

# In the United States Court of Federal Claims

No. 07-36V

(Filed under seal January 14, 2013)

(Reissued February 26, 2013)

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**KEITH and BEVERLY LANGLAND,\*  
on behalf of their daughter,  
[M.L.],**

Petitioners,

v.

**SECRETARY OF HEALTH AND  
HUMAN SERVICES,**

Defendant.

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Vaccine Act off-table case; *Althen*; DTaP; celiac disease; absence of plausible medical theory of causation; statements of treating physicians; document referenced in expert report as party admission; no appropriate temporal association without reputable explanation of mechanism.

*Paul S. Dannenberg*, Huntington, Vermont, for petitioners.

*Melonie J. McCall*, Trial Attorney, Torts Branch, Civil Division, Department of Justice, with whom were *Tony West*, Assistant Attorney General, *Timothy P. Garren*, Director, *Mark W. Rogers*, Deputy Director, and *Vincent J. Matanoski*, Assistant Director, all of Washington, D.C., for respondent.

## OPINION AND ORDER<sup>1</sup>

WOLSKI, Judge.

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<sup>1</sup> Petitioners moved for the redaction of their names, and their daughter’s name and date of birth, from this opinion prior to its publication. The government opposes the first part of this request. The Court agrees with the reasoning of the then-Chief Special Master, who determined that including petitioners’ names in the decision below did not result in an unwarranted invasion of privacy under 42 U.S.C. § 300aa-12(d)(4)(B)(ii) (a determination which was not appealed), given the nature of petitioners’ daughter’s illness. *See Langland ex rel. M.L. v. Sec’y of HHS*, No. 07-36V, 2011 WL 802695, at \*5-11 (Fed. Cl. Sp. Mstr. Feb. 3, 2011). Petitioners’ motion is thus DENIED-IN-PART, to the extent they seek anonymity, and GRANTED-IN-PART concerning their minor daughter’s name (which is replaced with her initials) and date of birth. The opinion is reissued for publication with some minor, non-substantive corrections.

Petitioners Keith and Beverly Langland have moved for a review of Special Master Richard B. Abell’s decision that petitioners are not entitled to compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 - 300aa-34 (“Vaccine Act” or “Act”). The petition was filed by Mr. and Mrs. Langland on behalf of their daughter, [M.L.], contending that [M.L.] suffered from a “neurologically regressive reaction” and the onset of celiac disease as a result of the diphtheria, tetanus and pertussis (“DTaP”) and inactivated polio (“IPV”) vaccines administered on January 28, 2004. Pet. at 1-2. Petitioners raised three objections to the Special Master’s decision, arguing that his decision was arbitrary and capricious, an abuse of discretion, and not in accordance with the law. See Pet’rs’ Mot. For Rev. at 2. According to petitioners, the Special Master disregarded statements of treating physicians and an admission of respondent, rejected what they characterize as a biologically plausible theory of causation, and failed to follow the standards of *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). For the reasons stated below, the Court DENIES petitioners’ motion and SUSTAINS the decision of the Special Master.

## I. BACKGROUND

### A. The Vaccination and Diagnosis of Celiac Disease

[M.L.], the daughter of Keith and Beverly Langland, was born on [XXXX], 2002. Pet’rs’ Ex. 12 at 15. She was fed soy formula as an infant, and her parents added rice cereal and sweet potatoes to her diet by her six-month visit. Pet’rs’ Ex. 3 at 2018; Pet’rs’ Ex. 3 at 2009. At her twelve-month visit, her parents reported a diet of whole milk. Pet’rs’ Ex. 3 at 2002. At [M.L.]’s 18-month visit, her growth and development were exhibited by the ability to use “mature jargonizing,” speak at least six words, point to five body parts, run and kick a ball. Pet’rs’ Ex. 3 at 1984. By that time, she had a diet of three meals a day. *Id.*

[M.L.] received her first dose of the DTaP vaccine on October 4, 2002. Pet’rs’ Ex. 8 at 1. Subsequent shots were administered on December 13, 2002 and February 5, 2003. *Id.* During [M.L.]’s 18-month visit on January 28, 2004, Dr. Pamela Carrington-Cooper noted that she had no previous reaction to these vaccines.<sup>2</sup> Pet’rs’ Ex. 3 at 1984. [M.L.] did, however, show symptoms of fever, low appetite, coughing with vomiting, and an ear infection at an acute care visit on December 24, 2003. *Id.* at 1985.

On January 28, 2004, [M.L.] received her fourth DTaP vaccination and third polio vaccination. Pet’rs’ Ex. 8 at 1. After returning home, she vomited twice, and developed a low-grade fever and diarrhea. Pet’rs’ Ex. 10 ¶ 5. She made a pediatric acute care visit on February

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<sup>2</sup> According to Mr. Langland, the normal reaction of his children to vaccinations was to appear “dehydrated” and “lethargic” for a period of one or two days. Pet’rs’ Ex. 10, ¶ 5. The parents also reported that, within two or three weeks after [M.L.] received a different vaccine in October 2003, she suffered from vomiting, diarrhea, listlessness, and a low-grade fever, and was sick for three to four weeks. See Pet’rs’ Ex. 6 at 1.

13, 2004, after two and a half weeks of intermittent vomiting and diarrhea. Pet'rs' Ex. 3 at 1982. During this time, she also "developed a yeast rash in the diaper area" and suffered from flu-like symptoms. Pet'rs' Ex. 7 at 6. She was reportedly not playing well, wanting only to sit on her mother's lap. Pet'rs' Ex. 3 at 1982. Doctor Carrington-Cooper observed that she had abdominal distension. *Id.* at 1983. A complete abdominal sonogram showed that her bowel had fluid-filled segments, which appeared to contain gas. Pet'rs' Ex. 5 at 3.

[M.L.] made another acute care visit on February 16, 2004, during which the Langlands reported concerns about her development: she had not been speaking as much in the last two weeks and did not want to play with siblings. Pet'rs' Ex. 3 at 1980. Her vomiting and diarrhea had persisted. *Id.* at 1981. [M.L.] returned to make another acute care visit on February 20, 2004. *Id.* at 3 at 1978. In addition to her previous symptoms, Dr. Cooper-Carrington also reported staring spells, in which [M.L.] would look a couple of minutes into space with eyes blinking but not otherwise responding. *Id.* at 1978-79. As part of her family history, the doctor also noted that a maternal aunt of [M.L.]'s had celiac disease. *Id.* at 1978. The doctor referred her to specialists. *Id.* at 1979.

On February 27, 2004, [M.L.] was examined by Dr. Julie Buckley, who found that she had a bloated and tense abdomen. Pet'rs' Ex. 7 at 6. Her parents reported to Dr. Buckley that [M.L.] received vaccinations on January 28 and threw up on the way home. *Id.*<sup>3</sup> She had "diarrhea and intermittent vomiting that [the] parents have associated w[ith] immunizations along w[ith] regressive behaviors." *Id.* Her mother had stopped giving her milk and resumed baby foods on February 16, and apparently stopped feeding her wheat on February 22. *Id.*

[M.L.] saw Dr. Jonathan Evans, a gastroenterologist, on March 3, 2004. Pet'rs' Ex. 4 at 22. Her parents reported to Dr. Evans that she had a viral-type illness in December and became ill again on January 28, 2004. *Id.* They also reported the child's physical symptoms, as well as the behavioral change from a happy, playful child to one who was often irritable. *Id.* Doctor Evans noted [M.L.]'s allergy to milk and a maternal great aunt with celiac disease. *Id.* at 22-23. The doctor recommended screening for celiac disease because of her family history. *Id.* at 23. On March 16, 2004, [M.L.] had a panendoscopy, with a duodenal biopsy and a gastric biopsy. Pet'rs' Ex. 4 at 35-36. The biopsy found chronic duodenitis consistent with celiac disease. *Id.* at 36. Doctor Evans, who conducted the panendoscopy, shared the celiac disease diagnosis with Mrs. Langland on March 18, 2004. *Id.* at 14.

Doctor William Turk, a neurologist, saw [M.L.] in consultation on March 12, 2004. Pet'rs' Ex. 4 at 16. According to Dr. Turk's correspondence with Dr. Carrington-Cooper, [M.L.]'s parents reported that all her difficulties began in January on the day she received some immunizations. *Id.* The doctor recorded the impression that [M.L.] had a "history of an illness

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<sup>3</sup> They also apparently reported that vomiting and diarrhea began two weeks prior to Christmas, "and toward end of Dec[ember 2003] bowels normalized although stomach stayed bloated." Pet'rs' Ex. 7 at 6; *see also* Pet'rs' Ex. 4 at 22.

that began coincident with immunizations in January.” *Id.* at 17. Both her MRI and EEG results were normal. *Id.* He felt that [M.L.]’s change in behavior was linked to a systemic and chronic illness, rather than autistic disorder. *Id.*

Subsequently, the Langlands switched to a gluten-free, casein-free diet for [M.L.]. Pet’rs’ Ex. 4 at 8; Pet’rs’ Ex. 7 at 4-5. Doctor Buckley recorded a visit on April 12, 2004, during which [M.L.] was able to start climbing again and use more words, including two-word phrases. Pet’rs’ Ex. 7 at 3. Her parents reported that she was no longer sitting in the corner at daycare. *Id.* Though her abdomen was still distended, [M.L.]’s ability to make eye contact improved through the visit. *Id.* Check-ups through July 7, 2005 showed improved appetite; alert and playful behavior; growth in height and weight; and nondistended, nontender abdomen. Pet’rs’ Ex. 4 at 1-7. Doctor Evans concluded that [M.L.] was doing well overall. *Id.* at 2.

