United States Court of Appeals for the Federal Circuit

JENNIFER HIBBARD,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2012-5007

Appeal from the United States Court of Federal Claims in Case No. 07-VV-446, Judge Thomas C. Wheeler.

Decided: November 2, 2012

SYLVIA CHIN-CAPLAN, Conway, Homer & Chin-Caplan, P.C. of Boston, Massachusetts, argued for petitioner-appellant. On the brief was RONALD C. HOMMER.

GLENN A. MACLEOD, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With him on the brief were TONY WEST, Assistant Attorney General, MARK W. ROGERS, Acting Director,

VINCENT J. MATANOSKI, Acting Deputy Director and GABRIELLE M. FIELDING, Assistant Director.

Before LOURIE, BRYSON, and O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* BRYSON.
Dissenting opinion filed by *Circuit Judge* O'MALLEY.

BRYSON, *Circuit Judge*.

Jennifer Hibbard received a flu vaccination in 2003. She claims that the flu vaccine caused her to develop a neurological disorder known as dysautonomia, a dysfunction of the autonomic nervous system. Her theory is that the vaccine provoked an immune reaction that damaged her autonomic nerves, and that the injury to her autonomic nerves, known as autonomic neuropathy, resulted in her dysautonomia. She seeks compensation for her injury under the National Childhood Vaccine Injury Act of 1986 ("the Vaccine Act"), 42 U.S.C. §§ 300aa-1 to 300aa-34.

The parties agree that Ms. Hibbard suffers from dysautonomia; the dispute between the parties is whether her dysautonomia is the result of autonomic neuropathy caused by the vaccine. Following a two-day hearing, a special master found that Ms. Hibbard had failed to show that her dysautonomia resulted from autonomic neuropathy caused by the vaccine she received in 2003. Accordingly, the special master found that she failed to meet her burden of demonstrating by a preponderance of the evidence that the vaccine resulted in a compensable injury, as required by the Act, 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1)(C)(ii)(I). On review, the Court of Federal Claims upheld the special master's decision. We affirm.

I

Ms. Hibbard was 41 years old and working as a first-grade teacher when she experienced a fainting spell in May 2003. She felt a wave of heat and lightheadedness, and she lost consciousness for approximately 10 seconds. She was taken to an emergency room; a neurological examination and laboratory tests were normal, and she was discharged that day. No specific tests were conducted for dysautonomia at that time. The respondent's expert later testified that the May episode was an instance of dysautonomia, and Ms. Hibbard's expert agreed that the episode was a symptom of autonomic dysfunction. When Ms. Hibbard saw her primary care physician in July 2003, she had recovered, but she reported that it took about a month after the fainting spell before she felt normal again. At the time of the May episode, Ms. Hibbard reported that in the past she had experienced other incidents of fainting or feeling lightheaded.

Several months later, on November 1, 2003, Ms. Hibbard received a flu vaccination. A week after the vaccination, Ms. Hibbard began to feel tired, achy, and nauseated. Her symptoms worsened during an extracurricular outing with some of her students and continued over the next few days. On November 11, she saw a physician, who prescribed antibiotics for what he believed was probably "[e]volving sinusitis." He also noted that Ms. Hibbard probably had "some underlying viral respiratory infection." The antibiotics did not alleviate Ms. Hibbard's symptoms, and during the following week she saw two other doctors, including her primary care physician, Dr. Amy Schoenbaum. Ms. Hibbard reported that she felt very weak, tired, and dizzy, especially when standing. Based on a recommendation of one of those doctors, Ms. Hibbard stopped taking the antibiotics. Both

doctors thought that a viral infection might be responsible for her symptoms.

Ms. Hibbard continued to follow up with Dr. Schoenbaum. On December 12, 2003, Dr. Schoenbaum noted that Ms. Hibbard presented with complaints of "vertigo, weakness, feeling of passing out, some heaviness and numbness in her extremities." Dr. Schoenbaum sent her to an emergency room at that time, where she was referred to a neurologist. The neurologist considered Guillain-Barré Syndrome ("GBS") as a possible diagnosis but concluded that GBS was unlikely based on Ms. Hibbard's medical history and physical examination. Ms. Hibbard returned to the emergency room the following day because she was having trouble breathing. She was admitted to the hospital at that time with a diagnosis of "malaise," which remained her principal diagnosis when she was discharged several days later. Over the next few months, Ms. Hibbard saw an otoneurologist for vestibular testing, which did not reveal anything abnormal. Ms. Hibbard also began seeing a psychiatrist, who initially prescribed selective serotonin reuptake inhibitor treatment. When Ms. Hibbard did not tolerate that treatment well, her psychiatrist prescribed a different antidepressant.

Ms. Hibbard's dizziness and weakness continued, and she saw Dr. Schoenbaum again on February 27, 2004. Dr. Schoenbaum encouraged Ms. Hibbard to continue working with her psychiatrist, because although her symptoms were "not classic for an anxiety disorder," she was "experiencing anxiety and depression secondary to the symptoms." Over the next several months, Ms. Hibbard saw a cardiologist and two neurologists. The cardiologist checked for mitral valve prolapse, for which Ms. Hibbard had been treated in the past, but found no definitive

evidence of that condition. The first of the two neurologists, Dr. Louis Caplan, concluded that Ms. Hibbard had "a postinfectious neuropathy with autonomic features," which he referred to as "kind of a Guillain Barré with partial dysautonomia." The second neurologist was Dr. Kenneth Gorson, an expert in GBS. Dr. Gorson reported that Ms. Hibbard's detailed neurological examination was normal and that the "[r]outine nerve conduction studies were pristine." Based on his examination, Dr. Gorson concluded that Ms. Hibbard did not have "electrophysiologic features, nor clinical features, of typical [GBS]," but he added that it was "certainly possible that she developed a modest dysautonomic neuropathy following a nonspecific viral illness or even the flu vaccination back in November." He noted that some patients with a condition known as Postural Orthostatic Tachycardia Syndrome ("POTS") have symptoms similar to Ms. Hibbard's.

