these conditions appear to be self-limited and resolve without sequelae. Transient urticaria rashes that occasionally occur after Pertussis immunization, unless appearing immediately, that is, within minutes, are unlikely to be anaphylactic, that is, IgE mediated in origin, and those reactions are unlikely to recur after a subsequent dose and are not contraindications to further doses."

So we heard about the use of the word IgE antibodies and anaphylactic reactions. Anaphylactic reaction connotes that a person had a reaction because of the presence of IgE antibodies. Those reactions may be mild or severe and so Dr. Frick talked about a spectrum of those reactions, and that's true. But typically those reactions occur rapidly and they're relatively short-lived, and there's no mention in here of chronic urticaria as the result of IgE reactions or anaphylactic type reactions.

We know that patients can also have reactions based on immune complexes that are IgG, plus the antigen, in this case, the DTaP vaccine proteins, and the *Redbook* addresses those two, and in number two of my affidavit I say, "Other types of hypersensitivity reactions that occur later in time may depend on IgG antibodies," but as stated in the same reference, "Reactions caused by circulating antigen antibody complexes form from antigens in the Pertussis --- in the vaccine and corresponding antibodies"–in this case IgG antibodies–"acquired from an earlier dose. Because the formation of such complexes depends on a precise balance between the concentration of the circulated antigen and antibody, such reactions are unlikely to recur after subsequent dose and are not contraindications to further doses."

Now, ordinarily if we're speculating that a person has an ongoing allergic or hypersensitivity reaction causing a skin problem, that would be a contraindication to re-exposing the person to the same vaccine, and in the *Redbook* they're very clear that patients can have relatively rapid onset reactions within the day, they can have the symptoms that Kimberly had, and then they get over it.

I was then unable to find any citations of chronic urticaria following [DTaP] vaccine, and so that's how I concluded that I thought it was unlikely.

Tr. at 120, 122-24 (referencing L.K. Pickering *et al.* (eds.), RED BOOK: 2006 REPORT ON THE COMMITTEE ON INFECTIOUS DISEASES 508-510 (27th ed. 2006)).

Dr. Josephs also saw Kimberly's various skin conditions all of a piece: from the notation of a macular rash in 2002, to the references of her continuing skin problems in the years following her vaccination. Discussing her skin condition in the first childhood medical record filed in this matter, from 2002, Dr. Josephs explained:

> [S]he had a rash that was to me very similar in description to many of the rashes that were described after the immunization and not too different from what the teacher's description is, that single episode that --- I mean, that single affidavit of the teacher.
>
> Where at least the doctor's note says that the skin breaks out with blotches when upset. Now, "breaks out" often is used to refer to urticaria, yet she refers to it as blotches, so we don't really know whether she was talking about maculars or urticaria or whether she distinguishes between those two. We just don't know that.

Tr. at 137-38. Dr. Josephs also noted the many possible allergic triggers that could have been at work to bring about an allergic response of the skin:

> [W]hen kids are sick, and especially if they're receiving antibiotic at the same time, they are prone to have a variety of rashes. Not necessarily urticaria, what I would call urticaria or what Dr. Frick would call urticaria, but rashes and the observers at the time, we don't know if they were distinguishing that fact.
>
> On at least one occasion she had a positive strep infection and scarlet fever type rash or scarlatina, it was referred to. So they're not all the same thing but they are occurring in the same person.
>
> ...Scarlatiniform means looking like scarlet fever, a skin rash disease associated with ... Group A beta strep infections, and her strep test was positive on that visit. ...[U]nder the assessment, it says ... strep pharyngitis with scarlatina rash, but also they talk about urticarial rash all over the body, so I don't know whether there were two rashes, whether the person wasn't sure what the rash was. It would be uncommon to have both scarlatina and urticaria, I think, and so we don't know whether they're being clear in distinguishing those two, or think it could be either one.
>
> ...Scarlatina rash typically would be a fine, small, slightly raised bumps that we call papular rash. Sometimes they're referred to as kind of a sandpaper appearance rash, fine papular looking rash that's usually bright red. So that was seen in the earlobes and in the groin area, and presumably the doctor thought there was another form of rash elsewhere that looked more like hives or urticaria.

Tr. at 138-141, discussing, *inter alia*, Pet. Ex. 8 at 6 (*see supra* at 5).

Regarding the several different antibiotics given to Kimberly when she was seen by her pediatrician, and whether her symptoms could be attributable to them, Dr. Josephs opined:

> I don't think there's any question that children with viral illnesses who receive antibiotics are likelier to have a rash than if they have a virus and don't get antibiotics, but whether --- I wouldn't want to say with certainty that the antibiotics were causing the rash in this case. It's just one more of the possibilities that could contribute to rashes.

Tr. at 143.

