Health Care Law – Resolving disputed diagnoses prior to applying the \textit{Althen} test in claims brought pursuant to the National Childhood Vaccine Act—\textit{Lombardi v. Sec’y of Health \& Human Services}, 656 F.3d 1343 (Fed. Cir. 2011)

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NCVIA claim differ depending on whether the alleged injury is listed on the Vaccine Injury Table. To state a claim for an off-Table injury, the claimant must satisfy the test set forth in Althen v. Sec'y of Health & Human Services (the “Althen test”), and prove the vaccine proximately caused the injury. In Lombardi v. Sec'y of Health & Human Services, the United States Court of Appeals for the Federal Circuit considered whether the Court of Federal Claims properly denied claimant Cheryl Lombardi compensation under the

recovery in a number of ways; for example, in the event someone dies from a childhood vaccine, his or her estate can recover no more than $250,000. 42 U.S.C. § 300aa-15(a)(2). Similarly, the claimant cannot recover more than $250,000 for pain and suffering and emotional distress. Id. § 300aa-15(a)(4). Although claimants cannot recover punitive damages, they are entitled to compensation for actual and anticipated loss of earnings, attorney’s fees, and other costs. Id. § 300aa-15(e)(1)(A)-(B).

See 42 U.S.C. § 300aa-14; H.R. REP. NO. 99-908, PR. 1, AT 19 (1986), REPRINTED IN 1986 U.S.C.C.A.N. 6344, 6360. The table lists common childhood vaccines, their possible adverse effects, and the time frame in which these effects will likely arise. 42 U.S.C. § 300aa-14. The biggest difference between on and off-Table claims is that causation is presumed when the injury appears on the Table. See id. §§ 300aa-13(a)(1), 300aa-14(a); Althen v. Sec'y of Health & Human Services, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (noting a statutory presumption of causation). In contrast, with off-Table injuries, the claimant must prove causation. Althen, 418 F.3d at 1279.

The legislative history of the NCVIA further highlights the differences between on- and off-Table injuries, stating:

If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both of these cases, however, the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a claimant. (Such a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.)


4 418 F.3d 1274 (Fed. Cir. 2005).

5 Id. at 1282; see infra notes 33-44 and accompanying text (discussing requirements to make a valid NCVIA claim). If the claimant presents a valid prima facie claim, he or she may recover unless the government proves by preponderance of the evidence that the vaccine did not cause the injury. Knudsen ex rel. Knudsen v. Sec'y of Dep't of Health & Human Services, 35 F.3d 543, 547 (Fed. Cir. 1994) (denying recovery where the government proved by preponderance of the evidence that viral infection caused injury).

6 656 F.3d 1343 (Fed. Cir. 2011).

7 For an explanation of the Court of Federal Claims see infra note 27.
NCVIA for failure to establish a causal link between her injuries and the Hepatitis B vaccine. The court affirmed the decision of the Court of Federal Claims, and Special Master Christian J. Moran held that Lombardi failed to prove by preponderance of the evidence that the vaccine caused her injuries.

Cheryl Lombardi received three doses of the Hepatitis B vaccine in 1997. Although Lombardi suffered no adverse reaction from the initial two doses, she visited the emergency room with right flank and chest pain twelve days after receiving the third and final dose. The hospital diagnosed Lombardi with atypical chest pain and discharged her the same day, but she returned to the emergency room five days later with the same symptoms. The doctors performed several tests, but did not arrive at a definitive diagnosis. Over the next several years, Lombardi visited numerous specialists who reached varying medical conclusions regarding her unresolved symptoms. In 1998, Lombardi began inquiring about a possible link between her

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8 *Lombardi*, 656 F.3d at 1345.
9 For an explanation of Office of the Special Masters see infra note 27.
10 *Lombardi*, 656 F.3d at 1356.
11 Id. at 1345. Lombardi received the first dose on April 1, 1997, and the second dose on May 6, 1997. Id. No injury arose from either injection. Id. She received the third dose on October 28, 1997, and checked into the emergency room on November 9, 1997. Id. The emergency room staff could not determine the cause of her right flank and chest pain. Id. at 1345-46. The emergency room staff again could not identify the cause of Lombardi's pain during her subsequent visit on November 14, 1997. *Lombardi*, 656 F.3d at 1346.
12 Id. at 1345-46.
13 Id. at 1346.
14 Id.
15 Id. Lombardi first sought treatment from Dr. Michael Conaway on January 15, 1998. Id. She listed symptoms including right flank pain, weakness, and fatigue. *Lombardi*, 656 F.3d at 1346. Dr. Conaway ordered blood tests and discovered that Lombardi had a positive antinuclear antibody rate ("ANA") rate. Id. Based on the blood tests and a chest X-ray that revealed pleural thickening, Dr. Conaway believed Lombardi may have been suffering from systemic lupus erythematosus ("SLE"). Id. In February 1998, rheumatologist Dr. Teresa George examined Lombardi and determined that her symptoms did not indicate SLE. Id. Dr. George noted the elevated ANA rate, but based her diagnosis on the fact that all other "serologies" indicative of SLE were normal. Id. Lombardi visited Dr. Conaway three times in February and March 1998 with the same symptoms. Id. Dr. Conaway could not identify a cause and referred Lombardi to the Cleveland Clinic. *Lombardi*, 656 F.3d at 1346. Lombardi visited the Cleveland Clinic on March 16, 1998, and Dr. John Campbell noted that her blood tests revealed a vitamin B12 deficiency and an elevated level of methylmalonic acid. Id. Further tests indicated Lombardi suffered from decreased bone density and osteoporosis in her left hip. Id. Dr. Campbell's notes, written on a form titled "impressions," stated "post Hepatitis B-fatigue." Id. On April 9, 1998, neurologist Dr. Patrick Sweeney of the Cleveland Clinic examined Lombardi and stated that he "doubt[ed] neuro disease." Id. Lombardi met with several other Cleveland Clinic specialists,
symptoms and the Hepatitis B vaccine.\textsuperscript{16} After two doctors concluded the vaccine was a possible cause, and two other physicians decided it was the probable cause, Lombardi filed a petition under the NCVIA seeking compensation for her injuries.\textsuperscript{17}