The record indicates that POTS is a syndrome in which the patient's heart rate increases significantly upon standing without a significant drop in blood pressure. POTS is indicative of dysautonomia, but it is a nonspecific finding. While it can be associated with autonomic neuropathy, it can have other causes as well. To test for POTS, Dr. Gorson recommended a tilt table test.

On June 16, 2004, Ms. Hibbard underwent a series of tests of her autonomic nervous system, including a tilt table test. The tests were conducted by Dr. Christopher Gibbons under the supervision of Dr. Roy Freeman, a leading expert on autonomic dysfunction. The tests resulted in a diagnosis of POTS. In addition to showing the presence of orthostatic tachycardia (rapid heart rate upon standing), the tilt table test revealed some drop in blood pressure when Ms. Hibbard was elevated into the standing position. The testing also showed "an exagger-

ated postural tachycardia . . . on active standing" and "symptoms of lightheadedness and shortness of breath while standing." The results of the other autonomic tests that Dr. Gibbons and Dr. Freeman administered to Ms. Hibbard were all in the normal range.

In their report, Drs. Gibbons and Freeman stated that the overall study was "abnormal" in that "one measure of sympathetic adrenergic function [the tilt table test for POTS] was in the pathologic range," although the measures of the "sympathetic cholinergic function were in the normal range." They reported that the tests showed "evidence of an exaggerated postural tachycardia." Although they identified that finding as "a non-specific finding," they added that "exaggerated postural tachycardia has been associated with mild or early autonomic neuropathy and an autonomic neuropathy that involves the distal vasculature sparing the cardiac autonomic innervation." They added that "[o]ther associations have included cardiovascular deconditioning, cardiac beta adrenoreceptor supersensitivity and mitral valve prolapse," that "fever, volume depletion and dehydration should be excluded," and that the same response has been seen "in patients diagnosed with chronic fatigue syndrome." Dr. Freeman concluded from the testing that "it is unclear . . . the extent to which autonomic dysfunction is contributing to her symptoms."

Ms. Hibbard followed up with another neurologist, Dr. Peter Novak. As part of his evaluation, Dr. Novak performed another tilt table test. That test again revealed orthostatic tachycardia. Dr. Novak's assessment of the tests was that they showed "moderate cardiac adrenergic and vasomotor adrenergic impairment with normal cardiac cholinergic functions," findings that he found to be

"suggestive of the autonomic neuropathy affecting predominantly sympathetic (adrenergic) fibers."

II

On June 28, 2007, Ms. Hibbard filed a petition for compensation under the Vaccine Act. Initially, she claimed that she suffered from GBS, caused by the flu vaccine. She later amended her petition to allege that she had suffered a neurological demyelinating injury. In support of her petition, Ms. Hibbard submitted an expert report from Dr. Thomas Morgan, a neurologist. The respondent submitted an expert report from another neurologist, Dr. Vinay Chaudhry.

The experts explained that the human nervous system is divided between the central nervous system, which refers to the brain and spinal cord, and the peripheral nervous system, which includes the rest of the nervous system. The peripheral nervous system includes the autonomic nervous system, which controls involuntary functions such as heart rate, respiratory rate, and perspiration. The autonomic nervous system is further divided between the sympathetic component and the parasympathetic component, which together keep the body's internal systems in balance, a condition known as "homeostasis."

In his initial report, Dr. Morgan stated that it was his medical opinion, based on Ms. Hibbard's medical records, that she "sustained a post influenza vaccine immunization autonomic neuropathy with signs and symptoms well documented in the record of dysautonomia." Dr. Morgan noted that several of Ms. Hibbard's symptoms involved the sympathetic nervous system, including POTS, or-

thostatic hypotension,[1] and sweating abnormalities. He also noted some parasympathetic symptoms, including "nasal sinus secretions, flushing, gastrointestinal motility problems, nausea, vomiting, diarrhea and constipation." Dr. Morgan stated that Ms. Hibbard's condition was consistent with a variant of GBS known as pandysautonomia, which he explained can be caused by "molecular mimicry," in which a vaccine generates an immune response that attacks the sympathetic nerve fibers to cause symptoms of dysautonomia. He added that the development of symptoms of autonomic neuropathy within ten days to two weeks after the vaccination is consistent with an autoimmune reaction caused by a vaccine.

Dr. Chaudhry stated that it was difficult to explain all of Ms. Hibbard's symptoms with a single diagnosis. While Dr. Chaudhry acknowledged that GBS "may rarely present with autonomic manifestations as the sole or predominant feature," he stated that autonomic manifestations usually would be accompanied by orthostatic hypotension, which is a drop in blood pressure upon standing without a corresponding rise in heart rate. He described orthostatic hypotension as not being documented in Ms. Hibbard's case. Dr. Chaudhry also noted that "[g]enerally [POTS] is a chronic syndrome and not an acute neuropathy like GBS." In light of Ms. Hibbard's symptoms, her normal examination, the limited documentation of abnormalities of autonomic function, her prior history of fainting, and the multiple other possible diagnoses, Dr. Chaudhry concluded that Ms. Hibbard did not

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[1] Orthostatic hypotension was defined by one of the references in the record as a reduction of systolic blood pressure of at least 20 mm Hg or diastolic blood pressure of at least 10 mm Hg within three minutes of standing.

"represent[] a GBS syndrome presenting as autonomic neuropathy." He added that her symptoms were "far more than can be explained by" a possible "mild or early autonomic neuropathy." For those reasons, Dr. Chaudhry concluded that there was "no causal link between the flu vaccine and her multiple symptoms."

In a supplemental report, Dr. Chaudhry responded to Dr. Morgan's report by stating that in his opinion "[t]here is no objective sign or laboratory test that has demonstrated that Ms. Hibbard has peripheral neuropathy from molecular mimicry or any other hypothesis." Specifically, Dr. Chaudhry noted that Ms. Hibbard displayed "no sensory loss, weakness, or reflex change," that a skin biopsy test of small sensory fibers and nerve conduction studies of the large sensory and motor fibers were normal, and that no spinal fluid changes were documented. He added that the autonomic laboratory tests that were performed on Ms. Hibbard did not indicate that she was suffering from autonomic neuropathy.