Dr. Josephs contested Kimberly's diagnosis as having been confirmed by direct observation as chronic urticaria by a qualified allergist, noting that the statement in Dr. Tate's medical records (Pet. Ex. 3 at 7)[26] was not based upon symptoms observed by the allergist, but was based upon the parental description given:

> The record --- it's not clear from the record who actually took the history here. The only name on the record is the name of A. Lance, the nurse, R.N. Dr. Tate's name doesn't appear on the typed record of the history and the background history.
>
> There's no physical exam noted in the record, so it may be a page missing, but the record that I had to look at, there was no physical exam noted, so we don't know from that particular encounter on --- that was on 3-17-03 --- what things looked like.
>
> ...The patient had a reaction to DTAP injection on January 29, been on Benadryl ever since. Still hiving every afternoon. Now, this is the nurse's statement of the complaint from mom, presumably, calling in. Mom had stopped Atarax and Benadryl and started Zyrtec. Now, that was what was recommended after the 17th, the visit of the 17th. However, they go on to say that before the visit the patient was off medications for one week, and mom noticed it was fading and eventually faded before the appointment, but after giving the Zyrtec that was after the appointment, the rash came back. Okay.
>
> My point here is that from what we can tell from Dr. Tate's notes, he did not see a skin rash. If there was an exam, we don't know, but the rash was gone, according to these notes, at the time that Kimberly was seen in the clinic, in the office.
>
> So I want to just be clear that the contention that Dr. Tate, a Board certified allergist, has diagnosed chronic urticaria is really only based on the history obtained and not on any personal visualization of any skin rash, and unfortunately she didn't go back at a point where there was a rash for him to assess whether he thought it was urticaria or something else, or whether he thought it was derm[o]graphism or something else.
>
> In addition, we typically test people for other potential causes of urticaria, albeit very rare, thyroid disease, kidney disease, liver disease, and others, and that was never undertaken.
>
> So for me the contention that the allergist diagnosed chronic urticaria is really --- I don't know if hearsay is the correct word in this setting, but it wasn't independently verified by Dr. Tate that we know of.

Tr. at 144-46.

Dr. Josephs summed up his theory of causation into the following synopsis:

> I believe, as mentioned by Dr. Frick, when you refer to hyper-reactive skin or hyper-sensitive skin, that's not really a medical term and if I had to use a medical

[26] Dr. Josephs did not have access to the "Physical Examination" portion of Dr. Tate's records, since Petitioner did not file it until after the Entitlement Hearing.

> term I would say that there was a tendency to have either derm[o]graphism or possibly physical urticaria, that preceded the immunization; that she received the immunization and had a relatively common manifestation of a reaction to the vaccine; or there may or may not be IgE or IgG, but typically they resolve spontaneously over a period of hours or days. There's no contraindication to immunizing later, which there would be if there were an ongoing IgE, anaphylactic type sensitivity, and so I believe that the two things are unrelated and that she continues to have sensitive or reactive skin, probably derm[o]graphic or physical type urticaria.
>
> And since those types of physical or derm[o]graphic urticarias are known to occur in two to five percent of people, and since I couldn't find any reference to chronic urticaria at all after DTAP, then to the degree of medical certainty exceeding 50 percent, I conclude that it's not the DTAP vaccine, but rather some other form of chronic urticaria, which we see very commonly.

Tr. at 149-50. Later he added that dermographism is "not IgE mediated," "not due to a specific allergen," and that it is currently unknown "why people have it, but we do know it's pretty darn common." Tr. at 154.

The Court queried Dr. Josephs specifically on whether the vaccine could persist in Kimberly's body for months and even years to cause and sustain an allergic response for that duration:

> THE COURT: Could you have an allergic reaction persists for months or for years without the continual exposure to the putative allergies or allergens?
>
> THE WITNESS: I would say the answer to that is no, except that what we do have patients with chronic urticaria who have idiopathic, meaning unknown cause, and so we don't know exactly what the cause is, so the dictum that you never say never applies, but I would not expect a person who ate peanuts and was allergic to peanuts to have chronic urticaria because of that exposure. So the peanut paradigm would be the immediate type reaction to allergy and I would not expect to have chronic urticaria for months or years after eating peanuts.
>
> THE COURT: What about the components of the DTAP, could that remain in the system long enough, several years, in order to in theory bring about that kind of reaction?
>
> THE WITNESS: No, and I think in fact that's what they were alluding to in the Redbook that we covered, that whether it's the tetanus or pertussis or diphtheria protein or whether its some non-medicative aspect of the vaccine, whether it's gelatin protein, fimarasol preservative.
>
> THE COURT: Some bonding element?
>
> THE WITNESS: Some other portion of the vaccine fluid, whichever one might trigger the new response, the amount of the antigen, that is, the protein that comes from the vaccine, inevitably goes down over time, and in order to have the immune

> complex type reactions that we think probably caused the short-term problems she had, they inevitably get better because as the amount of antigen is metabolized out of the body, you no longer have the right balance of antigen proteins and antibodies to trigger the type of immune complexes that cause the reaction, and Dr. Frick alluded to that earlier, that you have these immune complexes of IgG antibodies and then protein and antigen. They have to be present in the appropriate relative amounts in order for the type of complexes to be formed to cause problems.
>
> Once either level goes down, or for that matter up, the proper complexes aren't made any more and the reactions subside. So serum sickness if the classic paradigm for that. And that goes away over a period of days or weeks typically.

Tr. at 50-152. Dr. Josephs also spoke to dispel the contention that bovine serum as a vaccine medium could cause chronic urticaria:

> [P]roteins such as gelatin or in this case calf serum, so it's either called fetal calf serum or fetal bovine serum, they were just discovered to be useful commodious kind of environment for bacteria and viruses to live in, and so they're included in the growth media.
>
> Once the bacteria, in this case the bacteria grow, you try to remove as much of that as possible, but there could be traces left, and some of the articles provided show that in fact you can demonstrate immune responses to those trace irrelevant proteins, but again, that's not to say --- that doesn't say that they cause long-term problems. It simply says that you need to be aware that it may not be the diphtheria, tetanus or pertussis if you saw immediate hives. You have to consider these other possibilities, and would be looking primarily to immediate type reactions.

