In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-36V
Filed: 4 February 2011
Originally Filed: 21 October 2010

* *		
KEITH and BEVERLY LANGLAND, on behalf of their daughter, [M.L.],	*	
Petitioners,	*	
v.	*	Actual Causation; DTaP; IPV; Celiac Disease; General Causation ("*Althen*, Prong 1" or "Can It"); Temporal Association
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Paul S. Dannenberg, Esq., Huntington, Vermont, for Petitioner;
Melonie J. McCall, Esq., United States Department of Justice, Washington, District of Columbia, for Respondent.

DECISION[1]

ABELL, Special Master:

On 18 January 2007, Petitioners filed this Petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] alleging that, as a result of the DTaP vaccine administered to their daughter [M.L.] on 28 January 2004, she suffered the onset of Celiac Disease. *See* Petition.

Eventually, an evidentiary hearing on the ultimate issue of vaccine causation was convened by the Court *in vitro* (telephonically) from the Court's Chambers on 9 December 2008. Wherein, the Court heard from medical expert witnesses for both parties, Dr. Oscar Frick, an

[1] Pursuant to Petitioners' request, the name of the minor vaccinee has been redacted to her initials. Her birth date has also been redacted. See Order, Feb. 3, 2011.

[2] 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.

Allergist/Immunologist, for the Petitioner, and Dr. Andrew Warner, a Gastroenterologist, for the Respondent. Following those hearings, the parties filed closing briefs with the Court, and the case became ripe for a ruling. On 8 September 2010, the Court convened a hearing to announce its ruling to the parties, which is excerpted in relevant portion hereunder and incorporated herein.

As a preliminary matter, the Court notes that Petitioner had 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 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. On these matters, Respondent tenders no dispute.

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. LEGAL STANDARD

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).

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 she had suffered a "Table" injury, to her 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,[3] 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 Petitioners' 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 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 ...

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[3] *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).

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.[4] *Cf. Hargrove v. Sec'y of HHS*, No. 05-0694V, 2009 WL 1220986 * 39-40 (Fed. Cl. Spec. Mstr. Apr. 14, 2009).

II. DISCUSSION

The Court's Bench Ruling was as follows:

> All right, this is the Langland bench ruling, Entitlement. And that's what this is, a decision on entitlement.

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[4] The mandate of the Federal Circuit in *Shyface* to follow the RESTATEMENT (2D) OF TORTS on the application of actual causation did not indicate how this Court should approach the tectonic shift of the common law into the later Restatement(s). The short answer to this question is that the Federal Circuit incorporated the RESTATEMENT (2D) OF TORTS, and until the Circuit does otherwise to change that gloss, that is the mandatory precedent binding on this Court. By way of more detailed analysis, given the Circuit's reasoning in *Shyface* for incorporating the Restatement, *i.e.* that Congress contemplated the common law (in its then contemporaneous understanding) within the Vaccine Act draftsmanship, thus presuming the common law as a background legislative intent, it would appear that only the Second Restatement is binding on this Court in matters touching on actual causation, because that is the version in use at the time of the Act's drafting and passage. Likewise, when the Federal Circuit decided *Shyface* in 1999, the RESTATEMENT (3D) OF TORTS: PRODUCTS LIABILITY had already become available in published form, and yet the Circuit did not choose to incorporate or even reference that Restatement's provisions at all, notwithstanding the potential corollary to the Program's focus on causation in the absence of a fault element. Had it done so, a contrary argument could have been made that the Circuit's reading of congressional intent was a progressing correspondence to whatever Restatement provisions were most current. However, this would seem to correspond to the more dubious "statutory purpose" canon of interpretation. The Court's reading of *Shyface* leads to a result that the Third Restatement should be viewed at most as persuasive, but not mandatory authority, and is not to be followed where it conflicts with the Second Restatement. Therefore, to the extent the Court cites to the Third Restatement herein, it shall be only to bolster or elaborate citations to other sources.

First, let's do an introduction from the medical records. She was born [REDACTED] 2002. And had, for the most part, a normal development in the period preceding the period in question.

Her parents fed her a soy formula as an infant, which does not have gluten in it, or at least presumably it does not. Interestingly, [M.L.]'s history, Petitioner's Exhibit 7, page 6, indicates that she suffered from vomiting and diarrhea in mid-December 2003, but that those symptoms abated when she was put back onto her baby food.

This was several weeks before the reported onset of those same symptoms on 28 January 2004. At [M.L.]'s 18-month check up on 28 January 2004, she received her fourth DTaP and third IPV vaccinations. At that time she was able to run, kick a ball, point to five body parts and used a six-word vocabulary.

[M.L.] was returned to the doctor's office on 13 February 2004, complaining of a two and a half week history of intermittent emesis and diarrhea (beginning the date of vaccination), and reportedly had not been playing or eating well, but had only wanted to sit in her mother's lap. The doctor's examination indicated abdominal distention.

Two days later, on 15 February 2004, [M.L.]'s parents returned her to the doctor with concerns of developmental regression, due to a decrease in speech and play with her siblings. She was reported to be withdrawn, even antisocial. They also complained that her symptoms of emesis, diarrhea, and loss of appetite had persisted.

Five days later, on 20 February 2004, she returned again to the doctor, this time with complaints of having staring spells with eye blinking, so she was referred to gastroenterological and neurological consultations to consider the possibility of seizures.

[M.L.] saw the gastroentrologist on 3 March 2004. In his analysis, her health problems actually began in December 2003 with a viral-type illness (from which she recovered), then progressed to her becoming ill again on 28 January 2004 (the vaccination date), and her poor condition had persisted since that time.

He noted negative behavioral changes, that she changed from a happy child into an irritable one, and that she suffered from staring spells. He also noted that she also had an allergy to milk, although the specifics of her allergy were unknown at that time. Due to a family history with Celiac disease, she was recommended for testing regarding that illness.

[M.L.] underwent a duodenum biopsy on 16 March 2004, the results of which were consistent with and confirmed Celiac disease. [M.L.] was seen by a neurologist on 12 March 2004, who did not believe she suffered from a seizure disorder, nor from autism, based on EEG and MRI testing. The neurologist believed that her social

withdrawal and developmental regression were secondary to her gastroenterological problems, and that once those were addressed, she would go back to normal development.

The neurologist reported the parental history that her problems all began when she received immunizations and was never the same since, and later noted that she had "a history of an illness that began coincident with immunizations in January." Petitioners later argued that this meant the neurologist blamed the vaccine causally.

Sure enough, once [M.L.] was placed on a gluten-free diet, her physical symptoms stabilized and she became active and playful when observed at every six-month follow-up visit up to the date of the petition's filing.

At a doctor's visit on 12 April 2004, [M.L.] was noted to have been recovering from the previously reported developmental delays, had recovered her verbal vocabulary, and her behavioral problems had ceased.

At that time her development and speech were somewhat delayed, due to lost time while she was suffering from Celiac disease.

However, at her two-year well-child checkup on 3 February 2005 (a little over a year following the vaccination at issue), she was noted to have (nearly) normal speech and development, and that she had no problems with social interaction.