## **B. The Petition and Hearing Before the Special Master**

Petitioners filed a petition for compensation under the National Vaccine Injury Compensation Program on January 18, 2007, claiming that the administration of DTaP and polio vaccinations on January 28, 2004 caused [M.L.] to suffer from a “neurologically regressive reaction” and celiac disease. Pet. at 1-2. In addition to medical records from treating physicians and hospitals, petitioners filed an expert report from Dr. Oscar L. Frick, a physician specializing in pediatrics, allergy, and immunology. Pet’rs’ Ex. 11 at 1. In Dr. Frick’s opinion, [M.L.]’s vaccinations caused celiac disease by triggering an autoimmune response. *Id.* at 2. He believed the causation was “evidenced first by the timing of her symptoms of vomiting, diarrhea, rash and fever that occurred within hours of her vaccinations,” and stated that the “rash on [M.L.’s] left thigh for two months where the [DTaP] was given makes that the likely agent.” *Id.*

Pursuant to Vaccine Rule 4(c) of the Rules of the United States Court of Federal Claims (“RCFC”), the Secretary of Health and Human Services (“respondent”) filed a report on the petition for vaccine compensation, arguing that petitioners failed to demonstrate by preponderance of the evidence that [M.L.]’s vaccinations caused her celiac disease. Resp’t’s Rule 4(c) Rep. at 10-11. The report challenged Dr. Frick’s theory of causation, contending that Dr. Frick did not provide a link between the vaccinations and illness other than the timing of the onset of symptoms and the “plausibility” that [M.L.] already had a partial immunodeficiency. *Id.* at 10. The respondent also filed a report from Dr. Andrew Warner, a gastroenterologist who specialized in Crohn’s disease and ulcerative colitis. Resp’t’s Ex. A at 1. Dr. Warner contended that there was no medical or scientific evidence for the idea that DTaP or polio vaccines could cause or aggravate celiac disease. *Id.* at 2.

On December 9, 2008, the Special Master held a hearing in this matter, with Dr. Frick and Dr. Warner as expert witnesses. Transcript of Oral Argument Before Special Master (Dec. 9, 2008) (“Sp. Mstr. Tr.”) at 13, 46 (identifying the expert witnesses). Doctor Oscar Frick testified on behalf of the petitioner and provided his background. With an M.D. from Cornell, a Master of Medical Science degree in Pediatrics from the University of Pennsylvania Postgraduate School

of Medicine, and a Ph.D. in immunology from the Stanford University School of Medicine, Dr. Frick was one of the founding members of the American Board of Allergy and Immunology and is a professor emeritus of pediatrics at the University of California, San Francisco. Sp. Mstr. Tr. at 14-16; *see also* Pet'rs' Ex. 11 at 4. Post-retirement, he continued to run the pediatric allergy clinic at the University of California, San Francisco. Sp. Mstr. Tr. at 17. Doctor Frick had also written about allergies, particularly food allergies.<sup>4</sup>

Having reviewed her medical records and the affidavit from her father, Sp. Mstr. Tr. at 18, Dr. Frick testified that [M.L.]'s DTaP vaccination had "most likely" triggered her celiac disease. *Id.* at 22. He noted that [M.L.] "probably" had an immunoglobulin A ("IgA") deficiency, which, along with family history, indicated a predisposition to autoimmune disease. *Id.* at 19-20, 29. Petitioners' expert witness based his opinion of causation on a rash in the vicinity of the DTaP vaccination, which he believed was in an arm which "became very much swollen"--- in contrast to the lack of reaction on the side where her polio vaccination was administered. *Id.* at 20-21.<sup>5</sup> Though Dr. Frick acknowledged that [M.L.] could have developed celiac disease regardless of vaccination from some future event, he posited that the DTaP immunization triggered the expression of or induced the means for the development of celiac disease. *Id.* at 22-23, 29, 37.

Petitioners' expert's medical theory of causation was that the DTaP vaccine "just triggered the reaction" leading to celiac disease, Sp. Mstr. Tr. at 35, since vaccines act as an

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<sup>4</sup> Respondent had filed a motion to exclude the testimony of Dr. Frick, arguing that Dr. Frick's theory of causation did not meet the *Daubert* requirements for reliability. Resp't's Mot. to Exclude Evidence at 5. At the hearing, the Special Master accepted Dr. Frick's testimony. Sp. Mstr. Tr. at 27. Respondent's motion to exclude Dr. Frick's testimony was denied. *Langland ex rel. M.L. v. Sec'y of HHS*, No. 07-36V, 2011 WL 386985, at \*6 (Fed. Cl. Sp. Mstr. Oct. 21, 2010).

<sup>5</sup> The witness was confused on this point, as [M.L.]'s DTaP was received in the *left thigh*, not in the right arm as he testified. *See* Pet'rs' Ex. 3 at 1973. He was also mistaken in remembering that a measles shot was administered along with the polio vaccine. *See id.* at 1972. Most curious was his detailed recounting of her right arm being "swollen from the shoulder all the way down to the elbow," which he says was "a huge reaction" requiring hospitalization "about three days after the injection" and treatment with compresses, antihistamines, anti-inflammatories, pain killers, and intravenous fluids. Sp. Mstr. Tr. 21, 23; *see also id.* at 44. No swollen arm and associated hospital visit appears in her medical records or in her father's affidavit. *See, e.g.*, Ex. 7 at 6 (Dr. Buckley's note dated Feb. 27, 2004 describing [M.L.]'s symptoms after the vaccination); Ex. 4 at 16 (Dr. Turk's record dated March 12, 2004 describing post-vaccine illness); Ex. 10 ¶ 5 (affidavit of Mr. Langland); *see also* Ex. 11 ¶ 7 (Dr. Frick's affidavit noting rash on [M.L.]'s "left thigh for two months where the D[T]aP was given make[s] that the likely agent"). But in any event, petitioners focused on the DTaP vaccination, and apparently abandoned any argument concerning the polio vaccination.

“insult” to the body. *Id.* at 29, 34-35. When the Special Master asked Dr. Frick to explain the mechanism by which this triggering occurred, he replied, “I don’t think anybody really knows that.” *Id.* at 29. And when asked the follow-up question whether there was any medical literature that would support the contention that DTaP can cause or trigger celiac disease, Dr. Frick conceded that after an “extensive literature search” he “wasn’t able to come up with a specific reference” concerning it, and did not “have a direct link that way in the literature as such.” *Id.* at 29-30; *see also id.* at 34. He referred to an article showing that a disproportionate number of celiac patients did not respond to the hepatitis B vaccine, indicating a difference in the immune systems of these individuals. Sp. Mstr. Tr. at 30.<sup>6</sup> He also mentioned “some studies about antibodies being raised to the pertactin” contained in the pertussis vaccine, remarking that “it’s possible that maybe that was involved as well” in causing celiac disease. *Id.* Doctor Frick later acknowledged that the studies showing these antibodies were of rabbits, and that researchers “were not able to see the antibodies to pertactin in the humans” studied. *Id.* at 33. On this point, he concluded: “I can’t say it’s a cause, but it’s a possibility.” *Id.*<sup>7</sup>

After noting that the removal of gluten from [M.L.]’s diet resolved her celiac disease, Dr. Frick stated again his contention that the DTaP vaccine’s challenge to her immune system triggered celiac disease. Sp. Mstr. Tr. at 34-35. The Special Master asked petitioners’ expert to explain the connection between a vaccine injury and gluten intake, and Dr. Frick stated that people with a genetic disposition for celiac disease have the human leukocyte antigens (“HLA”) HLA-DQ2 or HLA-DQ8. *Id.* at 35. He further explained that an enzyme, tissue transglutaminase (“tTG”), can change gluten into a substance that “actually hooks onto these two HLA sites, and this is the thing then that triggers the [c]eliac disease in genetically disposed people,”<sup>8</sup> and hypothesized 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.” *Id.* Doctor Frick also testified that the sonogram showing gas in [M.L.]’s intestine, two weeks after the DTaP vaccination, “suggest[s] maybe the [c]eliac process already started,” and stated that he considered two weeks to be a medically appropriate time period for the disease to develop. *Id.* at 36. He added that his opinions were held to a reasonable degree of medical certainty. *Id.* at 38.

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<sup>6</sup> *See Pet’rs’ Ex. 11 at 2 (discussing the article), 9, 22-25 (Kyung W. Noh et al., Hepatitis B Vaccine Nonresponse and Celiac Disease, 98 Am. J. Gastroenterology 2289-92 (2003)).*

<sup>7</sup> A copy of the article discussing these studies was filed as Exhibit 15 after the hearing. *See Notice of Filing (Dec. 23, 2008).*

<sup>8</sup> This process is described in an article submitted with Dr. Frick’s affidavit. *See Pet’rs’ Ex. 11 at 29-30 (Detlef Schuppan et al., Celiac Disease: Epidemiology, Pathogenesis, Diagnosis, and Nutritional Management, 8 Nutrition in Clinical Care 54, 57-58 (2005) (“Schuppan”)).* The article, however, seems to indicate that for pediatric patients, celiac disease is a response to “unmodified gluten peptides,” and not to the negatively-charged gluten peptides that were modified by tTG. *Id.* at 29, 40 n.65 (Schuppan at 57, 68 n.65).

During cross-examination, Dr. Frick admitted that he had never treated a patient who developed celiac disease as a result of a vaccination. Sp. Mstr. Tr. at 42. He also attempted to clarify whether [M.L.]’s symptoms that began the day of vaccination, such as vomiting and diarrhea, signified the beginning of celiac disease. Doctor Frick thought “that may have been the beginning of it,” *id.*, but he then explained that while diarrhea is often associated with celiac disease, the rest of [M.L.]’s early symptoms were “[n]ot necessarily” associated with it. *Id.* at 42-43. When the Special Master asked if the apparent serum sickness and the triggering of the celiac disease were two separate reactions or “all part and parcel,” Dr. Frick stated he thought “it’s all part and parcel,” *id.* at 43-44, but later during redirect examination he stated that he did not think the symptoms [M.L.] exhibited the day of the vaccination were related to celiac disease. *Id.* at 71. He reiterated his belief that the reaction to the DTaP vaccination “was the insult that brought out the [c]eliac disease and within two weeks she started to have the bloating . . . and the whole process . . . was started subsequent to the DTaP injection.” *Id.* at 72.

