

# In the United States Court of Federal Claims

No. 99-406V

(Filed Under Seal: August 29, 2011)

(Reissued: January 28, 2013)

TO BE PUBLISHED

_____	)	National Childhood Vaccine Injury Act of
NATHAN HOUSE,	)	1986, 42 U.S.C. §§ 300aa-1 to -34; three-
	)	factor analysis under <i>Althen v. Sec’y of</i>
Petitioner,	)	<i>Health &amp; Human Servs.</i>
	)	
v.	)	
	)	
SECRETARY OF HEALTH AND	)	
HUMAN SERVICES,	)	
	)	
Respondent.	)	
_____	)	

Clifford Shoemaker, Vienna, VA, for plaintiff.

Lisa A. Watts, Trial Attorney, Catherine E. Reeves, Assistant Director, Vincent J. Matanoski, Acting Deputy Director, Mark W. Rogers, Acting Director, Tony West, Assistant Attorney General, Washington, D.C., for defendant.

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

GEORGE W. MILLER, Judge

Petitioner seeks review of a decision by Chief Special Master Patricia E. Campbell-Smith denying compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34. Petitioner alleges that after each hepatitis B vaccination he received in 1993 and 1994, he “experienced flu-like symptoms, joint pain, diarrhea and fever.” Published Decision Denying Compensation at 2 (docket entry 141, Mar. 3, 2011) (“Compensation Decision”). Petitioner further alleges that his symptoms became worse after each vaccination, and as a result, he was diagnosed with Crohn’s disease. *Id.* The Special Master denied relief on the ground that petitioner failed to prove by a preponderance of the evidence that the vaccinations caused his injury. *House v. Sec’y of Health & Human Servs.*, No. 99-406V (Fed. Cl. Sp. Mstr., Mar. 3, 2011).

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<sup>1</sup> Pursuant to the Rules of the Court of Federal Claims (“RCFC”), App’x B, Rule 18(b), this Opinion and Order was initially filed under seal. The parties were afforded fourteen days in which to propose redactions. Neither party proposed any redactions. Accordingly, the Opinion and Order is released in its entirety.

Petitioner filed a timely motion for review under RCFC Appendix B,<sup>2</sup> Rule 23, claiming that the Special Master improperly required petitioner to prove an elevated evidentiary burden. Petitioner’s Motion for Review (docket entry 143, Mar. 30, 2011) (“Motion”). Petitioner requests that the Court set aside the Special Master’s decision and enter a decision in his favor. Respondent argues that the Special Master correctly determined that petitioner failed to establish that a hepatitis B vaccine series caused-in-fact his Crohn’s disease. Response to Petitioner’s Motion for Review (“Response”) (docket entry 147, Apr. 29, 2011). Respondent requests that the Court affirm the Special Master’s Compensation Decision. For the reasons set forth below, the Court **GRANTS** petitioner’s motion for review, **REVERSES** the Compensation Decision and **REMANDS** the case to the Special Master for further consideration.

## I. Background

The record on review supports the thorough findings of fact set forth the in the Special Master’s Ruling Regarding Onset of Petitioner’s Symptoms (“Findings of Fact”) (docket entry 76, May 4, 2007), 2007 WL 5177470, and Compensation Decision. The facts most pertinent to this Opinion and Order are set forth below.

### A. Medical History

Nathan House was born on December 17, 1970. He suffered from a condition known as “nervous stomach” as a child. Findings of Fact at 2. Petitioner has a family history of Crohn’s disease and colon cancer. *Id.* at 13. Prior to receiving the hepatitis B vaccinations, however, he had reported “episodic symptoms of weakness, nausea, shakiness, vomiting, diarrhea, visual blurring and headaches,” *id.*, but had never formally been diagnosed with either Crohn’s disease or irritable bowel syndrome (“IBS”). *Id.* at 1-5.

Petitioner received his first hepatitis B vaccination on September 9, 1993. *Mot.* at 2. Two days later he complained to his family doctor, Dr. Thomas Devlin, of cramps and diarrhea, which continued until September 13, 1993. *Id.* After this first vaccination, petitioner also experienced headaches and an “aura” of flashing lights, which he also reported to Dr. Devlin. Findings of Fact at 14. Petitioner received his second hepatitis B vaccine on October 22, 1993. *Id.* Three days later he complained to Dr. Devlin of a burning in his stomach, chest burning, and green bowel movements. *Mot.* at 2. Petitioner’s symptoms continued after the receipt of the third vaccination on February 24, 1994. Findings of Fact at 14.