The special master who was assigned to the case held a two-day hearing. During the hearing, Dr. Morgan explained the rationale for his opinion that Ms. Hibbard suffered from autonomic neuropathy. Important to his conclusion was a Mayo Clinic study that described a retrospective study of POTS patients in an attempt to determine the cause of POTS. The authors of that study were specifically interested in determining the extent to which POTS was associated with autonomic neuropathy. The authors concluded that at least half of the POTS patients they studied had neuropathic features, and that about 50 percent of the patients who were tested had "evidence of peripheral sudomotor denervation." Sudomotor denervation involves impaired sudomotor function (sweat gland function in response to stimulation).

Dr. Chaudhry testified that the tests for autonomic neuropathy that were performed on Ms. Hibbard were negative, including the "skin sympathetic response test," Valsalva maneuver testing, and catecholamine level testing. Based on those tests, Dr. Chaudhry concluded that although Ms. Hibbard suffers from autonomic dysfunction, there were "so many symptoms with very little signs" that it is "hard to put this together and say this is autonomic neuropathy." Although Dr. Morgan in his initial report had identified several of Ms. Hibbard's symptoms as signs of autonomic neuropathy, in his testimony at the hearing he acknowledged that other than the tests for POTS, the objective tests for autonomic neuropathy in the sympathetic nerves were normal.

Following the hearing, the special master directed the parties to submit post-hearing briefs focusing on the issues that appeared to be the focus of the dispute. The special master referred to this court's decision in *Althen v. Secretary of Health & Human Services*, which requires the petitioner in a Vaccine Act case to show "(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." 418 F.3d 1274, 1278 (Fed. Cir. 2005). As to the first element of the *Althen* test, the special master invited the parties to comment on what he understood to be Dr. Morgan's medical theory as to how the flu vaccine could have caused Ms. Hibbard's condition—that through a process known as molecular mimicry, the vaccine had triggered a response that damaged the myelin around the pre-ganglionic portion of the sympathetic part of Ms. Hibbard's autonomic nervous system. As to the second part of the *Althen* test, the special master directed the parties to explain whether Ms. Hibbard had presented a

"logical sequence of cause and effect" by which the flu vaccine led to her condition. The special master explained that if Dr. Morgan's theory is "that the flu vaccine can lead to demyelination, which is damage to nerves, . . . it appears that petitioner needs to establish, by a preponderance of the evidence that she suffered from an autonomic neuropathy." As to the third part of the *Althen* test, the special master noted that respondent's expert had conceded that Ms. Hibbard's case satisfied the temporal relationship factor. In light of that concession, the special master did not require the parties to address the timing issue.

In response, Ms. Hibbard agreed with the special master's characterization of her "molecular mimicry" theory of causation, except that she added that the injury to her nerves could have occurred in an unmyelinated area of the sympathetic nervous system. She explained: "Where there is myelin, the mimicry could have been with the myelin. Where it is unmyelinated, the mimicry could have been with the proteins contained in the ganglia."

After receiving the parties' briefs, the special master issued a decision denying compensation for Ms. Hibbard. Although both parties (and the special master) agreed that Ms. Hibbard suffers from dysautonomia and that she has POTS, the special master found that "[a] preponderance of the evidence supports a finding that Ms. Hibbard does not have autonomic neuropathy." The special master based that conclusion on his finding that "when Ms. Hibbard was tested for signs of autonomic neuropathy, the results were normal." With respect to Dr. Morgan's reliance on the fact that Ms. Hibbard suffers from POTS as indicating damage to the sympathetic nervous system, the special master noted that POTS "does not always mean that the nerves in the autonomic nervous system

are damaged," and that Dr. Morgan had failed "to account for the substantial number of people who have POTS without autonomic neuropathy."

Because Ms. Hibbard's theory was that the flu vaccine caused an autoimmune reaction that damaged her sympathetic nerves resulting in dysautonomia, the special master found that Ms. Hibbard's failure to prove that she had autonomic neuropathy doomed her case. Having found that Ms. Hibbard failed to prove that critical step in Dr. Morgan's medical theory of causation, the special master concluded that Ms. Hibbard did not satisfy the second part of the *Althen* test, i.e., she failed to show that there was a logical sequence of cause and effect showing that the vaccine was the reason for her injury. For that reason, the special master stated that it was not necessary to address the other *Althen* factors.

The Court of Federal Claims affirmed the special master's decision. The court described Ms. Hibbard's theory of causation as follows: "the flu vaccine, through molecular mimicry, caused autonomic neuropathy, which manifested as dysautonomia and POTS." In light of that theory of causation, the court ruled, the special master did not commit legal error by deciding the case solely on the issue of whether Ms. Hibbard has autonomic neuropathy, which the court described as "the underpinning on which Ms. Hibbard's entire case hinges." As to that issue, the court concluded that the special master's finding of fact was not arbitrary and capricious. The court observed that although several of the physicians who examined Ms. Hibbard suspected autonomic neuropathy as a possible cause of her dysautonomia, the medical evidence was inconclusive. In particular, the court noted, the special master had relied heavily on objective test results, which for the most part were negative as to signs of autonomic

neuropathy. The court therefore upheld the special master's finding that Ms. Hibbard did not suffer from autonomic neuropathy.

III

In Vaccine Act cases, we review a ruling by the Court of Federal Claims *de novo*, applying the same standard that it applies in reviewing the decision of the special master. *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1330 (Fed. Cir. 2011) (en banc); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). Therefore, we review the rulings of the special master to determine whether they were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 869 (Fed. Cir. 1992).

