In The United States Court of Federal Claims

No: 01-0165 V

(Filed Under Seal: January 25, 2005)

(Reissued: February 9, 2005)[1]

LISA ANN PAFFORD and RICHARD LEON PAFFORD PARENTS AND NEXT FRIENDS of RICHELLE LORRAE PAFFORD,

***Petitioners*,**

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

***Respondent*.**

Vaccine Act; Causation-in-Fact; Standard of Proof; Burden of Proof; Alternative Causation; Temporal Relationship; But-For and Substantial Factor Analysis; Biologic Plausibility; Direct Causation; Systemic Onset JRA; Still's Disease; Vaccine-Related Injuries

Robert T. Moxley, Cheyenne, Wyoming, for petitioners.

Melonie J. McCall, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

Block, *Judge*.

I. Introduction

This case is before the court under the National Childhood Vaccine Injury Act[2] for review of the Special Master's decision to deny petitioners' claim for compensation. Young Richelle

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[1]This opinion originally was issued under seal on January 25, 2005. The court afforded the parties an opportunity to propose redactions in the opinion prior to its publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

[2]Public Health Services Act, § 2111(b)(1)(A) (codified as amended at 42 U.S.C. §§ 300aa -1 to -34).

Pafford was diagnosed with systemic onset Juvenile Rheumatoid Arthritis ("JRA"), also known as Still's disease. Richelle's condition is made all the more painful by the inability of modern medical science, especially given all of its recent spectacular advances, to understand the exact mechanism of the origin of JRA.

Under the guise of the great sleuth Sherlock Holmes, Sir Arthur Conan Doyle once posited that "when you have eliminated the impossible, whatever remains, however improbable, must be the truth."[3] Because of science's failure to here provide a concrete answer (a dispositive etiology for JRA is unknown), the fundamental issue in this case essentially involves the application of Holmes' maxim of deductive reasoning to the law—what Dr. Watson surely should have recognized as a specie of differential diagnosis—in an effort to determine the cause of Richelle's illness. Consequently, the dilemma petitioners face here is whether the quantum of proof they proffered ascertaining causation-in-fact rises to the level of legal sufficiency. Indeed, as discussed below, it is this very question of legal sufficiency of the proof of causation—which is at the very heart of this case—that has vexed both the Special Masters and the reviewing courts since the inception of the Act.

After a hearing held July 7-8, 2003, the Special Master concluded that petitioners did not meet their burden of demonstrating legal causation-in-fact under the Act. More particularly, the Special Master found that while petitioners had demonstrated that vaccine reactions hypothetically *could* trigger systemic onset JRA similar to Richelle's, petitioners failed to satisfy the burden of proof that Richelle's condition in this specific case was in fact triggered by a vaccine. *Pafford v. Sec'y of the Dep't of Health and Human Servs.*, No. 01-0165V (Sp. Mstr. Fed. Cl. July 16, 2004). The predicate for this determination was the failure of petitioners to produce any evidence (1) showing that Still's disease would manifest within a particular period of time following the triggering event or (2) discounting the causative role of other ailments that coincided with Richelle's vaccination. *Id.* On August 16, 2004, the petitioners filed a Motion for Review of the Special Master's decision in this court, seeking to overturn the denial of compensation, essentially arguing that the Special Master applied the wrong standard of legal causation-in-fact.

Upon review of the Special Master's opinion and the entire record, and for the reasons addressed more thoroughly below, the court concludes that the Special Master has satisfied the applicable legal standard in finding that the petitioners did not meet their statutory burden of proving Richelle's March 1998 vaccination was the cause-in-fact of Richelle's subsequent systemic onset JRA.

II. Background[4]

Richelle Pafford was born January 30, 1993. She received regular medical care from Dr. Jay Schmidt, and the Special Master noted "nothing remarkable" about Richelle's early development.

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[3]Arthur Conan Doyle, *The Sign of Four*, ch. 6 (1890) (original emphasis omitted).

[4]The court does not ordinarily make independent findings of fact in these cases, but rather reviews the findings of the Special Master. Accordingly, the factual background that follows is primarily taken from the Special Master's decision.

On August 5, 1993, when Richelle was just more than six months old, Dr. Schmidt administered her first DTP, OPV and Hib vaccinations.[5] The second series of these vaccinations followed eleven weeks later, on October 21, 1993. Nearly seven months later, on May 10, 1994, Dr. Schmidt administered Richelle's third DTP, OPV and Hib vaccinations and her first MMR[6] vaccination. During an examination on the same day, Dr. Schmidt noted normal development. Seventeen days later, on May 27, 1994, Richelle developed a faint rash on her face, legs and arms that lasted five days. When she visited Dr. Schmidt on June 1, he noted that Richelle's tonsils were "inordinately enlarged [and] red;" a subsequent strep throat culture was negative. Pet.'s Ex. 3 at 44-45. Dr. Schmidt also noted that Richelle's mother had recently experienced a flu-like illness that was followed by a rash. *Id.* at 44.

During November and December 1997, when Richelle was almost four years old, she was treated for otitis, an inflammation of the ear marked by pain, fever, hearing difficulty and vertigo. Dr. Schmidt noted that she complained of a cold lasting two months. Pet.'s Ex. 3 at 20. Three months later, on March 5, 1998 Richelle visited Dr. Schmidt with complaints of a cold and diarrhea that had lasted about three days. One week later, on March 12, Richelle returned to Dr. Schmidt with inflamed tonsils bearing white patches. She also ran a fever of 101-102 degrees Fahrenheit. Dr. Schmidt diagnosed Richelle with tonsillitis and conducted another throat culture that was negative for strep throat. Pet.'s Ex. 3 at 13-15. On March 24, Richelle returned for a follow-up visit, during which Dr. Schmidt noted that her tonsils were no longer inflamed and had regressed in size from the recent exam. *Id.* at 11. Richelle was noted to be "doing well" and was "suffering no symptoms of illness;" she was an active child with healthy physical and mental development. *Id.* During this March 24 visit, Richelle received a DTaP vaccination, her fourth OPV vaccination, and her second MMR vaccination. It is this series of vaccinations (the March 1998 vaccinations) that petitioners have placed at issue in this case.

Eleven days later, on April 4, 1998, Richelle complained of fever and neck pain. Her fever abated the next day, but her neck pain persisted. She developed a diffuse pink, macular rash and whitish spots on her tongue that may have been Koplik's spots[7] and also complained of limb pain. On April 7 Richelle returned to Dr. Schmidt for evaluation. She was then diagnosed with a vaccine-induced rash and instructed to avoid contact with others for five days.

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[5]The DTP vaccine protects against diptheria, pertussis (whooping cough), and tetanus; the DTaP vaccine, which Richelle received later, is the same as the DTP but contains an acellular pertussis vaccine and is recommended for children at 18 months and 4-6 years. The OPV is an oral polio vaccine, and the Hib immunization helps prevent diseases caused by Haemophilus influenzae type B, including meningitis. *See http://www.medterms.com*.