Dr. Devlin noted that petitioner’s mother called him on November 15, 1994, expressing concern that petitioner may have irritable bowel syndrome. Findings of Fact at 6. In February 1995, Dr. Devlin’s records show that petitioner complained of frequent abdominal cramps with intermittent diarrhea that occurred two or three times and lasted for days at a time. *Id.* Around this time, petitioner first noticed blood in his stools and notified Dr. Devlin, who referred him to a gastroenterologist, Dr. William Mark. *Id.* at 7. Dr. Mark performed a colonoscopy and

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<sup>2</sup> Petitioner states that he seeks review “pursuant to [RCFC] App. J, Rule 23.” The Court assumes petitioner intends to refer to Appendix B, which sets forth the Vaccine Rules of the Court of Federal Claims.

determined that petitioner suffered from proctitis, an inflammation of the rectum. *Id.* Petitioner did not respond to the treatments recommended by Dr. Mark. *Id.*

Petitioner was eventually referred to the Cleveland Clinic for an evaluation. Findings of Fact at 7. After numerous tests, the examining physicians diagnosed petitioner with Crohn's disease. *Id.* Since this diagnosis, several of petitioner's treating doctors have characterized petitioner's condition as Crohn's disease: Dr. Bayless, a gastroenterologist; Dr. Chou, a gastroenterologist; Dr. Lavery, a staff surgeon at the Cleveland Clinic Department of Colorectal Surgery; and Dr. Hull, a colorectal surgeon. Compensation Dec. at 11.

### *B. Petition Before the Special Master*

On June 28, 1999, Mr. House filed a petition seeking compensation pursuant to the Vaccine Act (docket entry 1). Record development halted in 2003 when the Office of Special Masters grouped together a number of hepatitis B vaccine cases for omnibus proceedings. Compensation Dec. at 2. In 2006, the Office of Special Masters discontinued the various omnibus proceedings, and record development for this case resumed. *Id.* Special Master Campbell-Smith conducted a fact hearing in October 2006 in LaVale, Maryland, Oct. 5, 2006 Symptom Onset Transcript ("Symptoms Transcript") (docket entry 61, Nov. 6, 2006), and issued Findings of Fact on May 3, 2007 (docket entry 76).

On November 9, 2007, petitioner filed an expert report by Dr. Joseph A. Bellanti (docket entry 91), and on February 25, 2008, respondent filed an expert report by Dr. Andrew S. Warner (docket entry 95). On May 13, 2010, these experts testified at an evidentiary hearing ("Hearing Transcript") (unnumbered docket entry, May 14, 2010). After both parties submitted post-hearing briefs, the Special Master issued a decision denying compensation on February 28, 2011 (docket entry 140). The Special Master issued an amended decision, the Compensation Decision, on March 3, 2011.

Petitioner filed a motion for review on March 30, 2011, arguing that the Special Master improperly required petitioner to prove an elevated evidentiary burden, in violation of the Federal Circuit's holding in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1279 (Fed. Cir. 2005). Mot. at 2. Respondent filed its Response on April 29, 2011, urging the Court to deny petitioner's motion for review.

## **II. Standard of Review**

This Court has jurisdiction over vaccine petitions pursuant to 42 U.S.C. § 300aa-12(e). The Court reviews findings of fact of a special master under the arbitrary and capricious standard and conclusions of law under the "not in accordance with law" standard. *Hall v. Sec'y of Health & Human Servs.*, 640 F.3d 1351, 1354 (Fed. Cir. 2011). The Court reviews discretionary rulings under the abuse of discretion standard. *Id.* "Generally in cases under the Vaccine Act, 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." *Id.* (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)) (internal quotation marks omitted). In reviewing a decision of a special master, this Court may (A) "uphold the findings of fact and conclusions of law," (B) "set aside any of the

special master’s findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” or (C) “remand the petition to the Special Master for further action in accordance with the court’s direction.” 42 U.S.C. § 300aa-12(e)(2); *Grant v. Sec’y of Dep’t of Health & Human Servs.*, 956 F.2d 1144, 1150 (Fed. Cir. 1992).