The role of appellate review of a special master's decision under the arbitrary and capricious standard "is not to second guess the Special Master's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." *Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1380 (Fed. Cir. 2012), quoting *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993); *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010). If the special master's conclusion is "based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010), quoting *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). Put another way, 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. Sec'y of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

Because Ms. Hibbard's injury is not listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), this is an off-Table case. *Moberly*, 592 F.3d at 1321-22; *Althen*, 418 F.3d at 1278. As such, Ms. Hibbard was required 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." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Ms. Hibbard acknowledges in her brief that it is her burden "to show, by a preponderance of the evidence, in accordance with [section 300aa-11(c)(1)(C)(ii)], that her dysautonomia is more likely than not due to her flu vaccine." Her theory of causation is that the vaccine provoked her immune system to attack her autonomic nerves, causing damage to those nerves that manifested as dysautonomia. Although at points in her brief Ms. Hibbard argues that she was not required to show that she suffers from autonomic neuropathy, her counsel acknowledged at oral argument that in order for Ms. Hibbard to recover, "she has to show that she has autonomic neuropathy." In light of her expert's theory of causation, which depended on a showing of autonomic neuropathy, it was plainly necessary for her to make that showing in order to satisfy the second of the *Althen* factors, which requires demonstrating "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Althen*, 418 F.3d at 1278.[2]

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[2] The dissent acknowledges that as part of her prima facie case Ms. Hibbard was required to show causa-

A

Ms. Hibbard argues at some length that it was improper for the special master to focus on the second *Althen* factor, to the exclusion of the other two factors. We discern no error in the manner in which the special master chose to address the *Althen* factors, however. The special master acknowledged that the temporal requirement (the third *Althen* factor) was satisfied in this case. He therefore had no need to discuss that factor in any detail. As to the requirement that Ms. Hibbard show a "medical theory causally connecting the vaccination and the injury" (the first *Althen* factor), the special master proceeded by assuming the medical viability of Dr. Morgan's theory of causation and going directly to the second *Althen* factor, i.e., determining whether Dr. Morgan's theory accounted for Ms. Hibbard's injury.

In arguing that the special master improperly short-circuited the *Althen* analysis, Ms. Hibbard insists that it was the special master's "obligation to determine whether a flu vaccine *can* cause dysautonomia and whether it did so in [her] individual case." In this case, she contends, "the special master preemptively determined that an

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tion by a preponderance of the evidence. *See Doe*, 601 F.3d at 1357 (citing cases). Given that Ms. Hibbard has conceded that in order to satisfy her burden of proof she had to show that she has autonomic neuropathy, it is not clear why the dissent regards it as improper for the special master to have focused on whether she succeeded in doing so. Although the dissent complains that the special master should have viewed Ms. Hibbard's condition as dysautonomia rather than autonomic neuropathy, her theory of causation was that the vaccine caused autonomic neuropathy, which manifested as dysautonomia, so it was necessary for her to prove that her dysautonomia resulted from autonomic neuropathy.

autonomic neuropathy did not cause [her] dysautonomia." Although she claims that the special master erred by "attacking one element of [her] proposed theory of how her injury occurred," it was not error for the special master to focus first on whether she actually had the injury that she claims was caused by the vaccine before addressing the question whether the vaccine actually caused that injury in her case. If a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by "reputable medical or scientific explanation," by which a vaccine can cause the kind of injury that the petitioner claims to have suffered. *Althen*, 418 F.3d at 1278.

In previous cases, this court has sanctioned an approach similar to the one taken in this case, in which a special master has addressed the nature of the injury suffered before addressing the question whether there is a viable medical theory by which a vaccine can cause the injury claimed by the petitioner. *See Locane*, 685 F.3d 1375; *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343 (Fed. Cir. 2011); *Brockelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339 (Fed. Cir. 2010). In each of those cases, there was a dispute as to the nature of the petitioner's injury, and in each case the special master's findings on the nature of the injury that the petitioner incurred was sufficient to resolve the case because the special master found that the injury the petitioner incurred was not one that could have been vaccine-induced according to the petitioner's medical theory.

The issue that the special master addressed in this case is whether Ms. Hibbard suffers from autonomic

neuropathy. As Dr. Morgan's report and testimony made clear, that was a necessary component of her theory of vaccine-induced injury. Therefore, even assuming the medical plausibility of Ms. Hibbard's theory of causation—that the vaccine triggered an immune response that damaged her autonomic nerves—her failure to show that she had autonomic neuropathy would be fatal to her case. Given that Ms. Hibbard had to show both the medical plausibility of her theory of causation and that she suffered an injury consistent with that theory of causation, there was no reason to require the special master to address the first question when the answer to that question could have no possible effect on the outcome of the case. As the Court of Federal Claims succinctly put it,

> Ms. Hibbard asserts that the flu vaccine, through molecular mimicry, caused autonomic neuropathy, which manifested as dysautonomia and POTS. . . . The special master, therefore, did not commit legal error by deciding Ms. Hibbard's case solely on the issue of whether she has autonomic neuropathy, the underpinning on which Ms. Hibbard's entire case hinges.

Hibbard v. Sec'y of Health & Human Servs., 100 Fed. Cl. 742, 749 (2011).

B

Ms. Hibbard makes the separate legal argument that the special master and the trial court imposed an unduly high burden of proof on her by requiring her to show actual causation in this case. Instead, she argues, the *Althen* standard of causation is satisfied—and should have been regarded as met in this case—by proof that the vaccine she received can cause the injury she suffered,

that the onset of her symptoms occurred within an appropriate time period, and that "no likely alternative cause of her injury has been identified."

This court has previously rejected the same argument—that proof that an injury could be caused by a vaccine and that the injury occurred within an appropriate period of time following the vaccination is sufficient to require an award of compensation unless the respondent can prove some other cause for the injury. *See Moberly*, 592 F.3d at 1323 ("temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury" is evidence of causation but does not by itself compel a finding of causation); *Althen*, 418 F.3d at 1278 ("neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation").