[M.L.] was being treated at "Progressive Pediatrics" where, it appears, one Dr. Julie Buckley stated to Dr. Valerie Miles in an email (that is not a diagnostic medical record) but an email: "I saw her in the worst of the worst and this kid's gut took a terrible hit. She's not getting any Calcium or Magnesium supplementation and probably not enough zinc, who knows about Selenium. She's also not on any probiotics. Those are changes I would absolutely make, no matter how fabulous she looks now. And I'd seriously think about methylating her with the B12/ Folic Acid/NAC combo as well as DMG. She was sick as an ever lovin' dog and Crohn's disease (sic) or not -- and the Court notes that she does not nor presumably ever had Crohn's Disease. It was Celiac disease, two very, very different diseases.

Back to quote, "or not, she got that way in direct association with her shots. Call me if you have any questions. Watch Channel 12 next Friday newscasts and pray that my words don't get twisted. Julie."

The Court is aware of this record, but finds it of dubious quality and minimal probative value regarding the issue of vaccine causation. It is even mistaken about what her actual condition is, calling it Crohn's when it is actually Celiac disease. It opines that her condition is extreme, ruminates as to what vitamin supplements should be part of her treatment, (notwithstanding the fact that she is doing

"fabulously"), and then just asseverates that her condition was "in direct association with her shots."

Of course, the law in the Vaccine Program is clear that temporal association alone is not sufficient to prove causation. And for example, *de Bazan* and a host of other cases.

Her height and weight were age-appropriate at her four-year well-child visit in 2006.

Petitioner pointed out in the medical records the recitation of parental histories temporally associating the 28 January 2004 vaccinations with the onset of symptoms. None of those references blame the vaccine causally, but only recite the pattern of events in [M.L.]'s course. As with much of Petitioner's case, temporal association is relied upon to prove causation, which it cannot.

Petitioner's expert, Dr. Oscar Frick, an Allergist/Immunologist. Now, his CV -- and I note because that's important because Respondent has leveled a Daubert challenge to his ability to testify. He went into the Service for two years -- military service -- and then University of Pennsylvania Postgraduate School of Medicine in Pediatrics in Philadelphia, studied to be a Master of Medical Science, graduated in 1960, went to Stanford University School of Medicine, Immunology for a Ph.D. in 1964. Internship at Babies Hospital of Columbia in New York, residency Children's Hospital, Buffalo and pediatric practice in Huntington, Long Island for eight years. To get his specialization in Allergy, he did a post-doctoral fellowship in allergy immunology at the Royal Victoria Hospital at McGill University in Montreal, 1958/59, post-doctoral fellowship in pediatric allergy/immunology at UCSF during '59 and '60, followed by a post-doctoral fellowship in allergy/ immunology at the Immunology Center Hospital, Drucais in Paris, France from '60 to '62. From there he went to the National Institute of Allergy and Infectious Disease, NIH, post-doctoral fellowship in immunology at Stanford and received his Ph.D. He's board certified in Pediatrics and Allergy and Immunology.

He stated that he's primarily an Allergist and has specialized in food allergy for a number of years, Whereas Celiac disease is an autoimmune disease, and he hasn't done as much research with autoimmunity, even though he has experience diagnosing autoimmune diseases.

The Court accepted the testimony of Dr. Frick, saying "I've heard no reason he should not be accepted. He certainly sounds most qualified." Respondent's preemptive motion in limine to exclude Dr. Frick's testimony in toto is hereby dismissed.

His written expert report raises his theory, which is basically a "trigger" mechanism similar, to the construct discussed in the Court's recent ruling of Sucher v. Secretary

of HHS, to wit, [M.L.] had a genetic predisposition to a disease and that it was the vaccine that triggered the appearance of symptomatic manifestation.

Said the doctor, "With such a genetic predisposition, it is likely that an insult like an infection or vaccination would trigger an autoimmune response like Celiac disease." The trouble with his report is that he never clearly articulates how a vaccine could trigger the onset of latent Celiac disease. The most he could say was to reference studies indicating, "celiac patients may have abnormal responses to viral and bacterial infections and to vaccines," such that they may not have the appropriate immunizing response to a vaccine like Hepatitis B.

Another problem with the expert report is that his report's conclusion relies heavily on temporal association in the clinical history, "With the clinical history of vaccination on 1/28/04 followed immediately by gastrointestinal symptoms and rash and fever and subsequent Celiac disease proven by biopsy and resolution on a gluten-free diet in a genetically-prone child, it is my opinion that the vaccination caused her Celiac disease onset.'

Now, at the hearing Dr. Frick found significant that [M.L.] had a history of ear infections during 2003, recurring about every two months, cumulating in the placement of ear tubes in September 2003.

To him, the recurrent ear infections, "suggested that she might have an IgA deficiency, which is the immunoglobulin that protects the membranes of the body, the internal membranes of the body like in the ear, the sinuses, respiratory tract, the GI tract, the urinary tract, and genital tract. So that's sort of a surface-protecting immunoglobulin. And that was low, below the range of normal."

He bases this below normal conclusion on the fact that, when [M.L.]'s immunoglobulins (including her IgA) were measured a year after this period surrounding the vaccination in question, her IgA was at a level of 18 units, whereas the normal range is 21 to 128. Also, her IgA was 394 on a scale where normal is 394 to 1052 and her IgM was at 36 on a scale where normal is 29 to 135.

This leads Dr. Frick to conclude that she had low IgA in the period surrounding the vaccination, stating, "she probably had an IgA deficiency, which could lead to some of these recurrent ear infections. An IgA deficiency is many times a predisposition to autoimmune disease, including Celiac disease."

Also on this point, he thinks IgA deficiency runs in the family because "there are four other siblings, and they, all three of them, had recurrent ear infections, and two of them had ET tubes placed in the ears as well, which suggests that there is an IgA deficiency in that whole family."

Petitioners introduced the primary theory of their case, asking Dr. Frick whether there was any symptomological evidence in the record of Celiac disease before the vaccination in question, to which he responded that, no, she had not. The Petitioners asked what happened after the vaccination, to indicate causation based on temporal association.

Dr. Frick responded: "within four hours after the vaccination, there was some rash that occurred, especially on the side on the right deltoid, which is the side that she had the DTaP injection. And the other side, the left deltoid, where she got the measles/mumps/rubella and the polio vaccine, were not swollen, were not involved. So that suggest that the DTaP was probably involved in the reaction," and not the polio vaccine.

He added, "the right arm, where the DTaP was, became very swollen from the shoulder all the way down to the elbow, a huge reaction. And on the other side, the left side, where the polio and the measles was given, was not swollen, which suggests that the DTaP was probably the culprit, although I can't rule it out that the measles is a cause."

Additionally, Dr. Frick thought it possible that the polio could cause the injury alleged, but found it less persuasive than 50 percent and a feather, because the arm that received the polio shot did not evidence the same visible reaction.

The Court found it odd that Dr. Frick mentioned measles vaccination twice, when it appears from the records that no MMR vaccine was given among the vaccinations at issue. Petitioners Exhibit 3 at pages 1 and 2.

More generally, the Court did not follow Dr. Frick's logic regarding how a swelling or rash reaction, which is a rather common, benign reaction to DTaP vaccination, indicated that the DTaP caused an intolerance of wheat gluten.

Dr. Frick continued his summary of what occurred following vaccination: "Gradually the swelling went down and she improved, after which she continued to have rashes, and she also had some personality changes, had some difficulty even in walking, became sort of withdrawn, whereas she had been a very happy, outgoing child before. And then she also had some vomiting and diarrhea and that persisted. And she became very protuberant in the abdomen, suggesting that something may have been going along in the bowel as well. And this we commonly see in Celiac. So it could well be that Celiac disease started then. The Celiac disease finally was diagnosed in March when the endoscopy was done and Celiac disease was confirmed by endoscopy and biopsy."