Tr. at 153.

Dr. Josephs noted his disagreement with Dr. Frick's analysis and reading of the medical literature filed in this matter, beginning with the *Redbook* (*see supra* at 20). Tr. at 127. To Dr. Josephs the *Redbook*'s comments that future vaccinations need not be avoided following a reaction indicates that such a reaction would be isolated and non-recurring:

> [Reading from the *Redbook*], "Entire limb swelling after the fourth dose of DTAP vaccine does not portend an increased risk of this reaction after the fifth dose. Because of the importance of the fifth dose in protecting a child during school years, a history of extensive swelling after the fourth dose should not be considered a contraindication to the receipt of the fifth dose at school entry."
>
> The reason I read that is that if you were dealing with an immunological reaction of an anaphylactic type, you would not expect to intentionally re-expose the patient, the person to that vaccine again. You would expect to have a more rapid and severe --- potentially more rapid and severe reaction.
>
> We have already discussed the fact that these things can be immune complex mediated, but again I believe the *Redbook* shows that these are relatively transient and in nowhere does it mention that the patients develop chronic rashes from the

exposure, even having developed one of those classic adverse effects, which I think describes fairly well what she had.

Tr. at 126-27. In Dr. Josephs' estimation, Kimberly's reaction to the vaccine ceased by the time of her discharge from the hospital on 31 January 2003. Tr.at 127.

A problem regarding determining causation in a case like Kimberly's, explained Dr. Josephs, is that urticaria is a generalized reaction symptom, and may be identical in gross appearance as between allergens, as well as between acute and chronic varieties:

> Well, we see urticaria very frequently in clinical practice, but one of the problems we face is that the hives, the urticaria that come from allergic reactions, that is, the IgE mediated reactions, whether it's shellfish or peanuts or penicillin or bee stings, those urticaria and indistinguishable in appearance from the urticaria that may come with immuniocomplex reactions or from the condition we call chronic urticaria, which depending on the reference, between 80 and 95 percent of the cases have no recognized cause. It's simply unknown exactly why they have chronic urticaria.
>
> So simply observing urticaria by its welts, whatever you want to call them, does not tell us that we're dealing with an IgE or An IgG mechanism. That's only one of the mechanisms that can trigger chronic urticaria.

Tr. at 128-29.

Dr. Josephs also discussed dermographism, where "if you stroke the skin, it will welt up and have an urticarial reaction," which is a form of physical urticaria, a "relatively uncommon type of urticarial reaction in which physical irritation of the skin prompts the development of the welt or the urticaria." Tr. at 129-130. He believed that much of Kimberly's recurring symptoms were actually dermographism:

> I used the term derm[o]graphism in my affidavit because I thought that it would cover the entirety of her rash problems before and after, with a reasonable diagnostic entity, a diagnostic entity that's reasonably common and does not invoke --- we don't know the cause of that, so you do not need to invoke a causality from an immunization or other allergies.
>
> Well, in some cases just rubbing the skin will do that, so [irritation around the] belt line, scratching because you're nervous, and I think that the lines of derm[o]graphism and other physical urticarias will sometimes blur. The observation is the person has a rash that itches, but whether it was stroked, rubbed, vibrated, the rash may look the same.

Tr. at 130-131.

As support for this opinion, Dr. Josephs read a selection from a textbook which had been filed along with his expert report:

> Talking about physical urticarias, [the text] summarizes some of what we've just talked about. So halfway down or ten lines down, "A variety of provoking stimuli

> have been described, including mechanical, pressures, thermal, solar and aquagenic. In its mildest form derm[o]graphism may occur in up to two to five percent of the general population, however, symptomatic derm[o]graphism can account for the majority of hives in some patients with chronic urticaria."
>
> So again, to summarize the thought process, the theory of the case, we have a condition like physical urticaria or derm[o]graphism that may occur in two to five percent of individuals, may not be related directly to having IgE or IgG antibodies that could explain rashes coming and going for long periods of time, and they need not invoke a heretofore unrecognized condition of chronic urticaria after DTaP injection.

Tr. at 131-132, citing Resp. Ex. A, Tab 1, Donald Y.M. Leung *et al.* (eds.), PEDIATRIC ALLERGY: PRINCIPLES AND PRACTICE 577 (Mosby 2003).

Discussing the text selection filed by Dr. Frick (*see supra* at 14-15), Dr. Josephs concluded that it was not analogous to Kimberly's condition:

> This is a chapter describing the types of reactions that have been observed, among which includes IgE mediated vaccine reactions and those would typically be occurring within minutes. It could be 30 or 60, but it's typically not hours or days. And they're pointing out that this has been known to occur.
>
> ...I think it is not [analogous] because of the rapidity with which these occur... Well, that's not an indication in my mind. These antibodies can occur --- in this case the time course of onset of the reaction and the associated symptoms, fever and leg pains, irritability, those don't relate specifically to immediate reactions in the first 30 or 60 minutes. So the answer is no.
>
> ...It says, "Although the presence of IgE antibodies may predispose to local reactions to subsequent doses of the vaccine, they have not generally predisposed to systemic reactions." My point there was that yes, we know there are IgE antibodies can be made. We know IgG antibodies can be made in this case --- even in cases where IgE antibodies have been found, those patients did not necessarily have reactions to subsequent immunization, and there's no reason to think that it caused long-term adverse effects.
>
> ...If we also look --- if we looked at Exhibit 20, it was just brought today, anaphylactic reaction to diphtheria-tetanus vaccine in a child, specific IgE and IgG determinations, that was a case where the child did have within minutes an immediate and severe reaction. The patient was treated with emergency medicine, namely epinephrin. They went on to show that the patient had IgE and IgG antibodies, but did not have chronic urticaria. *So the fact that we can either observe or posit IgE or IgG antibodies does not necessarily at all tell us that we're going to run into chronic urticaria*.