### III. Discussion

Petitioner’s motion for review of the Special Master’s Compensation Decision is based on petitioner’s claim that the “Special Master’s decision . . . [that] require[d] Petitioner to prove an elevated evidentiary burden . . . was arbitrary and capricious, an abuse of discretion and not in accordance with law.” Mot. at 2 (footnote omitted). The Court therefore first considers the legal standards applicable to petitions for compensation under 42 U.S.C. § 300aa.

#### A. Vaccine Act Legal Standards

A petitioner under the Vaccine Act can prove by a preponderance of the evidence that a listed vaccine caused an injury in one of two ways. See §§ 300aa-11(c)(1) and 300aa-13(a)(1)(A); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). First, a petitioner can demonstrate that he suffered a so-called “on-table” injury, *i.e.*, the petitioner received a vaccine listed on the Vaccine Injury Table (“Table”)<sup>3</sup> and suffered an injury known to be caused by that vaccine within the time frame described by the Table. See §§ 300aa-11(c)(1) and 300aa-13(b)(2). Under this approach, petitioner need only prove by a preponderance of the evidence that he received the vaccine and that the injuries occurred within the specified time frame.<sup>4</sup>

Second, a petitioner can demonstrate that he suffered a so-called “off-table” injury, *i.e.*, when a petitioner receives a vaccine listed on the Table, but alleges the vaccine caused an injury not listed on the Table. § 300aa-11(c)(1)(C)(ii). A petitioner establishes eligibility for compensation in an “off-Table” case by demonstrating by a preponderance of the evidence that: (1) petitioner received a vaccine set forth on the Vaccine Injury Table; (2) he received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the problem has persisted for more than six months. See *id.* §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). In this case, the first, second, and fourth elements are conceded; the only dispute is over the third element: whether petitioner’s hepatitis B vaccine series caused plaintiff’s autoimmune/autoinflammatory illness.

In an “off-Table” case, a petitioner must establish a *prima facie* case of actual causation. To prove his claim by a preponderance of the evidence, a petitioner must show that it is “more probable than not” that the vaccine caused petitioner’s injury. *Althen*, 418 F.3d at 1279.

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<sup>3</sup> Pursuant to the Vaccine Act, 42 U.S.C. § 300aa-14(c), the Secretary of Health and Human Services maintains a Vaccine Injury Table at 42 C.F.R. § 100.3 (2008).

<sup>4</sup> There are additional geographic requirements to qualify for compensation under the Vaccine Act, but none are at issue in this case. See § 300aa-(c)(1)(B)(i).

To show actual causation, a petitioner must establish the three factors set forth in *Althen* and explained in detail below. *Id.* at 1278. If the petitioner satisfies the three *Althen* factors and establishes a *prima facie* case of entitlement to compensation, the burden shifts to respondent to show “by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.” *Walther v. Sec’y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007); *accord Althen*, 418 F.3d at 1278.

Here, petitioner seeks to show that the hepatitis B vaccine caused Crohn’s disease, an “off-Table” injury. Therefore, petitioner must establish a *prima facie* case of actual causation.

### B. *Petitioner’s Prima Facie Case*

A petitioner makes out a *prima facie* case of actual causation by showing, “by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. The Federal Circuit requires a special master to proceed systematically through these three factors, analyzing each of their requirements in turn. *Cf. Andreu ex rel. Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1374-75 (Fed. Cir. 2009); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano*, 440 F.3d at 1325. While the requirements of the three factors are generally distinct, there is “no reason why evidence used to satisfy one of the *Althen* [] prongs cannot overlap to satisfy another prong.” *Capizzano*, 440 F.3d at 1326.

Here, the Special Master concluded that petitioner failed to satisfy any of the three factors. The Court reviews the Compensation Decision’s analysis of these factors in turn.