Doctor Andrew Warner testified on behalf of the respondent. A graduate of Chicago Medical School, Dr. Warner’s internship and residency training were performed at Harvard Medical School’s Mount Auburn Hospital. Sp. Mstr. Tr. at 47. Doctor Warner followed this training with a clinical fellowship in gastroenterology at Lahey Clinic, on whose staff he has remained as a board-certified gastroenterologist. *Id.* He is a clinical instructor at Harvard Medical School and an associate clinical professor at Tufts University School of Medicine. *Id.*

Respondent’s expert testified that in his opinion, to a reasonable degree of medical certainty, the vaccinations did not cause or in any way aggravate [M.L.]’s celiac disease. Sp. Mstr. Tr. at 49-50. He based this opinion on a review of [M.L.]’s medical records, a search of medical and scientific literature, and a search of certain textbooks and websites. *Id.* at 49. Doctor Warner first explained that there was no data to suggest a link between the vaccinations [M.L.] received and celiac disease. *Id.* at 50. Second, he noted that celiac disease was a common disorder for which there was always a latency. *Id.* Doctor Warner then testified that [M.L.] exhibited symptoms of celiac disease the day of her vaccinations, which was too soon for the vaccines to have caused celiac disease. *Id.* He also explained that physicians routinely vaccinate children who have celiac disease, and there “has not been a single report in the literature saying [any of the children] got sick after the vaccination.” Sp. Mstr. Tr. at 50-51. As his last point, Dr. Warner argued that the only known thing to trigger celiac disease was ingested gluten. *Id.* at 51. When the Special Master asked Dr. Warner to clarify how he came to the conclusion that a same-day causation of celiac disease by a vaccination was not temporally appropriate, he explained that selecting such a time period was a “problem,” as he knew of no mechanism by which a shot could trigger the disease. *Id.* at 51. Respondent’s expert emphasized that celiac disease was caused by “a direct toxic effect of” ingested “gluten on the small bowel.” *Id.* at 52. It was “basically a contact phenomenon,” rather than something which could arise from intramuscular vaccination. *Id.*

Referring to Dr. Frick’s testimony, Dr. Warner disputed that [M.L.] was immune-deficient, since her records did not show “recurring sinusitis, bronchitis or other opportunistic

infections,” and her ear infections were normal for a child of her age. Sp. Mstr. Tr. at 53-54. He also disagreed with the claim that patients with celiac disease had an immune system different from the general population, as a celiac patient “on a gluten-free diet is no more likely to get an infection than anyone else.” *Id.* at 54. When asked by the Special Master about the symptoms exhibited by [M.L.] within hours of receiving the DTaP vaccination, Dr. Warner posited that her reaction was normal for a child receiving such a shot. *Id.* at 55. He also testified that her behavioral problems had been typical of a child who was ill with undiagnosed celiac disease. *Id.* at 57. And Dr. Warner noted that Dr. Frick had not provided any literature linking the DTaP vaccination and celiac disease. *Id.*

During cross-examination, petitioners’ counsel questioned Dr. Warner about a statement the expert allegedly made in his report, to the effect that “gluten was introduced to [M.L.] early.” Sp. Mstr. Tr. at 60.<sup>9</sup> Referring to [M.L.]’s diet based on her medical records, Dr. Warner stated that cereal was listed as the anticipatory diet on [M.L.]’s four-month visit record, and that sweet potatoes --- which he believed to usually contain gluten --- were listed as part of her diet on her six-month visit record. *Id.* at 62-64. He ultimately agreed that [M.L.] started eating gluten-based food at the normal time for children, *id.* at 64-65, and that this was approximately six months prior to the January 28, 2004 vaccinations. *Id.* at 67. When asked whether there was a specific time period over which celiac patients develop the disease after gluten is added to their diets, Dr. Warner explained that only fifteen to twenty percent of people with celiac disease are symptomatic, and that symptoms could vary from iron-deficiency anemia to full diarrhea, weight loss, and malabsorption --- making it difficult to pinpoint a time period. *Id.* at 65. He added that patients who were diagnosed with the disease and felt recovered after switching to a gluten-free diet would “start getting sick pretty soon” when gluten is reintroduced, with “changes on their small bowel biopsies” within a month. Sp. Mstr. Tr. at 66. He reiterated that there had been no studies or case reports linking celiac disease to vaccinations. *Id.* at 68. And on redirect examination Dr. Warner emphasized “there’s simply nothing in the literature to suggest a link that there’s any particular trigger that causes [c]eliac disease other than ingestible gluten.” *Id.* at 74-75.

Shortly after the hearing, petitioners filed copies of two articles mentioned by Dr. Frick in his testimony --- one concerning antibody responses to pertactin and the other addressing the increased prevalence of IgA deficiency among celiac disease patients. *See* Notice of Filing (Dec. 23, 2008) & Pet’rs’ Exs. 15 & 16. Several months later, coincident with the filing of their post-hearing brief, petitioners filed as their Exhibit 17 a copy of another article. *See* Notice of Filing (May 8, 2009) & Pet’rs’ Ex. 17 (Dariusz Stepniak & Frits Koning, *Celiac Disease---Sandwiched between Innate and Adaptive Immunity*, 67 *Human Immunology* 460-68 (2006)) (“Stepniak”).

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<sup>9</sup> The premise of this line of questioning does not appear to be correct, as no such statement appears in Dr. Warner’s report. *See* Resp’t’s Ex. A. The report states, accurately, that [M.L.] was “[b]reastfed less than two months,” *id.* at 1 (citing Pet’rs’ Ex. 3 at 2018), and merely notes that “the shorter an infant is breastfed the sooner they start eating foods that contain gluten since gluten is present in most cereals.” *Id.* at 3; *see also* Sp. Mstr. Tr. at 70.

Quoting in part from the article's abstract, the only explanation offered by petitioners concerning this article was as follows:

This article indicates that both environmental and genetic factors have been implicated in the contraction of celiac disease and, 'viral infections and/or tissue damage in the intestine may cause inflammation and induce protective Th1-mediated immunity leading to loss of tolerance for gluten. Once tolerance is broken, a broad gluten-reactive T cell repertoire may develop through determinant spreading. This may be a critical step toward full-blown [celiac] disease.'

Notice of Filing (May 8, 2009) (quoting Stepniak at 460 (alteration by petitioners)).

In petitioners' post-hearing brief, they argued that Dr. Warner was mistaken in stating that sweet potatoes contained gluten. Post-Hr'g Br. at 8-9. They also noted that an information pamphlet issued by the National Institutes of Health ("NIH"), which was referenced by and attached to Dr. Warner's report, stated that celiac disease was sometimes "triggered---or becomes active for the first time---after surgery, pregnancy, childbirth, viral infection, or severe emotional stress." *Id.* at 9 (quoting from Attach. to Resp't's Ex. A, at 2). Petitioners argued that this statement supported the theory testified to by Dr. Frick, and that treating physicians' statements in the record also "connect[ed] [M.L.]'s injury with celiac disease to her vaccinations on January 28, 2004." *Id.* Applying the *Althen* factors to [M.L.]'s case, petitioners also contended that they had met the burden of proof by offering Dr. Frick's medical theory "that the D[T]aP vaccine acted as a viral insult to the body of a genetically predisposed [individual] which caused the development of celiac disease," *id.* at 10; by presenting a logical sequence of cause and effect that the DTaP shot was an insult to her immune-deficient state which triggered celiac disease, *id.* at 11; and by showing a proximate temporal relationship between the vaccination and the allergic reaction, serum sickness, and "intestinal difficulties" reflecting the onset of celiac disease. *Id.*

Respondent filed a post-hearing memorandum, arguing that petitioners failed to establish the logical sequence of cause and effect between DTaP vaccination and onset of celiac disease. Resp't's Post-Hr'g Mem. at 12. Challenging Dr. Frick's testimony, respondent contended that the expert witness's theory of causation inappropriately relied on speculation and lacked support from any medical literature. *Id.* at 13. Respondent maintained that neither Dr. Frick's theory nor the statements from [M.L.]'s treating physicians met the reliability standard of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993) or "another discernible test." Resp't's Post-Hr'g Mem. at 12 n.4, 13-14.

In their reply, petitioners disputed respondent's characterization of Dr. Frick's testimony on the issue of when [M.L.]'s celiac disease symptoms materialized. Pet'rs' Reply Br. to Resp't's Post-Hr'g Mem. ("Pet'rs' Reply") at 1. While acknowledging that Dr. Frick had stated that the diarrhea occurring the day of her vaccinations "may have been the beginning of" [M.L.]'s celiac disease, petitioners note that their expert also stated that the disease developed "probably within two weeks afterwards." Pet'rs' Reply at 2 (citing Sp. Mstr. Tr. at 42). Petitioners also

argued that the application of *Daubert* standards had been found inappropriate by the Special Master; that the Special Master had found Dr. Frick qualified to testify; and that when respondent's counsel chose to forego voir dire of Dr. Frick, the government waived all objections based on Dr. Frick's competence --- including those based on *Daubert*. *Id.* at 3.