> ...[E]ven when you can show IgE antibodies are present after an immunization, it *does not indicate that the patient will have chronic, persisting adverse effects from those antibodies*.

Tr. at 133-36 (emphasis added).

Regarding the article on MMR-related skin reactions filed by Petitioner (Pet. Ex. 14), as with much of the literature filed by Petitioner, Dr. Josephs found the studies' conclusions to be correct, but unrelated and ultimately irrelevant to the question posed by this Petition's facts. Tr. at 146. The distinguishment for Dr. Josephs arose from the different nature of the vaccines discussed:

> [MMR is] a viral vaccine. The reaction began three weeks after the immunization and the contention here in this single case from nearly 40 years ago is that the patient developed chronic urticaria after MMR vaccine. I think it's fair to say that viral vaccines would not be expected to perform the same way that bacterial vaccines would be; and, therefore, I don't think this is relevant --- is germane to the contention that DTaP, which caused a reaction within a day, therefore, led to chronic urticaria. I don't think they're comparable.

Tr. at 146. His conclusion was similar with other studies filed by Petitioner, such as Pet. Ex. 18:

> I believe this was provided to show that in this model in dogs, again, giving a viral vaccine, that you could show that you could potentiate development of allergy, in this case the pollens, but again I would say that while that is true, it's not really what we're dealing with here. If Kimberly has chronic urticaria at all, it's almost certainly not IgE mediated any more, as most chronic urticaria isn't, and the fact that one can breed dogs to be --- have a strong tendency for allergies isn't really the issue that we're discussing today.
>
> ...So once again, I would say it's true information but not related to the issue at hand.

Tr. at 147-48.

On cross-examination, Dr. Josephs defended his statements that a diagnosis of chronic urticaria was not truly a *fait accompli*:

> Q Would a doctor, an allergist, typically diagnose something as serious as chronic urticaria without having some evidence existing that she actually had that disease or actually was getting, you know, wheals or lumps and rashes?
>
> A I can't say what he would have done, but I'm assuming there was a history that was taken and that his best guess was urticaria, but I was trying to make the point that we don't really have independent observation. The fact is a Board certified allergist doesn't necessarily mean we have an independent observation of his seeing urticaria. We simply don't know. We know that that's what he thought based on the history. It's not an observation himself.
>
> Q Isn't that diagnosis typically made on an observation though by the physician?

A I think it would be hard to be certain of what you're talking about if you haven't seen the rash.... All I know is there's no record either in his note, his letter, or his office notes of a physical being done, and his nurse's note from two days later says that the rash had disappeared at the time of the office visit. So if he did a physical exam, I don't know how he would have seen a rash if the nurse says it was gone at the time of the visit.

Tr. at 159-161. This discussion continued to consider the period thereafter:

Q Okay. Is there any indication in the record that Kimberly's urticaria resolved in less than six months?

A We don't know from medical records whether she has ongoing urticaria. Really after the visit from Dr. Tate there are no --- I'm not aware of any records in '04 or '05 of diagnosed urticaria. So you're asking me whether something that I don't know if it continued stopped or not....

...Q The only record are the macules in 2007 that apparently were not raised; is that correct?

A Well, the doctor noted that there were no wheals so presumably that doctor made a differentiation between macules, which are flat, and raised lesions that are wheals.

THE COURT: Would the Court be correct in assuming that after the events of early 2003 the next medical notation would not support the contention of urticaria, which is the record you just mentioned; however, there is the teacher's reference in 2005 that could support the contention of urticaria. Is that a correct statement?

THE WITNESS: That's a correct statement, and the reason I hesitate to give you a simple absolute yes or no is that it's not uncommon for me and I'm quite certain other physicians to see people who make statements regarding a rash, which use terms that they think are correct but are actually technically not correct.

Tr. at 167, 169.

Dr. Josephs also defended his characterization that chronic urticaria is typically idiopathic or cryptogenic:

Q Now, do you ever get a patient with chronic urticaria that know what set off their rash?

A In the case of chronic urticaria, almost never.

Q And so they just come in with a rash and they have no idea what started it all?

A They often think --- they're often concerned about some specific things that may have started it, food or something in their household environment, but that typically does not end up being the case.

Q And did you ever get a patient that knew and that you could rely on some certainty that there was some particular trigger that had chronic urticaria?

A I can actually only think of one patient that I know had chronic urticaria and who eventually figured out that it was something he was eating, but two allergy consultations, including at Johns-Hopkins Hospital, had not uncovered that, so it's conceivable.

Q And did the urticaria continue after they stopped eating that substance?

A No, they did not.

Tr. at 162.

Lastly, during cross-examination, Dr. Josephs defended his conclusion that dermographism is a likely cause of Kimberly's skin condition:

Q Does derm[o]graphia usually include hives and wheals?

A Yes, derm[o]graphia refers to the wheals or hives. It refers in my mind to the fact that you can stimulate them by stroking the skin, so it's irritating or stroking the skin will cause them to rise, even if they weren't there to begin with.