At trial, Lombardi claimed the vaccine caused three different injuries—transverse myelitis, chronic fatigue syndrome, and systemic lupus erythematosus ("SLE").\textsuperscript{18} None of the ailments appeared on the Vaccine Injury Table, so they were classified as off-Table injuries.\textsuperscript{19} At the initial evidentiary hearing on November 1-2, 2007, Lombardi’s expert witness testified that her transverse myelitis resulted from the Hepatitis B vaccine.\textsuperscript{20} The government’s expert, on the other hand, disputed the causal
link between the vaccine and Lombardi’s injuries. At the second evidentiary hearing, on April 9, 2008, Lombardi’s expert asserted that her chronic fatigue syndrome was a “direct” result of the vaccine. In response, the government’s expert offered numerous alternative diagnoses, none of which was chronic fatigue syndrome. At the final evidentiary hearing on November 25, 2008, Lombardi’s expert stated that her symptoms met the “diagnostic criteria” for SLE, but the government expert testified that Lombardi’s condition did not meet the diagnostic criteria set forth by the American College of Rheumatology.

Special Master Christian J. Moran ultimately denied the claim on the theory that Lombardi failed to prove she suffered from transverse myelitis, chronic fatigue syndrome, or SLE. Special Master Moran concluded that Lombardi failed to prove the first element of the three-pronged Althen test—a medical theory causally connecting the vaccine to an injury; therefore, he did not analyze the remaining factors. The United States Court of Federal Claims affirmed the Special Master’s decision.

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21 Id. at 1348-49. Dr. Thomas Leist believed Lombardi suffered from: “(1) a vitamin B12 deficiency; (2) an evolving, mixed collagen vascular disorder; and (3) osteopenia, with degenerative changes in her cervical spine.” Id. at 1349.

22 Lombardi, 656 F.3d at 1349.

23 Id. Dr. Lawrence Kagen’s diagnoses included: “(1) a mixed connective tissue disease with rheumatoid arthritis overlap, (2) osteoarthritis with spinal cord and nerve root compression, (3) a nutritional deficit due to a lack of vitamin B 12 in her diet, (4) an allergic reaction to mold, and (5) depression.” Id.

24 Id.


26 Id.; see also infra note 34 and accompanying text (discussing Althen test).

States Court of Appeals for the Federal Circuit also affirmed, holding that Lombardi failed to prove by a preponderance of the evidence that her injuries resulted from the Hepatitis B vaccine.\textsuperscript{28}

Congress enacted the NCVIA to provide no fault compensation for injuries caused by childhood vaccines in order to ease the potential burden on both claimants and manufacturers.\textsuperscript{29} The NCVIA not only allows claimants the opportunity to avoid the tribulations of the tort system, but also limits the potential liability of vaccine manufacturers.\textsuperscript{30} For example, in providing a less stringent avenue toward

\textsuperscript{28} Lombardi, 656 F.3d at 1356. In Althen, the court explained that a claimant who satisfies the three-part test is entitled to compensation unless the government can prove by a preponderance of the evidence that the claimant’s injury is not related to the vaccine. \textit{Althen}, 418 F.3d at 1278.


compensation, Congress hoped claimants would forego traditional tort litigation.31 By funneling vaccine claims away from the tort system and thereby limiting the insurance and litigation costs to manufacturers, Congress hoped to stem the rising costs of childhood vaccines and encourage manufacturers to continue producing and creating new vaccines.32