### C. The Special Master's Decision Denying Compensation

On September 8, 2010, the Special Master ruled from the bench, finding that petitioners were not entitled to compensation and dismissing the petition with prejudice. *Langland ex rel. M.L. v. Sec'y of HHS*, No. 07-36V, 2011 WL 386985, at \*25 (Fed. Cl. Sp. Mstr. Oct. 21, 2010). The Special Master found that petitioners had not demonstrated by a preponderance of the evidence that the vaccination could have been a substantial factor causing [M.L.]'s injury. *Id.* at \*24. In the Special Master's view, petitioners failed to explain how celiac disease would not have occurred but for the vaccination. *Id.* The Special Master's decision was publicly released in redacted form on February 4, 2011.

As a preface to his ruling, the Special Master explained that in this non-Table case, the petitioners would need to show by a preponderance of the evidence that the vaccination was "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." *Langland ex rel. M.L.*, 2011 WL 386985, at \*3 (quoting *Pafford v. Sec'y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006)). He noted that, to meet the burden of proof, petitioners would have to provide: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* (quoting *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).<sup>10</sup>

The Special Master began his ruling with a discussion of [M.L.]'s medical records. *Id.* at \*4-6. Included among these records was an email from Dr. Buckley dated February 27, 2005 and sent to Dr. Valerie Miles, who began treating [M.L.] earlier that month. Pet'rs' Ex. 9 at 18; *id.* at 1, 12. Doctor Buckley said of [M.L.], "I saw her in the worst of the worst and this kid's gut took a terrible hit." Pet'rs' Ex. 9 at 18. After recommending changes to the vitamins and nutrients prescribed for the patient, Dr. Buckley added: "She was sick as an ever lovin['] dog and Crohn's disease or not, she got that way in direct association with her shots." *Id.* The Special Master quoted from this email, which he determined was "not a diagnostic medical record." *Langland*

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<sup>10</sup> The Special Master explained that he often "bifurcated the issue of actual causation into the 'can it' prong and 'did it' prong," which he described as "(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." *Langland ex rel. M.L.*, 2011 WL 386985, at \*3. In *Pafford*, the Federal Circuit "perceive[d] no significant difference between the Special Master's test and that established by [the] court in *Althen* and *Shyface*." *Pafford*, 451 F.3d at 1356.

*ex rel. M.L.*, 2011 WL 386985, at \*5-6. He found it to be “of dubious quality and minimal probative value regarding the issue of vaccine causation,” noting it was mistaken about the child’s actual condition, substituting Crohn’s disease for celiac disease. *Id.* at \*6. The Special Master found that the email “just asseverates that [M.L.’s] condition was ‘in direct association with her shots,’” based apparently on “temporal association alone.” *Id.* He later concluded that “the curious ruminations in the email” were “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.” *Id.* at \*21. The Special Master noted that this “private email correspondence” occurred “well after the period at issue” when Dr. Buckley first treated [M.L.], and found it “neither helpful nor persuasive” --- as it did “not even mention the correct condition” and did “not explain how the vaccine at issue could cause the injury alleged.” *Id.* at \*24.

Concerning the other medical records highlighted by petitioners, the Special Master found these to be merely “the recitation of parental histories temporally associating the 28 January 2004 vaccinations with the onset of symptoms.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*6. He found that “[n]one of those references blame the vaccine causally,” *id.*, and that “no treating physician actually rendered an explanation of diagnostic etiology in the medical records concluding that the vaccine was the ca[use] of [M.L.]’s [c]eliac disease,” in contrast to “the focus of the *Capizzano* opinion.” *Id.* at \*21 (citing *Capizzano v. Sec’y of Dep’t of HHS*, 440 F.3d 1317 (Fed. Cir. 2006)); *see also id.* at \*24 (“Not one single medical record asserts an opinion of causation, stating or implying that the vaccines administered caused or triggered [M.L.]’s [c]eliac disease.”).

Discussing petitioners’ expert, the Special Master characterized Dr. Frick’s report as positing that [M.L.] “had a genetic predisposition to a disease and that it was the vaccine that triggered the appearance of symptomatic manifestation.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*7. The Special Master found that this report “never clearly articulates how a vaccine could trigger the onset of latent [c]eliac disease,” and that its “conclusion relies heavily on temporal association in the clinical history.” *Id.* The Special Master then turned to Dr. Frick’s testimony. He noted that petitioners’ expert believed that [M.L.]’s prior history of ear infections, as well as those of her siblings, showed that she “probably” had an IgA deficiency, consistent with test results taken a year after the vaccinations in question. *Id.* Doctor Frick testified that this demonstrated “a predisposition to autoimmune disease, including [c]eliac disease.” *Id.*

The Special Master “found it odd that Dr. Frick mentioned measles vaccination twice” in discussing [M.L.]’s reaction to the January 28, 2004 vaccinations, when this was not among the vaccines administered that day. *Langland ex rel. M.L.*, 2011 WL 386985, at \*8. He also stated he “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.” *Id.* The Special Master noted that Dr. Frick saw the “DTaP vaccine as a ‘trigger’ for the [c]eliac 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.’” *Id.* Though he explained how rashes and hives resulted from [M.L.]’s

vaccination, Dr. Frick could not elaborate on how the DTaP vaccine could have triggered celiac disease. *Id.* at \*9. When the Special Master asked specifically how the vaccine could trigger the disease, Dr. Frick acknowledged, “I don’t think anybody really knows that.” *Id.* (quoting Sp. Mstr. Tr. at 29).

The Special Master also noted that Dr. Frick could not find any literature or references supporting a link between the DTaP vaccine and celiac disease. Doctor Frick’s explanation of the relevance of petitioners’ Exhibit 15 was found to be “frankly cryptic, and left unclarified.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*10. According to Dr. Frick, this article discussed the presence, in rabbits, of antibodies to the pertactin proteins contained in the pertussis vaccine, but noted these antibodies were not detected in humans. *Id.* The Special Master noted that, concerning celiac disease and the reaction to pertactin, Dr. Frick merely stated “it’s possible that maybe that was involved as well,” and later added he “can’t say it’s a cause, but it’s a possibility.” *Id.* With “no linkage of the experimental model to humans,” the Special Master found nothing of relevance in this article. *Id.*

Doctor Frick also posited that a low level of IgA could have predisposed [M.L.] to an autoimmune disorder like celiac disease. He relied upon an article on immunoglobulin tests used to diagnose celiac disease, of which the Special Master found “no patently relevant portions.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*10 (citing Pet’rs’ Ex. 16). In an exchange with the Special Master, Dr. Frick gave his opinion that the vaccine was an insult to the body, and [M.L.]’s subsequent reaction triggered her celiac disease. *Id.* at \*11. The Special Master found this explanation to be vague and determined that it did not meet petitioners’ burden of proof under *Althen*, which requires “an articulated, plausible ‘medical theory causally connecting the vaccination and the injury.’” *Id.* (quoting *Althen*, 418 F.3d at 1278).

The Special Master then recounted that he followed up with a question to Dr. Frick, inquiring “how does ceasing gluten intake resolve a vaccine-related injury?” *Id.* He noted that the response of petitioners’ expert was that the enzyme tTG converts gluten into a substance that “hooks onto the HLA sites” of celiac disease patients, triggering the disease, and 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.” *Id.* The Special Master found that this explanation “was not really supported by any medical literature relied upon in the formation and composition of Dr. Frick’s report,” and that the later-filed Exhibit 17 “did not raise vaccines as possible triggers.” *Id.* The Special Master characterized Dr. Frick’s testimony as a “meager and hardly explained ratiocination” that left him “at a loss as to how a vaccine might plausibly trigger an autoimmune reaction to wheat gluten.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*11.

On the medically-appropriate temporal relationship between vaccination and the onset of celiac disease, the Special Master noted a contradiction in Dr. Frick’s testimony. The medical records indicated that [M.L.] had experienced vomiting and diarrhea on the day of vaccination, which Dr. Frick acknowledged can be symptoms of celiac disease, but he believed that her celiac disease began two weeks later. *Langland ex rel. M.L.*, 2011 WL 386985, at \*11-12. In Dr.

Frick's view, [M.L.] likely had a serum sickness reaction directly after the vaccination and developed celiac disease symptoms later. *Id.* at \*12. Yet, he also considered the short-term and long-term symptoms to be "all part and parcel" of her celiac disease. *Id.* To the Special Master, this explanation was "neither coherent, nor consistent, nor persuasive." *Id.* at \*13.

The Special Master also found Dr. Frick's explanation of a medical article on celiac patients' non-response to the hepatitis B vaccine to be unpersuasive and unhelpful. *Langland ex rel. M.L.*, 2011 WL 386985, at \*13. According to Dr. Frick, the article showed that celiac patients had disturbed immune systems, because they did not respond to the hepatitis B vaccine. *Id.* During cross-examination, respondent's counsel asked whether the article suggested that the DTaP vaccine would have even less impact on someone with celiac disease. *Id.* The Special Master agreed with the premise of the question and considered Dr. Frick's answer to be "nonspecific and vague," and thus "unpersuasive and unhelpful." *Id.*

The Special Master also noted that "Dr. Frick conceded . . . that he's never treated a patient with vaccine-related [c]eliac disease." *Langland ex rel. M.L.*, 2011 WL 386985, at \*13. He also found petitioners' expert's rebuttal testimony on the purported "vaccine-related autoimmune process" to consist of "rather obtuse comments." *Id.* In this testimony, Dr. Frick reiterated his explanation that [M.L.] "was prone to the autoimmune thing," and that "[a]n insult is often a viral infection or some sort of an infection that sets off the process and the thing starts." *Id.*

Respondent's expert's testimony was next addressed. The Special Master noted Dr. Warner's opinion "that the vaccinations did not cause or in any way aggravate" the celiac disease suffered by [M.L.]. *Langland ex rel. M.L.*, 2011 WL 386985, at \*14. Doctor Warner testified there was no data linking celiac disease and the vaccination; that the disease is common and latent; that celiac disease symptoms were noticed the day of the vaccination, which was "simply too soon" for causation; that children with the disease are routinely vaccinated, as "there is no concern about an increase in [c]eliac symptoms following vaccination"; and that he knew of no mechanism by which a shot could cause or aggravate the disease, which is only caused by "the ingestion of gluten." *Id.* The Special Master explained that with no postulated mechanism of causation, Dr. Warner believed it was "impossible to know" the "appropriate time[]frame" that "would be expected for onset." *Id.* When asked "whether DTaP shared any chemical commonality with wheat gluten," respondent's expert testified this would not matter, because gluten had "direct toxic [e]ffect . . . on the small bowel," a "contact phenomenon" that would not be implicated by an injection. *Id.* He also testified that petitioners' medical literature did not support any link between DTaP and celiac disease, and that he knew of no medical literature that even discussed a temporal association between vaccines and the disease. *Id.* at \*15.