[6]The MMR immunization is the standard vaccine given to prevent measles, mumps and rubella (German measles). *Id.*

[7]Koplik's Spots are "small, irregular, bright red spots on the buccal and lingual mucosa, with a minute blueish white speck in the center of each; seen in the prodromal stage of Measles." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 971 (27th ed. 1988). Koplik's Spots are often, if not always, a definitive symptom of Measles.

Six days later, on April 13, Richelle was treated at the emergency room in United Medical Center, Cheyenne, Wyoming; she had a 103.9 degree fever and a blanching red maculopapular rash on the palms and soles of her hands, upper legs, chest and upper abdominal area. She was vomiting upon arrival and refused intake of fluids. The consulting physician, Dr. Valorie Bell, noted that Richelle was tearful and crying, and Dr. Bell "could not localize any tenderness specifically because she cried everywhere she was touched." Pet.'s Ex. 5 at 16. Dr. Bell also noted that "[t]he rash was very viral in character and I did not feel it was related to her immunizations but suggested a [complete blood count] to see if it supported the viral picture." *Id.* By the time that Richelle was admitted to the hospital floor from the emergency room, her fever had abated to 97.2 degrees and the rash "had greatly diminished by that time." *Id.* at 8. She was by then "playful and happy." *Id.* at 16. Dr. Schmidt noted that the "fever and rash abated quite remarkably and rapidly" and he sensed that the rash was related to the fever. *Id.* at 8-9. At this time, Richelle also tested positive for a mycoplasma infection, and Dr. Bell thought that this was responsible for the April 13 symptoms. *See* Pet.'s Ex. 4 at 79. Upon discharge, Richelle was afebrile and "her rash, for the most part, had disappeared." Pet.'s Ex. 5 at 9.

After she had gone home, Richelle experienced recurring fever and rash over the next two weeks and increasingly complained of joint pain. On April 30, 1998 she returned to Dr. Bell, who noted that Richelle had a 102.9 degree fever, a painful, swollen right elbow and left knee, and a recurrence of the earlier rash. While Dr. Bell had previously thought that Richelle's rash, joint pain and fever "were all due to mycoplasma," by this point it "seem[ed] the illness has extended longer than would be expected with mycoplasma." Pet.'s Ex. 4 at 79. Although Dr. Bell noted that the joint discomfort associated with mycoplasma can last for weeks, the rash and fever do not usually relapse to the extent that Richelle experienced. *Id.* at 80. Instead, Dr. Bell "strongly suspect[ed] systemic onset JRA as the cause of the month long recurrent rash, fever and discomfort." *Id.* Richelle's lab results revealed an elevated sedimentation rate of 80, mild anemia, and negative ANA and rheumatoid factor tests.

Richelle subsequently embarked on a medication regime to treat her JRA. Dr. Bell's diagnosis was later corroborated by Dr. Hollister, a pediatric rheumatologist at Children's Hospital in Denver, Colorado. Despite treatment, Richelle's disease remained active with recurrent arthritis through at least the next two years.

In 2001 Richelle's parents filed a petition for compensation under the Vaccine Act. It was their theory that Richelle's JRA was caused by her adverse reactions to the vaccines that she received in March 1998. The Special Master who reviewed Richelle's case conducted a two-day hearing with both parties' experts, and filed a decision denying compensation to the Paffords on July 16, 2004. *Pafford*, No. 01-0165V (Sp. Mstr. Fed. Cl. July 16, 2004).

III. The Vaccine Act

The Vaccine Act provides a program by which individuals who claim to have been injured by certain vaccines may be compensated for their injury. The program was created in large part to preempt tort litigation against vaccine manufacturers and provide compensation to injured individuals without requiring the rigorous burdens of proof associated with products liability litigation, including causation, negligence, and product defectiveness. *See generally Stevens v. Sec'y*

of the Dep't of Health and Human Servs., No. 99-594V, 2001 WL 387418 at *6 (Sp. Mstr. Fed. Cl. Mar. 30, 2001). Instead, a petitioner under the Act may circumvent proof of causation by relying on the "Vaccine Injury Table." *See* 42 U.S.C. § 300aa-14(a). If the petitioner's injury is "on-Table" then the Act establishes a presumption that the vaccine caused the injury if the petitioner demonstrates that the onset or "significant aggravation" of predicate injuries occurred within a statutorily prescribed time period. *See* § 300aa-11(c)(1)(C)(I); *Bunting v. Sec'y of the Dep't of Health and Human Servs.*, 931 F.2d 867, 872 (Fed. Cir. 1991). If the petitioner establishes the presence of an on-Table injury, then the Act authorizes compensation so long as the presumption is not rebutted by "a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B); *see also Grant v. Sec'y of the Dep't of Health and Human Servs.*, 956 F.2d 1144, 1146-47 (Fed. Cir. 1992).

On the other hand, if the claimed injury is not an on-Table injury—as is the case here with Richelle's systemic onset JRA—then the petitioners may still seek compensation provided they are able to prove causation-in-fact. § 300aa-11(c)(1)(C)(ii); *Grant*, 956 F.2d at 1147. A petitioner's path to compensation for an "off-Table" injury is considerably more tortuous because the petitioner does not benefit from the presumption of causation that attaches to an on-Table case. Instead, the petitioner must demonstrate by a preponderance of the evidence that the vaccination in question, more likely than not, was in fact the cause of the alleged injury. *Grant*, 956 F.2d at 1147-48. Unlike an on-Table case, proof of causation in an off-Table case must comprise more than just a literal temporal association between the onset of the injury and the vaccination. "When a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Id.* at 1148. As part of the burden of proof, a petitioner must present "a medical theory causally connecting the vaccination and the injury." *Id.* (citing *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983)). Furthermore, this causal connection must be supported by "reputable medical or scientific explanation." *Id.*; 42 U.S.C. § 300aa-13(a)(1). Finally, according to Federal Circuit precedent, the petitioner bears the burden of proving that "the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of the Dep't of Health and Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999). Ultimately, as discussed at length below, it is this "but-for" standard where petitioners here fall short.

IV. The Special Master's Decision

As an initial matter, the Special Master endeavored to clarify just what systemic onset JRA, or Still's disease, is. *See Pafford*, No. 01-0165V at 5-6 (Sp. Mst. Fed. Cl. July 16, 2004). A type of juvenile rheumatoid arthritis, it typically begins with symptoms of a systemic (body wide) illness including high fever "spikes," gland swelling and internal organ involvement that all coincide with joint inflammation. "Extreme fatigue can accompany waves of high fevers that rise daily . . . and rapidly return to normal levels. . . . A faint salmon-colored skin rash characteristically comes and goes and does not itch. Arthritis, with joint swelling, often occurs after rash and fevers have been present for some time." *Id.* at 6. In children, Still's disease inflames large joints and may retard bone growth. As to the culprit that causes Still's disease, "[a] dispositive etiology is unknown, but like many other types of arthritis, abnormal immune response, genetic predisposition and environmental triggers, and infectious agents are all being considered." *Id.*

The Special Master then proceeded to evaluate petitioners' causation-in-fact claim. Citing *Grant*, the court organized the legal criteria of the causation-in-fact analysis into two overriding considerations. "*First*, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. . . . *Second*, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case." *Id.* at 7. The first prong of this evaluation was distilled to concentrate on the "biologic plausibility" of the petitioners' theory "by proffering a scientific pathogenesis underlying the alleged causal relationship." *Id.* Generally, the Special Master noted, biologic plausibility is established through epidemiological studies, peer-reviewed published articles in medical journals, and acceptance of theories in at least a subset of the medical community. If biologic plausibility is established, then the second prong of the Special Master's causation-in-fact analysis turns to whether the petitioner has proved whether her case is consistent with the mechanism or model presented, *i.e.* whether the petitioner has explained "*how* and *why* the injury occurred" in that particular instance. *Id.* at 8. Furthermore—and this was key to the Special Master's decision—"[r]uling out other potential causes is an essential element [of the plausibility causation-in-fact analysis] but does not itself establish causation." *Id.* In other words, the Special Master determined that elimination of alternative causes of Richelle's Still's disease (other than the vaccines) was a necessary, but not sufficient, element of the petitioners' case.

