

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

**JORDIA NUNEZ, JOHN DIAZ, AS LEGAL
REPRESENTATIVES OF J.J.D., AN INFANT,
DECEASED,**
Petitioners-Appellants

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,**
Respondent-Appellee

2020-1021

Appeal from the United States Court of Federal Claims
in No. 1:14-vv-00863-LAS, Senior Judge Loren A. Smith.

Decided: August 28, 2020

SYLVIA CHIN-CAPLAN, Law Office of Sylvia Chin-Caplan LLC, Boston, MA, argued for petitioners-appellants.

LISA WATTS, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by ETHAN

P. DAVIS, ALEXIS B. BABCOCK, C. SALVATORE D'ALESSIO,
CATHARINE E. REEVES.

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

Opinion for the court filed by *Circuit Judge* LOURIE.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

LOURIE, *Circuit Judge*.

Jordia Nunez and John Diaz (collectively, “Nunez”), the parents of a deceased minor child (“J.J.”), appeal from the decision of the United States Court of Federal Claims (“Claims Court”) upholding the Special Master’s Decision on Entitlement, which denied vaccine injury compensation after J.J.’s death from Sudden Infant Death Syndrome (“SIDS”). *See Nunez v. Sec’y of Health & Human Servs.*, 144 Fed. Cl. 540 (2019) (“*Claims Court Decision*”); *Nunez v. Sec’y of Health & Human Servs.*, No. 14-863V, 2019 WL 2462667 (Fed. Cl. Mar. 29, 2019) (“*Special Master Decision*”). We *affirm*.

BACKGROUND

On the afternoon of November 14, 2012, J.J. visited his doctor for his four-month well-baby examination. During that visit, J.J. received hepatitis B virus, rotavirus, Diphtheria-Tetanus-acellular Pertussis, haemophilus influenza type B, inactivated polio, and pneumococcal conjugate vaccinations. The following morning, J.J. was found unresponsive by his parents. He was taken to the hospital and pronounced dead shortly after arrival. It is undisputed that the cause of death was SIDS.

Nunez petitioned for vaccine injury compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10–34 (2012) (“Vaccine Act”), alleging that J.J.’s death from SIDS was caused by adverse effects from the vaccinations he received. The Special

Master assigned to the case held an entitlement hearing and applied the three-prong test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), which is used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. That test requires that a petitioner set forth “(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.* In applying the *Althen* test, the Special Master considered the evidence presented by Nunez’s expert witness, Dr. Douglas Miller, and the Secretary’s expert witness, Dr. Christine McCusker, both of whom have testified in numerous prior cases involving petitions for compensation under the Vaccine Act for incidents of SIDS.

For the first prong of the *Althen* test, Dr. Miller proposed the Triple Risk Model as the relevant medical theory causally connecting J.J.’s vaccinations to his death from SIDS. The Triple Risk Model proposes that SIDS results from the intersection of three overlapping factors: (1) a vulnerable infant; (2) a critical developmental period; and (3) an exogenous stressor. For purposes of this appeal, it is not disputed that J.J. was a vulnerable infant because of his gender, prematurity, and because he had a defective brainstem. It is also undisputed that J.J. died at the age of four months, which was within the critical developmental period that occurs during the first year of life. The dispute in this appeal is regarding the third factor of the Triple Risk Model, and specifically Dr. Miller’s theory that vaccinations act as an exogenous stressor. According to Dr. Miller, vaccinations cause the body’s immune system to produce cytokines that enter the brain and impair the medullary serotonin system’s ability to rouse the body in response to elevated levels of carbon dioxide during sleep. Dr. McCusker challenged Dr. Miller’s theory based on the

current state of scientific knowledge about cytokine production, transport, and expression.

After weighing the evidence, the Special Master found two primary problems with Dr. Miller's application of the Triple Risk Model to explain causation in this case. First, the Special Master found that Dr. Miller failed to provide evidence of a transport mechanism for cytokines to enter the brain. *Special Master Decision*, 2019 WL 2462667, at *41. Second, the Special Master found that Dr. McCusker persuasively explained that J.J.'s defective brainstem would not have allowed cytokines to affect the brain in a manner consistent with Dr. Miller's proposed theory. *Id.* (“[C]ytokines need a normal brainstem to affect the 5-HT system because it is through functioning receptors that their messages are received.”). Ultimately, the Special Master denied compensation, finding that Nunez failed to carry her legal burden of establishing causation. *Id.* at *42.