Dr. Frick did state that [M.L.]'s symptoms were controlled by the eradication of gluten in her diet.

He saw the DTaP vaccine as a "trigger" for the Celiac disease, but not an independent cause since it was dependent on genetic abnormality and he could not rule out "that eventually she would develop it anyway with some other future event like a virus infection or maybe a future immunization, because I think the DPaT probably triggered the Celiac."

Now she has Celiac, which "is a lifelong condition. Fortunately, we do have a treatment, which is just avoidance of gluten in the diet, mainly wheat, rye and barley in the diet. And she actually has done quite well since then on the diet. Actually, within a month I think she was improved."

Unfortunately, Dr. Frick's only explanation of how the Celiac could be triggered by vaccination was "well, I think that the immunization triggered the onset of the Celiac disease because she apparently was quite well beforehand and that all the reactions occurred after the immunization so that I think that the immunization was the trigger for that. I think what actually happened with the big swelling, I don't think it's so much an IgE typical allergic reaction, that part of it. I think the swelling was probably what we call serum sickness disease, which is mitigated by immune complexes of antibodies and the additives in the DTaP injections, and then those things take sometimes a number of weeks to resolve or even sometimes months to resolve."

Instead of elaborating how the vaccine would thus trigger the onset of Celiac, Dr. Frick went into an explanation of rashes and hives that [M.L.] experienced in the weeks to months following vaccination. He went into great detail describing the biologic mechanism of these temporary hives, after which the Court queried, "Dr. Frick, you certainly explained the mechanism for the rash, but what is the mechanism between DTaP triggering Celiac disease specifically?"

The Court's question lead to the following interchange:

> "DR. FRICK: I think it's the insult that, I think what she had, she had a genetic predisposition to develop Celiac disease or maybe even other autoimmune diseases because of the family history and also the low -- I think the low IgA. She had this predisposition. And I think the immunization was the thing that triggered the expression of or induced the means for development of the Celiac disease.
>
> THE COURT: Okay, how did it do that?
>
> DR. FRICK: I don't think anybody really knows that."

That statement is made at page 29 of the hearing transcript.

Following Dr. Frick's admission that he could not explain how a vaccine might trigger Celiac, the Court questioned where there was an explanation within the extant medical literature that might propound such a process.

Dr. Frick explained, "I did an extensive literature search actually, and I wasn't able to come up with a specific reference that the DTaP caused the Celiac disease. I don't have a direct link that way in the literature as such. But there are other things where the immune system is somewhat different in Celiac patients. For example, they don't respond to Hepatis B vaccine when that's given and so there's some problems there."

So the answer to the Court's question is basically "no."

Petitioner's medical literature, Exhibit 15, the Hijnen article considered the specific epitopes of Pertactin, which is a protein located in B. pertussis. The article identifies "which defined regions of the pertactin molecule against which antibody responses are induced and also suggests that the amount of pertactin type-specific antibodies will not be very large and that the variation in pertactin probably will not constitute a problem in highly immune individuals."

Their findings are very specific regarding how and precisely where pertactin molecules attach in both animal and human models, but it is unclear what the relevance is to the present matter at bar.

Dr. Frick's only explanation on this article was frankly cryptic, and left unclarified: "There is some interesting work that was done a few years ago on protein in pertussis, pertactin, which is the business end of the pertussis vaccine, and there were some studies about antibodies being raised to the pertactin. So it's possible that maybe that was involved as well."

That statement does not explain how pertactin in the acellular pertussis component of the DTaP vaccine might cause Celiac disease and his use of the word "maybe" signals to the Court that Dr. Frick himself was not clear on that point either.

Dr. Frick added to his explanation of this article later, stating, "In this study, pertactin is the active ingredient of pertussis vaccine, and it's the immunodominant group in both rabbits and in humans. However, in this particular study they had some human patients and they were not able to see the antibodies to pertactin in the humans. So there may be some difference between rabbits and humans on that for the Court. But I think it's something that's still open as a possibility. I can't say it's a cause, but it's a possibility."

Under this explanation there is no linkage of the experimental model to humans.

This was a summary of the article, but left the Court without any explanation of how this might be at all relevant to the matter at bar.

Exhibit 16, the Kumar article. The article discusses the immunoglobulin serological assay tests used to diagnose Celiac disease, with no patently relevant portions appurtenant to this case.

This was the only other article of medical literature that Dr. Frick mentioned specifically at the hearing, and all he said about it was that it was, "The one about Celiac disease and immunoglobulin A."

For providing such passing commentary on the article, Dr. Frick relied upon the article throughout the hearing to aver that a low level of IgA can predispose a person to autoimmune diseases, and specifically Celiac disease, but he never elucidated any such connection.

The Court asked Dr. Frick to explain the connection of "any other articles" that could explain how a vaccine could trigger Celiac disease, to which Dr. Frick replied, "There's other articles, but I think those are what I need for now."

The Court was so confused by Dr. Frick's lack of explanation of mechanism, that it queried Dr. Frick with the following interchange:

> "THE COURT: Okay, let me ask. If I understand this, the gluten caused or aggravated the Celiac disease, correct?
>
> DR. FRICK: Yes.
>
> THE COURT: And once gluten was eliminated from [M.L.]'s diet, I guess things resolved, correct?
>
> DR. FRICK: That's right. Yes.
>
> THE COURT: Okay. And what is again the resolution or the explanation for the gluten issue as it pertains to the DTaP?
>
> DR. FRICK: I couldn't find an exact reference of the DTaP causing Celiac disease. I didn't find the literature on that. But because the immune system is prone to autoimmune diseases in patients who develop Celiac disease, Celiac disease being an autoimmune thing, I think that the DTaP is an insult to the body and the reaction to it triggered the Celiac disease."

That vague explanation cannot surmount Petitioner's burden of proof on the issue of "can it," explained by the Federal Circuit as an articulated, plausible "medical theory causally connecting the vaccination and the injury." *Althen* at 1278.

The Court followed with a question that cut to the quick of this proceeding:

> "THE COURT: Dr. Frick, I don't know if I'm phrasing this correctly, but how does ceasing gluten intake resolve a vaccine-related injury?
>
> DR. FRICK: Well, first of all, one of the things that was not done to -- well, there's a couple of things that weren't done to diagnose the Celiac disease beforehand. Patients with Celiac disease have a particular type of tissue typing called DQ2 or DQ8 and this is a genetic predisposition to Celiac disease. And apparently these two sites, the gluten -- there's an enzyme called tissue transglutaminase and this changes the gluten down to what actually hooks onto the HLA sites, and this the thing then that triggers the Celiac disease in genetically disposed people so that the thing that insults the body, such as a vaccination or possibly a viral infection or even a bacterial infection, can trigger this reaction."

This was not really supported by any medical literature relied upon in the formation and composition of Dr. Frick's report. The first and only article brought to the Court's attention on infections as triggers of Celiac disease was Petitioner's Exhibit 17, filed only after the hearing as an afterthought. Even it did not raise vaccines as possible triggers. The Court will discuss Exhibit 17 in greater detail shortly.

Given the meager and hardly explained ratiocination stated by Dr. Frick at trial, the Court still is at a loss as to how a vaccine might plausibly trigger an autoimmune reaction to wheat gluten.

