United States Court of Appeals for the Federal Circuit

CHASE BOATMON, MAURINA CUPID, PARENTS OF J.B., DECEASED,
Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2018-2333

Appeal from the United States Court of Federal Claims in No. 1:13-vv-00611-TCW, Judge Thomas C. Wheeler.

Decided: November 7, 2019

JOSEPH PEPPER, Conway Homer, PC, Boston, MA, argued for petitioners-appellants. Also represented by RONALD C. HOMER.

THOMAS G. WARD, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by ROBERT PAUL COLEMAN, III, JOSEPH H. HUNT, C. SALVATORE D'ALESSIO, CATHARINE E. REEVES.

Before PROST, *Chief Judge*, NEWMAN and WALLACH, *Circuit Judges*.

Opinion for the court filed by *Chief Judge* PROST.

Concurring opinion filed by *Circuit Judge* WALLACH.

Dissenting opinion filed by *Circuit Judge* NEWMAN.

PROST, *Chief Judge*.

This case, brought under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34, as amended (the "Vaccine Act"), presents the question of whether Petitioners Chase Boatmon and Maurina Cupid have proven by a preponderance of the evidence that the vaccinations their son, J.B., received caused or substantially contributed to his death from sudden infant death syndrome ("SIDS"). The Special Master found that Petitioners had met their burden and were entitled to compensation. *Boatmon v. Sec'y of Health & Human Servs.*, No. 13-611V, 2017 WL 3432329 (Fed. Cl. Spec. Mstr. July 10, 2017) ("*Special Master Decision*"). The United States Court of Federal Claims reversed the Special Master's finding. *Boatmon v. Sec'y of Health & Human Servs.*, 138 Fed. Cl. 566 (2018). While we disagree with most of the Court of Federal Claims' rationale, for the reasons explained below, we affirm its judgment.

I

A

J.B. was born four weeks prematurely on April 7, 2011. *Special Master Decision*, at *4. Despite being born prematurely, J.B. was progressing with normal growth and development. At his four-month well baby visit on September 2, 2011, J.B. was healthy, with normal chest and lungs and no fever, nasal congestion, or cough. At that appointment, J.B. received vaccinations for diphtheria-tetanus-acellular pertussis (DTaP), inactivated polio (IPV),

pneumococcal conjugate (PCV), rotavirus, and Hepatitis B (Hep B). *Id.*

Later that evening, J.B. reportedly had a fever and did not sleep well. *See id.* at *5. At 4:00 AM on September 3, 2011, J.B.'s parents gave him Advil for his fever, and he went back to sleep. By approximately 8:00 AM, J.B. was again running a fever and was given another dose of Advil.

In the early afternoon, J.B.'s father put him down for a nap on his back in his crib. J.B.'s mother checked on him and replaced his pacifier. She returned to check on him a second time and found him unresponsive on his right side. At 2:39 PM, J.B.'s mother called 911 and attempted CPR. Responders arrived at the house within minutes and transported J.B. to the hospital. Efforts to resuscitate J.B. were unsuccessful and he was pronounced dead at 4:01 PM. *See id.* at *6.

A death investigation and scene reenactment indicated that J.B. was placed to sleep on his back and was found on his right side. Photographs of the scene showed that his crib contained soft blankets and a flat soft pillow but no clutter or toys.

The medical examiner performed an autopsy and concluded that the cause of death was SIDS.[1] *Id.*

B

The Vaccine Act, enacted in 1986, created the National Vaccine Injury Compensation Program, through which claimants can petition to receive compensation for vaccine-related injuries or death. *See* 42 U.S.C. § 300aa-10(a).

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[1] The dissent's assertions that "no cause of death was established" and that "SIDS is not a cause of death" are incorrect. Dissent Op. 9, 7. The autopsy report listed "the cause of death" as "SIDS." J.A. 519.

There are two ways a petitioner can qualify for compensation under the program. First, if the petitioner can establish an injury listed on the Vaccine Act Injury Table that occurred after the administration of a designated vaccine within a designated period of time ("Table cases"), then causation is presumed. *See id.* §§ 300aa-11(c), 300aa-14(a). Second, if the petitioner claims an injury not listed in the Vaccine Act Injury Table ("off-Table cases"), the petitioner must prove, by a preponderance of the evidence, that the vaccine was the cause-in-fact of the claimed injury. *Id.* §§ 300aa–11(c)(1)(C)(ii)(I), 300aa-13(a)(1). "[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *see also LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("As we have stated before, a temporal correlation alone is not enough to demonstrate causation."). The dissent's suggestion that temporal proximity of the vaccination to the injury creates a prima facie case of connection or causation is contrary to our precedent. Dissent Op. 7–10.

Rather, to prove causation in fact in an off-Table case, the petitioner must

> show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321–22 (Fed. Cir. 2010) (quoting *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). These requirements are known as the three *Althen* prongs. If a petitioner proves all three *Althen* prongs by a

preponderance of the evidence, he or she is entitled to recover unless the government shows "by a preponderance of evidence[] that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen v. Sec'y of the Dep't of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994)).