#### 1. First *Althen* Factor

To satisfy the first *Althen* factor, the petitioner must provide “a medical theory causally connecting the vaccination and the injury.” *Althen*, 418 F.3d at 1278. The Federal Circuit has held that a medical theory can be established by “reputable medical or scientific explanation,” *i.e.*, “evidence in the form of scientific studies or expert medical testimony.” *Id.* (internal quotation marks omitted). The theory need not be corroborated by medical literature or epidemiological evidence. *Capizzano*, 440 F.3d at 1325. It need only be a “biologically plausible” theory showing that the vaccine can cause the injury. *Andreu*, 569 F.3d at 1375. In other words, the pertinent question under this factor is simply, “*can* [the] vaccine(s) at issue cause the *type* of injury alleged?” *Pafford*, 451 F.3d at 1356 (alteration in original) (emphases added). As such, this factor does not require a petitioner to show that—in this particular instance—the vaccine actually caused his injury.

Here, petitioner’s medical theory is that because of a certain autoimmune genetic vulnerability, the hepatitis B vaccine that he received in 1993 caused him to develop Crohn’s disease. Mot. at 16-17 (“A person with genetic susceptibility receives a vaccine, certain components/antigens of which are improperly processed by the body leading to inflammation,

tissue damage, chronicity of inflammation and ultimately the disease – in this instance Crohn’s disease.”).

In analyzing petitioner’s theory under the first factor, the Compensation Decision misapplies pertinent legal standards in several instances, conflating requirements from other stages of the *Althen* analysis with those required under the first factor. Three such instances are discussed below.

First, in concluding that petitioner failed to establish the first factor, the Compensation Decision appears to rely on its conclusion that “[t]he opinion put forth by Dr. Bellanti falls short of the ‘more likely than not’ showing of a scientifically sound and reliable theory of causation required for petitioner to prevail.” Compensation Dec. at 16 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). But *General Electric*’s “more likely than not” requirement is not the proper standard at this stage. *General Electric*, not a vaccine, but a products liability case, used that language in characterizing an expert witness’s conclusion that certain toxic products *actually caused* the plaintiff’s illness. 522 U.S. at 146 (noting that expert witness testified at deposition that it was “more likely than not that Mr. Joiner’s lung cancer was causally linked to cigarette smoking and PCB exposure”). Under the first *Althen* factor, a petitioner is not required to show specifically that the vaccine caused the precise injury in question; he is required only to put forth a theory that is “biologically plausible,” *Andreu*, 569 F.3d at 1375, and which indicates, by a preponderance of the evidence, that the vaccine *can, in theory*, cause such an injury, *see id.*; *Pafford*, 451 F.3d at 1356. To the extent the Compensation Decision requires petitioner to show that it was “more likely than not” that Dr. Bellanti’s theory established the cause of petitioner’s injury *in this case*, the Compensation Decision imposes an unduly elevated evidentiary standard on petitioner at this stage of the *Althen* analysis. *Cf. Andreu*, 569 F.3d at 1375. (“The first prong was satisfied because . . . the [petitioner’s]’ expert, presented a ‘biologically plausible’ theory establishing that toxins in the . . . vaccine *can* cause seizures.” (emphasis added)).

The Compensation Decision also notes that “petitioner’s expert [did not] offer evidence that the administered hepatitis B vaccine series was either ‘a but-for’ causal factor or a ‘substantial factor’ in inducing the proposed course of autoinflammation in petitioner.” Compensation Dec. at 15 (citing *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999))). This standard is misplaced: the cited cases do not require such a showing—particularly the “substantial factor” requirement—as part of the *first Althen* factor; the cases require that showing as part of the petitioner’s overall, cumulative burden. *E.g.*, *Pafford*, 451 F.3d at 1355 (“[T]hese [three] prongs must *cumulatively* show that the vaccination was a “but-for” cause of the harm . . . .” (emphasis added)).<sup>5</sup> Indeed, requiring a petitioner to show

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<sup>5</sup> In *Pafford*, the Federal Circuit characterized the *Althen* three-factor test as an “alternative” to proving but-for and substantial factor causation, *Pafford*, 451 F.3d at 1355, thus suggesting that after *Althen*, a petitioner may no longer need to show that the vaccine was a “substantial factor” in his injury, provided he satisfies the causation-in-fact requirement using the three *Althen* factors. *See id.* (“[T]hese prongs must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.”).

that—in his specific case—the vaccine was both a but-for cause and a substantial factor in the injury is inconsistent with the first-factor standard, which demands only that a petitioner produce a “biologically plausible” theory as to how the vaccine in question *can* cause the relevant injury, *Andreu*, 569 F.3d at 1375. Moreover, requiring specific “but-for” and “substantial factor” showings for every factor would obviate the *Althen* three-factor approach, since resolving the question for any three of the factors would necessarily answer the ultimate question of causation. Specifically, a requirement to establish “but-for” and “substantial factor” causation for the first factor would render the second *Althen* factor, which requires “a logical sequence of cause and effect showing that the vaccination was the reason for the injury,” *Althen*, 418 F.3d at 1278, a nullity.