Dr. Frick, explained in response to direct examination, that not everyone with a genetic susceptibility to Celiac disease develops symptoms, saying, "Some people harbor the gene for life-long and never actually develop it. And then some people develop it as an adult and it's known as sprue in adults." And therefore, a person would "have to be exposed to some sort of trigger like a vaccination to develop it."

On the matter of medically-appropriate temporal association, Dr. Frick stated the following on direct examination:

> "MR. DANNENBERG: Is that time period appropriate for the development of Celiac from when she got vaccinated in January of 2004?
>
> DR. FRICK: I think so because I think two weeks after, when they had the ultrasound and showed the stomach -- I mean the intestines full of gas suggest maybe the Celiac process had already started, and this was two weeks after the vaccination -- after the DpaT vaccination,

> MR. DANNENBERG: Okay. So do you consider that a medically appropriate time period for the development?
>
> DR. FRICK: I think so.

Dr. Frick also noted his disagreement with Respondent's expert, Dr. Warner.

> "MR. DANNENBERG: Have you reviewed Dr. Warner's opinion?
>
> DR. FRICK: Yes. Yes, I have.
>
> MR. DANNENBERG: And you have some criticism, I guess. Point one, you say it was evidence by the timing, and he says that these reactions aren't uncommon.
>
> DR. FRICK: He mentioned that he felt that otitis, ear infections, were common in children, and he didn't accept the fact that the child was IgA deficient. And that's the difference of opinion.
>
> MR. DANNENBERG: Okay. But you believe otherwise than Dr. Warner on those two points?
>
> DR. FRICK: I believe otherwise. Yes. Yes.
>
> THE COURT: Would you like to explain why you disagree or believe differently from Dr. Warner?
>
> DR. FRICK: Well, because the low IgA, as I indicate in this publication I just mentioned a few minutes ago, Petitioner's Exhibit 16, "that a low IgA system predisposes people to autoimmune disease, including Celiac disease."

On cross-examination, Dr. Frick restated his reliance on Petitioner's Exhibit 16 for that proposition.

Also, regarding the timing interval of onset, Dr. Frick did not believe the onset of Celiac disease occurred until two weeks afterward, not hours later that same day as the vaccination. But the record indicates that [M.L.] experienced the symptoms complained of on the day of vaccination.

Dr. Frick tried, unsuccessfully, to explain this apparent contradiction in his testimony.

> "DR. FRICK: Yes, I think that may have been the beginning of it. But I think that vomiting with a number of kinds of reactions. It isn't just Celiac disease that causes vomiting and diarrhea.

THE COURT: Dr. Frick, are vomiting and diarrhea associated with the onset of Celiac disease?

DR. FRICK: Diarrhea often is -- diarrhea or constipation. It's a disturbed gastrointestinal system.

THE COURT: What about the other indicia that we find with [M.L.] those first couple of days, the items that you mentioned?

DR. FRICK: Yes, well, she also had some neurological things by being withdrawn, and sometimes that happens, especially with pertussis vaccine. There's quite extensive literature on that.

THE COURT: Okay. But let's say arguendo that those are all vaccine reactions.

DR. FRICK: Yes.

THE COURT: Are they also associated with the onset of Celiac disease?

DR. FRICK: Not necessarily. No.

THE COURT: And I guess what I'm asking in a sense is, but this could be speculative, were there two separate reactions, an initial short-term reaction definitely, presumably sequela to DTaP, and then there's a longer-term Celiac disease or illness, or is it all of one piece? Is it all part and parcel, or are we talking about two different items?

DR. FRICK: No, I think it's all part and parcel. I think that I mentioned that I think that she probably had a serum sickness reaction, which is by circulating immunocomplexes causing this huge reaction in the arm that lasted for several days, which required a hospitalization. And then, initially, she also had some vomiting with that and then subsequently diarrhea, and that continued. And she had this intestinal, the abdominal protuberance, which was showing a lot of gas in the intestine. And that sort of focused people on the digestive tract and eventually the Celiac disease diagnosis a month later."

So if the symptoms were all of a piece, then onset of those symptoms seems to have begun the day of vaccination. But what about his statement of just within two weeks. Dr. Frick's testimony on this point did not aid the Court's understanding and was neither coherent, nor consistent, nor persuasive.

When Dr. Frick was recalled for rebuttal testimony, he disputed Dr. Warner's opinion that the symptoms that occurred on the date of vaccination were Celiac disease symptoms. Dr. Frick did not believe that those symptoms were related to Celiac disease.

However, his explanation on this point did anything but clarify the issue being discussed, "What I think is that [M.L.] was getting gluten before. She was getting it from six months on in her cereals and bread and other sources of wheat, and that my contention is that there is some sort of an insult in this Celiac-prone person that sets off the Celiac process and that's why I think the DTaP in reaction was the insult that brought out the Celiac disease and within two weeks she started to have the bloating and she lost two pounds in weight. And the whole process, I think, was started subsequent to the DTaP injection."

This answer did not address the question raised, whether the symptoms on the date of vaccination were or were not properly viewed as symptoms of the Celiac disease.

On cross-examination, Dr. Frick was asked whether other vaccinations have been associated with causing or triggering Celiac disease, which led to the following interchange.

> "DR. FRICK: Celiac patients don't respond to hepatitis B vaccine. There's a problem in the immune system in patients with Celiac disease.
>
> MS. MCCALL: But sir, if they don't respond to it, wouldn't that suggest that the vaccine wouldn't cause them to have Celiac disease?
>
> DR. FRICK: No. I'm just saying that they have an immune system that's somewhat disturbed. Thats what I'm saying."

His explanation that Celiac patients have a disturbed immune system does not address or explain any part of how any vaccine could cause or trigger Celiac disease. Respondent's question was a good one. The article on hepatitis B vaccine not triggering the intended immune response would militate that vaccines would have less impact on such a "disturbed" immune system, not more. And just avoiding the issue by being nonspecific and vague is unpersuasive and unhelpful to the Court.

Respondent also challenged Dr. Frick because one of the articles he relied upon (but decided to discuss at the hearing) had Dr. Wakefield as an author who has since been publicly shamed by the British medical system for his more spurious claims.

Dr. Frick conceded to Respondent's questioning that he's never treated a patient with vaccine-related Celiac disease, although he has worked closely with gastroentrologists in treating Celiac patients.

When called for rebuttal testimony, Dr. Frick made the following, rather obtuse comments regarding whether a vaccine-related autoimmune process preceded [M.L.]'s initial reaction to gluten. "I believe she was prone to the autoimmune thing. And as Dr. Warner mentioned, some people are fine into adulthood because it's actually before it's actually diagnosed. But what does happen, I think, is an insult of some sort. An insult is often a viral infection or some sort of an infection that sets off the process and the thing starts, the disease process starts after an insult. I think Dr. Warner probably agrees that people do have gluten for sometimes many, many years, sometimes even lifelong and never express the disease, the symptoms of the disease. And my contention is that there's an insult that triggers the response."

Respondent's expert, Dr. Andrew Warner, a gatroenterologist and his CV. Graduated from Chicago Medical School in 1987, internship, residency Harvard Medical School, Mount Auburn Hospital from 1987 to '90, clinical fellow in gastroenterology at the Leahy Clinic, been on the staff at Leahy Clinic since '92. Leahy Clinic is a large multi-specialty group practice and 325-bed hospital with about 500 physicians on staff treating about a million patients a year.