Turning to petitioners' Exhibit 17, filed after the hearing, the Special Master found it "interesting and helpful, but certainly not dispositive." *Langland ex rel. M.L.*, 2011 WL 386985, at \*17. The Special Master quoted at length the passages from the article that he found relevant. *See id.* at \*17-19. The article noted that some people develop celiac disease long after they begin

ingesting gluten, and that the default mode of the immune system cells in the small intestine is to tolerate harmless antigens. *Id.* at \*17-18. Because this identification of substances is a constant process, the authors felt “it seems unlikely that gluten could initiate adaptive immune responses by itself,” and that “inflammatory stimuli” were also needed. *Id.* at \*18. Since cross-reactivity involving pathogens can lead to autoimmunity, the authors considered whether gluten was similar enough to certain viruses or bacteria such that molecular mimicry could trigger celiac disease. *Id.* The Special Master noted that “inasmuch as nothing has been demonstrated in that regard, the authors acknowledged that the hypothesis remains speculative.” *Id.*

The authors also thought it was “conceivable” that interferon-alpha, a protein produced in response to diarrhea-causing intestinal viruses, could change the instruction of certain immune system cells “to prime gluten-specific T cells and support inflammation instead of sustaining oral tolerance,” triggering a process that could ultimately result in celiac disease. *Langland ex rel. M.L.*, 2011 WL 386985, at \*18-19. The Special Master noted that “the only trigger for [c]eliac disease discussed by this paper that was not merely speculative, was gluten itself.” *Id.* at \*19. After quoting a discussion of how the introduction of gluten into a diet can be managed to reduce the incidence of the disease, he quoted from the paper’s conclusion. The authors questioned whether it was genetic differences or “unrelated events, such as enteroviral infections,” that explained why some people develop celiac disease later than others. *Id.* They believed “many combinations of these two options are possible,” but recognized that an animal “model still does not exist” to allow them to answer whether viral infections can trigger the disease’s onset. *Id.*

Summing up the article, the Special Master noted that its “discussion of triggering events remains quite speculative and hypothetical with a lot of unexplained loose ends in their hypothesis regarding the biologic process involved.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*19. He further noted “that vaccines are never mentioned as potential triggers,” but noted he was “cognizant” that certain disorders could be triggered by both vaccines or “viral insults,” and that if a mere “immune challenge” can trigger an autoimmune disorder, “certain vaccines” could have that effect. *Id.*

In his final analysis of petitioners’ case, the Special Master found that petitioners failed to satisfy the first prong of *Althen*, because they could not show “whether the vaccine at issue can cause the injury alleged.” *Id.* at \*22. He explained that without the identification of a biologic mechanism that would work over a particular time frame, consideration of prongs two and three --- “whether the facts, circumstances, and temporal period of the specific case matches the postulated theoretical construct” --- would be impossible. *Id.* at \*23. He found petitioners had “not postulated a coherent and sufficiently detailed theory of how the vaccine or vaccines at issue could have either caused or triggered [their daughter’s] [c]eliac disease.” *Id.* He did not find the narrative that [M.L.]’s abnormal immune system “went haywire” in reaction to the DTaP vaccination to be “detailed enough to be considered a plausible theory demonstrating biologic causation.” *Id.* The Special Master concluded that “there was no source of further detail to be found” in the record. *Langland ex rel. M.L.*, 2011 WL 386985, at \*23. Neither clinical experience nor medical literature demonstrated a link between the vaccine and celiac disease. *Id.*

Rather than explain how a DTaP vaccination could trigger celiac disease, the medical literature relied upon by petitioners' expert "related to some other vaccine, some other injury, or some other effect," and was thus not applicable to the key question. *Id.* The literature submitted was found to "support[] only the most general and undisputed propositions and not the central issue in contention," *id.* at \*24, and the Special Master found Dr. Frick's testimony to be "nonresponsive, obtuse" or "unhelpful." *Id.* at \*23-24. The Special Master explained that, under *Capizzano*, the opinions of treating physicians could only satisfy the second and third prongs of *Althen* (or, in his formulation, the "'did it' prong"), and "cannot substitute for the explanation of a plausible theory as to how a given vaccine can cause the alleged injury in the abstract." *Id.* at \*24. Moreover, the medical records were not found to contain "an opinion of causation" or "to explain how the vaccine at issue could cause the injury alleged," but rather reflected petitioners' recitations or temporal associations. *Id.* The Special Master thus concluded that petitioners did not meet their burden of proof and dismissed the petition. *Id.* at \*24-25.

#### **D. Petitioners' Motion for Review**

Petitioners filed a motion for review in our court, raising three objections to the Special Master's decision. Pet'rs' Mot. for Rev. ("Pet'rs' Mot.") at 2. First, they argue that the Special Master was arbitrary and capricious and abused his discretion by allegedly disregarding medical records --- particularly the e-mail from Dr. Buckley --- and a purported "admission" in the report of Dr. Warner. *See id.* at 2-6. According to petitioners, Dr. Buckley's e-mail to Dr. Miles, Pet'rs' Ex. 9 at 18, stating that [M.L.]'s illness was "in direct association with her shots," should not have been discounted but rather given significant weight as a record "which clearly implies causation." Pet'rs' Mot. at 3-5. Petitioners identify other statements in the medical records which, they believe, reflect opinions on causation. *Id.* at 3-4. And petitioners contend that the statement that "[s]ometimes [celiac] disease is triggered---or becomes active for the first time---after surgery, pregnancy, childbirth, viral infection, or severe emotional distress," Attach. to Resp't's Ex. A at 2, contained in the NIH pamphlet attached to and referenced in the report of respondent's expert, *see* Resp't's Ex. A at 3, should have been considered an important admission confirming the theory of their own expert. Pet'rs' Mot. at 5-6.<sup>11</sup>

Second, petitioners argue that the Special Master was arbitrary and capricious, abused his discretion, and failed to act in accordance with law, in rejecting the theory of causation offered by their expert, Dr. Frick. Pet'rs' Mot. at 2, 6-10. Petitioners contend that Dr. Frick's theory that the vaccine was an insult to the immune system, which triggered an autoimmune response in the form of celiac disease due to a genetic predisposition, was a biologically plausible theory. *Id.* at 6-7. In petitioners' view, the Special Master impermissibly raised petitioners' burden of proof by requiring a scientific explanation of the mechanism of injury, and by rejecting petitioners'

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<sup>11</sup> Petitioners also contend that the Special Master erred in stating that [M.L.]'s "behavioral problems had ceased" as of April 12, 2004, Pet'rs' Mot. at 5 (quoting *Langland ex rel. M.L.*, 2011 WL 386985, at \*5), but this does not appear to have any bearing on the question of whether the decision was arbitrary.

explanation as “hypothetical” and suffering from “a lot of unexplained loose ends.” *Id.* at 7. They argue that the decision was contrary to law, and to the *Althen* third prong in particular, in rejecting the “highly probative” evidence of temporal association. *Id.* at 6, 15-16. Petitioners reiterate that the Special Master ignored the alleged admission in the respondent’s expert’s report and the causation findings in the medical records, and argue that the testimony of their expert concerning the onset of symptoms was misinterpreted. *Id.* at 8-10.

Finally, petitioners contend that the Special Master’s decision required medical literature to support Dr. Frick’s opinion. Pet’rs’ Mot. at 11. In doing so, they argue, the Special Master violated the Federal Circuit’s holding in *Althen*. *Id.* at 11-12 (citing *Althen*, 418 F.3d at 1280-82).

The Secretary of Health and Human Services responded to petitioners’ motion for review. *See* Resp’t’s Resp. To Pet’rs’ Mot. for Rev. (“Resp.”) Respondent contends that the Special Master properly concluded that petitioners failed to provide an explanation of how the vaccine could cause celiac disease. Resp. at 6-7. According to respondent, Dr. Frick’s testimony contained only “a general assertion that [M.L.] had an abnormal immune system which caused her to develop celiac disease as a result of vaccination.” *Id.* at 7. The Secretary further argues that Dr. Frick failed to provide any explanation for how the vaccine caused the disease or “any prior instances when the vaccine was linked to the disease.” *Id.* at 7-8. In contrast, respondent notes, Dr. Warner testified that there was no plausible mechanism for the vaccine to trigger celiac disease, and the only thing known to cause celiac disease was the ingestion of gluten. *Id.* at 9.

In the Secretary’s view, the issue is not the scientific validity of petitioners’ explanation of vaccine injury, but rather the absence of a coherently-articulated theory of vaccine causation in the first place. Resp. at 10. Respondent agrees with the Special Master that an article stating that “viral infection and/or tissue damage in the intestine” may trigger the disease does not support a connection to the DTaP vaccine, which is neither viral nor is injected into the small intestine. *Id.* at 10-11. The Secretary argues that the Special Master did not abuse his discretion in weighing the statements of the treating physicians in light of the medical records, medical literature, and expert testimony. *Id.* at 12-16. Respondent contends the Special Master properly found that the statements of [M.L.]’s treating physicians failed to address the absence of a plausible theory as to how the DTaP vaccine can cause celiac disease. *Id.* at 15-16.