In *Althen v. Sec'y of Health & Human Services*, the United States Court of Appeals for the Federal Circuit issued the authoritative opinion on the elements of an NCVIA claim.33 The so-called "*Althen* test" required the plaintiff to demonstrate: "(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."34 *Althen* also stands for the proposition that the claimant does not bear the burden of disproving alternative causes in establishing the elements of the *Althen* test.35 Specifically, the court emphasized that the government could only present an alternative theory of causation after the claimant had first presented a valid prima facie case.36 In other words, the government could only assert its alternative theory to rebut the claimant's successful satisfaction of the *Althen* test; it could not assert a causal theory to prevent the claimant

31 Blackmon, 267 F. Supp. 2d at 671. Notably, claimants cannot recover under both the NCVIA and a tort claim; it is one or the other. See id. at 671–72. The claimant can either accept the decision of the special master and waive his or her right to bring a future civil suit against the manufacturer, or reject the decision and bring a civil suit. See 42 U.S.C. § 300aa-11(a)(2)(A); Betsy J. Grey, The Plague of Causation in the National Childhood Vaccine Injury Act, 48 HARV. J. ON LEGIS. 343, 353 n.66 (2011).

32 See Militrano, 769 N.Y.S.2d at 845; Clare Looker & Heath Kelly, No-Fault Compensation Following Adverse Events Attributed to Vaccination: A Review of International Programmes, 89 BULL. OF THE WORLD HEALTH ORG. 371, 371-72 (2011), available at http://www.who.int/bulletin/volumes/89/5/10-081901.pdf (noting one purpose of NCVIA is protecting vaccine manufacturers). Prior to the passage of the NCVIA, for example, many manufactures were forced to increase their prices exponentially in the face of uncertain liability. *Militrano*, 769 N.Y.S.2d at 845. The result was excessively expensive vaccines, supply shortages, reduced research, and closure of many smaller manufacturers. Emily Marcus Levine et al., Legal Issues, in VACCINES ch. 75 (5th ed., 2008). Thus, encouraging vaccine manufacturers to continue researching and producing was a major motivating factor in enacting the NCVIA. See McDonald v. Lederle Laboratories, 775 A.2d 528, 533 (N.J. Super. Ct. App. Div. 2001); Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir.1994).

33 *Althen*, 418 F.3d at 1278.

34 Id.

35 Id. The court explained that if the claimant proved the elements of the *Althen* test she could "recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." Id.

36 Id.
from satisfying the test. In keeping with the Congressional deference to petitioners, the court in *Althen* also confirmed that the NCVIA employs a preponderance of the evidence standard for off-Table injuries. In fact, the court took affirmative steps to refute the movement toward even a minimally elevated burden of proof.

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37 Id.

38 See *Althen*, 418 F.3d at 1279-80 (confirming the preponderance of the evidence standard). The statute unambiguously states that the standard is “preponderance of the evidence.” 42 U.S.C. § 300aa-13(a)(1) (2006). Prior to the decision in *Althen* there was a question as to whether the courts sought to elevate the standard of proof. See *Althen*, 418 F.3d at 1279-80. For example, in *Althen*, the government argued that there existed a definite trend in the case law suggesting that off-Table injuries require more “heavy lifting” on the part of the plaintiff than on-Table injuries because causation in fact is not presumed. *Id.* at 1280; see Hodges v. Sec'y of Dep't of Health & Human Services, 9 F.3d 958, 961 (Fed. Cir. 1993) (emphasizing that the “heavy lifting” required to prove causation is an especially “heavy” burden); accord Lampe v. Sec'y of Health & Human Services, 219 F.3d 1357, 1360 (Fed. Cir. 2000). However, the court in *Grant v. Secretary of Department of Health & Human Services* explained that the heavy lifting simply connoted a difference in the claimant’s burden of proof between on and off table injuries. 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). In on-Table cases, the Vaccine Table essentially proves causation by operation of law. *Id.* at 1147. In contrast, off-Table injuries require proof of causation by preponderance of the evidence, rather than as by operation of law. *Id.* at 1148. The courts recognized that the legislative intent was to allow proof of causation of off-Table injuries because the table itself did not represent an exhaustive list of possible injuries. *Id.* Congress stated:

> The Committee recognizes that there is public debate over the incidence of illnesses that coincidently occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines (discussed below in Section 2119) may propose to revise the Table, as provided below in Section 2114. Until such time, however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.