Ultimately, this two-pronged approach was tailored as "(I) Is it biologically plausible that one or more of the vaccinations in question can cause Still's disease?; and, (ii) Did one or more of [Richelle's] vaccinations result in her Still's disease?" *Id.* As to the initial prong, the court concluded that petitioners had proven by a preponderance of the evidence that it is indeed biologically plausible for one or more of the vaccinations at issue to cause the onset of Still's disease. *Id.* at 9. Generally, both parties' experts agreed that certain individuals have a genetic predisposition to Still's disease. One of the hallmarks of the disease, according to these experts, is an increase in the expression of pro-inflammatory cytokines,[8] which fuel the symptoms of Still's disease. Respondent's expert, Dr. Berger, noted that it is the excessive and prolonged cytokine production that results in the manifestation of the disease. *Id.* Indeed, one of the highly successful treatments for Still's disease involves reducing the level of certain cytokines in the body. However, unfortunately for those with a genetic predisposition to the disease, and as agreed by the experts in this case, vaccines induce cytokine production. *Id.* "Cytokines are produced by the host after receiving the vaccination. If vaccines could not induce cytokines, they could not induce immunity for you to protect against the infectious agent." *Id.* (quoting respondent's expert, Dr. Rosé). Ostensibly, the body's natural expression of cytokines following a vaccination is misregulated in individuals predisposed to Still's disease, and the over-expression of those cytokines results in the manifestation of the actual condition.

Having concluded that petitioners carried their burden for the first prong, the Special Master then evaluated their effort to prove that Richelle's systemic onset JRA was in fact an autoimmune response triggered by the over-production of cytokines specifically induced by her March 1998 vaccinations, consistent with petitioners' proffered mechanism. The court concluded that there was ample evidence of a literal temporal relationship between the vaccinations and Richelle's subsequent

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[8] "A genetic term for non-antibody proteins released by one cell population on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." DORLAND'S at 427-28.

symptomatic expression of Still's disease. She seemed to demonstrate "typical post-vaccinal side effects" from the MMR vaccine in early April, eleven days after the vaccination. *Id.* at 11-12. Through the first week in April 1998, her symptoms appeared to be ordinary side effects of the vaccine, including fever, neck pain, rash and fatigue.[9] According to the Special Master, "[t]he onset of [Richelle's] Still's disease is apparent some time during the second week of April 2004," or about three weeks after the vaccination. *Id.* at 12. It was by that point that she demonstrated the spiking fever accompanied by a transient and recurring rash. Furthermore, during the final weeks of April, Richelle complained of joint pain. These symptoms were consistent more with Still's disease than a reaction to the vaccines (or the mycoplasma, as Dr. Bell had earlier suspected), and the doctors concluded by late April, just one month after the vaccination, that Richelle was indeed suffering from Still's disease.

The petitioners argued that the onset of Still's disease within just a few weeks of the March 1998 vaccinations was strong evidence suggesting a causal connection between the two. The Special Master, however, refused to place such great weight on this mere literal temporal relationship, noting that such "is not itself sufficient for Petitioners to meet this Court's burden of proof by a preponderance of the evidence." *Id.* at 13. Since the petitioners in this case seemed to rely solely on the temporal relationship between alleged cause and ultimate effect, the Special Master noted that the one instance in which such temporal evidence is "telling" in a causation-in-fact case is where the manifestation of the claimed injury "falls within an established time period subsequent to an antecedent or triggering event." *Id.* However, petitioners failed to demonstrate that Still's disease necessarily, or at least routinely, manifests symptoms within any certain timeframe following a given triggering event. *Id.* Therefore, the literal temporal relationship alone was not dispositive: "The link missing from Petitioners' argument that gave this Court pause was the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event. Without such a defined time period, the link between the vaccinations and the injury is tenuous." *Id.* at 15

Additionally, the Special Master noted that "[a]ll experts agree that a number of things can trigger Still's disease." *Id.* at 14. In Richelle's case, along with the March 1998 vaccinations there was evidence of concurrent events, including an ear infection, tonsillitis and the high mycoplasma count, that might have potentially triggered the manifestation of Still's disease instead of the vaccinations.[10] Although respondent did not point to any one of these potential alternative causes

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[9]"As with other vaccines, MMR can cause a local reaction with pain and induration at the injection site. Because it is a live virus vaccine, mild illness with symptoms similar to measles, mumps or rubella may occur. About 7-12 days after vaccination, five percent of children develop a fever with temperature greater than 103 degrees, which lasts 1-2 days. A transient rash may occur 7-10 days post vaccination in 5 percent of children (due to the measles and rubella components). Transient lymphadenopathy (rubella component) and rare parotitis (mumps component) have also been described." *Pafford*, No. 01-0165V at 11-12 n. 37 (quoting http://www.corexcel.com/courses/body.immunizations.page9.htm) (citations omitted).

[10]*See* Hearing Transcript, filed Aug. 8, 2003, at 171 ("[A]utoimmune disease . . . [is] an immune mediated inflammatory disorder. It's a disregulation of certain proinflammatory cells and . . . these cells tend to be triggered by something. . . . [T]hey could be triggered by . . . toxic chemicals, viral

as a specific triggering event, respondent's experts tended to suggest that either an infection or tonsillitis could trigger an autoimmune response that resulted in Richelle's Still's disease, consistent with petitioner's proffered mechanism. *Id.* Ultimately, the Special Master concluded that although it was not clear at all that one of these potential alternatives in fact caused Richelle's Still's disease, "the point is that the vaccinations at issue were not the only contemporaneous events." Implicitly, then, the Special Master seemed to weigh against petitioners the fact that they had not discounted the role of viable alternative causes in Richelle's case. Ultimately, the Special Master's concerns about (a) the absence of evidence of a defined temporal relationship between a triggering event and the manifestation of Still's disease symptoms and (b) the petitioners' failure to discount possible alternative causes of Richelle's condition led him to conclude that petitioners were not entitled to compensation.