Finally, respondent argues that the Special Master properly concluded that it was impossible to use temporal association as an analytical tool for determining causation, because petitioners did not first establish a coherent biological mechanism by which vaccination caused celiac disease. Resp. at 16. Respondent contends that the Special Master could not determine the medically-appropriate time frame in the absence of a plausible theory of causation. *Id.* at 16-18.

The Court held oral argument on petitioners' motion.<sup>12</sup> After careful consideration of the medical records, testimony, and submitted literature in the record, the decision below, and the arguments of counsel, this opinion issues.

## II. DISCUSSION

### A. Legal Standards

#### 1. Court's Standard of Review of a Special Master's Decision

Under the Vaccine Act, the special master must award compensation if, “on the record as a whole,” he finds “that the petitioner has demonstrated by a preponderance of the evidence” the claims of the petition. 42 U.S.C. § 300aa-13(a)(1)(A) (2006). By this same standard, the special master must find that nothing else is responsible for causing the injury. *Id.* § 300aa-13(a)(1)(B). “The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” *Id.* § 300aa-13(a)(1). The special master must consider all the “relevant medical and scientific evidence contained in the record,” including any “diagnosis, conclusion, medical judgment, or autopsy . . . regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death” and “the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” *Id.* § 300aa-13(b)(1). The Act further specifies that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court.” *Id.* The special master is entrusted with evaluating the “weight to be afforded to any” of these sources of information. *Id.* A special master’s “assessments of the credibility of the witnesses” are “virtually unchallengeable on appeal.” *Lampe v. Sec’y of HHS*, 219 F.3d 1357, 1362 (Fed. Cir. 2000). This deference rests on the special master’s “broad discretion in determining credibility because he saw the witnesses and heard the testimony,” *Bradley v. Sec’y of Dep’t of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993), and extends to assessments of expert testimony. *See Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1325-26 (Fed. Cir. 2010).

Medical records “warrant consideration as trustworthy evidence.” *Cucuras v. Sec’y of Dep’t of HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). These records are “generally contemporaneous to the medical events,” and “accuracy has an extra premium” because a patient’s proper treatment is “hanging in the balance.” *Id.* Moreover, because medical records are contemporaneous documentary evidence, conflicting oral testimony “deserves little weight.” *Id.* (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947)).

In reviewing a special master’s decision, the Court may “set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of

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<sup>12</sup> See Tr. (Feb. 15, 2011) (“Tr.”).

law.” 42 U.S.C. § 300aa-12(e)(2)(B) (2006). Findings of fact are to be reviewed under the “arbitrary and capricious” standard; legal questions are to be reviewed under the “not in accordance with law” standard; and an abuse of discretion standard is used for discretionary rulings. *See Munn v. Sec’y of Dep’t of HHS*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). With respect to the arbitrary and capricious review, “no uniform definition of this standard has emerged,” but it is “a highly deferential standard of review” such that “[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.” *Hines ex rel. Sevier v. Sec’y of Dep’t of HHS*, 940 F.2d 1518, 1527-28 (Fed. Cir. 1991).

## 2. Standard of Causation in Vaccine Cases

A special master may award compensation through an “off-table” or “causation-in-fact” case. *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). Causation-in-fact --- the basis for the legal entitlement to compensation when a petitioner’s injury is either not listed in the Vaccine Injury Table or did not occur within the time period set forth in the Table --- must be proven under two formulations adopted by the Federal Circuit. *See Pafford*, 451 F.3d at 1355. Petitioners must establish that the vaccine was both a “but-for” cause of the injury and a substantial factor in causing the injury. *See Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Under a three-part test more recently articulated by the Circuit, petitioners must prove “(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).<sup>13</sup> Petitioners bear the burden of proving causation by preponderant evidence. *See* 42 U.S.C. § 300aa-13(a)(1)(A).

Petitioners must show more than a proximate temporal relationship between the vaccination and the injury to meet their burden of showing actual causation. *Althen*, 418 F.3d at 1278; *see also Grant v. Sec’y of Dep’t of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Furthermore, “[t]here may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine.” *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1327 (Fed. Cir. 2006). Petitioners could meet the first and third prongs of the *Althen* test without “satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.” *Id.* The sequence only has to be “‘logical’ and legally probable, not medically or scientifically certain,” and thus can be established by “epidemiological evidence and [a] clinical picture,” even “without detailed medical and scientific exposition on the biological

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<sup>13</sup> Although the Federal Circuit has described the *Althen* test as an “alternative,” the very same opinion makes plain that the *Althen* “prongs must cumulatively show” that the *Shyface* standard is met. *See Pafford*, 451 F.3d at 1355.

mechanisms.” *Knudsen v. Sec’y of Dep’t of HHS*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Nonetheless, the Federal Circuit has stated that while “epidemiological studies are probative medical evidence relevant to causation,” *Grant*, 956 F.2d at 1149, they are not necessarily dispositive. *See id.*

If petitioners satisfy their burden, they are entitled to compensation “unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” *Althen*, 418 F.3d at 1278 (quoting *Knudsen*, 35 F.3d at 547) (alteration in original).

## **B. The Special Master Properly Reviewed the Record**

Petitioners’ first objection is that the Special Master arbitrarily disregarded evidence in the record. They claim that statements of causation by treating physicians were either ignored or discounted, and that an important admission by respondent was ignored.

### 1. The Statements of Treating Physicians

Petitioners cite five examples of statements in the medical records that they contend “in fact show a treating physician statement of vaccine causation.” Pet’rs’ Mot. at 3. There are several problems with this aspect of the objection. First, the Special Master’s principal determination was that petitioners failed to satisfy prong one of *Althen*, which requires “a medical theory causally connecting the vaccination and the injury” that is based on a “reputable medical or scientific explanation.” *Althen*, 418 F.3d at 1278 (quoting *Grant*, 956 F.2d at 1148); *see Langland ex rel. M.L.*, 2011 WL 386985, at \*24. The Special Master explained that a treating doctor’s opinion that a vaccination caused a particular injury “cannot substitute for the explanation of a plausible theory as to how a given vaccine can cause the alleged injury.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*24. In other words, in the absence of a theory showing a vaccine *could* cause a particular injury, a doctor’s belief that it *did* will not prove causation --- prong one of *Althen* must be demonstrated, for prongs two and three to matter. It is not clear whether petitioners intended to argue that the Special Master erred as to the law on this point, but it is clear that he did not. Federal Circuit precedent makes it evident that the first prong of *Althen* must be proven before the opinions of treating physicians may clinch causation under the other prongs. *See, e.g., Andreu ex rel. Andreu v. Sec’y of HHS*, 569 F.3d 1367, 1375 (Fed. Cir. 2009) (“If a claimant satisfies the first and third prongs of the *Althen* standard, the second prong can be met through medical opinion testimony.”) (citing *Capizzano*, 440 F.3d at 1326).

The Court supposes, however, that in certain circumstances the opinion of a treating physician could suffice to prove the existence of a plausible medical theory of causation. For instance, a doctor’s diagnosis could express a belief as to how the vaccination caused the particular injury. Or the treating physician could record that he had seen the same injury or

illness following the same vaccination on a number of occasions, tantamount to a review of case reports which --- although not as rigorous as typical epidemiological studies, “designed to reveal statistical trends,” *Moberly*, 592 F.3d at 1324 --- may be probative of a medical theory. *Cf. Campbell v. Sec’y of HHS*, 90 Fed. Cl. 369, 385 (2009) (finding that case reports are not “deprived of evidentiary value in support of [petitioner’s] medical theory”). But in this regard, the Special Master scrutinized the physicians’ statements and properly found them wanting. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*5-6, \*24. He determined that they were “mere recitation of intake history given by Petitioners,” *id.* at \*24, summaries of “the time[]line of symptoms,” *id.*, or --- in the case of the email from Dr. Buckley that petitioners particularly rely upon --- correspondence that was “not a diagnostic medical record,” *id.* at \*5, was “mistaken” about [M.L.]’s “actual condition,” *id.* at \*6, and in any event “does not explain how the vaccine at issue could cause the injury alleged.” *Id.* at \*24.

Taking the email from Dr. Buckley to Dr. Miles first, the Special Master found “it of dubious quality and minimal probative value,” *id.* at \*6, and determined it was a “private email correspondence.” *Id.* at \*24. In this email, Dr. Buckley stated that [M.L.] “was sick as an ever lovin[’] dog and Crohn’s disease or not, she got that way in direct association with her shots,” Pet’rs’ Ex. 9 at 18. This statement was not a contemporaneous medical record but was made over one year after the vaccination in question, contained casual language, and referenced personal topics. *Id.* (“Watch channel 12 next Friday newscasts and pray that my words don’t get twisted . . .”). In this email, as the Special Master noted, *Langland ex rel. M.L.*, 2011 WL 386985, at \*5-6, \*24, Dr. Buckley reported the wrong condition for [M.L.], calling it Crohn’s disease rather than celiac disease. *See* Pet’rs’ Ex. 9 at 18. Although the results of the two diseases may be similar, both associated with diarrhea and malabsorption, *see* Pet’rs’ Mot. at 4, they operate in different ways, as Crohn’s disease has nothing to do with gluten. *See* Tr. at 76. Thus, it is inconceivable that this message can be taken as even implying that its author had some inkling of the process by which the vaccination received by [M.L.] could have resulted in the disease allegedly triggered, as she had an entirely different disease in mind at the time. *Cf. Broekelschen v. Sec’y of HHS*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (finding it was appropriate to require the injury to be determined before the *Althen* test is applied, when conditions with “overlapping symptoms” have “underlying causes or etiology [that] are completely different”). The Special Master was not at all arbitrary in finding the statement did not support *Althen* prong one. Nor, for that matter, was the Special Master arbitrary in finding the statement of “direct association” to reflect nothing more than a temporal association, *see Langland ex rel. M.L.*, 2011 WL 386985, at \*6, which does not alone suffice to establish causation. *See Althen*, 418 F.3d at 1278.<sup>14</sup>

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<sup>14</sup> In this regard, the Court notes that the recipient of the email, Dr. Miles, did not appear to attribute any significance to Dr. Buckley’s statement associating [M.L.]’s illness with the vaccination. In her medical log discussing the email she did not mention that aspect of it, but merely noted the vitamin recommendations. *See* Pet’rs’ Ex. 9 at 11.