Nunez moved the Claims Court to review the Special Master's decision. The Claims Court denied Nunez's motion, finding that the Special Master “neither abused her discretion nor acted contrary to law, as she appropriately considered the record as a whole and adequately explained her determinations as to the reliability of the evidence and credibility of the expert witnesses.” *Claims Court Decision*, 144 Fed. Cl. at 547. The Claims Court entered judgment dismissing the petition, and Nunez appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

DISCUSSION

In Vaccine Act cases, we review the Claims Court's decision *de novo*. *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1338 (Fed. Cir. 2014) (citing *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010)). In so doing, we apply the same standard that the Claims Court applies in reviewing a

special master's decision. *Id.* We review a special master's factual findings under the arbitrary and capricious standard, and we review legal rulings to determine whether they are in accordance with law. *Id.* at 1339.

Less than a year ago, this court decided *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351 (Fed. Cir. 2019), which presented the same issue we have in this case, *i.e.*, a petitioner claiming compensation under the Vaccine Act after a child died from SIDS. In *Boatmon*, the petitioner relied on the testimony of Dr. Miller, who presented the Triple Risk Model as the theory of causation linking vaccinations to SIDS. Affirming the decision of the Claims Court, which had reversed the decision of a special master, we held that Dr. Miller's theory was an "unsound and unreliable theory that constitutes a significant extension of the Triple Risk Model" *Id.* at 1361. We faulted the special master in that case for accepting Dr. Miller's theory "in the absence of any indicia of reliability." *Id.*

In this case, Dr. Miller has again presented the same theory of causation based on the Triple Risk Model. Thus, the question before us boils down to whether the record in this case contains the "indicia of reliability" for Dr. Miller's theory that we found lacking in *Boatmon*. Indeed, under the appropriate standard of review, we must consider whether the evidence in this case so persuasively demonstrates the reliability of Dr. Miller's theory that it renders the Special Master's rejection of the theory arbitrary and capricious. *See Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) ("In effect, this court performs the same task as the Court of Federal Claims and determines anew whether the special master's findings were arbitrary or capricious."). We see no such indicia of reliability.

Nunez attempts to distinguish this case by arguing that there is additional evidence in the record that was not present in *Boatmon*. *See Oral Arg.* at 2:03,

<http://oralarguments.ca9.uscourts.gov/default.aspx?fl=20-1021.mp3>. For example, Nunez argues that medical literature was presented in this case demonstrating that the effects of vaccinations, specifically cytokine production, are comparable to the effects of mild infections. *See, e.g., id.*; J.A. 367 (2014 study by Kashiwagi); J.A. 457 (2007 meta study by Vennemann). Ultimately, however, the record reflects no major advances in the state of medical knowledge concerning a relationship between vaccinations and SIDS in the short time that has passed since this court decided *Boatmon* less than a year ago. And we have no basis to conclude that studies from 2006 and 2014 are the type of new evidence that is so indicative of the reliability of Dr. Miller's theory that it makes the Special Master's factual findings arbitrary and capricious for having rejected it.

Beyond the medical literature, Nunez attempts to distinguish this case from *Boatmon* by pointing to one additional piece of evidence that is present here, namely, that “physical evidence obtained during a neuropathological evaluation supported the presence of the anatomical defect” in J.J.'s brainstem. *See* Appellant Br. 42 n.8 (citing J.A. 115–17). But after both parties' experts addressed that evidence, the Special Master found that, not only does the evidence of J.J.'s defective brainstem not support Dr. Miller's theory, it actually cuts against the theory. That finding was based on the logical chain of evidence demonstrating that Dr. Miller's theory is based on the premise that cytokines affect the medullary serotonin system by sending messages through functioning—*i.e.*, non-defective—receptors in the brain. *See Special Master Decision*, 2019 WL 2462667, at *41. It was thus logical and reasonable for the Special Master to find that, because J.J.'s brainstem was defective, the medullary serotonin system would not be affected by the cytokines in the way that Dr. Miller proposed and that “[t]he ultimate cause of death is the cause of the increased CO₂ that leads to the cessation of breathing and not the cytokines' effect on the arousal

system.” *See id.*; *see also id.* at *40 (citing Dr. McCusker’s testimony in a prior case that “cytokines could not suppress the respiratory response in a brain with a defective 5-HT system because, by the nature of the defect, the system is incapable of responding to the cytokines”).