Q And can that be irritated also by something else besides contact with the skin? Like would you describe someone who is allergic to the sun as having derm[o]graphia?

A No, that would be --- if someone had urticaria from sunlight exposure, that would be called solar urticaria. It's another type of physical urticaria, quite rare, but not unheard of.

Q And what about heat? That wouldn't be a derm[o]graphia either, would it?

A No. There are heat-related urticarias where there are people actually break out in welts when their body gets hot. There are other people that get blotchy or have flushing appearance when they get overheated. That happens to everybody to some degree. In some it may be more pronounced than others.

Q And that would --

A That wouldn't be an allergy. I'm sorry, that wouldn't be a hypersensitivity. That would be just --- that would be the way that their skin blood vessels react to being heated.

Q Okay. So in Kimberly's case it sounds like that's more of a physical type urticaria, would you agree, rather than derm[o]graphia?

A I thought that it was more a relation to her tendency to have flushing or what we might call blushing or flushing as opposed to actual raised welts....

...[Q The reference in the medical records indicating that Kimberly] occasionally breaks out in hives when she gets upset. That's not a derm[o]graphia, is it?

A What happens --- I have seen patients who, especially young children, when they're upset they may start scratching, rubbing, picking, touching themselves, and break out in hives from that. It's --

Q But this doesn't indicate any touching or --

A It's a limited amount of information to conclude.

Q Okay. So would you agree that urticaria is a different type of disease than derm[o]graphia?

A I usually include derm[o]graphia as one of the types of urticaria.... Urticaria is the exact appearance that we talked about, of which there can be many triggers. There are people with chronic urticaria that may not have derm[o]graphism.

Tr. at 163-66.

D. Post-Hearing Submissions

At the conclusion of the hearing, the Court ordered briefing by the parties, whose arguments are summarized here.

1. Petitioner argued that, although medical literature was not a necessary component of proving causation,[27] she believed that the reference in Pet. Ex. 16, to a 16-month-old who developed "generalized urticaria" following diphtheria and tetanus vaccination due to IgE reaction, was strongly persuasive that the DTaP vaccine could cause chronic urticaria. Unfortunately, Petitioner never elucidated how the immediacy of an IgE reaction could extend to persist over weeks, months, and years. Nor did Petitioner explain how it was more likely than not that Kimberly was affected by an IgE reaction.[28] Tr. at 88-89.

2. Petitioner recapitulated that Kimberly's pediatrician, Dr. Juric, noted on 14 January 2002 (roughly one year prior to vaccination) that Kimberly's skin "breaks out with blotches when upset," but Petitioner added that, "Subsequent medical records do not describe blotches again until 2007."

3. Petitioner noted that, "Although Respondent filed a motion to exclude Dr. Frick's testimony, [Respondent] indicated during the hearing that [she] had no objections to his qualifications to testify."

4. Petitioner incorrectly recounted that "Dr. Frick stated it was his theory that the reason Kimberly's allergies have continued for years is that the vaccine contained bovine serum albumin

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[27] Petitioner also argued that "*Daubert* [*v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)] does not require an expert's testimony to be corroborated by scientific literature." While true that peer-reviewed publication was deemed persuasive but unnecessary as an indicium of methodological reliability by the Supreme Court there, the context of *Daubert* is not the one presented here: *Daubert* considered the bottom threshold of reliability for purposes of admissibility, not persuasive, probative weight. Nor is the support of peer-reviewed medical literature a necessary element of Petitioner's case, to be sure (*see Althen*, *infra*); but its absence, when joined by the absence of a thorough and cogent theoretical explanation, and the absence of professional experiences in support, can certainly lead the Court to conclude that a petitioner has not met his burden of preponderant proof.

[28] The Redbook citation that both doctors discussed and relied upon stated expressly that the urticarial reactions that occasionally have been known to follow pertussis immunization "are unlikely to be anaphylactic (IgE-mediated) in origin." *See supra* at 15.

which triggered the allergic reaction, and then eating beef over the next few years after the initial onset could keep the hives going because the beef would contain the same allergen, bovine serum albumin which is in the blood of the beef." In reality (*see supra* at 18), Dr. Frick described this postulate as "a theory," one which "may seem sort of far-fetched, but at least it could explain why the situation is chronically continuing." Tr. at 176. He did not seem to be offering that "theory" as what was more likely than not what happened in this case. Also, Petitioner herself testified that Kimberly is does not react allergically to any foods. See Tr. at 51-52. Furthermore, Petitioner did not offer proof of such a food allergy, which would not have been difficult to do, and she carries the burden of proof on that element. In sum, this argument did not accurately represent the actual record, and is unpersuasive for other reasons as well.

5. Petitioner conflated two distinct concepts when she argued that because specific scientific proof is not required in Vaccine Act cases (citing *Knudsen v. Sec'y of HHS*, 35 F. 3d 543, 548 (Fed. Cir. 1994)), Respondent was wrong to require a "scientifically reliable" expert opinion from Petitioner. The law in the Vaccine Program is that an expert's opinion must be scientifically reliable in its methodology, even if specific scientific proof is not required for each and every postulate of an expert's theory.

6. Petitioner pointed out that, "The allegation by Dr. Josephs that Kimberly has dermographia is not only unsupported in the record, but as an idiopathic illness, cannot be used by the Respondent to prove that Kimberly was not vaccine injured." See § 13(a)(2)(A) (a factor unrelated shall not "include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition").