39 *Althen*, 418 F.3d at 1279-80. Early off-Table cases had stated that the plaintiff had to demonstrate the causal connection between immunization and injury through “scientific studies or expert medical testimony[.]” *Grant*, 956 F.2d at 1148 (emphasis added). The court in *Stevens* took this one step further by requiring that supporting medical literature accompany every claim. Stevens v. Sec'y of Dep’t of Health & Human Services, No. 99-594V, 2001 WL 387418, at *24, *30 (Fed. Cl. 2001), abrogated by *Althen* v. Sec’y of Dep’t of Health & Human Services, 58 Fed. Cl. 270 (2003). The *Stevens* court added this additional hurdle to ensure that the medical community
In keeping with earlier NCVIA cases, the Althen court reaffirmed the principle that the special master was tasked with applying the law on a case-by-case basis, not effecting substantive change to the NCVIA. As the court stated, “The special master’s role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard to be used in causation-in-fact cases.” Moreover, the Althen court affirmed the special master was not tasked with determining the underlying science behind vaccine related injuries. Instead of diagnosing the injury, the special master was to decide if the claimant proved the vaccine caused the injury by preponderance of the evidence. Thus, the court also confirmed that the NCVIA had actually recognized the possibility of a link between the vaccine and alleged injury. Stevens, 2001 WL 387418, at *24. The court described this as a minimal burden because the plaintiff could offer proof in the form of “epidemiological studies, animal studies, case series, case reports, anecdotal reports, journal articles, manufacturing disclosures, Physician Desk Reference citations, and institutional findings, similar to those reported by the Institute of Medicine.” Id. Moreover, the court emphasized that the literature did not have to evince a substantial link between the vaccine and the injury, but merely demonstrate that the medical community had recognized the possibility of an association. Id. Nonetheless, the Althen court abrogated the decision stating that the additional requirement impermissibly raised the burden of proof. Althen, 418 F.3d at 1280. Specifically, the court stated the added requirement, “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” Id; see 42 U.S.C. § 300aa-13(a)(1) (2006) (permitting proof by medical opinion). Moreover, the court reiterated the sentiment in Knudsen that requiring the claimant to identify the specific biological mechanisms linking the disease to the vaccination would contravene Congress’ desire to avoid typical tort litigation (recall that the purpose of the NCVIA was to create a quick and easy mode of compensation). Knudsen ex rel. Knudsen v. Sec’y of Dep’t of Health & Human Services, 35 F.3d 543, 547, 549 (Fed. Cir. 1994).

Althen, 418 F.3d at 1280-81. Akin to the description of the special master’s role under Federal Rule of Civil Procedure 53(b), the special master’s role under the NCVIA is to simply apply the law, not to displace the interpretive role of the courts. Id. at 1281; see also La Buy v. Howes Leather Co., 352 U.S. 249, 256 (1957) (describing special master’s duties under Federal Rule of Procedure 54(b)). For more on the role of special masters see generally Erica A. Little, The Role of Special Masters in Off-Table Vaccination Compensation Cases: Assuring Flexibility over Certainty, 16 FED. CIR. B.J. 355 (2007).

Id; accord Knudsen, 35 F.3d at 549.

Althen, 418 F.3d at 1280-81; see also Strother v. Sec’y of Dep’t of Health & Human Services, 18 Cl. Ct. 816, 820 (1989) (noting that plaintiffs must show causation in fact to prevail). Causation in fact “requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.” Id; accord Hines ex rel. Sevier v. Sec’y of Dep’t of Health & Human Services, 21 Cl. Ct. 634, 643 (1990), aff’d, 940 F.2d 1518 (Fed. Cir. 1991). A plaintiff must demonstrate more than a simple temporal relationship between immunization and injury
employs a preponderance of the evidence standard for off-Table injuries.\textsuperscript{44}

The burden of proof remained the same under the NVCIA until the court in \textit{Broekelschen v. Secretary of Health \& Human Services}\textsuperscript{45} espoused an additional requirement applicable in cases where the two parties dispute the diagnosis.\textsuperscript{46} In such cases, the court stipulated that, as a prerequisite to performing the \textit{Althen} analysis, the special master should determine which diagnosis is best supported by the evidence.\textsuperscript{47} This decision seemed to contradict the previous sentiment that the special master should only consider the government's alternative theory of causation to rebut the claimant's prima facie proof of causation.\textsuperscript{48} For instance, previously, if the claimant could prove all five

and must demonstrate that the injury more probably than not resulted from the vaccine. \textit{Strother}, 18 Cl. Ct. at 820. In these cases, “petitioners must show by a preponderance of the evidence either that they sustained a Table injury or that the vaccine in fact caused their injury.” \textit{Id.} at 818. The special master should employ the same preponderance of the evidence standard typical in tort cases. \textit{Moberly ex rel. Moberly v. Sec'y of Health \& Human Services}, 592 F.3d 1315, 1322 (Fed. Cir. 2010).

\textsuperscript{44} See \textit{Althen}, 418 F.3d at 1279-80 (confirming the preponderance of the evidence standard). The statute unambiguously states that the standard is “preponderance of the evidence.” 42 U.S.C. § 300aa-13(a)(1). However, prior to the decision in \textit{Althen} there was at least an argument that the court had sought to elevate the standard. See \textit{Althen}, 418 F.3d at 1279-80. For example, in \textit{Althen}, the government argued that there was a definite trend in the case law suggesting that more “heavy lifting” was required of off-Table claimants. \textit{Id.} at 1280; see \textit{Hodges v. Sec'y of Dep't of Health \& Human Services}, 9 F.3d 958, 961 (Fed. Cir. 1993) (emphasizing that the “heavy lifting” required to prove causation is an especially “heavy” burden); \textit{accord Lampe v. Sec'y of Health \& Human Services}, 219 F.3d 1357, 1360 (Fed. Cir. 2000). However, the court explained that the concept of “heavy lifting” did not affect the preponderance standard. \textit{Althen}, 418 F.3d at 1280. Instead, “heavy lifting” served to distinguish the claimant’s differing burdens between on and off-Table claims. \textit{Hodges}, 9 F.3d at 961. Whereas on-Table cases carry a presumption of causation, off-Table injuries more “heavy lifting” because the claimant must prove causation by preponderance of the evidence. \textit{Althen}, 418 F.3d at 1280.