The other physicians' statements are no more probative of causation than the email. Not one of them actually states that the DTaP vaccination caused [M.L.]'s celiac disease, let alone explains a medical theory by which this could happen. *See* Pet'rs' Ex. 1 at 2; Pet'rs' Ex. 6 at 1-2; Pet'rs' Ex. 7 at 7. The Special Master properly concluded that these statements cannot make up for the lack of a plausible medical theory of causation, making their value as proof of the other *Althen* prongs beside the point. In any event, even considered under prongs two and three, the Court cannot find arbitrary the Special Master's determination that the records reflect no more than intake histories or temporal associations. Doctor Buckley's record that [M.L.] "had a significant neurologically regressive reaction associated with vaccines given 1/28/03 [sic]," Pet'rs' Ex. 1 at 2, could reasonably be considered to be based on the mere temporal association between the vaccination and illness. Her determination that a Vaccine Adverse Event Reporting System report should be filed may also be based on the timing of the two, and her recommendation against further vaccinations, *see* Pet'rs' Ex. 7 at 7, does not seem to have much probative value in the context of this particular case, given the theory that the vaccination triggered a particular disease --- as it is hardly logical to fear a second triggering of the disease.<sup>15</sup>

The final two statements highlighted by petitioners were contained in an "Encounter Note" dated August 4, 2004, in which Dr. Jerry Kartzinel recounted a phone conversation with petitioners. *See* Pet'rs' Ex. 6 at 1-2. On one page, the doctor wrote: "Shots in Jan 2004: immediately developed fever, rash, vomiting, diarrhea, lethargic, this lasted 6 weeks. Diagnosed her with [c]eliac[sic] disease." *Id.* at 1. On the next, he wrote: "Discussion: Vaccine VAERS to be made out / Consider involving a lawyer." *Id.* at 2. These statements easily fit within the Special Master's assessment of a "recitation of intake history" or a "time[ ]line of symptoms." *See Langland ex rel. M.L.*, 2011 WL 386985, at \*24.<sup>16</sup> Particularly given the "great deference to a Special Master's determination on the probative value of evidence" that is owing, *Pafford*, 451 F.3d at 1359, the Court cannot find the Special Master's assessment of medical records to have been arbitrary. Rather, the Court concludes that he properly exercised his responsibility as the fact-finder. *See Moberly*, 592 F.3d at 1325.

## 2. The Statement in the NIH Pamphlet

In his report, respondent's expert wrote, "[f]or more information on [c]eliac disease please see the enclosed patient information pamphlet on [c]eliac disease from the National Institutes of Health." Resp't's Ex. A at 3. The referenced pamphlet contains the following sentence: "Sometimes the disease is triggered---or becomes active for the first time---after surgery, pregnancy, childbirth, viral infection, or severe emotional stress." Attach. to Resp't's

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<sup>15</sup> During oral argument, petitioners' counsel speculated that Dr. Buckley may have worried that subsequent vaccinations could cause other injuries. *See* Tr. at 31-32.

<sup>16</sup> Another record, quoted but not highlighted by petitioners, *see* Pet'rs' Mot. at 3, is clearly of the same ilk. *See* Pet'rs' Ex. 4 at 16-17 (record from Dr. Turk describing what [M.L.]'s "parents report" and noting that he did "not have medical records available").

Ex. A at 2.<sup>17</sup> Petitioners maintain that this is an admission that celiac disease is triggered by viral infections, and was ignored by the Special Master. Pet'rs' Mot. at 5. They contend that it supports the testimony of Dr. Frick that the DTaP vaccine can insult the body like a viral infection, and note that the Special Master acknowledged that some illnesses may be caused by both viral infections and vaccinations. *Id.* at 6, 8-9; Tr. at 9-10, 47; *see also Langland ex rel. M.L.*, 2011 WL 386985, at \*11, 19. They argue that the Special Master erred in not recognizing this admission, and fault him for not explaining why. Pet'rs' Mot. at 9, 16.

The Court rejects this aspect of petitioners' objection, for several reasons. As an initial matter, the Court doubts that a single sentence in an informational pamphlet attached to an expert report can be considered a party admission, particularly when the expert provides testimony to the contrary, *see* Sp. Mstr. Tr. at 51 --- petitioners have failed to identify any case law supporting such a claim. The Special Master certainly considered petitioners' argument concerning the sentence in this pamphlet. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*20. While he may not have explained why he did not agree with petitioners as to the significance of the sentence, under the circumstances this is understandable. The sentence itself has nothing to do with vaccines, which are conspicuously absent from the list it contains. Nor does it actually state that the matters listed cause the onset of celiac disease --- at most, it says the disease is "triggered . . . after" the things listed, not by them. Attach. to Resp't's Ex. A at 2. This leaves open the possibility of other, independent causes for any triggering. The sentence reflects nothing more than a temporal association, and is not supported or substantiated in the pamphlet --- no studies or case reports are cited. Thus, even if it did represent the belief that viral infections can trigger celiac disease, it does nothing to provide a biologic mechanism by which vaccinations may do the same --- the absence of which was the overarching reason for the Special Master's decision. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*23-24.

### **C. The Special Master Did Not Err in Concluding that Petitioners Failed to Present a Plausible Theory Showing Biologic Causation**

Petitioners' second objection is best summed up in one sentence of their motion: "As petitioner[s] do[] not need to prove a scientifically certain theory, they also do not need to prove a scientific explanation of a mechanism of injury, as required by the [S]pecial [M]aster in this decision." Pet'rs' Mot. at 6-7. Because the Special Master found petitioners' expert's testimony on the mechanism by which a DTaP vaccination could trigger celiac disease to be confusing, and found petitioners' Exhibit 17 to have "a lot of unexplained loose ends," *Langland ex rel. M.L.*, 2011 WL 386985, at \*19, petitioners argue that the Special Master was impermissibly requiring scientific certainty. Pet'rs' Mot. at 7.

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<sup>17</sup> The pamphlet, entitled "Celiac Disease," was issued by the National Digestive Diseases Information Clearinghouse (NDDIC), and, as of September 5, 2007, was apparently found at <http://digestive.niddk.nih.gov/ddiseases/pubs/celiac/index.htm>.

To be sure, to establish causation, the standard of proof is preponderance of evidence, not scientific certainty. *Bunting v. Sec’y of Dep’t of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991). “A persuasive medical theory is demonstrated by ‘proof of a logical sequence of cause and effect,’” supported by “‘evidence in the form of scientific studies or expert medical testimony.’” *Althen*, 418 F.3d at 1278 (citation omitted). When a petitioner has an epidemiological study, showing a statistically-significant correlation between a given vaccine and a particular injury, a detailed theory of how the vaccine could cause the injury is not needed. *See Knudsen*, 35 F.3d at 549 (explaining that causation may be “based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms”). But in the matter before us, the petitioners have no such epidemiological evidence, and thus they need to present a “reputable medical or scientific explanation” of their theory of causation. *Grant*, 956 F.2d at 1148. This may require an explanation of the steps by which the vaccination was believed to result in the harm, so that what was actually observed by treating physicians may be compared to the posited process and the appropriateness of the time frame involved could be determined. Such a requirement does not raise the standard of proof, but rather makes sure that there is one. In the absence of epidemiological evidence suggesting causation, the Special Master did not commit a legal error by requiring a sufficiently-detailed explanation of how a DTaP vaccination could trigger celiac disease.

The Special Master has the responsibility of “[w]eighing the persuasiveness of particular evidence . . . to assess the reliability of testimony, including expert testimony.” *Moberly*, 592 F.3d at 1325. In this case, the Special Master was “confused by Dr. Frick’s lack of explanation of mechanism” by which a DTaP vaccination could trigger celiac disease. *Langland ex rel. M.L.*, 2011 WL 386985, at \*10. When asked by the Special Master to explain the triggering mechanism, Dr. Frick replied, “I don’t think anybody really knows that.” Sp. Mstr. Tr. at 29. In response to the Special Master’s query about medical literature that supports his theory, Dr. Frick said he “did an extensive literature search” and “wasn’t able to come up with a specific reference that the DTaP caused the [c]eliac disease.” *Id.* at 30. The Special Master concluded that Doctor Frick’s “vague explanation” could not meet petitioners’ burden of proof under *Althen*. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*11, 23-24.