Similarly, the Compensation Decision’s first-factor discussion conflates the analysis of the first *Althen* factor with the respondent’s burden to rebut the petitioner’s *prima facie* case. In explaining the Compensation Decision’s “determinative consideration” in failing to find the first factor, the Compensation Decision notes that the

hepatitis B vaccination series was but one of a number of agents that could have led to the autoinflammatory process. . . . Other agents identified as possibly causal were ingested food or encountered bacteria. . . . Dr. Bellanti’s assertion that a number of presented causal factors could be equally responsible for causing a petitioner’s condition does not advance petitioner’s claim, without more, that the received hepatitis B vaccine series was *the responsible factor in this case*.

Compensation Dec. at 15-16 (emphasis added). Again, the only relevant inquiry at this stage is “*can* [the] vaccine(s) at issue cause the *type* of injury alleged?” *Pafford*, 451 F.3d at 1356 (emphases added). Whether “[o]ther agents” may have caused the injury is wholly irrelevant to whether there exists a plausible theory linking the vaccine with the injury. As such, it is inconsistent with *Althen* and its progeny to require the petitioner to show as part of the first factor that “[o]ther agents” did *not* cause the injury, or that the “vaccine series was *the responsible factor in this case*.” (Emphases added). That inquiry is most significantly<sup>6</sup> part of respondent’s rebuttal—during which *respondent* must show, by a preponderance of the evidence, that the injury was caused by other factors. § 300aa-13(a)(1)(B). “So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes.” *de Bazan*, 539 F.3d at 1353 (citing *Walther*, 485 F.3d at 1149-50).

Having concluded that the Compensation Decision applied incorrect legal standards in analyzing the first *Althen* factor, the Court remands the case to the Special Master to address petitioner’s showing with respect to the first *Althen* factor under the legal standards described above.

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<sup>6</sup> Under some circumstances, alternative causes may be relevant in the *prima facie* case, but only as to the analysis of the other two *Althen* factors. See *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1353 (holding that alternative causation may be relevant in determining whether temporal relationship exists between vaccine and injury).

## 2. Second Althen Factor

To satisfy the second *Althen* factor, the petitioner must “demonstrate a logical sequence of cause and effect showing the vaccination was the reason for the injury.” *Althen*, 418 F.3d at 1278. At this stage, he must show specifically that the vaccine was the but-for cause of the injury. See *Pafford*, 451 F.3d at 1356; *Capizzano*, 440 F.3d at 1326; *Shyface*, 165 F.3d at 1353. Put another way, the second factor asks: “[D]id the vaccine at issue cause the injury alleged?” *Pafford*, 451 F.3d at 1356 (emphasis added). While the vaccine must be the “but-for cause” of the injury, *Shyface*, 165 F.3d at 1353, it “need not be the sole factor or even the predominant factor.” *Id.* at 1352-53.

To meet the second-factor threshold, a petitioner may not be required to show “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” *Capizzano*, 440 F.3d at 1325. Circumstantial evidence and reliable medical opinions may satisfy this factor.<sup>7</sup> *Id.* at 1325-26; see *Andreu*, 569 F.3d at 1378 (“[T]he special master erred in requiring conclusive evidence in the medical literature linking the . . . vaccine to [the injury].”). “[M]edical opinion testimony” is “quite probative” because “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” *Capizzano*, 440 F.3d at 1326 (alteration in original) (internal quotation marks omitted).

Here, the Compensation Decision applies the correct law but appears to base its decision, at least partially, on an internally contradictory factual premise: that petitioner does not, or may not, have Crohn’s disease. In discussing petitioner’s expert’s testimony of petitioner’s symptoms, the Compensation Decision states that “over the course of more than twelve years, petitioner’s test results fail to show that he suffered from the type of chronic gastrointestinal inflammation associated with the inflammatory bowel disease of Crohn’s.” Compensation Dec. at 17. The Compensation Decision appears to rely on this statement in concluding that the absence of Crohn’s symptoms undermines petitioner’s theory—critical to his second *Althen* factor showing—that “an autoinflammatory process led to the development of a serious inflammatory bowel condition.”