He's board certified in gastroenterology, clinical instructor in medicine at Harvard, and an associate clinical professor of medicine at Tufts. He treats Celiac patients almost every week.

At trial, the Court accepted Dr. Warner as an expert in gastroenterology. It's Dr. Warner's opinion: "that the vaccinations did not cause or in any way aggravate [M.L.]'s Celiac disease." He bases this conclusion on a five-part thought process.

"First, there's simply no data at all to suggest a link between the vaccination and the Celiac disease."

""Secondly, Celiac disease is just an exceedingly common disorder. We diagnosis it all the time and there's always a latency. Celiac disease can be around for years or decades before someone is diagnosed with it. It's very variable how it's diagnosed."

"Thirdly, was the timing of the shot. She got her shot on the 28th of January 2004. She started having symptoms that day. That's simply too soon to cause symptoms of Celiac disease."

"Fourthly, again, Celiac disease is extremely common and we routinely vaccinate children with Celiac disease. There is no board that recommends not vaccinating a child with Celiac disease. So every year kids with Celiac disease get vaccinated and there has not been a single report in the literature saying they got sick after the vaccination."

He later amplified this point that the reason there is no recommendation against vaccination is because there is no concern about an increase in Celiac symptoms following vaccination.

"Fifthly, the only known thing to trigger an attack of Celiac disease is gluten, which as you now know is wheat. A shot is a shot. I have no idea what mechanism by which the shot would even cause Celiac disease or aggravate Celiac disease since the only thing we know to do that is the ingestion of gluten, which is in wheat."

Based on this latter point, said Dr. Warner, it's impossible to know what an appropriate timeframe would be expected for onset since no mechanism of vaccine-related Celiac disease has be postulated.

The Court notes that this was all the more puissant in this case since Dr. Frick did not postulate a detailed account of how a vaccine mechanistically could cause or trigger Celiac disease.

The Court queried Dr. Warner whether DTaP shared any chemical commonality with wheat gluten, to which Dr. Warner that it would not matter, since the DTaP was injected and Celiac disease is only aggravated by ingested wheat gluten. "It's a direct toxic affect of the gluten on the small bowel. It's basically a contact phenomenon."

Dr. Warner rebutted Dr. Frick's argument linking Celiac disease to immunodeficiency, stating that immunodeficiency has nothing to do with Celiac disease. He acknowledged that [M.L.] "had minimal decrease in a couple of the immune levels. They were nothing significant and she really has no signs of an immuned deficiency."

On this same point, Dr. Warner did not think the history of ear infections was relevant. "She had a few ear infections and she had some tubes placed, but that's exceedingly common. Lots of kids get ear infections and lots of kids get tubes placed. A few ear infections that get better after you place tubes is just normal kid stuff."

Dr. Warner also opposed Dr. Frick's attempt to make something out of the submitted articles on lack of normal immune response to hepatitis B vaccination. He thought that specific phenomenon was specific to hepatitis B vaccine, which is not at issue in this case. Similarly, he did not think that a Celiac patient's basic immune response was qualitatively different from the average vaccinee, adding, "Someone with Celiac disease who's on a gluten-free diet is no more likely to get an infection than anyone else."

Dr. Warner believed the symptoms that [M.L.] experienced the day of the vaccination were most likely a reaction to the vaccine -- or to the vaccination, but that such reaction was just a normal, local response to vaccination and did not cause or trigger

anything further, in contrast to Dr. Frick's position that Celiac remained latent until some triggering mechanism made it turn symptomatic.

Dr. Warner stated, "The only thing that's known to trigger Celiac disease is dietary gluten," and there need not be anything other than exposure to exposure to gluten in the digestive tract to cause Celiac disease to manifest symptoms.

Dr. Warner did not find anything in Petitioner's submitted medical literature to support a link of any relation between DTaP and Celiac disease. In fact, he could find nothing in the medical literature discussing the incidence of Celiac disease after vaccination, not even depicting a simple temporal association, not even a single case report.

Dr. Warner attributed her behavioral changes and related cognitive symptoms as a side affect related to her gastrointestinal distress and not any independent organic cause. "With undiagnosed Celiac disease she's not going to want to eat or drink like other kids might. But once the Celiac disease was treated, she was fine. The last notation I saw is when she was five-years old and apparently she was doing very well."

Dr. Warner admitted on cross-examination that he does not have any certifications in immunology, and although he is a general gastroentrologist he does specialize in Crohn's disease. He edited a book, though, and there is a chapter on Celiac disease.

He stipulated that Celiac disease is an autoimmune disorder.

Dr. Warner discussed the surprising prevalence of wheat gluten in a variety of foods, especially processed foods, of which only a small amount can cause symptoms for someone with Celiac disease.

He indicated, in response to cross-examination, that "gluten is found in almost everything we eat and many things that we drink. So I assumed if she was on a normal diet she would have gotten gluten. If you so much as give a child a cracker -- give a child those little fish crackers that they all eat, they're getting gluten."

Even though early on [M.L.] was fed soy formula, which was gluten free, at a doctor's visit on 2 December 2002, the doctor recommended an "anticipatory diet" of "cereal with a spoon," which signals to Dr. Warner that she began eating gluten sometime not long after that visit, since almost all cereal has gluten.

Later medical records indicated that [M.L.] was eating rice cereal, gluten-free, and sweet potatoes, gluten-free, but Dr. Warner surmised that she was consuming some amount of gluten, even if indeterminate.

Apparently, Petitioner's line of questioning sought to undermine a statement in Dr. Warner's expert report that [M.L.] "had gluten introduced early." As it happens Dr. Warner simply meant early in life, not early relative to normal feeding patterns for children. The Court does not make much of that exchange, but did consider it.

Dr. Warner stated in cross-examination that he cannot pin down with certainty when [M.L.]'s Celiac disease truly emerged, because symptoms can vary in type and severity and symptom presentation: "Symptoms could be none at all. It could just be iron deficiency anemia or it could be full diarrhea, weight loss and malabsorption. So it's a little hard to tell when the Celiac disease is developed."

Additionally, "you can develop Celiac disease decades after you first ingest gluten." However, once someone manifests symptoms of Celiac disease, if they ingest wheat gluten, they will experience a return of symptoms and their small intestine will physically evidence the reaction.

On the question of what would happen to a Celiac patient if they were left untreated, Dr. Warner elaborated, "It depends on how sick the person is. Most people have untreated Celiac disease for decades and they do just fine. For someone who developed it at [M.L.]'s age, diarrhea and weight loss, the natural history is going to be failure to thrive."

In [M.L.]'s case specifically, Dr. Warner stated, "Well, about the time she was diagnosed I don't believe she had failure to thrive. I believe she was growing normally, but she was having some gastrointestinal symptoms and those resolved."

It seemed to the Court that Petitioner's cross-examination of Dr. Warner was attempting to draw a "post hoc ergo propter hoc" association of relying on temporal association between vaccination and the onset of symptoms.

> "MR. DANNENBERG: Okay, [M.L.] was completely normal from what we know from the record until she's vaccinated as far as Celiac is concerned, is that correct?
>
> DR. WARNER: Sometime after the vaccination she was diagnosed with Celiac disease. That's correct.
>
> MR. DANNENBERG: Okay. And there was no evidence of that prior to vaccination, was there?
>
> DR. WARNER: Not from the record, no.
>
> MR. DANNENBERG: And we know from the record also that she was eating gluten-containing foods prior to the vaccination?
>
> DR. WARNER: That's correct.