To the extent that Ms. Hibbard argues that the court's decision in *Althen* relieves petitioners of the obligation to show actual causation, this court has rejected that contention. Instead, the court has repeatedly held that in off-Table cases such as this one the task of the special master is to determine, "based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249-50 (Fed. Cir. 2011), quoting *Lombardi*, 656 F.3d at 1351; *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012); *Moberly*, 592 F.3d at 1321-22; *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009).

In the recent en banc decision in *Cloer v. Secretary of Health & Human Services* the court once again made clear that *Althen* does not lessen the ultimate burden of proof on a petitioner to show actual causation by a preponderance of the evidence. In *Cloer*, the court characterized *Althen* as setting forth "three pleading requirements for a non-Table injury petition," *Cloer*, 654 F.3d at 1333 n.4, and it noted that the *Althen* "pleading burden is, of course, lower than the preponderance burden that must be met in order to receive compensation." *Id.* at 1331 n.3. Thus, by characterizing the *Althen* factors as "pleading requirements," and emphasizing that a petitioner must ultimately satisfy the preponderance burden in order to obtain an award of compensation, *Cloer* supports the decision of the special master and the Court of Federal Claims in this case, which applied the preponderance test to the issue of causation, and not a lesser standard as urged by Ms. Hibbard.

C

Ms. Hibbard's final argument is that the evidence in this case points so decidedly in her favor that the special master's conclusion that "[a] preponderance of the evidence supports a finding that Ms. Hibbard does not have autonomic neuropathy" is arbitrary and capricious. Based on the evidence of record and the factual findings the special master made following the two-day evidentiary hearing, we reject Ms. Hibbard's contention that the special master's decision denying compensation was so plainly contrary to the evidence that it must be reversed even under the uniquely deferential arbitrary and capricious standard of review.

The special master found that Ms. Hibbard has POTS but concluded that she failed to show that her POTS was

caused by autonomic neuropathy. He based that conclusion on the fact that the various objective tests for autonomic neuropathy that were conducted in Ms. Hibbard's case were all negative. Dr. Chaudhry summarized the results of the objective testing for autonomic neuropathy as follows: Except for the tests confirming that Ms. Hibbard has POTS, the remaining tests for autonomic neuropathy in the sympathetic nervous system—tests for orthostatic hypotension, skin sympathetic response, Valsalva maneuver, catecholamine levels, vasomotor function, and sweating abnormalities—were all normal. The tests for abnormalities in the parasympathetic nervous system were likewise normal, except for one test that produced borderline results but on subsequent testing returned to normal. As the special master summarized, apart from the fact that she suffers from POTS, "there are no signs that Ms. Hibbard has autonomic neuropathy."

The special master accepted the experts' testimony that the Mayo Clinic study indicated that approximately 50 percent of all POTS patients have a limited form of autonomic neuropathy. He further found, however, that the evidence of record did not suggest that Ms. Hibbard was among the half of POTS patients with autonomic neuropathy. As the special master explained, "Ms. Hibbard did not have other problems that people who have POTS associated with an autonomic neuropathy have. For example, Ms. Hibbard did not have low blood pressure when standing, heart rate variation with deep breathing, sweating abnormalities, or an abnormal skin sympathetic test." Many of the POTS patients in the Mayo Clinic study had other indicators of autonomic neuropathy. For example, the Mayo Clinic paper reported that approximately half the patients in the study who were tested for sudomotor denervation tested positive for that condition, which is a sign of autonomic neuropathy.

By contrast, Ms. Hibbard tested negative on tests for sudomotor denervation, as well as on all the other objective tests for autonomic neuropathy that were performed on her. In light of the fact that Ms. Hibbard, unlike many of the patients in the Mayo Clinic study, did not have objective signs of autonomic neuropathy, the special master was not plainly wrong in finding that she was not shown to be among the 50 percent of POTS patients whose condition, according to the Mayo Clinic study, was caused by autonomic neuropathy.[3]

In addition to relying on the Mayo Clinic study, Ms. Hibbard looks for support to the reports of several of her treating physicians who, she argues, "suspected she suffered an autonomic neuropathy that caused her dysautonomia and POTS." The special master reviewed the numerous medical reports in the record and found that while two of her treating physicians concluded that Ms. Hibbard had autonomic neuropathy, several others, including experts on Guillain Barré Syndrome and autonomic dysfunction, did not. For example, Dr. Gorson concluded from his examination and testing that autonomic neuropathy was "a possibility," but he stated that he was "hesitant to confirm autonomic neuropathy without more objective data to support such entity." Dr. Gorson recommended additional testing "to confirm an autonomic element to her disorder." And following the

[3] Dr. Chaudhry noted that a consistent pattern of orthostatic hypotension without a corresponding rise in heart rate is a common sign of autonomic neuropathy. He stated that although Ms. Hibbard showed reduced blood pressure upon standing in some instances, that syndrome was not consistent and therefore was not a sign of autonomic neuropathy. Dr. Morgan, Ms. Hibbard's expert, agreed that the reduction in her blood pressure observed on several occasions was not significant.

recommended testing, Dr. Freeman found that it remained "unclear" the "extent to which autonomic dysfunction is contributing to her symptoms."

Other physicians likewise had doubts about autonomic neuropathy as a diagnosis. Two of her treating physicians suggested that she might have vestibular migraines, the diagnosis that Dr. Chaudhry regarded as most consistent with her symptoms. Another suggested that she might have a mitochondrial disorder. A fourth stated that he was "suspicious that some of these symptoms could be psychosomatic in origin, given the extensive negative work-up." And a fifth concluded that "the cause of her symptoms remains unclear. I don't see anything pathologic on exam and her work-up in the past has been extensive and unremarkable." In view of the array of different opinions among Ms. Hibbard's examining and treating physicians as to the cause or causes of her symptoms, it was not arbitrary and capricious for the special master to conclude from the medical evidence, including the medical records of her physicians, that "the evidence weighs in favor of a finding that Ms. Hibbard did not have autonomic neuropathy."[4]