Petitioners then filed in this court a motion for review of the Special Master's decision, generally raising two lines of arguments focusing on the "critical time" element and the alternative causation theory that were the lynchpins of the decision. First, they argue that the Special Master's opinion was legally flawed because he misinterpreted the appropriate standard of proof that applies when a petitioner introduces evidence of a temporal relationship between alleged cause and effect in a causation-in-fact case. They argue that in this case there was ample evidence that indicates a definite time period in which the medical community would expect a patient to demonstrate symptoms of a reaction to a vaccine, and that Richelle's vaccine reactions did in fact occur within those periods. Accordingly, the Special Master's failure to consider this evidence, petitioners argue, was arbitrary and capricious. Furthermore, they claim that the Special Master abused his discretion by raising the issue of "critical time" *sua sponte* after the hearing when neither party had raised any question with regard to the timing of Richelle's Still's disease. Second, petitioners claim that it was legal error for the Special Master to attribute the burden of proof as to potential alternative causes of Richelle's condition to them and not respondent.

V. Discussion

At its heart, then, petitioners' contentions in this court focus squarely on the appropriate standard of proof to which a petitioner should be held in an off-Table Vaccine Program causation-in-fact case. It raises issues regarding both a petitioner's burden of production, *i.e.* the types of evidence the petitioner must demonstrate to establish a *prima facie* entitlement to compensation, as well as the burden of persuasion, *i.e.* the degree to which the petitioner must persuade the fact-finder.

A. Jurisdiction And Standard Of Review

Pursuant to 42 U.S.C. § 300aa-12(e), this court may review the Special Master's decision

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infections, vaccines . . . you name it.") (Testimony of Dr. Levin), 174-75, 212 (Q: "You would agree, Doctor, that mycoplasma infections have been known to cause other autoimmune diseases, correct?" A: "Yes") (Testimony of Dr. Levin), 363-65, 436, 460-65 (Q: "You mentioned in your expert report that cytokines can be produced by smoke inhalation, cancer, things like that. You can't identify any of those factors in Richelle Pafford's case, can you?" A: "Well, what about the eight to twelve infections a year? The tonsillitis that she got in March? Is it not there? How about the sinus infection; how [about] the IGM form with mycoplasma?").

upon motion by the parties. The court, in turn, may (a) uphold the findings of fact and conclusions of law of the Special Master and sustain the decision, (b) set aside any finding of fact or conclusion of law that is arbitrary, capricious, or an abuse of discretion, or (c) remand the petition to the Special Master for further action. *See* § 300aa-12(e)(2). These standards, however, vary in application as well as in degree of deference. Under the Act, this court reviews findings of fact according to the "arbitrary and capricious standard," focusing on whether the Special Master examined the relevant data and articulated a "satisfactory explanation for [his] action including a rational connection between the facts found and the choice made." *Dixon v. Sec'y of the Dep't of Health and Human Servs.*, 61 Fed. Cl. 1, 8 (2004) (quoting *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The arbitrary and capricious standard of review accorded to the Special Master's decision by statute is highly deferential. "If 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 v. Secretary of Sec'y of the Dep't of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Legal questions, on the other hand, are reviewed under the less deferential "not in accordance with law" standard. Discretionary rulings are reviewed for an abuse of discretion. *Saunders v. Sec'y of the Dep't of Health and Human Servs.*, 25 F.3d 1031, 1034 (Fed. Cir. 1994).

B. The Standard Of Proof In Causation-In-Fact Cases

"There is a dearth of precedent discussing the requirements for *prima facie* causation." *Shyface*, 165 F.3d at 1350. It has been noted that petitioners in off-Table Vaccine cases tend to rely on similar types of evidence in proving their claims. *See generally Stevens*,[11] 2001 WL 387418 at *12 ("For the most part, petitioners submit the same type of evidence in almost every vaccine claim."). Traditionally, it appears to this court that petitioners often, if not always, choose one of two paths in their journey to establish causation-in-fact in off-Table cases. For convenience, these two paths may be thought of as the *direct causation* argument and the *plausibility* argument. The type of case that a petitioner should mount is entirely dependant upon the type of evidence able to be produced.

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[11]The *Stevens* decision has come under some scrutiny by this court, *see Althen v. Sec'y of the Dep't of Health and Human Servs.*, 58 Fed. Cl. 270 (2003), for the five-step analytic framework that the Chief Special Master promulgated. In *Stevens* the Chief Special Master indicated that a petitioner satisfies the *prima facie* burden of demonstrating causation-in-fact by a preponderance of the evidence if he demonstrates proof of each of the following: (1) medical plausibility; (2) confirmation of medical plausibility from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes. *See Stephens*, 2001 WL 387418 at *23-26.

Despite *Althen*'s treatment of *Stevens*, this court notes that *Stevens* does take considerable care to explain the Vaccine Act and the manner by which petitioners routinely try to establish causation-in-fact. *See id*. at *9-23. The court finds *Stevens*' thorough review and discussion of the state of Vaccine Program causation-in-fact jurisprudence extremely useful as an analytic tool and a starting point for analysis.

1. Direct Causation

If and when a petitioner has scientific or medical evidence that demonstrates a direct causal relationship between the vaccine and the injury, then proof of causation-in-fact via *direct causation* is the preferred path. "[S]pecial masters initially look for direct evidence linking the vaccine to the alleged injury." *Id.* Evidence of direct causation may be found in the form of "an epidemiologic study demonstrating a relative risk greater than two . . . or dispositive clinical or pahtological markers evidencing a direct causal relationship."[12] *Id.* Although the minimum *legal* burden of persuasion required in causation-in-fact cases is only a preponderance of the evidence and "not scientific certainty," *see Bunting*, 931 F.2d at 873, direct evidence tends to move the physician and fact-finder towards the "scientifically certain" end of the spectrum of proof, which far exceeds a mere preponderance legal standard. Logically, the presence of direct evidence establishing a causal link between vaccine and injury obviates the need for an analysis of biologic plausibility because direct proof that the vaccine *did* in fact cause the injury necessarily means that it *could* have done so. Similarly, given the strong causal relationship established by evidence of direct causation, petitioners do not need to also rely on circumstantial factors that are often implicated in a *plausibility* argument, discussed below. For example, the need to prove a medically accepted time frame for the onset of injuries or to discount the presence of alternative causes present in the record—which were both implicated in the Special Master's opinion here—is subsumed by the highly probative direct evidence.

Unfortunately for most petitioners, epidemiologic studies, dispositive clinical markers or pathological "footprints" are not often available. Epidemiologic studies may be unavailable because "relevant research regarding causation is often extremely limited. A number of factors restrict the medical community's efforts to conduct such studies including the costliness of the research and the rarity of the illnesses studied." *Id.* at *14. Clinical markers may be absent because certain tests were not conducted at the time of sickness or because science has not yet identified acceptable markers. *Id.* Indeed, in this case petitioners could not present direct evidence supporting the theory of one of its experts because at the time "nobody looked" for the markers that might have supported that theory, *i.e.*, potentially supportive tests were not conducted.[13] Similarly, petitioners were unable to produce evidence that Richelle had higher levels of cytokine expression because, at the time of onset, the medical field had yet to develop testing sophisticated enough to identify specific cytokines.[14] An

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[12]"[F]or example, the presence of anterior horn cells on autopsy as evidence of polio contracted from the oral polio vaccine or the presence of the rubella virus in synovial fluid taken from the joints as evidence of a rubella-related arthropathy." *Stevens*, 2001 WL 387418 at *12.