\textsuperscript{45} 618 F.3d 1339, 1346 (Fed. Cir. 2010).

\textsuperscript{46} \textit{Id.} The court decreed that determining the injury was a prerequisite to the \textit{Althen} analysis. \textit{Id.}

\textsuperscript{47} \textit{Id.}

\textsuperscript{48} 42 U.S.C. § 300aa-13(a). Section 300aa-13(a) stipulates that “on the record as a whole,” the special master must find (1) the claimant “has demonstrated by a preponderance of evidence the matters required in the petition by section 300aa-11(c)(1) . . .” and (2) “there is not a preponderance of the evidence that the . . . death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.” 42 U.S.C. § 300aa-13(a)(1) (emphasis added) (quoted in Doe ex rel. Doe v. Sec'y of Health \& Human Services, 601 F.3d 1349, 1357 (Fed. Cir. 2010), \textit{cert. denied}, 131 S. Ct. 573 (2010)). Prior to \textit{Broekelschen}, to fulfill requirement (1) and present a prima facie case, the claimant simply had to satisfy the \textit{Althen} test. \textit{Doe}, 601 F.3d at 1357. After that, the special master could deny compensation if the government proved the injury resulted from a “factor unrelated” to the vaccine (i.e. if the government could prove an alternative theory of diagnosis or causation). \textit{Id.}
elements of the *Althen* test, he or she could recover—despite the possibility of alternative diagnoses; all that mattered was that the claimant’s particular diagnosis and theory of causation passed the *Althen* test. In contrast, under *Broekelschen*, the claimant cannot reach the *Althen* analysis without first disproving alternative diagnoses. The decision was met with a rigorous dissent arguing that the additional hurdle thwarted legislative intent by raising the burden of proof and inflating the authority of special masters by allowing them to interpret and alter the NCVIA.

In *Lombardi v. Sec'y of Health & Human Services*, the United States Court of Federal Appeals adhered to recent trends in case law by upholding the special master’s decision to choose between differing diagnoses prior to applying the *Althen* test appears to condone the special master’s decision to do more than simply apply the law. However, the majority argued that the additional hurdle only becomes relevant in a limited factual scenario when no clear diagnosis exists, and thus does not represent a substantive change to the NCVIA. Moreover, in a sense, there is no additional hurdle because determining whether an injury exists is an implicit component of a cause of action for a “vaccine related injury.” The dissent contrasted the specific requirement that the claimant demonstrate an injury with the broad language of the NCVIA. The dissent emphasized that even without a definitive diagnosis, a claimant can satisfy the elements of the NCVIA by making the required showing of causation.

Circuit Judge Haldane Robert Mayer ultimately concluded that the majority’s decision, “is not supported by statute, case law, or logic, and its effect was to impermissibly heighten Broekelschen’s burden.” For more on the history of imposing additional standards to the *Althen* test, see Meredith Daniels, Note, *Special Masters in the National Vaccine Injury Compensation Program: Placing A Heightened Burden on Vaccine Program Petitioners by Straying from Precedent and Congressional Intent*, 6 J. Health & Biomedical L. 79, 92-96 (2010).
authority to make preliminary diagnostic determinations in cases involving disputed diagnoses.\(^5\) Although the court highlighted the \textit{Althen} test as the ultimate determinant in settling a claim for an off-Table injury, the court concluded that the Special Master could not analyze the causal link between the vaccine and injury without first deciding if an injury in fact existed.\(^3\) Circuit Judge Kathleen McDonald O’Malley argued vigorously that the continued application of the \textit{Broekelschen} standard impermissibly altered the \textit{Althen} standard and incorrectly allowed special masters to effectively assert a diagnosis.\(^4\) Nonetheless, Circuit Judge O’Malley concurred in the majority opinion that Lombardi failed to prove she suffered from transverse myelitis, chronic fatigue syndrome, or SLE.\(^5\)

The \textit{Lombardi} case is particularly instructive because it demonstrates the strength of the arguments both for and against the pre-\textit{Althen} step and the need for Congress to intervene and settle the debate.\(^5\)\(^6\) First, consider the compelling argument that imposing a pre-\textit{Althen} step violates the statutory intent of the NCVIA by increasing the evidentiary burden of claimants and thwarting Congress’s intent to provide claimants with a quick, easy, and efficient means of redress.\(^5\)\(^7\) For example, because scientific evidence is often lacking and mostly conjectural in off-Table claims, claimants will struggle to surmount