Finally, Ms. Hibbard invokes the testimony of the two experts in this case. While her own expert stated that it was his medical opinion that she had autonomic neuropa-

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[4] Several of the physicians' notes on which Ms. Hibbard relies appear to be simply repeating Dr. Novak's initial diagnosis of autonomic neuropathy rather than reflecting any additional testing or independent diagnostic work. Dr. Novak's original diagnosis, moreover, appears to be based, at least in part, on his conclusion that "Autonomic testing by Dr. Freeman showed . . . autonomic neuropathy," when in fact, Dr. Freeman did not conclude from his group's testing that Ms. Hibbard had autonomic neuropathy.

thy, the respondent's expert, Dr. Chaudhry, disagreed. Dr. Chaudhry agreed with the report prepared by Drs. Gibbons and Freeman that Ms. Hibbard has POTS, and he agreed with their statement that POTS, although a non-specific finding, "has been associated with mild or early autonomic neuropathy." Ms. Hibbard relies on that statement as supporting her claim. In fact, however, that statement merely reaffirmed that some POTS patients have a limited form of autonomic neuropathy, a proposition that was undisputed. As Dr. Chaudhry explained at length in his testimony, he concluded that Ms. Hibbard's POTS did not point to autonomic neuropathy. He based his opinion that Ms. Hibbard did not have autonomic neuropathy largely on the fact that the specific tests of Ms. Hibbard's autonomic nervous system returned normal results. In addition, he testified that a limited form of autonomic neuropathy of the sort that Dr. Morgan believed was present in Ms. Hibbard's case would not explain the large number and range of symptoms that she reported. The special master reached the same conclusion as Dr. Chaudhry, and for the same reasons. Thus, contrary to Ms. Hibbard's contention, Dr. Chaudhry's testimony does not provide any support for her claim. Instead, his testimony constitutes substantial evidence in support of the special master's decision.

In sum, considering the limited nature of our statutory role in reviewing factual determinations by special masters in Vaccine Act cases, we cannot conclude that the contrary evidence in this case is so compelling that we must reverse the special master's finding that Ms. Hibbard has not shown that she suffers from autonomic neuropathy. The special master's finding is "based on evidence in the record that [is] not wholly implausible," *Cedillo*, 617 F.3d at 1338, and the special master has articulated a rational basis for his decision, *Hines*, 940

F.2d at 1528. Because, as we have noted, a finding of autonomic neuropathy is critical to Ms. Hibbard's theory of causation, we hold that the special master's finding on that issue is fatal to Ms. Hibbard's petition for compensation under the Vaccine Act.

AFFIRMED

United States Court of Appeals for the Federal Circuit

JENNIFER HIBBARD,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2012-5007

Appeal from the United States Court of Federal Claims in case no. 07-VV-446, Judge Thomas C. Wheeler.

O'MALLEY, *Circuit Judge*, dissenting.

For the reasons explained in my concurrence in *Lombardi v. Secretary of Heath & Human Services*, 656 F.3d 1343, 1356 (Fed. Cir. 2011), I continue to question whether our decision in *Broekelschen v. Secretary of Health & Human Services*, 618 F.3d 1339 (Fed.Cir.2010) represents an appropriate extension of our prior holdings. I do not dissent here on those grounds, however, or merely to repeat those concerns. I dissent here because the Special Master, and now the majority, incorrectly apply *Broekelschen* to this case and, in doing so, further erode what is left of this court's precedential holding in *Althen v. Secretary of Health & Human Services*, 418 F.3d

1274 (Fed.Cir.2005). If this court wishes to abandon the burden shifting framework *Althen* describes—and thereby increase the hurdles Vaccine Act Claimants must overcome—it should do so expressly and en banc. Instead, we have condemned *Althen* to a tortured end by continuing to endorse Special Masters' concerted efforts to narrow its application. I can not endorse such a cause, particularly on the record here.

Ms. Hibbard's case presents what should have been a straightforward application of *Althen*, where once Ms. Hibbard put forward a prima facie showing of causation, the burden should have shifted to the respondent to establish an alternative cause for her injury. As explained below, that is not the methodology the Special Master employed in finding against Ms. Hibbard on her Vaccine Act claim and is not the methodology to which the majority now defers, however. Putting questions of methodology aside, moreover, I believe the Special Master's finding that Ms. Hibbard did not suffer from an autonomic neuropathy to be arbitrary and capricious.

I.

In *Althen*, this court explained that a claimant seeking compensation for an off-Table injury must show that the "vaccination caused her malady." 418 F.3d at 1278. Specifically, the court set forth the following three-part test for causation:

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her 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.

Id. By broadly defining what constitutes sufficient preponderant evidence of causation, this framework represents a balance between providing compensation to an injured claimant and permitting the government an opportunity to demonstrate that the claimant's injury is due to factors unrelated to the vaccine. *Id.* Because Ms. Hibbard established a prima facie case for causation, the burden should have shifted to the government to identify an alternative, more likely, cause of Ms. Hibbard's dysautonomia.

In *Broekelschen*, the court addressed a scenario in which the parties contested the existence and nature of claimant's injury. 618 F.3d at 1343. Specifically, the parties disputed whether Dr. Broekelschen, the petitioner, suffered from transverse myelitis or anterior spinal artery syndrome. *Id.* While the two different injuries are associated with the symptoms presented by Dr. Broekelschen, the underlying cause of each injury is materially different, and it was undisputed that *only* transverse myelitis is arguably related to the flu vaccine. *Id.* at 1346. Therefore, "the question of causation turn[ed] on which injury Dr. Broekelschen suffered . . . [and] it was appropriate in this case for the special master to first determine which *injury* was best supported by the evidence presented in the record before applying the *Althen* test . . . ." *Id.* (emphasis added). The majority here finds similarity between Ms. Hibbard's claim and that made in *Broekelschen* and sanctions the *Broekelschen* approach, claiming "it was not error for the special master to focus first on whether she actually had the injury that she claims was caused by the vaccine before addressing the

question whether the vaccine actually caused that injury in her case." Majority at 16.