[13]Specifically, petitioner's expert Dr. Geier opined that the rubella virus contained in the MMR vaccine can produce chronic infection in synovial tissue resulting in the onset of JRA. Dr. Geier stated that direct proof of that infection would be the presence of the rubella virus in the synovial fluid, but the rubella virus was not isolated in any of Richelle's synovial fluid because those tests were not conducted. *See* Pafford, No. 01-0165V at 2 n.2.

[14]The Special Master did note, however, that indirect tests revealing a high white blood cell count, which *were* conducted by Richelle's doctors, correlate with a high cytokine count because white blood cells secrete cytokines. Therefore, a high white blood cell may indicate a corresponding

inability to generate direct evidence of causation forces a petitioner to instead try and prove causation-in-fact using circumstantial evidence as part of a plausibility argument.

2. Plausibility

"With few exceptions, the special masters encounter the absence of dispositive epidemiology or vaccine footprints in the vast majority of causation-in-fact cases under the [Vaccine] Program." *Id.* In those cases, the petitioner is forced to make his argument employing circumstantial evidence that helps meet the preponderance standard. Such circumstantial evidence may include:

> epidemiology (evidencing a relative risk less than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles, institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive but inferential clinical and laboratory findings.

Id. The speculative nature of proving causation-in-fact in Vaccine cases with circumstantial evidence requires the petitioner to do much more of the "heavy lifting" than in an on-Table case or even in an off-Table case where there is direct evidence. *See Lampe v. Sec'y of the Dep't of Health and Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Hodges v. Sec'y of the Dep't of Health and Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). First, as the Special Master here proceeded, the petitioner must establish that the vaccine could possibly cause the claimed condition. The need for this initial analysis of biologic plausibility is obvious: in evaluating whether the vaccine was more likely than not the cause of a condition, we must first know if it was even possible for the vaccine to have such an effect. If the petitioner's proffered mechanism is beyond the realm of plausibility, then any other circumstantial evidence that remains, no matter how persuasive, cannot overcome the petitioner's initial fallacy.

Once biologic plausibility has been established, as it was in this case, the petitioner must demonstrate some nexus between the mechanism and the actual condition that shows, more likely than not, that the vaccine caused the condition. *See*, *e.g.*, *Munn v. Sec'y of the Dep't of Health and Human Servs.*, 970 F.2d 863, 867 (Fed. Cir. 1992) (affirming Special Master's decision that petitioner "failed to establish a nexus" between the vaccine and injury). As *Stevens* illustrates, though, it is not clear just what suffices for this "nexus":

> [C]onflict also surrounds what *amount or combination* of evidence sufficiently demonstrates causation generally and in the particular case. Some cases consider the combination of a demonstrated mechanism or medical plausibility and a termporal relationship insufficient. . . . Others consider the combination of medical plausibility (an accepted or plausible medical theory) and the elimination of alternate causes satisfactory. Some cases suggest plausibility, a medically appropriate temporal relationship, and the elimination of alternate causes suffices to prove causation.

Id. at *20 (citations omitted).

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increase in cytokine expression.

With regard to the temporal relationship between vaccination and the onset of a subsequent condition, there is a distinction drawn between what some courts refer to as the "literal temporal relationship" and a more refined "scientific temporal relationship." The former refers merely to the period of time between the vaccination and the onset of symptoms; it is a mechanical approach. The latter, however, refers to a more analytic relationship in which the medical or scientific community recognizes a specific period of time following a vaccination within which a certain condition might materialize. *See Stevens*, 2001 WL 387418 at *2 n.6 ("The term 'temporal relationship' has two possible meanings as used in litigation under the Vaccine Act: (1) the literal meaning, in other words, that the injury occurred subsequent to and close in time to the administration of the vaccine, or (2) the scientific meaning, in other words, that there is an accepted time frame supported by scientific evidence within which the injury should manifest itself following vaccination."). The Federal Circuit has indicated in *Grant* that a literal temporal association between vaccine and condition, alone, is not sufficient to establish causation-in-fact. *See Grant*, 956 F.2d at 1148. Instead, the petitioner must also demonstrate "a medical theory causally connecting the vaccination and the injury" and a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.*

But these elements of causation-in-fact identified in *Grant* force a question that is key to the case at bar: if a petitioner demonstrates a plausible biologic mechanism and *also* shows a literal temporal relationship between the vaccination and the manifestation of a subsequent condition, has the petitioner satisfied his burdens? As petitioners contend, it would seem that such production would, at least facially, satisfy the limited requirements that *Grant* espouses.

To this court , however, the flaw in that argument is that the Federal Circuit has extended the analysis such that those minimum causation-in-fact elements enunciated in *Grant* may not be sufficient to establish a *prima facie* entitlement to compensation, depending on the unique circumstances of a given case. The Federal Circuit has instructed that an actual-causation vaccine petitioner "must prove by a preponderance of the evidence that the vaccine, *and not some other agent*, was the actual cause of the injury." *Munn*, 970 F.2d at 863 (emphasis added). This would seem to engender the need for a petitioner to eliminate other possible causes of the condition (other than the vaccine) that exist in the record.

This deductive reasoning analysis has its origin in traditional tort law. Drawing parallels between the Restatement (Second) of Torts substantial factor standard in negligence cases and the vaccine cases, the Federal Circuit has indicated that "an action is the 'legal cause' of harm if that action is [both] a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." *Shyface*, 165 F.3d at 1351-52 (citing Restatement (Second) of Torts §§ 431, 433) ("Some other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor."). It is the petitioner who bears the burden of proving that the vaccine was both the "but for" cause as well as a "substantial factor" of the harm. *Id.* "Implementing this principle in terms of the Vaccine Act statutory provisions, establishment of *prima facie* entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Id.* To be sure, if the record indicates the existence of other possibilities as a reasonable culprit for the cause of the

disease, it is very possible that the petitioner has not met either the "but for" or "substantial factor" requirement because those other possible culprits may well remain as viable alternatives that undercut the vaccine's causative role. In other words, as a practical matter, in such a circumstance, petitioners must eliminate other reasonably possible causes that exist in the record to meet its burden of establishing a *prima facie* case for causation-in-fact.

Shyface and *Munn*, accordingly, seem to require the court to evaluate the record as a whole, and take into account whatever considerations that record may reveal, in determining whether the vaccine is the but-for cause and substantial factor of the subsequent condition. Consequently, if the record in a Vaccine case contains incidents that might put at issue whether the vaccine is a substantial factor contributing to the condition, even in light of the petitioner's demonstrated biologic mechanism and the literal temporal proximity between vaccine and condition, the Special Master may need to delve beyond the *Grant* requirements to establish causation-in-fact.[15] In light of the *Shyface* analysis, those minimum *Grant* requirements may become necessary, but not sufficient, elements of the analysis due to the entirety of the record.