During oral argument, Nunez’s counsel attempted to address the Special Master’s finding by arguing that because J.J. had a defective brainstem, he “was not able to respond to the cytokines that were generated as a result of the immunizations.” Oral Arg. at 4:15. First and foremost, that characterization of the evidence appears to be attorney argument that is unsupported by Dr. Miller’s actual testimony. Even if it were supported by the evidence, however, it demonstrates only that Nunez disagrees with the Special Master’s factual findings, not that those findings were arbitrary or capricious. Ultimately, the Special Master agreed with the Secretary’s expert that J.J.’s defective brainstem would not have allowed cytokines to affect the medullary serotonin system in the manner necessary to support Dr. Miller’s theory. *Special Master Decision*, 2019 WL 2462667, at *41. We see no basis to abandon that finding in favor of Nunez’s alternative factual explanation. Deciding between factual explanations was the job of the Special Master, and her findings were reasonable and supported by the evidence.

Moreover, whether or not J.J. had a defective brainstem, the Special Master’s decision was also based on her separate finding that Dr. Miller had not presented sufficient evidence of a transport mechanism for cytokines to cross the blood-brain barrier into the brain. *Special Master Decision*, 2019 WL 2462667, at *41. For that finding, the Special Master weighed Dr. Miller’s general testimony on how cytokines can enter the brain against Dr. McCusker’s specific testimony concerning the localized cytokine response to vaccinations, the short half-life of cytokines, and the need for the cytokines to have an active transport system to enter the brain for a specific purpose. *Id.* The

Special Master's finding in favor of the Secretary on this point was not arbitrary or capricious, and we thus have no basis to reweigh the evidence.

We conclude by noting that we recognize the timing in this case of a child having died from SIDS within a day of receiving his vaccinations. We are sympathetic to the tragedy of SIDS and to the policy goals of the compensation programs under the Vaccine Act. We are aware of the significant medical uncertainty surrounding SIDS, and we do not doubt that further research can be done to investigate whether there are possible relationships between vaccinations and SIDS. But these concerns are not within our purview as it pertains to our consideration of this case. Here, we are tasked only with reviewing the decisions of the Claims Court and the Special Master under the appropriate standard of review. We find that the Special Master's factual findings were not arbitrary or capricious, and the decisions of both the Claims Court and the Special Master were in accordance with the law, specifically this court's decision in *Boatmon*. And, finally, contrary to the dissent, it is not the law that, in the absence of evidence of causation, the burden of proof is reversed. Therefore, we must affirm.

CONCLUSION

We have considered Nunez's remaining arguments but find them unpersuasive. Accordingly, we affirm the decision of the Claims Court.

AFFIRMED

COSTS

No costs.

NOTE: This disposition is nonprecedential.

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Appeal from the United States Court of Federal Claims
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NEWMAN, *Circuit Judge*, dissenting.

Infant J.J.D., at his 4-month well-baby check-up, was inoculated with vaccines derived from pathogens of viral and bacterial diseases hepatitis B, rotavirus, diphtheria, tetanus, acellular pertussis, haemophilus, influenza type B, polio, and pneumococcal conjugate. J.J.D. came home, his lips turned blue, and he was declared dead the next morning. The Medical Examiner could not determine the “cause of death,” and therefore listed the cause as Sudden Infant Death Syndrome, or SIDS.

SIDS is not a “cause” of death; SIDS is an announcement that the cause is unknown.¹ Yet the court holds that because the physiologic/medical cause was not explained, it must be held that there was no causative relation to the immunizations—or anything else—that preceded J.J.D.’s death. That is not a reasonable presumption, and it contravenes the text and purpose of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, as amended (“Vaccine Act”). From the court’s contrary ruling, I respectfully dissent.

DISCUSSION

When death occurs within hours after a healthy baby is inoculated with powerful pathogens, it is at least reasonably possible that the material injected into the baby, or the baby’s reaction to that material, contributed to the fatal event. The occurrence of unpredictable vaccine injury is what led to the need for the Vaccine Act, for some parents were withholding vaccinations out of concern about unknowable, unpredictable vaccine injury. In addition, Congress “recognize[d] that because of many States’ standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law.” H.R. Rep. No. 99-908, at 13 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6354.