But no such dispute exists with respect to the injury claimed by Ms. Hibbard. The majority's analysis, like the Special Master's, focuses entirely on questions of causation rather than injury. All parties—and the Special Master and court below—agree that Ms. Hibbard suffers from dysautonomia. They differ only with respect to the *cause* of the dysautonomia. Ms. Hibbard, and her expert, Dr. Thomas Morgan, contend that the flu vaccine caused her to suffer postural orthostatic tachycardia syndrome ("POTS"), a limited form of autonomic neuropathy, which manifested itself as dysautonomia. The respondent, and its expert, Dr. Vinay Chaudhry, argue that Ms. Hibbard cannot prove by a preponderance of the evidence that she suffered an autonomic neuropathy, and, therefore, can not confirm the cause of her dysautonomia. The respondent notes that other possible causes of dysautonomia exist, but makes no effort to connect any of the alternative causes to Ms. Hibbard. Specifically, Dr. Chaudhry testified that he does not know the cause of Ms. Hibbard's dysautonomia. Unlike the "unusual" case in *Broekelschen*, where "the exact injury and its nature—inflammatory response or vascular event—is in dispute, and, more importantly, the causation question turns on the determination of the injury," no alternative theory of causation was presented here and no alternative injury or diagnoses other than dysautonomia is in play. *Broekelschen*, 618 F.3d at 1349.

Even accepting it as true, the contention that Ms. Hibbard's autonomic neuropathy "was a necessary component of her theory of vaccine-induced injury" does not give license to either the Special Master, or this court, to sidestep the inquiry that we have endorsed in *Althen*.

The majority inappropriately conflates an element within the medical causation theory with the injury itself, and it is exactly this focus on causation that *Althen's* burden shifting approach was designed to prevent. The danger of permitting a Special Master to circumvent *Althen* is apparent on this record. By characterizing his determination with respect to causation as a predicate factual finding, the Special Master effectively avoided both the appropriate burden of proof and the relevant standard of review.

The majority is correct that Ms. Hibbard has not presented definitive confirmation that she suffered an autonomic neuropathy, or that the flu vaccine caused her dysautonomia, but that is not what *Althen* or the Vaccine Act asks of a petitioner. *See Althen*, 418 F.3d at 1279-1280. As *Althen* explains, a petitioner makes his or her prima facie case by satisfying a three part test—namely showing a medical theory causally connecting the vaccination and the injury, a logical sequence of cause and effect that the vaccination was the reason for the injury, and a proximate temporal relationship between vaccination and injury—before returning the burden to the respondent to show causation by factors unrelated to the vaccine. *Id.* If the respondent then fails to meet that burden by a preponderance of the evidence, the petitioner has, under the *Althen* framework, necessarily made a proper showing of causation. *Id.* No further showing by the petitioner is necessary. Requiring that a petitioner show actual causation by a preponderance of the evidence not only eliminates the burden shifting mechanism contemplated by *Althen* but also renders meaningless the words "theory" and "logical sequence." Simply put, nothing in *Althen*—nor in the Vaccine Act itself—requires showing actual causation by a preponderance of the

evidence; satisfaction of the three prongs is sufficient absent rebuttal by the government.

It is undisputed that, on this record, the failure to place the burden on the government to establish an alternative cause for Ms. Hibbard's injury was determinative; the government proffered evidence of none. The failure here to apply correctly the test set forth in *Althen*, and the unwarranted extension of *Broekelschen* to this very different factual scenario, is legal error requiring reversal of the Special Master's determination.

II.

Even accepting the majority's decision to endorse the Special Master's extension of *Broekelschen* well beyond its facts, I would still reverse the Special Master's determination, finding it to be arbitrary and capricious on the evidence presented. We review factual findings of the Special Master with a high level of deference, but those findings must reflect a consideration of the relevant evidence of record, not be wholly implausible, and articulate a rational basis for the conclusion reached. *See, e.g., Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010); *Hines v. Sec'y of the Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). I cannot agree that the Special Master's conclusion that Ms. Hibbard did not suffer an autonomic neuropathy is plausible.

For example, the record demonstrates that Ms. Hibbard received multiple diagnoses of autonomic neuropathy from her treating physicians. As the majority recognizes, after an evaluation in 2004, neurologist Dr. Louis Caplan concluded that Ms. Hibbard had "a postinfectious neuopathy with autonomic features." Majority at

5. Testing by Dr. Christopher Gibbons and Dr. Roy Freeman resulted in an abnormal result that led to a diagnosis of POTS. Majority at 5. Specifically, the testing found "evidence of an exaggerated postural tachycardia . . . [which] has been associated with a mild or early autonomic neuropathy . . . ." A neurological examination by Dr. Russel Chin in 2005 noted these abnormal results and the previous diagnosis of POTS and autonomic neuropathy. While Dr. Chin was unable to confirm the prior diagnosis, he did state that many of the other possible causes for her symptoms had been ruled out. And in 2007, Dr. Peter Novak, concluded that the results of his evaluation of Ms. Hibbard are suggestive of an autonomic neuropathy.

The Special Master, however, rejected this record evidence as inconclusive by noting that other doctors have "refrain[ed]" from making a diagnosis of autonomic neuropathy. He complains that one of the other treating physicians only identified autonomic neuropathy as a "possibility" and that he was "hesitant to confirm" it. And he further relies on an evaluation, from a doctor who performed later testing, stating that it was "unclear" the *extent* to which autonomic dysfunction was contributing to her systems. These equivocal statements do not, however, justify the conclusion that Ms. Hibbard does not have an autonomic neuropathy, especially when there is little indication that a conclusive diagnosis of autonomic neuropathy is generally given. In fact, it is only Dr. Chaudhry—and, by extension, the Special Master—who has reached this absolute conclusion.