This court therefore concludes that a Special Master does not act contrary to the law and commit reversible error if he determines that a plausible biologic mechanism and a literal temporal relationship, alone, do not establish such a nexus between vaccination and condition that causation-in-fact must obtain. *See Shyface*, 165 F.3d at 1351-52. A Special Master is well within his realm to demand that a petitioner demonstrate a degree of acceptable scientific support that goes beyond mere plausibility and temporal proximity, based on the given circumstances of the case before him. *See Hodges*, 9 F.3d at 961-62 ("The fact that the opinion of petitioner's doctors was rejected does not mean that the Special Master was demanding scientific certainty; he might simply have been demanding some degree of acceptable scientific support when concluding that the [petitioner's] claim for causation in-fact was not supported by a preponderance of the evidence."). This additional scientific support might come in the form of a medically accepted time frame between the vaccination and the onset of the subsequent condition. Or, if the petitioner has succeeded in presenting only evidence of biologic plausibility and a literal temporal proximity, the Special Master may look to other facts apparent in the record, including potential alternative causes, that may undermine the petitioner's case and lead the Special Master to conclude that the petitioner has failed to establish causation-in-fact. That a vaccine *may* cause a specific response or condition is not proof that it did in a particular case.[16] *Id.* at 961-62 & n. 4.

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[15]*See Wagner v. Sec'y of the Dep't of Health and Human Servs.*, No. 90-2208V, 1997 WL 617035, *10 (Fed. Cl. Spec. Mstr. Sept. 22, 1997). In a decision on remand, explaining his prior decision that had been reversed by the Court of Federal Claims, the Special Master noted in *dicta*: "[M]y view has been that for a petitioner to make the necessary 'actual causation' showing, there must be a preponderance of *all the evidence in the record* indicating that the injury was vaccine-caused." *Id.*

[16]This is not to say that biologic plausibility combined with literal temporal proximity will not ever satisfy the petitioner's burden of proof. The determination is one to be made by the fact finder in light of the entire record. Indeed, one can imagine a hypothetical case where a completely healthy individual receives a vaccine and suffers some condition shortly thereafter. The Special Master may conclude that, based on the entirety of facts—including the petitioner's relative health prior to the vaccine—the petitioner has satisfied his burden of proof. This might be the case if there is an

The court must emphasize that, ultimately, there appears to be no hard and fast rule for what specific, individual elements of proof a petitioner must present in order to establish a *prima facie* case of causation-in-fact; *the rule is really one of reason*, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time. "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." *Knudsen*, 35 F.3d at 548. Certainly, though, when a petitioner travels the *plausibility* route to causation-in-fact, he should endeavor to buttress his argument with more factors than just a plausible mechanism and a literal temporal relationship. In that analysis, the presence of a scientific temporal relationship and the elimination of alternative causes are persuasive factors that weigh significantly in the Special Master's evaluation.

C. Did The Special Master Employ The Proper Standard In Determining That Petitioners Failed To Prove Causation-In-Fact?

Employing this "rule of reason" regarding plausibility and causation-in-fact to the Special Master's decision in this case, it is clear that the decision withstands legal scrutiny. Arguing that the Special Master impermissibly heightened the legal standard in this case, petitioners claim that "[i]f the vaccine 'can cause' the injury via the process recognized, the fact that the process is shown to have occurred is *prima facie* proof that the 'timing' of the injury was a perfect fit for the theory of causation." Pet.'s Mem. of Objections at 29. This characterization, however, both oversimplifies the standard to which petitioners are held (as discussed above) and misstates what they seem to have actually proven.

First, it does not appear that petitioners ever succeeded in demonstrating that the mechanism of causation they espoused was, in fact, the biological process by which Richelle's condition developed. Had they been able to do so, then petitioners would have succeeded in proving *direct causation* and they would not have needed to rely on a circumstantial *plausibility* argument.

Instead, petitioners have demonstrated here that it is generally possible for the administration of certain vaccines to cause a reaction that, in certain genetically predisposed vaccinees, might trigger the manifestation of systemic onset JRA, or Still's disease. They have presented a medically accepted mechanism by which such a result *might* occur. Specific to Richelle, petitioners have demonstrated that she received a series of vaccines in March 1998, that she experienced a typical temporary reaction to those vaccines, and that shortly thereafter she experienced the symptoms of a permanent condition (Still's disease). The record also presents evidence that shortly before Richelle received her March 1998 vaccines, she also experienced other temporary ailments that could have "triggered" the manifestation of her Still's disease according to the same mechanism that petitioners argue the vaccines operated. Petitioners did not offer any evidence that would establish a scientifically accepted or medically recognized time frame between a triggering event (such as the vaccine reactions or the tonsillitis or mycoplasma infection) and the manifestation of symptoms of Still's disease. And what is also significant, they did not offer evidence that tended to suggest that the vaccines were more likely to be the triggering event in Richelle's specific case than were her

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absence of alternative causes apparent in the record or the biologic mechanism that petitioner demonstrates is particularly compelling.

other ailments. In other words, other reasonably possible factors were not eliminated. In light of this entire record, taken as a whole, the court cannot conclude that it was error for the Special Master to decide that petitioners failed to establish by a preponderance of the evidence that the vaccines at issue were the but-for cause and substantial factor inducing injury. Rather, the Special Master was correct to hold that petitioners failed to establish a *prima facie* entitlement to compensation.

If the petitioners here had been able to demonstrate, as the Special Master indicated, that a temporal relationship *in the medical sense* existed—that is, that the onset of Richelle's Still's disease occurred upon the passage of a medically accepted period of time after her March 1998 vaccination and not after some other potential triggering event—then the weight of petitioner's circumstantial evidence would have been much stronger and this would be a much closer case. The presence of a medically recognized time frame between the trigger and the manifestation of symptoms, which would causally link the trigger and the condition, would serve here as a sufficient nexus to establish causation-in-fact, and would also have aided the court by eliminating alternative causes.

Petitioners did succeed in demonstrating that Richelle experienced vaccine-specific reactions within a six and fourteen day window that is typical of the five percent or so of the population that experiences such reactions. The Special Master noted these reactions were "typical" and "did not appear out of the ordinary." At no point, however, do petitioners appear to make the case for an accepted period of time between a "triggering" event and the onset of Still's disease symptoms, which in this case the Special Master determined to be about three weeks after Richelle's March 1998 vaccinations. Therefore, while the record appears clear that Richelle experienced a general reaction to the vaccines within a medically recognized time period, the same cannot be said with regard to the onset of her Still's disease symptoms, which the Special Master concluded to occur within a period distinct from her general vaccine reaction.

Petitioners argue that the expression of Richelle's initial reaction to the vaccines was the beginning of a "logical sequence of cause and effect" that triggered a cascade of symptoms culminating with her Still's disease. They do not distinguish between Richelle's initial symptoms in early April 1998 (those the Special Master concluded were "typical post-vaccinal side effects") and her later symptoms weeks later that the Special Master deemed consistent with the Still's disease profile. They rely on evidence of an "entire chain of events from vaccination to autoimmune injury [that] occurred in the appropriate and expected time frame." Pet.'s Mem. of Objections at 28. The flaw in their argument that the Special Master seized on was that petitioners never established the expected time period in which the alleged "chain of events" would occur, but instead only established when the *alleged* "triggering event," or the initial vaccine reactions, would occur. There was no proof as to when any Still's-specific symptoms would be expected. The Special Master was not convinced that this was proof enough to establish causation-in-fact, especially in light of the fact that other contemporaneous events, each of which might have been potential triggers in petitioners' model, were present in the record. Had the petitioners demonstrated that Still's disease symptoms would be expressed within one or two weeks of a triggering event, it would have supported petitioners' argument and made their case for causation-in-fact much stronger. On the other hand, if Still's disease symptoms generally manifest three to four weeks from a triggering event, for instance, then petitioners' model would seem to favor Richelle's tonsilitis or mycoplasma infection as a more likely triggering event. In light of these viable alternative causes of Richelle's Still's disease inherent in the record, the court can not conclude that the Special Master's rejection of the

petitioner's causal argument was arbitrary or capricious. As noted above, the standard of proof that he employed in his analysis is consistent with the Vaccine Program case law, and his factual analysis considered relevant facts. The conclusion that he reached was rational.