7. Petitioner argued in the alternative for a significant aggravation injury–that if Kimberly's post-vaccinal skin condition is found to be of a piece with what preceded the vaccine, then what followed was at least a "significant and substantial aggravation" of what preceded.

8. For her part, Respondent summated Dr. Josephs' expert opinion as holding that "Kimberly suffered a common, non-allergic reaction to the DTaP vaccine that was self-limited and resolved in fewer than six months," that she "suffers from dermographism that pre-dates her vaccination," and that "Dr. Josephs saw no evidence that Kimberly's condition had been caused or aggravated by the vaccination."

9. Respondent argued that "Dr. Frick's testimony was based on pure speculation and unsupported hypotheses, and should therefore be afforded no weight." Apparently, at some point, Respondent's objection to Dr. Frick's testimony ceased to be that his scientific methodology was unreliable or his credentials unqualified such that exclusion was proper. Respondent's objection became that Dr. Frick's opinion should not be viewed as persuasive and should be afforded little weight. As such, the Court views Respondent's original argument for exclusion to be waived, and not preserved for further consideration.

10. Respondent pointed out (citing Tr. at 78-79) that, "Dr. Frick testified that all of the skin conditions from which Kimberly suffered–maculars, blotching, urticaria, and wheals–are manifestations of the same underlying condtion, which he identifie[d] as urticaria," but regardless

"maintains that althought she was chronic urticaria now, Kimberly did not have chronic urticaria prior to vaccination, only [labile] skin."

11. Respondent honed in on the facts that "Dr. Frick acknowledged that no medical literature provided direct support for his theory of vaccine causation of chronic urticaria," that he "testified that in his sixty-two year career in medicine, he had never treated a patient who had chronic urticaria following DTaP vaccination," and that he had "never seen it described in the medical literature."

12. Respondent reiterated Dr. Josephs' point that "the only *medical* observation of Kimberly suffering a rash after March 2003 is [a notation from 31 January 2007] in which the examiner specifically noted that although Kimberly's skin was remarkable for 'large blancheable macules,' 'no wheals [were] noted.'"

13. Respondent argued that, "Although Petitioner alleges that Kimberly suffers daily rashes, Kimberly's alleged daily skin eruptions are not documented in her medical records and by Petitioner's own testimony remain undiagnosed and untreated."

II. Ultimate Findings of Fact

The Court accepted the testimony of both experts as professionally credible and sufficiently scientific in their methodology to be admissible. Therefore, the Court's task now is to analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect, having occurred in a medically appropriate time frame, which is biologically plausible to tie together the factual sequence and explain Petitioner's injury. *See Althen v. Sec'y of HHS*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005); *Pafford v. Sec'y of HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007); *Walther v. Sec'y of HHS*, 485 F. 3d 1146 (Fed. Cir. 2007); *de Bazan v. Sec'y of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008).

The Court begins its assessment of whether Petitioner carried her burden of proof by considering the "can it" prong of causation. Has Petitioner provided a well-explained, plausible theory of causation whereby the DTaP vaccine could be a substantial factor in causing chronic urticaria? Is the plausibility of such a theory supported by external proofs, such as support from others in the field of medical science? Has the professional experience of Petitioner's expert borne out that such a postulated process has been observed before? If the Court is persuaded that Petitioner has proven this element, only then does the Court proceed to inquire whether such a process was at work in the instant case, as the "did it" prong.

First, it is clear that Petitioner's expert, Dr. Frick, has never witnessed, let alone treated, someone suffering chronic urticaria lasting over several months, which had been causatively linked to a DTaP vaccination. Tr. at 177. Likewise, Dr. Frick could not call to mind "any case reports or case studies showing DTaP vaccine caused chronic urticaria." *Id.*

Second, Dr. Frick's selection of medical literature indicated that, while allergic reaction of the skin to a vaccination, even of the DTaP vaccine, might be plausible, there is nothing in those sources that indicate such a reaction could have the capability of lasting for months or years, long after the injected vaccine contents had been metabolized, which would only take days or weeks. Petitioner's medical literature is replete with mentions of brief allergic reactions, even those that are "generalized" across the body, or systemic in the form of anaphylaxis. None of them, however, support or explain a chronic condition following that initial, brief reaction.

Even under the theory Dr. Frick brought up at the end of the Entitlement Hearing–that an allergy to beef, caused by sensitivity triggered by the bovine serum used in the DTaP vaccine, was to blame for Kimberly's longstanding symptoms–is unpersuasive. Unless she had the same reaction to the stimulus every time, with the same severity (*i.e.*, it did not worsen with each exposure), and unless Kimberly ate beef daily (or nearly daily), it is unlikely that this explanation would fit the symptomotology alleged and described by Petitioner. Still less likely is it that an allergic sensitivity to beef products would be so actively responsive to environmental phenomena like solar heat and stress.

Third, Dr. Frick did not explain a coherent theory of how a reaction to DTaP could persist for months or years. Even where personal experience and medical literature do not support a part of a petitioner's theoretical mechanism, this Court has found a petitioner's theory persuasive where it is well conceived and explained, and predicated on accepted medical knowledge, principles, and doctrines. If Dr. Frick had proffered an articulable, plausible theory as to how an allergic reaction could persist long after the vaccine components themselves would have been metabolized, the Court might yet have found an anchor upon which to place probative weight. However, Dr. Frick's testimony left out important–if not critical–portions of explanation and analysis. Besides the missing link of causation having to do with how a vaccine reaction becomes chronic, Dr. Frick did not explain how such a long term reaction would be responsive to other aggravating stimuli, such as heat and stress.