The mechanism of vaccine injury is not well understood, although scientific progress is being reported. Here, the experts for each side presented different theories, and agreed on nothing except that J.J.D. died after his

¹ The Department of Health and Human Services defines SIDS as “the sudden, unexplained death of an infant younger than 1 year of age that remains unexplained after a complete investigation.” NIH, *Sudden Infant Death Syndrome (SIDS)*, <https://www.nichd.nih.gov/health/topics/sids>.

vaccinations, and that this event was unforeseen and unforeseeable. When an extreme event such as death follows the administration of powerful antigens, it is reasonably possible that there was a relation between these events. Such a possibility should affect the placement of the burden of proof in Vaccine Cases.

“There are no hard-and-fast standards governing the allocation of the burden of proof in every situation. The issue, rather ‘is merely a question of policy and fairness based on experience in the different situations.’” *Keyes v. School Dist. No. 1*, 413 U.S. 189, 209 (1973) (quoting 9 J. Wigmore, *Evidence* § 2486, at 275 (3d ed. 1940)). Congress intended to establish a “compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity.” H.R. Rep. No. 99-908, at 3. Therefore, the burden should be on the opponent to show that there was not a causal relationship. Such placement conforms to the Vaccine Act:

42 U.S.C. § 300aa-13(a)(1). Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300-aa11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

* * *

§ 300aa-13(a)(2)(A). For purposes of paragraph (1), the term “factors unrelated to the administration of the vaccine” . . . does not include any idiopathic,

unexplained, unknown, hypothetical, or undocumented cause, factor, injury, illness, or condition.

Thus the statute states that to negate entitlement to compensation, “unrelated factors” must be proved by a preponderance of the evidence; that is, the burden of proof is on the government. *See Walther v. Sec’y of Health & Human Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007) (explaining that to negate compensation “[a] plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence”).

This court has recognized that it is incorrect to require “general acceptance in the scientific or medical communities” of every vaccine injury, for such requirement, on the present state of scientific knowledge, “impermissibly raises a claimant’s burden under the Vaccine Act and hinders the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Andreu v. Sec’y of Health and Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

It is encouraging to read of scientific progress in understanding vaccine behavior and response, for the hope is that eventually vulnerable infants (and others) can be identified in advance, and steps taken to avoid injury, as well as sudden infant death. However, until such responses can be predicted in advance, whereby injury might be avoided, “to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.” *Knudsen v. Sec’y of Health and Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994).

In *Knudsen* this court warned against requiring the special masters to diagnose how and why some vaccines cause some injury to some children. The court stated:

This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not “diagnosing” vaccine-related injuries. The sole issues for the special master are, 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 child’s injury or that the child’s injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child’s injury.

Id. (citing 42 U.S.C. § 300aa-13(a)(1), (b)(1)).

The panel majority states that “it is not the law that, in the absence of evidence of causation, the burden of proof is reversed.” Maj. Op. at *8. However, the burden of proof under the Vaccine Act is not consistently placed:

The Vaccine Act currently requires petitioners to prove their cases by the “more likely than not” or “preponderance of the evidence” standard. There is substantial confusion and uncertainty in applying this standard today. Several recent Federal Circuit decisions, emphasizing Congress’s compassionate intent in the statute, have held that “close calls regarding causation” should be resolved in favor of petitioners, while other recent Federal Circuit cases have emphasized that traditional tort causation standards should be strictly applied in off-Table cases. This has created an unpredictable and confusing situation. Congress should act to clarify the burden of proof requirement central to the resolution of off-Table cases.

Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 Admin. L. Rev. 785,

845–46 (2011) (citations omitted). Clarification of the placement of the burden of proof is warranted.

At the hearing on J.J.D.’s claim, the government’s expert stated that J.J.D. was found on autopsy to have a “defective brainstem” and thus was “vulnerable” to the “stressors” of vaccines. The Special Master held that this observation required denial of compensation, for no vaccine-related cause of death was shown. But if there indeed was an unknown vulnerability whereby the immunizations were immediately and suddenly fatal, reasonable interpretation of the Vaccine Act would deem this to be grounds for grant of compensation, rather than denial of compensation, for “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen v. Sec’y of Health and Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Placement of the burden of proof on the government conforms to this purpose.

From the court’s contrary ruling, I respectfully dissent.