D. Abuse Of Discretion

The petitioners also argue that the Special Master abused his discretion by raising the "critical time" issue *sua sponte* after hearing when neither party had themselves raised it as an issue during the case in chief. But this argument misses the mark because "[i]n general . . . the parties are responsible for the traditional tasks of identifying and developing information supporting or opposing an award, securing and presenting fact witnesses and expert testimony, and meeting their respective burdens of proof." Pet.'s Mem. of Objections at 6 (quoting Guidelines for Practice Under the National Vaccine Injury Compensation Program, § V, *available at* http://www.uscfc.uscourts.gov/OSM/OSMGuidelines.pdf). Here, the role of a medically accepted temporal relationship between a vaccination and the onset of a subsequent condition has long been recognized as an important, if not essential element of a petitioner's burden of proof in Vaccine Program cases. *See Hasler*, 718 F.2d at 205 ("[I]noculation is not the cause of every event that occurs within the ten day period [afterward]. . . . Without more, this proximate temporal relationship will not support a finding of causation."). It is recognized as one of the tools in a petitioner's arsenal that may help to establish causation. *See*, *e.g.*, *Stevens*, 2001 WL 387418 at *25-26. Indeed, establishing proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury was specifically identified by the Chief Special Master in *Stevens* as one of the essential criteria a petitioner needs to establish as part of his *prima facie* causation-in-fact case. *Id.* While the court does not wholly adopt the Chief Special Master's analytic framework set forth in *Stevens*,[17] *but see Althen*, 58 Fed. Cl. 270 (criticizing the analytic framework), that framework is key in this case because on several occasions the petitioners claim to have tried to prove their case *based on the Stevens model*.[18] Petitioners were therefore on notice of the unique role that the "critical time" element plays in Vaccine Program cases. Since the role of a medically acceptable temporal relationship is both a widely recognized issue in Vaccine Program cases, and since the

[17] Here, Congress has provided no test by which the courts are to evaluate causation-in-fact claims. The courts, therefore, should be wary to blindly or mechanistically apply a court-made test as some sort of talisman that replaces the *process* of applying the law. *See Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 465 (1996) (citing *Hanna v. Plumer*, 380 U.S. 460, 466-67 (1965)). On the other hand, analytic frameworks such as that espoused by the Chief Special Master in *Stephens* do play an important role as a starting point for analysis. As an element of a broader "rule of reason" that is more of a means than an end, such a framework can play an important jurisprudential role in the absence of a hard-and-fast rule set forth by Congress.

[18] *See* Pet.'s Mem. of Objections at 4 n.6 (quoting *Stevens* "Petitioners must satisfactorily prove that the onset occurred within a time frame deemed medically appropriate according to the scientific or medical evidence"), 12 (noting that the parties had been directed by the Special Master to address the *Stevens* analytic framework), 13 ("Beginning with the *Prima Facie* memo, Petitioners religiously followed the template of the *Stevens* and *Shyface* cases."), 13 n. 27 (noting that *Stevens* contemplates "proof of a medically acceptable temporal relationship between the vaccination and the onset of the injury").

petitioners here claim to have followed a framework that explicitly includes that relationship as one of its key components, the court concludes that the Special Master did not err or abuse his discretion in raising this issue in his opinion, despite the fact that it may not have been specifically addressed at hearing or raised as an issue by respondent.

E. Alternative Causation

Finally, the petitioners challenge the Special Master's reliance on potential alternative causes of Richelle's Still's disease, which in his view weakened the petitioner's causation-in-fact case because they never discounted the role of these other causes in the context of the cytokine mechanism that petitioners espoused. Petitioners point to statute and case law[19] that seem to implicitly place upon the government the burden of proving the existence of alternate causation by a preponderance of the evidence. Essentially, they argue that the government never proved that a factor unrelated to the vaccine caused Richelle's Still's disease, so therefore the Special Master should not have considered the role of alternative causes *vis-a-vis* the vaccines in deciding this case.

In addition to either establishing an on-Table injury or proving causation-in-fact, the Vaccine Act requires the fact finder to determine that "there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine." *Grant*, 956 F.2d at 1149-50 (quoting § 300aa-13(a)(1)(B)) (alterations in original). In other words, it must be demonstrated that there is an "absence of alternative causes" for the alleged injury. *Id.* "These are two separate inquiries under the statute. . . . [T]he Act requires a finding on both causation and alternative etiologies." *Id*. In an *on-Table case* where the petitioner has successfully demonstrated that he is entitled to the presumption of causation, the burden of proof of alternative causation rests with the government. In other words, the government must affirmatively prove the *presence* of some alternative cause. *See Knudsen v. Sec'y of the Dep't of Health and Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994) ("Thus, if a petitioner has . . . obtained the benefit of a presumption [by proving an on-Table condition], and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation."). Particularly in on-Table cases, the role of § 300aa-13(a)(1)(B) is essential. Since petitioners obtain the presumption of causation merely by establishing that a Table injury occurred within an established temporal proximity to the vaccine, the statute provides a means by which respondent may overcome that presumption if, in fact, some factor unrelated to the vaccine caused the condition or illness.

Apportioning the burden of proof of alternative causation in off-Table cases where the petitioner attempts to establish causation-in-fact, however, has been the subject of considerable debate within this Circuit. *Compare Wagner v. Sec'y of the Dep't of Sec'y of the Dep't of Health and Human Servs.*, 37 Fed. Cl. 134 (1997) ("To the extent that the [Special Master's analysis] operated in this case to place the burden of disproving every alleged alternative cause on the petitioner . . . it is not in accordance with the requirements of the Vaccine Act.") *with Wagner v. Sec'y of the Dep't of Health and Human Servs.*, No. 90-2208V, 1997 WL 617035 (Fed. Cl. Spec. Mstr. Sept. 22, 1997)

[19]Petitioners cite to *Knudsen* and *Althen* to support their argument. The court notes that those two cases are inapposite to the present matter. *Knudsen* was an "on-Table" case; *Althen* was not a case in which potential alternative causes were at issue. *See Knudsen*, 35 F.3d 543; *Althen*, 58 Fed. Cl. 270.

(on remand) ("[P]etitioner's theory [that the government bears the burden of proof of alternative causation in the first instance] leads to an interpretation of the 'actual causation' avenue of proof that is radically different from any that has been set forth in any published opinion during the Program's existence.") (dicta). Much of the apparent uncertainty on this issue seems to stem from the contrast between the legal standard of proof that the courts have employed as part of the traditional tort theory of actual causation and the statutory analysis required by § 300aa-13(a)(1)(B). *See Stevens*, 2001 WL 387418 at *21 & n. 58.