The so called "objective tests" similarly provide little support for the Special Master's determination that Ms. Hibbard does not have an autonomic neuropathy. As the majority notes, the Special Master relied "on the fact that

the various objective tests for autonomic neuropathy that were conducted in Ms. Hibbard's case were all negative." Majority at 20. But this determination misrepresents the significance of the tests, statements made by Ms. Hibbard's expert, and statements made by the respondent's expert. In fact, the majority acknowledges a sentence later that not all of Ms. Hibbard's test results were normal. *Id.* The Special Master ignored these abnormal test results, because, in his words, "Dr. Morgan agreed that Ms. Hibbard did not have any objective signs for a neuropathy." Dr. Morgan does not, however, make the concessions that the Special Master attributes to him. He testified that he agrees that the tests performed had "mostly" normal results—excluding the abnormal results—but that statement does not support the Special Master's leap to "no objective signs." Dr. Morgan did testify that he agrees that Dr. Chaudhry's report states that there are no objective signs of Ms. Hibbard having a peripheral neuropathy. But in the question and answer immediately following that statement, Dr. Morgan clarified that he believes Ms. Hibbard has a case of autonomic neuropathy without peripheral involvement.

The Special Master, moreover, applied an unwarranted significance to those results. Nowhere does Dr. Chaudhry opine that the objective tests are conclusive for diagnosing an autonomic neuropathy. In fact, all evidence points to the fact that the tests do not reliably disprove the existence of autonomic neuropathy, despite the fact that they offer "objective" outputs. Dr. Chaudhry admitted that there is a possibility Ms. Hibbard has mild neuropathy, failed to provide any alternative diagnosis for Ms. Hibbard's POTS or dysautonomia, and testified that he actually had ruled out many of the alternative causes for Ms. Hibbard's POTS. Dr. Morgan's testimony on this topic is enlightening:

> Q: And, Doctor, having employed that method, you indicated are there other diseases associated with it, in Ms. Hibbard's case were there any other causes found for her dysautonomia?
>
> A: There were not.
>
> * * *
>
> Q: What tests did they do in May to rule out dysautonomia?
>
> A: Tests don't make the diagnosis. All right? Tests help support a diagnosis. If it was that easy, you don't need doctors, just plug it into the computer, spit it out and you've got your diagnosis. So, there were no tests and they wouldn't necessarily drive the diagnosis, but, more importantly, there's probably no need to do those tests.

A169; A246.

The error in over-reliance on these objective tests is amply seen in the Special Master's—and the majority's—treatment of the Mayo Clinic study introduced by Ms. Hibbard. In that study, researchers concluded that a neuropathic basis existed for at least half of the cases of POTS they examined, which supported their initial postulate that POTS is a limited autonomic neuropathy. Here, all parties agree that Ms. Hibbard has POTS. They disagree only as to the significance of this finding with respect to a conclusion of autonomic neuropathy. Ms. Hibbard contends that the Mayo Clinic study shows that her POTS is indicative of an autonomic neuropathy. The Special Master, in contrast, agreed with the respondent's view that Ms. Hibbard's predominantly normal test

results support a conclusion that she is not in the approximately 50 percent of all POTS patients that have a limited form of autonomic neuropathy.

The majority's acceptance of the respondent's position suffers from the same flaw as the Special Master's before it. Ms. Hibbard does not dispute that causes other than neuropathy exist for POTS, but, as Dr. Chaudhry testified, no other cause for Ms. Hibbard's POTS was identified and many of the possible alternative causes were expressly ruled out. As such, the likelihood that Ms. Hibbard's POTS was caused by a neuropathy is actually significantly greater than the 50 percent likelihood trumpeted by the majority. More importantly, the lack of abnormal test results provides almost no support for the conclusion that Ms. Hibbard is not part of the 50 percent of people whose autonomic neuropathy caused their POTS. In the Mayo Clinic study, 90.8 percent of the participants exhibited predominantly normal results in response to tests similar to the ones performed on Ms. Hibbard. Therefore, even assuming all of the patients that had abnormal results suffered from autonomic neuropathy, over 80 percent of the participants in the study identified as having POTS and autonomic neuropathy would have had to exhibit predominantly normal results to the "objective" tests relied on so heavily by the special master.

I agree that a Special Master's factual findings are accorded deference, but in light of the great evidence to the contrary, I must conclude that the Special Master's determination that Ms. Hibbard did not suffer an autonomic neuropathy was arbitrary and capricious.

III.

Based on the record before us, I think it clear that Ms. Hibbard has put forward a prima facie case under *Althen* that the administered flu vaccine caused her dysautonomia. The Special Master characterized Dr. Morgan's medical theory as "poorly supported," but the respondent appears to present no real challenge to Ms. Hibbard's satisfaction of the first *Althen* prong. Rather, the respondent focused on whether Ms. Hibbard affirmatively established that she suffered from one of the links in the causal chain leading to her injury. Regardless of the respondent's attack on the adequacy of the evidence of autonomic neuropathy, the respondent cannot dispute that the evidence establishes a logical sequence of cause and effect. I therefore see no legitimate dispute as to Ms. Hibbard's satisfaction of the second *Althen* prong. Finally, as the majority notes, the respondent expressly conceded that Ms. Hibbard's claim satisfies the temporal prong. Majority at 11. Having presented a prima facie case of causation, the burden, in accordance with *Althen*, appropriately shifts to the respondent to demonstrate a likely alternative cause for Ms. Hibbard's injury.[1] As Ms. Hibbard contends, the respondent failed to put forward any alternative cause, let alone a likely one. Dr. Chaudhry's testimony fails to back any alternative theory that would explain Ms. Hibbard's injury. As such, reversal of the determination of the Special Master and entry of judgment for the petitioner is appropriate.

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[1] If the majority and the Special Master were correct that, in addition to the *Althen* showing, a Vaccine Act claimant must also separately establish each link in the causal chain by a preponderance of the evidence, there would be no burden left to shift back to the government.

Separately, and in addition, I would find that the Special Master erred in determining that Ms. Hibbard did not establish that she suffered an autonomic neuropathy by a preponderance of the evidence. This error standing alone warrants reversal.