Petitioners object to the Special Master’s determination that Dr. Frick’s theory of causation was “not detailed enough to be considered a plausible theory demonstrating biologic causation.” *See Langland ex rel. M.L.*, 2011 WL 386985, at \*23. According to Dr. Frick’s theory, [M.L.] had a genetic predisposition to develop celiac disease because of her family history and low IgA immunoglobulin levels. Pet’rs’ Mot. at 6 (citing *Langland ex rel. M.L.*, 2011 WL 386985, at \*7). With such a genetic predisposition, in Dr. Frick’s view, an insult to the immune system such as an infection or vaccination would likely trigger an autoimmune response to cause celiac disease. *Id.*; Pet’rs’ Ex. 11 at 2. But a review of the record shows that the closest petitioners’ expert came to explaining *how* a vaccination could trigger this response was his discussion of the ability of the enzyme tTG to convert gluten to a substance that would be captured by HLA-DQ2 or HLA-DQ8, which “is the thing then that triggers the [c]eliac disease.” *See Sp. Mstr. Tr.* at 35; *Langland ex rel. M.L.*, 2011 WL 386985, at \*11. Doctor Frick stated 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.” Sp. Mstr. Tr. at 35; *Langland ex rel. M.L.*, 2011 WL 386985, at \*11. But petitioners’ expert failed to explain how the reaction could be triggered by a vaccination, or even why he thought so. He did not reference the article attached to his report which described the process involving tTG, *see* Pet’rs’ Ex. 11 at 29-30 (Schuppan at 57-58), nor was that article among the seven identified in petitioners’ Post-Hearing Brief. *See* Post-Hr’g Br. at 3.<sup>18</sup>

The Special Master carefully considered the testimony of Dr. Frick, *see Langland ex rel. M.L.*, 2011 WL 386985, at \*6-13, 22-25, as well as the medical literature petitioners’ expert discussed. *See id.* at \*9-11. And he considered (and quoted from) at great length petitioners’ Exhibit 17. *See id.* at \*17-19. The Special Master did not have the benefit of Dr. Frick’s interpretation of this article and its relevance, as it was submitted after the hearing. *See* Notice of Filing (May 8, 2009). Petitioners themselves merely explained that the article “indicates that both environmental and genetic factors have been implicated in the contraction of celiac disease,” and quote from the abstract that “viral infections and/or tissue damage in the intestine may cause inflammation and induce protective Th1-mediated immunity leading to loss of tolerance for gluten,” after which “a broad gluten-reactive T cell repertoire may develop through determinant spreading” that “may be a critical step toward full-blown [celiac] disease.” *Id.* (quoting Stepniak at 460); Post-Hr’g Br. at 3 (same). The interpretation of the article, thus, was left in the hands of the Special Master --- which is entirely proper, as special masters are themselves experts who can make their own assessments and provide their own interpretations of medical literature. *See Moberly v. Sec’y of HHS*, 85 Fed. Cl. 571, 597-98 (2009), *aff’d*, 592 F.3d 1315 (Fed. Cir. 2010).

The Special Master found Exhibit 17 to be “interesting and helpful, but certainly not dispositive.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*17. The authors speculate that a viral infection, such as rotavirus gastroenteritis and other enteroviruses that frequently cause diarrhea in children, could shift immune responses from oral tolerance of gluten to support inflammation. Stepniak at 463; *see Langland ex rel. M.L.*, 2011 WL 386985, at \*18. They ultimately state that it is “possible” that “unrelated events” --- that is, non-genetic reasons --- could be responsible for the “loss of tolerance” of gluten in celiac disease patients. Stepniak at 465; *Langland ex rel. M.L.*, 2011 WL 386985, at \*19. The authors raise the question: “Are viral infections the incriminated environmental factors directly triggering the onset?” Stepniak at 466; *Langland ex rel. M.L.*, 2011 WL 386985, at \*19. They note that the question cannot at this time be addressed using “an animal model,” and explain that they “will therefore continue to work with patients.” Stepniak at 465; *Langland ex rel. M.L.*, 2011 WL 386985, at \*19.

Carefully considering Exhibit 17, the Special Master ultimately dismissed the authors’ speculation about viral infection as the trigger for celiac disease as “hypothetical,” with many

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<sup>18</sup> Perhaps the article was not cited because it seems to indicate that the process involving tTG is not the manner in which celiac disease starts in pediatric patients. *See* n.8, *supra*.

“unexplained loose ends in their hypothesis regarding the biologic process involved.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*19. Petitioners argue that the Special Master should have accepted the Stepniak article as a scientific explanation of the mechanism of causation. Pet’rs’ Mot. at 7. Despite conceding that the article was speculative, *see* Tr. at 47, petitioners contend that the Special Master should have identified the connection between vaccine-triggered and virus-triggered autoimmune disorders. Pet’rs’ Mot. at 8; *see Langland ex rel. M.L.*, 2011 WL 386985, at \*19. As the Special Master noted, Exhibit 17 never mentions vaccinations as potential triggers of celiac disease. *Langland ex rel. M.L.*, 2011 WL 386985, at \*19. And even if certain viral infections and certain vaccinations may cause the same injuries, a theory that attempts to bootstrap onto speculation that infections or tissue damage *in the small intestine* can cause a particular injury should, at the least, explain how the vaccination causes damage in that same organ. No such explanation is found in the record, other than the general notion that a vaccination causes an immune system response.

The Special Master found that other medical literature proffered by petitioners was not applicable, “relat[ing] to some other vaccine, some other injury, or some other effect.” *Id.* at \*23. One study, for example, showed that children with celiac disease more frequently fail to respond to the hepatitis B vaccine. *See* Pet’rs’ Ex. 11 at 9 (S. D. Park, et al., *Failure to respond to hepatitis B vaccine in children with celiac disease*, 44 J. Pediatr. Gastroenterol. Nutr. 431-35 (2007)). “If anything,” the Special Master reasoned, the study supported “the proposition that [c]eliac disease is an independent, free-standing disease that affects the body’s response to vaccination, not the other way around.” *Langland ex rel. M.L.*, 2011 WL 386985, at \*24.

In reviewing the Special Master’s decision, the Court cannot “reweigh the factual evidence” or examine the credibility of the witnesses. *Munn*, 970 F.2d at 871. The Court can only ensure that the Special Master considered all relevant evidence, drew plausible inferences, and articulated a rational basis for his decision. *Hines*, 940 F.2d at 1527. To meet the preponderant evidence standard, petitioners provided Dr. Frick’s testimony and submitted medical literature. Doctor Frick, however, could not report any incidence of celiac disease following DTaP vaccination. *Langland ex rel. M.L.*, 2011 WL 386985, at \*23. Nor does any literature in the record so much as mention vaccinations as a possible trigger for celiac disease. With no epidemiological evidence upon which to base causation, the Special Master was “entitled to require some indicia of reliability to support the assertion of the expert witness.” *Moberly*, 592 F.3d at 1324. In asking for a scientific explanation of a mechanism of injury or for medical literature, the Special Master was acting within his purview as the fact-finder. The Special Master articulated his conclusions and the grounds for them, identifying the evidence underpinning them. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*19-25. His determination that petitioners did not meet their burden of proof was not arbitrary or capricious, and cannot be disturbed upon review.

Petitioners raise one subsidiary point under this objection --- that the Special Master misinterpreted Dr. Frick’s testimony concerning the onset of [M.L.]’s celiac disease, and should have found an appropriate temporal relationship established. Pet’rs’ Mot. at 9-10, 15-16. But to

satisfy the “proximate temporal relationship” prong of the *Althen* test, petitioners must demonstrate, by a preponderance of the evidence, that the onset of symptoms occurred within a time frame for which it is medically acceptable to infer causation-in-fact. *de Bazan v. Sec’y of HHS*, 539 F.3d 1347, 1352 (2008). With no reputable theory as to how the vaccination could cause the injury, this exercise is not possible. Moreover, the Special Master explained the confusing aspects of Dr. Frick’s testimony concerning onset --- as petitioners’ expert did testify that [M.L.]’s diarrhea and vomiting, both symptoms of celiac disease, began the day of her vaccination and were “all part and parcel” of the disease. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*12-13, 22, 25; Sp. Mstr. Tr. at 42-44. Reviewing the transcript below, the Court concludes it was certainly reasonable for the Special Master to find the testimony contradictory and confusing. *See Munn*, 970 F.2d at 871.

#### **D. The Special Master Did Not Require Medical Literature to Support Causation**

In their final objection to the Special Master’s decision, petitioners contend that the Special Master required medical literature as proof of causation, contravening the holding of *Althen*, 418 F.3d at 1280-82. *See Pet’rs’ Mot.* at 11. But in the decision below, he did nothing of the sort. Petitioners base this objection on a statement in the decision which followed the quotation of Dr. Frick’s surmise that a “thing that insults the body, such as a vaccination or possibly a viral infection” could result in tissue transglutaminase changing gluten into a substance which provokes an immune system reaction. *See Langland ex rel. M.L.*, 2011 WL 386985, at \*11; *Pet’rs’ Mot.* at 11. The Special Master considered petitioners’ expert’s attempts at describing the biologic process by which a DTaP vaccination could trigger celiac disease to be a “meager and hardly explained ratiocination,” which “was not really supported by any medical literature relied upon in the formulation and composition of Dr. Frick’s report,” but instead related to Exhibit 17, filed after the hearing --- which the Special Master would later discuss at length. *Langland ex rel. M.L.*, 2011 WL 386985, at \*11, 17-19. The point was not that petitioners’ expert did not back up his theory with medical literature, but rather that his theory was not found to be coherent and persuasive, and its shortcomings were not rectified by any other evidence submitted, including medical literature. The Special Master’s decision did not violate *Althen*.

### **III. CONCLUSION**

After reviewing the submissions and arguments of the parties, the evidence in the record, the transcript of the hearing below, and the decision of the Special Master, for the foregoing reasons the Court concludes that the Special Master did not err when he denied compensation to petitioners under the Vaccine Act. The Special Master applied the correct legal standard and was not arbitrary or capricious in his decision.

Accordingly, the petitioners’ motion for review is **DENIED** and the decision of the Special Master is **SUSTAINED**. The Clerk of Court is directed to enter judgment for respondent.

**IT IS SO ORDERED.**

s/ Victor J. Wolski

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**VICTOR J. WOLSKI**

Judge