As stated above, it is essentially undisputed that petitioner has Crohn’s disease: all of petitioner’s treating physicians named in the record diagnosed him with Crohn’s; petitioner’s expert witness physician stated that petitioner had Crohn’s and even respondent’s expert witness acknowledged that “[i]t’s possible that he didn’t, but it’s most likely he had mild Crohn’s

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<sup>7</sup> In evaluating expert medical testimony, a special master may determine the value of medical theories, but he should not make “credibility determination[s]” “to evaluate whether an expert witness’ medical theory is supported by the weight of epidemiological evidence.” *Andreu*, 569 F.3d at 1379 (citing *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1373-74 (Fed. Cir. 2000) (Plager, J., dissenting) (noting that “credibility” is not an issue when a highly qualified expert presents a biologically plausible theory linking a petitioner’s injury to a vaccine)).

Disease,” Hr’g Tr. at 123. And most importantly, the Special Master herself concluded that petitioner suffered from Crohn’s disease: “[T]he undersigned is persuaded that a preponderance of the evidence supports a finding that petitioner experienced an extremely mild case of Crohn’s disease . . . .” Compensation Dec. at 13.

Given the undisputed evidence and the Special Master’s own finding that petitioner had Crohn’s disease, the Compensation Decision cannot base a conclusion that petitioner fails to meet the second *Althen* factor on the notion that he may not have the disease. To do so would constitute an arbitrary, capricious, and internally contradictory finding.

On remand, the Special Master should reconsider the causal connection issue using a consistent factual predicate. In doing so, the Special Master should be mindful of the fact that it is error to “requir[e] conclusive evidence in the medical literature linking the . . . vaccine to [the injury],” *Andreu*, 569 F.3d at 1378, and that “medical opinion testimony” is “quite probative” because “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury,” *Capizzano*, 440 F.3d at 1326 (alteration in original) (internal quotation marks omitted). Petitioner may or may not ultimately succeed in showing the required causal relationship, but he must be allowed to do so under the clear premise that he does in fact have Crohn’s disease.

### 3. Third *Althen* Factor

To satisfy the third *Althen* factor, the petitioner must demonstrate a “proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. A petitioner must present evidence that the injury occurred within a medically acceptable time frame to link the injury to the received vaccine. *See Pafford*, 451 F.3d at 1358-59. “[W]ithout some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” *Id.* at 1358.

Here, the Special Master concluded that:

Dr. Bellanti’s ambiguity about what type of immunological process was at work in petitioner and correspondingly, what time frame was applicable does not support a finding that the temporal association between petitioner’s receipt of the hepatitis B vaccine series and the onset of his symptoms was more likely than not medically appropriate. Petitioner has failed to show that his hepatitis B vaccination series more likely than not led to the development of his Crohn’s disease, and without more than a speculative assertion of temporal association, petitioner’s vaccine claim cannot prevail.

Compensation Dec. at 19.

As with the first *Althen* factor analysis, the Compensation Decision imports standards from other parts of the *Althen* analysis into the third-factor discussion, thereby imposing an unduly elevated legal standard. For instance, the Compensation Decision concludes that “[p]etitioner has failed to show that his hepatitis B vaccination series more likely than not led to

the development of his Crohn's disease, and without more than a speculative assertion of temporal association, petitioner's vaccine claim cannot prevail." Compensation Dec. at 19. This statement implies that petitioner was again required to prove—as part of the third factor—the specific causal mechanism between the vaccine and his injury. That requirement, however, is part of the second *Althen* factor; the third factor requires only a showing of *temporal proximity* that is consistent with the petitioner's medical theory.

In requiring more than a “speculative assertion of temporal association,” to meet the third factor, the Compensation Decision cites *Grant v. Secretary of Department of Health and Human Services* for the proposition that, without more, a “proximate temporal relationship will not support a finding of causation.” Compensation Dec. at 19 (citing 956 F.2d at 1148 (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))). Notably, *Grant* was decided over a decade before the court developed the *Althen* factors, so *Grant* is not applying the third (or any) *Althen* factor in making that observation. Rather, *Grant* is noting that the petitioner may have demonstrated a temporal proximity between vaccine and injury, but that he has failed to show a causal mechanism between the two. 956 F.2d at 1148. Put in *Althen* terms, the *Grant* court is essentially saying that the petitioner may have established the third factor, but not the first or second, and therefore cannot prevail. *Grant* does not suggest that a petitioner must demonstrate more than appropriate temporal association to satisfy the third factor.