\(^{52}\) Lombardi v. Sec'y of Health & Human Services, 656 F.3d 1343, 1352 (Fed. Cir. 2011). The court stated, “[U]nder \textit{Broekelschen}, identification of a claimant’s injury is a prerequisite to an \textit{Althen} analysis of causation.” \textit{Id.}

\(^{53}\) \textit{Id.} at 1352. The court explained, “if the existence and nature of the injury itself is in dispute, it is the special master’s duty to first determine which injury was best supported by the evidence presented in the record before applying the \textit{Althen} test to determine causation of that injury.” \textit{Id.} Thus, the issue of causation turns on the existence of an injury. \textit{Id.}

\(^{54}\) \textit{Id.} at 1356-58 (O’Malley, J., concurring). Circuit Judge O’Malley concurred in the decision but wrote separately to address the perceived impropriety of \textit{Broekelschen}. \textit{Lombardi}, 656 F.3d at 1356. Judge O’Malley echoed the \textit{Broekelschen} dissent by arguing that the court strayed too far from the \textit{Althen} standard. \textit{Id.} at 1357-58. Specifically, she argued that the new standard impermissibly elevated the claimant’s burden of proof because the statute does not require a “definitively diagnosed injury.” \textit{Id.} at 1357. Judge O’Malley also opposed the seemingly enhanced level of authority granted to special masters such that they might make an independent diagnosis whenever the government offered a possible alternative. \textit{Id.} at 1358. Ultimately, Judge O’Malley concluded that \textit{Broekelschen} contravened statutory intent by rendering the process neither quick, easy, certain, or generous. \textit{Id.}

\(^{55}\) \textit{Id.} at 1356.

\(^{56}\) \textit{See infra} notes 57-67 and accompanying text. Although the pre-\textit{Althen} step may be efficacious, the goal of this memorandum is to highlight \textit{Lombardi} as a case that offers Congress the chance to take a side in this well-argued debate. \textit{See infra} text accompanying notes 65-66. The two sides offer such persuasive points that Congressional intervention is not only warranted but also needed. \textit{See infra} note 65, 68.

\(^{57}\) \textit{See supra} notes 30-32.
the burden of proving their diagnosis and disproving that of the government. Moreover, requiring claimants to disprove alternative causes at the outset of their cases will likely result in increasingly adversarial litigation, prolonged cases, and fewer awards. In the face of increasing costs, delays, and evidentiary burdens, the NCVIA would seem decreasingly palatable as an alternative to traditional tort litigation. If more claimants decide to pursue tort litigation, the NCVIA would fail in its goal to protect vaccine manufacturers from expensive litigation and insurance costs.

On the other hand, the Lombardi majority makes the practical yet poignant argument that to show a vaccine-caused harm, one must logically show that harm occurred. The majority argued that proving diagnosis is not an additional step, but an implicit requirement to the first prong of the Althen test. As the majority noted, establishing causation contains the inherent assumption that an injury in fact exists.

58 Katherine E. Strong, Note, Proving Causation Under the Vaccine Injury Act: A New Approach for a New Day, 75 GEO. WASH. L. REV. 426, 429 (2007). Strong notes that proving an off-Table claim “can be a very heavy burden due to the lack of definitive scientific and medical knowledge regarding the injuries associated with many vaccinations.” Id. The problem is that off-Table claims are often based on novel theories of disease etiology and causation that the medical field cannot yet prove through scientific evidence. See Grey, supra note 31, at 407, 412. As Grey notes, “petitioners are forced to litigate long before epidemiologic or other research is available.” Id. at 407.

59 Grey, supra note 31, at 402. For claimants with “injuries whose exact cause cannot be proven,” Grey suggests that a heightened sufficiency standard in establishing a preponderance of the evidence “would likely result in prolonged proceedings, increased transaction costs, more difficult and more adversarial proceedings, along with fewer awards.” Id. at 402.

60 See supra notes 30-31 and accompanying text.

61 See supra notes 30-32 and accompanying text.

62 Lombardi, 656 F.3d at 1352.

63 Id. at 1352; see also supra note 51. Broekelschen adherents would argue that the special master neither elevated the standard of proof nor reshaped the law because the fundamental test remains unchanged. See Broekelschen v. Sec'y of Health & Human Services, 618 F.3d 1339, 1349 (Fed. Cir. 2010). The only difference is that the unique facts in cases of disputed diagnosis implicate an implicit requirement in the causal analysis that the claimant must actually suffer from the disease he or she claims. Id. Otherwise, one is making a bare assertion that the vaccine can potentially cause this specific injury without regard to whether the claimant actually suffered the injury. Id. Thus, although the court suggested that determining whether an injury exists must precede the Althen analysis, it actually seems like the first prong of the Althen test implicitly requires a finding of injury. Id. Therefore, the standard of proof under Broekelschen arguably remains the same. Id. 64 See Lombardi, 656 F.3d at 1352. The crux of the NCVIA is to compensate for vaccine-related injury. Broekelschen, 618 F.3d at 1346. To argue that defining an injury is not an inherent part of a claim seems counter intuitive. See id. However, one must consider that Congress allowed for off-Table claims in order to allow flexibility and to permit claimants to recover for injuries even though science had yet to establish a causal link to a vaccine. See infra note 76. The courts in
Although Circuit Judge O'Malley and the Broekelschen dissent are correct in noting that a primary motivation of the NCVIA was to provide an efficient and generous avenue of redress for claimants, the claimants must demonstrate the existence of injury in furtherance of their claims.\footnote{5} Despite the policy arguments against the requirement, the most fundamental purpose of the NCVIA was to compensate for vaccine based injury.\footnote{66} Nonetheless, as Lombardi so aptly demonstrates, requiring the special master to determine the injury creates another problem because it forces the special master to effectively assert a diagnosis rather than just weigh the sufficiency of the evidence.\footnote{67}