MR. Dannenberg: For approximately six months, is that correct?

DR. WARNER: Yes, that's correct.

MR. Dannenberg: Okay. And what is the difference between people who obviously can eat gluten and those who get Celiac disease from eating gluten, is there a genetic difference?

DR. WARNER: Yes, there is."

The Court reminds the parties that a simple temporal association cannot satisfy the legal standard applicable to the Vaccine Program, as that standard has been stated in cases like Munn, Grant, Shyface, *Althen*, *Pafford*, *Walther*, and *de Bazan*.

When cross-examined, Dr. Warner discussed the interactions between genetics and environmental stimulus and the symptoms of Celiac disease.

"MR. DANNENBERG: Okay, so there's something going on besides just the ingestion of gluten. There's some genetic process going on, would you agree with that?

DR. WARNER: Yes, like with most genetic diseases, they have what we call variable traits. Some people express more of it. Some people less of it.

Lastly, Dr. Warner addressed Dr. Frick's central contention that Celiac is unsymptomatic, as merely a genetic predisposition, until such time as an environmental trigger elicits the onset of symptoms.

Dr. Warner stated his disagreement with that premise. "There is no data on that whatsoever. I understand Dr. Frick's position, but there's simply no evidence to that affect. I can tell you one thing. I'm an adult physician and I diagnose people with diseases literally every day of my career and all these people never had the diseases before and they always try to link it to something. 'I live next to a nuclear power plant.' 'I had unpasteurized milk as a child.' 'My child was sick.' 'We just came back from Alaska.'

No matter what I diagnose someone with they always to link it with something that just happened to them. Most diseases just happen. There's nothing to suggest that a particular insult or incident cases Celiac disease."

Specifically, for [M.L.]: "Lots of things are going on in her life. And the parents picked out one particular thing and they're linking it. That's something that parents commonly do, that people commonly do. But there's simply nothing in the literature to suggest a link that there's any particular trigger that causes Celiac disease, other than ingestible gluten."

After the hearing, Petitioner filed an article as Petitioner's Exhibit 17, the Stepniak article entitled Celiac Disease: Sandwiched Between Innate and Adaptive Immunity. The Court found it interesting and helpful, but certainly not dispositive, and now quotes the relevant passages.

Celiac disease "is a small intestinal disorder and common manifestations include chronic diarrhea, abdominal distension and malnutrition. These symptoms result from an inflammatory immune response to wheat gluten and related proteins in barley and rye causing villous atrophy, hypertrophic crypts, and infiltration of intraepithelial lymphocytes in the small intestine. The clinical manifestation normalizes upon strict compliance to a gluten-free diet. Celiac disease can occur early in life shortly after the introduction of gluten into the diet, but it can develop much later in life."

"Celiac disease is a multi-factorial disorder in which both genetic and environmental factors contribute to disease development. Genetic factors exert a strong influence."

"Gluten proteins have several unique features that contribute to their immunogenic properties." "Gluten is now known to encode many peptides with T cell stimulatory capacity. Once a T cell response to a particular gluten peptide has been initiated, a broad, gluten-specific T cell response develops. The generation of such a broad T cell response may be a prerequisite for disease development."

"The gut associated lymphoid tissue is the largest and probably most complex part of the immune system. It is in continuous contact with a complex mixture of foreign antigens over a surface measuring 400 square meters. The gut associated lymphoid tissue has to discriminate between pathogenic microorganisms and harmless antigens such as dietary compounds and commensal bacteria.

The default setup of the intestinal immunity is therefore the generation of tolerance, unless specific signals evoke inflammatory reactions. The antigens present in the gut lumen are constantly sampled by intestinal dendritic cells and presented to the T cells in either Peyer's patches or mesenteric lymph nodes, which results in the generation of regulatory T cells.

Therefore, it seems unlikly that gluten could initiate adaptive immune responses by itself, rather inflammatory stimuli are required to polarize the normally quiescent and tolerogenic dendritic cells so that they will generate Th1 responses."

This is the thesis and purpose of this paper: to examine what triggering mechanism might initiate pathogenic sensitivity to gluten.

"Several mechanisms that could lead to the development of a gluten-specific T cell response have been proposed. First, cross-reactivity between autoantigens and pathogen-derived antigens can lead to the development of autoimmunity. Similarly,

it has been hypothesized that molecular mimicry between pathogens and gluten could trigger the immune responses that result in Celiac disease."

The article then discussed possible viruses and bacteria that might be similar enough to gliadins, such that cross-reactivity might occur. But inasmuch as nothing has been demonstrated in that regard, the authors acknowledged that the hypothesis remains speculative.

The article notes, "a growing body of evidence suggesting a role for interferon alpha in Celiac disease development," and relates that to the typical enteroviruses that cause diarrhea in early childhood, noting "Th1 responses and inflammation play important roles in anti-enteroviral immunity and are associated with local production of interferon alpha.

This led the authors to the conclusion that "it is therefore conceivable that interferon alpha production as the result of viral infection would lead to a shift toward Th1 responses and preinstruct previously tolerogenic dendritic cells to prime gluten-specific T cells and support inflammation instead of sustaining oral tolerance.

The subsequent cytokine production would cause an upregulation of white blood cell antigen expression, facilitating T cell priming, expansion, and determinant spreading. T cell cross-reactivity towards various gluten epitopes and homologous peptides in other cereals may further contribute to the spreading of the T cell responses. Ultimately, this results in full-blown disease."

However, the Court notes that the only trigger for Celiac disease discussed by this paper that was not merely speculative, was gluten itself.

"The introduction of large gluten amounts into the infants' diet significantly increased the incidence of Celiac disease in Sweden. Conversely, a more gradual introduction of lower amounts of gluten into the diet may help the immune system to cope with the dietary proteins that are strongly immunogens. There is also evidence that introduction of gluten while breast-feeding has beneficial effects which may at least partially result from reinforced protection against pathogenic microorganisms because of maternal IgA antibodies in the breast milk."

The authors' conclusion: "But the grand challenge of elucidating why disease develops in only a minority of individuals who have the specific antigen that makes them vulnerable to Celiac disease still awaits researchers. Are unrelated events, such as enteroviral infections, responsible for loss of tolerance or do patients have a genetic makeup that will lead to disease development anyway?

In our opinion, many combinations of these two options are possible. The child that develops Celiac disease directly after the first introduction of gluten in the diet is likely to have a genetic makeup difference from that of the individual that has eaten

gluten without problems for 50 years, but now develops Celiac disease. Are viral infections the incriminated environmental factors directly triggering the onset? To address this question it would be ideal to have an animal model. Unfortunately, such a model still does not exist."

The Court notes that the article's discussion of triggering events remains quite speculative and hypothetical with a lot of unexplained loose ends in their hypothesis regarding the biologic process involved.

The Court notes also that vaccines are never mentioned as potential triggers. However, the Court remains cognizant that many of the autoimmune or cross-reactive disorders that have been postulated to be vaccine-triggered may also be triggered by viral insults as well.

In the same vein, if a trigger for an autoimmune disorder is nonspecific and is merely an immune challenge, certain vaccines could possible challenge the immune system to a significant enough degree.

The article does not say that Celiac diseases requires a trigger for onset to occur. Even in the authors' conclusion, they concede that for some patients merely ingesting gluten and nothing more is enough to bring the onset of Celiac disease symptoms.