It is for this reason that the Court finds that Petitioner has not met her burden of proving that the DTaP vaccine can cause chronic urticaria, presuming that is what Kimberly's injurious condition was. This is dispositive against the Petition; nevertheless, the Court will analyze the "did it" prong as well, in the interest of being thorough.

Regarding the "did it" portion of causation–which the Federal Circuit has described as "a logical sequence of cause and effect," there is not much to say, since Petitioner's proof of a plausible theory in the "can it" portion was unpersuasive. The Court does not see reason to upset the medical records' diagnosis of chronic urticaria. Similarly, the Court likewise agrees with both parties' experts and with the medical records, that Kimberly's reaction following vaccination was most likely vaccine-related. However, the Court has not been given evidence to persuade it that the same reaction could extend *or did extend* for a period of months or years. The Court is more persuaded by Dr. Josephs, that, as Dr. Frick stipulated, Kimberly has highly reactive skin, and that such reactivity showed itself over a year prior to the vaccination, manifested strongly in the days following the vaccination, and resurfaced periodically ever since in mild to medium skin reactions to external physical stimuli, such as heat, stress, and possibly manual agitation.

There was a dispute between the experts regarding dermographia. Petitioner argued that it was fundamentally different from urticaria, and conflicted contradictorily with a diagnosis of chronic urticaria. A couple of points are worth making here. The first is that the medical records describe Kimberly's skin as manifesting "urticarial rash for few minutes *when scratching*." Pet. Ex. 7 at 13. This is dermographism without the name, and yet the rash was described as "urticarial," leading the Court to see this as a false dichotomy. Urticaria is a symptomological descriptor, and, in isolation, does not indicate the cause of the skin rash. Based on the record presented, dermographia and urticaria are not mutually exclusive categories. On the record in this case, it appears that dermographia may cause urticaria, even though it remains unclear what exactly predisposes a person to dermographia, just as it also remains unclear what causes many if not most cases of chronic urticaria. Dermographic urticaria is not completely cryptogenic or unexplained, because the physical agitation is clearly what triggers it, even if the preexisting sensitivity is unexplained, or even idiopathic. Ultimately, however, the Court does not need to resolve whether Kimberly did (more likely than not) suffer from dermographism, but considers the issue as part of the material in weighing probative weight herein.[29]

The only evidence that Kimberly's skin reaction continued in the same level of severity and qualitatively distinct aspects following vaccination is Petitioner's own fact witness testimony, which was rather too nonspecific to rely on in this regard. Kimberly's father averred that Kimberly had to take her medicine every day lest she break out in a rash, but that the medication regimen she was on was effective to control her skin rash symptoms. Tr. 24-26. In contradiction, Kimberly's mother (Petitioner) testified that the medicine Kimberly takes is only for her sinus and cold symptoms, is not an antihistamine, and has no effect on Kimberly's skin condition; Petitioner stated that just keeping Kimberly cool–and not any medication–was how Kimberly's rash was kept under control. Tr. at 52-57. There was no consensus in the record regarding Kimberly's ongoing symptoms; yet Petitioner relied upon that indeterminate period to prove her case. Also, Petitioner sought to make much of the specific wording of a teacher's affidavit about phenomena she had witnessed, perhaps singly or sporadically, over previous months (i.e., not contemporaneous to her affidavit), with the intention to link it strongly with the symptoms that followed in the days immediately following the vaccine. There is quite simply a paucity of persuasive evidence in the record to conclude in Petitioner's favor on a history of the months and years following 2003.

The truth is that, as both experts discussed, Kimberly is one of those individuals whose skin is just more highly reactive to allergens than the norm. She even suffered an allergic reaction to allergy medicine! Her skin reacts to solar heat. Her skin reacts to stress (either spontaneously or because she is more prone to rub her skin at that time and such rubbing spawns dermographia).[30] All of these cause a skin reaction of variable quantitative severity, but which is qualitatively very close, if not indistinguishable or indeterminate. Attempts by Petitioner to parse between these reaction forms, based on passing references to medically specific terms in lay testimony, are unavailing.

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[29] Consistent with § 13(a)(2)(A), the Court does not find dermographia to rise to the level of factor unrelated.

[30] Kimberly's skin may also react to a host of allergens that are currently unknown, as she has never been tested to determine the scope of her allergies.

This circumstance is not a pure result of the wheel of fortune. Petitioner had the prerogative of building up the record by allergy skin testing and more extensive allergist consultation. Petitioner actively decided to forego allergy testing when it was recommended by Dr. Tate. She has foregone further allergist visits to provide a later or continuing diagnosis and treatment regimen. It is difficult to afford an injury great weight when no treatment is being given for it, despite knowledge of the condition by parents and primary care physician. The record is simply unclear regarding her continuing condition.

As an aside, the Court notes once more that close temporal association between vaccination and experienced symptoms is not a sufficient proof of causation (of those symptoms, or those that might follow later), and further, such an association cannot suffice to meet Petitioner's burden on either the "can it" or "did it" prong. *See*, *e.g.*, *de Bazan v. Sec'y of HHS*, 539 F. 3d 1347, 1351-53 (Fed. Cir. 2008). Moreover, as has just been discussed, it is not at all clear that the symptoms that did follow within hours to days of the vaccine were qualitatively unique, or that those distinctive symptoms continued for six months or more.