Despite potential ambiguities or other decisions from the Court of Federal Claims that may appear facially inconsistent, this court concludes that the overwhelming weight of authority in this Circuit is consistent with traditional notions of tort law that place an initial burden of proof regarding alternative causation on the petitioner—not as part of the § 300aa-13(a)(1)(B) "factor unrelated" test, but rather as part of establishing a *prima facie* case of causation-in-fact. Consistent with the Federal Circuit's instructions, discussed above, that an actual-causation vaccine petitioner "must prove by a preponderance of the evidence that the vaccine, *and not some other agent*, was the actual cause of the injury," *Munn*, 970 F.2d at 865 (emphasis added), the attendant burden of proof in an actual causation case *subsumes* the obligation to successfully eliminate potential alternative causes of the alleged injury that have been identified in the record. This is so because, in proving that the vaccine is the actual cause of the alleged harm, the petitioner bears the burden of proving that the vaccine was both the "but for" cause as well as a "substantial factor" of the harm. *Shyface*, 165 F.3d at 1351-52.

While this burden is separate and distinct from the § 300aa-13(a)(1)(B) "factor unrelated" examination that the fact finder must conduct once the petitioner has established causation, there may well be overlap in the types of facts that might be considered. *See*, *e.g.*, *Johnson v. Sec'y of the Dep't of Health and Human Servs.*, 33 Fed. Cl. 712, 721 (Fed. Cl. 1995) ("While petitioner is correct that, under the statute, § 300aa-13(a)(1)(B) is literally applicable in non-Table cases, logically, the application of that section fails to add anything to the required analysis."), *aff'd* 99 F.3d 1160 (Fed. Cir. 1996) (table decision). This is not to say, however, that the § 300aa-13(a)(1)(B) "factors unrelated" analysis is formally "collapsed into a single determination," *but see id.*, because the Federal Circuit has made clear that they are "two separate inquiries," *Grant*, 956 F.2d at 1149-50, and because the statutory analysis only obtains once the petitioner has first made out a *prima facie* case of causation. *See Bradley v. Sec'y of the Dep't of Health and Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) ("[W]hen, as here, the special master concludes that a petitioner has *not* demonstrated by a preponderance of the evidence . . . causation required under subsection (A), the alternative causation theories of subsection (B) need not be addressed."). For practical purposes, though, the court's determination of whether the petitioner has proven causation in fact will necessarily incorporate an analysis of whether the petitioner has demonstrated that the vaccine is the substantial factor behind the injury, and this analysis requires recourse to and discounting of other potential factors behind the harm. *See Shyface*, 165 F.3d at 1351-52; *see also Johnson*, 99 F.3d 1160 (table decision) ("As a matter of logic, however, a preponderance of the evidence cannot show both actual causation by the vaccine and causation due to factors unrelated to the vaccine.") (citing *Bradley* and *Munn*).

"Thus, in a nontable case, the single inquiry is whether the petitioner has established by a preponderance of the record evidence that his or her injury or condition was actually caused by the

vaccine." *Johnson*, 99 F.3d 1160. This does not suggest that the petitioner must discount *every* potential cause that exists within the entire realm of possibility, or "prove that an infinite number of potential causes were not at work causing the injuries suffered," *Wagner*, 37 Fed. Cl. at 139, but rather the petitioner must confront the range of potential causes that are evidenced in the record. *See Stevens*, 2001 WL 387418 at *26 ("Reasonable efforts to rule out known alternate causes is sufficient to meet the preponderance standard. The reasonableness of the efforts is usually apparent from the medical records.").

This conclusion is not inconsistent with other opinions from this court and its predecessor that implicitly place the burden of proof on the government in the § 300aa-13(a)(1)(B) "factors unrelated" analysis. *See*, *e.g.*, *McClendon v. Sec'y of the Dep't of Health and Human Servs.*, 24 Cl. Ct. 329, 333 (1991). The *McClendon* court noted that:

> If a *prima facie* case of entitlement exists, § 300aa-13(a)(1)(B) instructs the fact finder to determine whether a preponderance of the evidence shows that the injury was due to 'factors unrelated' to the administration of the vaccine . . . . The Act implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent. . . . [I]t is not the petitioners' burden to disprove all possible alternative causes in order to prevail.

Id.[20] This is a proper iteration of the allocation of the burden of proof *once petitioner has established that he is entitled to the presumption of causation*, either by demonstrating that his is an on-Table case or by *proving causation-in-fact*. Indeed, only once either of those preconditions to the presumption of entitlement are satisfied in accord with § 300aa-13(a)(1)(A) does the fact finder turn to subparagraph (B) to address the "factors unrelated" analysis. *See Bradley*, 991 F.2d at 1575. The element of analysis that is critical to this case, and seems to be either omitted or assumed away by other cases, is that in establishing his *prima facie* case of entitlement, the petitioner must discount other potential causal factors that the record reveals, because the required "substantial factor" analysis requires as much. This requirement does not saddle petitioner with the unfair burden of disproving the role of the entire spectrum of alternative causes or "every possible ground of causation," but rather limits the petitioner's burden to proving, by a preponderance of the evidence, why the vaccine at issue and *not those other factors evidenced in the record* was the substantial factor in the alleged injury. *Bunting v. Sec'y of the Dep't of Health and Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991); *see also Wagner*, 37 Fed. Cl. at 139. If a petitioner fails to satisfy this burden, then he has failed to establish his *prima facie* case of entitlement and the burden of proof for the § 300aa-13(a)(1)(B) inquiry never shifts to the respondent.

Therefore, in this case, the Special Master committed no error by factoring in to his analysis the unexplained role that causes other than the vaccines at issue may have played in triggering

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[20]The court notes that *McLendon* concluded that the petitioners had proven by a preponderance of the evidence the existence of a "table seizure disorder" and that the case was therefore an "on-Table" case. The petitioner was not obligated to prove causation-in-fact, but rather the presence of a Table injury. Once a Table injury had been established, therefore, the burden of proof for the § 300aa-13(a)(1)(B) analysis clearly, and properly, shifted to respondent. *See McClendon*, 24 Cl. Ct. at 336-37.

Richelle's Still's disease. These alternatives were present in the record and comprised part of the body of evidence that the Special Master was required to weigh in determining whether petitioners had succeeded in demonstrating, based on the record as a whole, that the vaccines at issue were indeed the but-for cause of the condition. Since the petitioners relied exclusively upon circumstantial evidence in proving their case, it was incumbent upon them to discount the role of these potential alternatives in order to prove that the vaccines were, more likely than not, the cause of Richelle's Still's disease. Without doing so, or without providing other persuasive evidence that tended to show that the vaccines specifically caused the disease, Richelle's other prior ailments remained as possible "triggers" that were just as likely as the vaccines to cause her Still's disease.

VI. Conclusion

For the foregoing reasons, the court AFFIRMS the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

IT IS SO ORDERED.

s/*Lawrence J. Block*

Lawrence J. Block
Judge