Petitioner's closing argument seeks to make much of the temporal association noted between the vaccination and the onset of symptoms noted in the medical records, many of them based solely or primarily on the history given by her parents.

This was especially true of those records engendered by Dr. Julie Buckley, author of the cryptic email message considered earlier, who wrote such things as: "Has had diarrhea and intermittent vomiting, that the parents have associated with immunizations along with regressive behaviors. Would not recommend any further vaccinations for now."

"Then she had shots again January 28. Has vomiting and diarrhea on and off since."

Petitioners summarize Dr. Frick's theory as stating, "[M.L.] had an immune system that was prone to autoimmune disorders such as Celiac and the DTaP injection was an insult to the body's immune system that triggered immune system reaction to Celiac" and that an onset of two weeks was a medically appropriate temporal association.

Petitioners' arguments try to resolve the conflict in Dr. Frick's testimony concerning date of onset and how to classify the symptoms [M.L.] experienced the day of vaccination. "Dr. Frick testified that [M.L.]'s early symptoms were the result of serum sickness disease from the DTaP vaccine."

The previous argument raised above about the treaters' notes in the medical records undercuts this argument, though, inasmuch as those same notations also record the parental recollection that "all of her difficulties began in January on the day she received some immunizations." Petitioners' Exhibit 4, at 16.

Petitioners pointed out that materials submitted by Respondent, along with Dr. Warner's own expert report support the "trigger" theory, and analysis relied upon by Petitioners. The information sheet from the National Digestive Diseases Information Clearinghouse states, "Celiac disease is a genetic disease, meaning it runs in families. Sometimes the disease is triggered or becomes active for the first time after surgery, pregnancy, childbirth, viral infection, or severe emotional distress."

Petitioners argue that this supports Dr. Frick's theory that a petition is an immune challenge, just as viral infection is, and that a vaccine could trigger the onset of Celiac in the same fashion.

Petitioners urge the Court to rule for entitlement on the evidence presented based on the Federal Circuit's opinion in *Capizzano*. "In our view, the Chief Special Master erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of the injury. The fact that these physicians' diagnoses may have relied in part on the temporal proximity of the injuries to the administration of the vaccine is not disqualifying. In other words, if close temporal proximity, combined with the finding that the vaccine at issue can cause the injury alleged, then medical opinions to this effect are quite probative."

The problem for Petitioners in this citation in that this verbiage does not relieve them of proving "can it." In fact, the Circuit's wording indicates that the "can it" question must have already been answered in the affirmative through sufficient proof in order for the treaters' conclusions to weigh heavily on the "did it" questions.

Also, no treating physician actually rendered an explanation of diagnostic etiology in the medical records concluding that the vaccine was the case of [M.L.]'s Celiac disease, which is the focus of the *Capizzano* opinion.

As the Court has already discussed, the curious ruminations in the email of Dr. Julie Buckley are not entitled to the presumption of reliability that medical records enjoy, and thus, are also not entitled to the same weight as a treater's conclusion on causation.

Respondent's closing arguments. Respondent objected to the filing of Petitioners' Exhibit 17 after the hearing as unfair surprise, leaving Respondent and Respondent's expert no opportunity to comment thereupon.

The Respondent also pointed out, concerning that exhibit, that its authors admit that their hypothesis is speculative about the role of environmental factors as triggers of

Celiac disease. Respondent noted that Dr. Warner does not believe that a triggering event is need for Celiac disease to turn symptomatic and stated the real cause of symptoms is intestinal exposure to ingested gluten.

Respondent also recounted Dr. Warner's opinion that onset on the same day as the vaccine was too short under any cognizable theory attempting to link the vaccine to the onset of Celiac. Respondent raised the argument that according to Dr. Warner's reading, even though [M.L.] was diagnosed with Celiac disease some weeks after the vaccination, she had been exposed to gluten for six months prior to that diagnosis.

That argument is misplaced, and is not helpful in rebutting Petitioners' trigger hypothesis. If she had been eating gluten, but was unsymptomatic until symptoms arose following vaccination, isn't that more helpful to Petitioners? The Court did not understand the point Respondent was trying to make with this argument.

In making her legal arguments, the Respondent did not respond to Petitioners' legal argument about *Capizzano*. Instead, curiously, she quoted at length from Judge Block's opinion in *Pafford* instead of the Special Master's decision in *Pafford*, which was the rationale ultimately affirmed by the Federal Circuit.

The Court is at a loss as to why and how Respondent chose her legal arguments as they were largely unhelpful and unpersuasive. Respondent also included an ambiguous portion of boilerplate on how *Daubert* applies to Vaccine Act proceedings. But the Court has already admitted Dr. Frick's testimony and has recently corrected Respondent's view of *Daubert* in two opinions, *Garcia* and *Veryzer*.

However, the Court proceeds to rule on the issue of entitlement, Dr. Frick's methodology was scientific enough to satisfy minimal applicable legal standard. Therefore, the Court dismisses Respondent's arguments on *Daubert*.

In her legal argument, the Petitioner had not satisfied the *Althen* test for off-Table cases. Respondent did not argue that Petitioners had not proffered a plausible medical theory explaining how the vaccine at issue can cause the injury complained of. Instead, Respondent's focus was arguing that Petitioners had not proffered a logical chain of cause and affect demonstrating that the vaccine did cause the injury alleged.

Respondent pointed out that Dr. Frick acknowledged at trial that no medical literature or clinical experience of his own either propounded or supported a theory of vaccine-related Celiac disease.

Respondent summarized Dr. Frick's testimony of the onset, calling it "confusing." "Dr. Frick testified that the vaccine brought out the disease within two weeks in [M.L.]." Transcript at 71.

Dr. Frick also testified, somewhat confusingly, that the initial vomiting and diarrhea that [M.L.] experienced immediately after vaccination was all part and parcel of her Celiac disease. Transcript at 43, 44"

Petitioners' rebuttal argument. Petitioners argued that Dr. Frick didn't really say that the symptoms the day of vaccination were part and parcel with the rest of her Celiac disease symptoms. According to Petitioners, Dr. Frick said, "Not necessarily. No."

However, Petitioners are wrong on this point. What Dr. Frick replied, "Not necessarily. No." to was the Court's question whether her social withdrawal and other symptoms, symptoms besides diarrhea and constipation, were associated with the onset of Celiac disease, assuming that there were vaccine reactions. When asked directly about the diarrhea [M.L.] experienced on the day of vaccination, Dr. Frick conceded, "Yes, I think that may have been the beginning of it. But I think that vomiting happens with a number kind of reactions. It just isn't Celiac disease that causes vomiting and diarrhea."

Petitioners argued that Dr. Frick elsewhere stated that Celiac took two weeks to develop. "I think the symptoms for Celiac disease developed probably within two weeks afterwards, as shown by the ultrasound." However, that's merely the first time her symptoms were recorded in the medical records because that was the first time she'd gone to a doctor since the day of vaccination.

At that visit, which was approximately two weeks following vaccination, she presented with complaints, including diarrhea for the two weeks previous, going back to the date of vaccination.

It is true what Dr. Frick said, that vomiting and diarrhea can be nonspecific and might have been somehow distinguishable from those same exact symptoms later on that were diagnosed as Celiac disease. However, that was why the Court asked him to give a rational explanation, delineating an onset of Celiac disease that was distinct from the symptoms that began on the date of vaccination.