In short, it is not at all plain to the Court that Kimberly's DTaP vaccination could have caused a long-term allergic-type reactive skin condition like chronic urticaria, and it is not at all clear that Kimberly even suffered a distinctly severable injury (or significant aggravation of an existing injury) following vaccination. There is no indication to the Court that Kimberly's skin condition would not have occurred but for the vaccine's influence (either as an initial, direct injury or as a significant aggravation of a preexisting injury), and there is surely no sufficient quantum of evidence that Kimberly's vaccines were a substantial factor in causing any such injury.

III. CONCLUSIONS OF LAW

As aforementioned, the Court is authorized to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a cognizable Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). If Petitioner had claimed that Kimberly had suffered a "Table" injury, to her then would §13(a)(1)(A) have assigned the burden of proving such by a preponderance of the evidence. In this case, however, Petitioner does not claim a presumption of causation afforded by the Vaccine Injury Table, and thus the Petition may prevail only if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury alleged. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Sec'y of HHS*, 956 F. 2d 1144 (Fed. Cir. 1992); *Strother v. Sec'y of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F. 2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F. 2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit has articulated an alternative three-part causation-in-fact analysis as follows:

> [Petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

As part of that analysis, the Federal Circuit recently explained:

> [T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's aetiology, it is medically acceptable to infer causation-in-fact.

de Bazan v. Sec'y of HHS, 539 F. 3d 1347, 1352 (Fed. Cir. 2008).

Under this analysis, while a petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Sec'y of HHS*, 35 F. 3d 543, 549 (1994).

As a matter of elucidation, the Undersigned takes note of the following two-part test, which has been vindicated and viewed with approval by the Federal Circuit,[31] and which guides the Court's practical approach to analyzing the *Althen* elements:

> The Undersigned has often bifurcated the issue of actual causation into the "can it" prong and the "did it" prong: (1) whether there is a scientifically plausible theory which explains that such injury could follow directly from vaccination; and (2) whether that theory's process was at work in the instant case, based on the factual evidentiary record extant.

Weeks v. Sec'y of HHS, No. 05-0295V, 2007 WL 1263957, 2007 U.S. Claims LEXIS 127, slip op. at 25, n. 15 (Fed. Cl. Spec. Mstr. Apr. 13, 2007).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of

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[31] *See Pafford v. Sec'y of HHS*, No. 01-0165V, 2004 WL 1717359, 2004 U.S. Claims LEXIS 179, *16, slip op. at 7 (Fed. Cl. Spec. Mstr. Jul. 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd* 451 F. 3d 1352, 1356 (2006) ("this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*"), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007).

the vaccination." *Pafford v. Sec'y of HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007), citing *Shyface v. Sec'y of HHS*, 165 F. 3d 1344, 1352 (Fed. Cir.1999). This threshhold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that Petitioner would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*. "[T]he relevant inquiry ...[is]... 'has the petitioner proven ... that her injury was in fact caused by the ... vaccine, rather than by some other *superseding*[,] *intervening* cause?' ...[The petitioner need not] rule out every possible explanation ...[but]... must simply show ... that her injury was caused by a vaccine." *Johnson v. Sec'y of HHS*, 33 Fed. Cl. 712, 721 (1995), *aff'd* 99 F. 3d 1160 (Fed. Cir. 1996) (emphasis added).

"To prove causation, a petitioner in a Vaccine Act case must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Moberly v. Sec'y of HHS*, __ F.3d __, 2010 WL 118661 (Fed. Cir. 2010) quoting *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999); *see also Id*. citing *Walther v. Sec'y of HHS.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (for causation analysis in off-Table cases, the Restatement (Second) of Torts applies and 'the petitioner is treated as the equivalent of the tort plaintiff'). In the watershed case of *Shyface v. Sec'y of HHS*, 165 F. 3d at 1352, the Federal Circuit "adopt[ed] the Restatement [(2d) of Torts] rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action," and that rule continues to guide the Court today in the instant matter. *Cf. Hargrove v. Sec'y of HHS*, No. 05-0694V, 2009 WL 1220986 * 39-40 (Fed. Cl. Spec. Mstr. Apr. 14, 2009).

Based upon these legal predicates, the Court cannot award compensation to Petitioner, as it has not been proven to a preponderance of evidence that Kimberly suffered an injury that was actually caused by a vaccine, which must be proven to demonstrate entitlement to compensation. Petitioner did not persuade the Court that the DTaP vaccine can cause chronic urticaria ("a medical theory causally connecting the vaccination and the injury"), and Petitioner did not persuade the Court that DTaP did cause chronic urticaria in Kimberly ("a logical sequence of cause and effect showing that the vaccination was [a substantial] reason for the injury"). Petitioner did not persuade the Court that Kimberly's condition and course would not have followed the trajectory it did, but for the influence of the DTaP vaccine, nor that the DTaP vaccine was a substantial factor in bringing about a chronic condition in Kimberly. Temporal proximity between vaccination and a apparently short-lived vaccine reaction cannot, of itself, carry Petitioner's burden. The Court has no alternative but to **DISMISS** this Petition.

IV. CONCLUSION

Therefore, in light of the foregoing, the Court **RULES** that Petitioner is not entitled to compensation, and **DISMISSES** this Petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, **the clerk shall forthwith enter judgment** in accordance herewith. In the event the parties have any questions about this Decision, the Court may be reached *via* my law clerk, Isaiah Kalinowski, Esq., at 202-357-6351.

IT IS SO ORDERED.

Richard B. Abell
Special Master