For the same proposition, the Compensation Decision also cites *Hennessey v. Secretary of Department of Health and Human Services*, which holds that *Althen* third-factor temporal proximity is not satisfied when the vaccine and injury occur far apart in time. 91 Fed. Cl. 126, 142 (2010) (stating that expert witness's “proposed timing suffers from . . . overly broad scope . . . Under his theory, nearly any conceivable timing could qualify as an appropriate temporal relationship.”). *Hennessey* is inapposite.

An examination of the record reveals that the temporal relationship between petitioner's receiving the vaccine and his Crohn's and IBS symptoms could scarcely be more stark. Just hours after petitioner received his first hepatitis B vaccination on September 9, 1993, he experienced “chills, body aches, onset of diarrhea, [and] cramping,” Symptoms Tr. at 15, and two days later, he reported his symptoms to his family doctor, who diagnosed him—for the first time in his life—with IBS. Mot. at 2; Symptoms Tr. at 17. And just three days after petitioner received his second vaccine on October 22, 1993, he reported to his doctor burning in his stomach, chest burning, and green bowel movements. Mot. at 2; Findings of Fact at 14. Finally, after the third vaccination, petitioner's symptoms were so severe that he could not go to work the next day, which resulted in his being fired on the spot. Symptoms Tr. at 21-22. Petitioner's expert witness testified that “the timing of petitioner's symptomatic responses in this case would have been consistent with one of the various timeframes that is appropriate for immunological responses.” Compensation Dec. at 18-19. Based on this time line and the expert witnesses' testimony, this Court has no trouble concluding that petitioner has shown by a preponderance of the evidence that an appropriate “proximate temporal relationship” exists between vaccination and injury, *Althen*, 418 F.3d at 1278. Cf. *Heinzelman v. Sec'y of Health & Human Servs.*, No. 07-01V, 2011 WL 2746329, at \*4 (Fed. Cl. June 24, 2011) (holding that twenty-day span between flu vaccine and Guillain-Barré syndrome symptoms was appropriate temporal

relationship under third *Althen* factor). Petitioner has therefore successfully established the third *Althen* factor.

For the reasons described above, the Court concludes that the Compensation Decision's *Althen* factor analysis renders the decision arbitrary, capricious, and not in accordance with law. *See Hall*, 640 F.3d at 1354. The Court holds that petitioner has successfully established the third *Althen* factor of his *prima facie* case of entitlement to compensation. The Court remands to the Special Master to determine, in a manner consistent with this opinion, whether petitioner can establish the first *Althen* factor, *i.e.*, "a medical theory causally connecting the vaccination and the injury," *Althen*, 418 F.3d at 1278, and the second *Althen* factor, *i.e.*, "a logical sequence of cause and effect showing the vaccination was the reason for the injury," *id.*

In reevaluating petitioner's evidentiary showing, the Special Master, the Court is confident, will be mindful of the Federal Circuit's mandate that "close calls regarding causation are resolved in favor of injured claimants," *Althen*, 418 F.3d at 1280 (citing *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)), and that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program," *Knudsen*, 35 F.3d at 549; *see also Althen*, 418 F.3d at 1280 ("While this case involves . . . a [vaccine-illness] sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.").

If petitioner satisfies both the first and second *Althen* factors, thereby establishing his *prima facie* case, the burden will shift to respondent to show, by a preponderance of the evidence, "that the injury was in fact caused by factors unrelated to the administration of the vaccine." *Walther*, 485 F.3d at 1151.

## CONCLUSION

For the foregoing reasons, petitioner's motion for review is **GRANTED**, the Special Master's March 3, 2011 Compensation Decision is **REVERSED**, and the case is **REMANDED** to the Special Master for further proceedings consistent with this Opinion and Order. *See* RCFC App'x B, Rule 28.1.

**IT IS SO ORDERED.**

s/ George W. Miller  
GEORGE W. MILLER  
Judge