It was to this question that Dr. Frick said he saw it all as "part and parcel." Neither the Court nor Petitioners' counsel can retroactively state that Dr. Frick did not mean what he said and did not say what he meant. To read into his answer an explanation differentiating the two would be preposterous.

The Court's analysis on entitlement. As explained at trial, the Court uses a "can it/did it" analysis to adjudicate entitlement in off-Table cases, which is a streamlined version of the three-factor test elaborated in the *Althen* decision of the Federal Circuit. Under either rubric, the first question to be asked is whether the vaccine at issue can cause the injury alleged. And if so, what would be the theoretical, biologic mechanism in the temporal period appropriate for that mechanism.

As stated in *Althen*, this medical theory must articulate a causal connection between the vaccine and the injury.

Once this theoretical rubric has been explained, the "did it" question determines whether the facts, circumstances, and temporal period of the specific case matches the postulated theoretical construct. If no coherent theory is satisfactorily explained, this latter step is impossible, because there is no theoretical standard for comparison.

As the Federal Circuit held in *de Bazan*, *Althen*'s reference to temporal association as an analytical tool is not near proximity in time, but an association in time that is medically appropriate. On this point, the Court can only derive what is medically appropriate timeframe from comparison to the theoretical construct that Petitioner is obligated to proffer as part of the burden of "can it."

In this case, Petitioners has not postulated a coherent and sufficiently detailed theory of how the vaccine or vaccines at issue could have either caused or triggered [M.L.]'s Celiac disease. Petitioners' narrative that "[M.L.] had an abnormal immune system, which following routine vaccination went haywire and this is what resulted" is not detailed enough to be considered a plausible theory demonstrating biologic causation.

Furthermore, there was no source of further detail to be found anywhere. While it is true that no single type of evidence is outcome determinative, be it clinical experience or medical literature, the fact that no one has ever reported, in any source in the purview of either expert witness, any incidence of Celiac disease following DTaP vacation. Not only has no one ever postulated a theory of causation whereby administration of the DTaP vaccine could cause or trigger Celiac disease, no one has even recorded those two events in connection with one another anywhere in the medical literature, not even on the basis of simple temporal proximity.

And Dr. Frick certainly has had no personal, professional experience with vaccine-related Celiac disease. Dr. Frick himself stated, when asked by the Court how the vaccination at issue "triggered the expression of or induced the means for development of the Celiac disease," that he did not think that anyone knows the answer to the question. This concedes that neither Dr. Frick nor any other credible medical source had postulated or could have postulated, a plausible theory to explain the biologic process whereby a vaccination could cause or trigger Celiac disease.

All in all, Dr. Frick's testimony was not all that helpful to the Court's understanding in this case and required the Court to tease out reasoned explanations for the conclusions Dr. Frick asserted. In more than one response to such queries, Dr. Frick's answer was either nonresponsive, obtuse, or directed towards some unrelated point.

Petitioners' medical literature filed in preparation for the hearing and upon which Dr. Frick supposedly based his testimony of a "trigger" analysis none of it was applicable

to the question presented. Without exception, it related to some other vaccine, some other injury, or some other effect.

Compounding this problem was the unhelpful or nonexistent explanation given by Dr. Frick on the relevance of each article to the scientific issues of dispute in this case. For example, stating that Celiac patients encounter difficulty forming immunity to hepatitis B vaccination and using that to argue that the DTaP vaccine triggered the onset of Celiac disease seemed a colossal non sequitur. Even the explanation presented that Celiac patients have an abnormal immune system is unhelpful since, during the relevant time period between vaccination and onset of Celiac disease, it is Petitioners' contention that she did not have Celiac disease then.

By that logic, the abnormal immune system that Petitioners associate with Celiac disease for which [M.L.] would not be symptomatic, but for her DTaP vaccine, according to Dr. Frick was the active cause for why she reacted to the DTaP vaccine. If anything, the study stands for the proposition that Celiac disease is an independent, free-standing disease that affects the body's response to vaccination, not the other way around.

Most of the rest of the literature was similar and/or useful, supporting only the most general and undisputed propositions and not the central issue in contention.

Petitioners have argued that cases like *Capizzano* and its progeny eliminate the need for certain elements of the *Althen* test. Assuming, *arguendo*, that such an argument had merit, it would only be the "did it" prong, the "logical sequence of cause and effect" prong that would be satisfied by an unexplained opinion of vaccine causation by a treating doctor. A treater's opinion cannot substitute for the explanation of a plausible theory as to how a given vaccine can cause the alleged injury in the abstract. Furthermore, Petitioners based their claim and support in the opinions of treating physicians on mere recitation of intake history given by Petitioners in the medical records or else where the treating physicians were summarizing the timeline of symptoms in [M.L.]'s course. Not one single medical record asserts an opinion of causation, stating or implying that the vaccines administered caused or triggered [M.L.]'s Celiac disease.

As the Court noted earlier, Petitioners' reliance on a private email correspondence between two doctors at the same practice where [M.L.] was being treated well after the period at issue, is neither helpful nor persuasive. It does not even mention the correct condition when referencing [M.L.]. Most of all, though, is that it does not explain how the vaccine at issue could cause the injury alleged. That is the fatal defect of the Petitioners' case and nothing Petitioners have offered has satisfied that burden.

Petitioners have not carried their burden of proof regarding how the vaccines administered to [M.L.] could have been a substantial factor in her injury. And they

have not articulated how the onset of Celiac disease would not have occurred when it did but for the administration of her vaccines.

Of secondary importance, Petitioners' expert was also unpersuasive in his discussion of onset. On the one hand, he stated that onset occurred two weeks following vaccination, despite the presence of symptoms that were similar or identical to the symptoms of Celiac disease, which began the day of vaccination. These symptoms include emesis and diarrhea and they are recorded in the medical records and corroborated by the parental accounts.

On the other hand, when the Court tried to understand Dr. Frick's position, asking whether the symptoms could be divided into a non-Celiac set of symptoms immediately following vaccination, which could be associated merely as a response to the vaccination, separate and distinct from a later onset of true Celiac disease symptoms, Dr. Frick stated that no, it was all of a piece, a unitary course of Celiac symptoms. If that were true, doesn't this concede that the Celiac disease began on the day of vaccine administration?

Normally, an autoimmune reaction occurring in just a few hours, not days or weeks, would be hard to prove in its own right. Here, given the dearth of explication of a plausible theory proposing a biologic mechanism, the Court has no standard against which to judge if the temporal association was "medically appropriate" as the Federal Circuit's *de Bazan* case would require.

This hearkens back to the Court's main problem in this case, the absence of proof on the issue of "can it." Even if molecular mimicry or some other cross-reactive process that was raised speculatively by the late-filed medical literature had been at work, any such process presumably requires days, not hours, to mount an immune response such as a T cell reaction that only then can begin to attack self cells.

Given these explanations, the Court cannot find that Petitioners surmounted their burden of proof on the issue of entitlement to compensation. As such, the Court must dismiss this petition.

Tr. at 3-60.

III. CONCLUSION

Therefore, in light of the foregoing, the Court **RULES** that Petitioners are not entitled to compensation on this Petition. Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** 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.

IT IS SO ORDERED.

s/Dee Lord
Dee Lord
Chief Special Master[5]

[5] This decision originally was issued by Special Master Abell. Petitioners filed a Motion for Redaction of this decision, and while it was pending, Special Master Abell retired. This case was reassigned to me, and I am reissuing a redacted version of his decision.