In determining the sufficiency of the evidence, the special master has no alternative but to assert a diagnosis.\footnote{68} For example, in the Lombardi case, with regard to SLE, the special master independently applied the eleven criteria for the disease outlined by the American College of Rheumatologists, and, contrary to the findings of Lombardi's medical expert, found that Lombardi did not suffer from SLE.\footnote{69} Here, one

\footnotesize{Broekelschen and Lombardi did not claim that claimants cannot argue for some novel causal link. Lombardi, 656 F.3d at 1353; Broekelschen, 618 F.3d at 1346. Instead, they proclaimed that the claimant must first demonstrate an injury to which the vaccine could be linked. Id.\footnote{65} Broekelschen, 618 F.3d at 1351-52 (Mayer, C.J., dissenting) (discussing requirement to show evidence of an injury). Congress clearly designed the NCVIA to quickly and generously compensate victims, but some threshold must exist to bar unsuitable claims. 42 U.S.C. §300aa-11 (2006) (establishing limits on compensation and filing requirements). Otherwise, Congress would have stipulated that any person who received a vaccine could recover for potentially any symptom whether or not some degree of relatedness was established. Id. §300(a)(a)-16 (identifying and explaining limitations on compensation from vaccine related injuries). As Grey notes, "insuring victims against risks from vaccines does not remove the need to prove connection to the vaccine." Grey, supra note 31, at 414. For example, "[n]ot every child with epilepsy who had a seizure in time relationship to [a vaccine] would have to be considered to have [the vaccine] as the etiology." Id. (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Services, 592 F.3d 1315, 1320 (Fed. Cir. 2010)); see also supra notes 30, 62 and accompanying text.\footnote{66} See supra note 64; see also 42 U.S.C. §300aa-10 (a) (stating the purpose of the NCVIA).\footnote{67} See infra notes 69-70 and accompanying text.\footnote{68} See generally Vaccine Program/Office of Special Masters, supra note 27. Under the current system, the special master plays the role of the doctor. Id. For instance, a doctor normally (1) investigates the nature of the patient's symptoms, (2) applies diagnostic criteria, and (3) decides between a series of possible diagnoses. See supra note 40 and accompanying text. The goal should be to make special masters look less like doctors and more like judges by creating a legal standard that allows them to judge the sufficiency of the evidence without performing steps (1) or (2). See supra note 40 and accompanying text. The special master should apply the law, not analyze the science. See supra note 40 and accompanying text.\footnote{69} Lombardi, 656 F.3d at 1355. In fact, the special master expressly rejected Lombardi's expert witness Dr. Schoenfeld's evaluation of three of the criteria in favor of her own. Id. The differing conclusions between the expert and special master may reflect the fact that "science and law}
could argue that the special master crossed the line between distilling a diagnosis as a matter of law and asserting a diagnosis as a matter of medicine, because rather than weighing the sufficiency of the evidence, he independently evaluated Lombardi's symptoms and determined she did not suffer from SLE. However, the line is blurred in these types of cases to an extent because there is no distinction between evaluating the evidence and making a diagnosis. For example, to resolve a dispute between competing diagnoses, the special master must necessarily determine the more probable diagnosis. Moreover, to determine the more probable diagnosis, the special master must necessarily employ the applicable evaluative criteria (i.e. the criteria outlined by the American College of Rheumatologists). In applying the diagnostic criteria to the claimant's symptoms, the special master must necessarily assess the symptoms and effectively assert a diagnosis.

Rather than forcing the special master to independently evaluate the claimant's symptoms to determine a diagnosis, Congress should define the standard at which point the claimant's scientific evidence rises to a level of legal proof. The goal is to allow special masters to judge the sufficiency of scientific evidence without analyzing the underpinnings and etiology of that evidence. Thus, Congress should intervene and require different levels of certainty to determine the validity of a proposition.

70 See supra note 43 and accompanying text. When the special master becomes an active agent in making a diagnosis as a matter of medicine, he or she violates Congress' intent. See Knudsen ex rel. Knudsen v. Sec'y of Dep't of Health & Human Services, 35 F.3d 543, 549 (Fed. Cir. 1994) (stating special masters are not to diagnose injuries). In this case the special master seemed to cross the line between administering a legal standard and actively asserting a diagnosis. See id.

71 See supra note 51 and accompanying text. The crucial point is that there is supposed to be a distinction between a special master asserting an independent medical diagnosis and concluding as a matter of law that a claimant has proved a diagnosis by a preponderance of the evidence. See generally Vaccine Program/Office of Special Masters, supra note 27. However, in claims where the diagnosis is disputed, this distinction disappears and the special master is left with no choice but to effectively diagnose the claimant's injury. See supra note 51 and accompanying text.

72 See Lombardi, 656 F.3d at 1353-57 (describing the special master's analysis of Lombardi's injuries).

73 See id. at 1354. See also Doe v. Sec'y of Health & Human Services, No. 99-VV-523, 2010 WL 1506010, at *7 (Fed. Cl. 2010).

74 See Doe, No. 99-VV-523, 2010 WL 1506010. Logically, to determine whether a person suffers from a given disease, a special master would have to investigate the nature of the symptoms. Id.

75 See Grey, supra note 31, at 349. As previously noted, "science and law require different levels of certainty to determine the validity of a proposition." Id.

76 See generally DAVID L. FAIGMAN ET AL., MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY § 1:1-7 (2011-2012 ed. 2011) (describing various tests developed to weigh the sufficiency of scientific evidence). The tension lies in allowing special
elucidate a clear standard that allows special masters to determine the sufficiency of evidence as a matter of law rather than forcing them to make a diagnosis as a matter of medicine. Given the fact that the NCVIA allows special masters to utilize independent experts, and independent experts already contribute in other areas of the law, perhaps an independent medical arbiter could intervene in these limited factual scenarios. The independent medical expert could deliberate alongside the special master and analyze the scientific evidence, and the special master could then use the expert’s conclusions in determining whether the claimant met his or her legal burden. Thus, the expert would analyze the science, and the special master would apply the legal standard.

In Lombardi v. Sec'y of Health & Human Services, the United States Court of Appeals for the Federal Circuit faced the question whether a claimant must prove a cognizable injury before the traditional Althen analysis. The court followed recent precedent, and held that determining whether a given vaccine caused an injury requires an initial finding that an injury in fact exists. Although contrary to the NCVIA’s purpose of providing quick and generous compensation to claimants, defining an injury masters sufficient authority to adjudicate disputes and recognizing the reality that off-Table claimants often argue for a causal link that science cannot yet prove definitively. See Grey, supra note 31, at 409. How else can the special master solve a claim based on novel science without analyzing the science? The whole claim revolves around the practicality, probability, and etiological underpinnings of the scientific evidence. See id. Thus, to evaluate off-Table claims, special masters must evaluate these factors to determine how to quantify the novel theory into law. See id. at 407. Indeed, the suggestion that Congress create a standard that synthesizes unproven scientific evidence into legal proof is much easier said than done. See Jennifer L. Mnookin, Expert Evidence, Partisanship, and Epistemic Competence, 73 BROOK. L. REV. 1009, 1023 (2008) (asking “[h]ow do you aggregate the variety of imperfect evidence into a conclusion about general causation? How do you assess the disparate items and make a judgment about the probability that the substance is capable of causing the harm at issue?”). See Mnookin, supra note 76, at 1031-32. Since scientific and legal determinations do not neatly align, Congress should clarify when a scientific diagnosis sufficiently satisfies the legal standard. See generally id. Congress, of course, must define the legal standard and what types of scientific evidence would meet it. See Grey, supra note 31, at 413. One possibility is to “create a minimum level of sufficiency of evidence by merely requiring some temporal relationship with some plausible scientific theory.” See id. at 403. The concept is obviously rudimentary and would require serious discussion (i.e. Congress would have to find some way to quantify different levels of scientific certainty), but the key point is developing some system whereby special masters without medical expertise do not render expert medical opinions. See id. See Grey, supra note 31, at 409-10 (discussing the costs and benefits of employing the services such independent experts).

Id.

Id.

See Lombardi v. Sec'y of Health & Human Services, 656 F.3d 1343, 1351 (Fed. Cir. 2011).

Id. at 1353.
is an integral part of compensating for vaccine related injury.\textsuperscript{83} The Special Master violated statutory intent by asserting an independent diagnosis in this case.\textsuperscript{84} To fulfill his statutory obligation and resolve the claim, however, the Special Master had no option but to investigate the nature of the injury.\textsuperscript{85} Moreover, because the line between asserting a diagnosis and judging the sufficiency of the evidence is virtually nonexistent in cases of disputed diagnoses, Congress should intervene and formally define the level of scientific proof the claimant must establish to satisfy his or her legal burden.\textsuperscript{86}

\textsuperscript{83 Id.}
\textsuperscript{84 Id.}
\textsuperscript{85 Id.}
\textsuperscript{86 See supra notes 30-32 and accompanying text.}