C

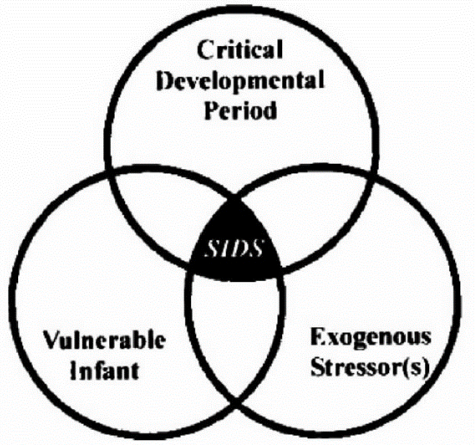
J.B.'s parents filed a petition for compensation under the Vaccine Act, alleging that the vaccinations their son received contributed to his death from SIDS. Because this was an off-Table case, the Petitioners were required to prove causation in fact by establishing each of the three *Althen* prongs by a preponderance of the evidence.

The case was assigned to a Special Master, who held an evidentiary hearing. The Special Master considered medical and scientific literature as well as expert testimony from Dr. Douglas Miller for the Petitioners and Dr. Christine McCusker and Dr. Brent Harris for the government.

The parties do not dispute that J.B.'s cause of death was SIDS. *See Special Master Decision*, at *6. "SIDS is defined as 'the sudden death of an infant under one year of age which remains unexplained after a thorough case investigation, including performance of a complete autopsy, death scene investigation, and review of the clinical history.'" *Id.* at *7 (quoting James J. Filiano & Hannah C. Kinney, *Arcuate Nucleus Hypoplasia in the Sudden Infant Death Syndrome*, 51 J. Neuropathology & Experimental Neurology 394 (1992)). Studies indicate that SIDS occurs during sleep or transitions between sleep and waking. *Id.*

Dr. Hannah C. Kinney, a neuropathologist at Harvard, is an undisputed leader in SIDS research and understanding. In 1994, Dr. Kinney and her colleagues "synthesized many neuropathological studies into their proposed 'Triple Risk Model.'" *Id.* This model posits that SIDS is

"multifactorial," occurring "when: (1) an infant in a critical development period; (2) possessing an underlying vulnerability; (3) encounters an exogenous stressor." *Id.* at *7–8, *33. The following Venn diagram has been used to illustrate the Triple Risk Model:



Id. at *7.

The first factor, the critical development period, was initially defined as the first year of life, but has more recently been understood to be the first six months of life. *Id.* at *8. The second factor, an underlying intrinsic vulnerability in the infant, includes prematurity, "'male gender, African-American race, poverty, adverse prenatal factors such as maternal smoking or alcohol use during pregnancy, . . . genetic polymorphisms,'" and "brainstem abnormality in the neuroregulation of cardiorespiratory control." *Id.* (quoting Hannah C. Kinney et al., *The Brainstem and Serotonin in the Sudden Infant Death Syndrome*, 4 Annu. Rev. Pathol. Mech. Dis. 517, 519, 521 (2009) (J.A. 553–88) ("Kinney 2009")). The third factor, exogenous stressors, has been identified in the literature to include "prone sleep position, face-down position, covered face in the supine position, soft bedding, bed sharing, over-bundling, elevated room temperature, and minor infection at the time of death." *Id.* at *10 (citing Kinney 2009, at 519 (J.A. 555)).

Dr. Miller, the Petitioners' expert, theorized that receiving a vaccine can be an exogenous stressor for SIDS because its prompts the upregulation of cytokines. *Id.* at *21 ("Dr. Miller stated that vaccinations can be an extrinsic risk factor in SIDS, as they prompt the upregulation of cytokines that, among other things, produce fever."). According to Dr. Miller, the upregulation of cytokines following vaccinations can be similar to the upregulation of cytokines associated with a mild infection, a known extrinsic risk factor for SIDS. *Id.* at *20–21. Dr. Miller theorized that the cytokines can inhibit the activity of 5–hydroxytryptamine ("5–HT" or serotonin) neurons in the medulla causing prolonged apneas and interference with autoresuscitation. *Id.* Approximately 50–70% of infants who die of SIDS appear to have abnormalities in the medullary 5–HT system. *Id.* at *8. According to Dr. Miller's theory, "[w]hen the vaccines are administered in the presence of the defects in the medulla, during the critical developmental period, they are likely to have a similar effect as mild infection that may cause a failure of the medullary response system and ultimately a death." *Id.* at *21. But by Dr. Miller's own admission, no other medical professionals or researchers have adopted his theory. *See* J.A. 161–62; *see also Special Master Decision*, at *21.

Dr. McCusker disagreed with Dr. Miller's theory. Specifically, she disagreed that upper respiratory infections—and by Dr. Miller's extension, vaccinations—act as *neurochemical* exogenous stressors. *Special Master Decision*, at *23. Instead, Dr. McCusker testified that upper respiratory infections, like the other identified exogenous stressors, are *mechanical*, meaning that they interfere with an infant's ability to exhale carbon dioxide and inhale fresh oxygen. *Id.* at *23, *25.

The Special Master found that the Petitioners had established all three *Althen* prongs by a preponderance of the evidence. On *Althen* prong one, the Special Master adopted Dr. Miller's extension of the Triple Risk Model, concluding

that "vaccines can . . . play a critical role . . . by stimulating the production of inflammatory cytokines." *Id.* at *39. We note for clarity that the Special Master also stated that "I have not concluded that vaccines present a substantial risk of SIDS. In fact, the evidence is to the contrary." *Id.* at *42.

On the second *Althen* prong, the Special Master found that "the cytokines triggered by the vaccines" in combination with "other intrinsic and/or extrinsic risk factors *in the presence of a defective or underdeveloped brainstem* seems likely to have produced the perfect storm that resulted in J.B.'s death." *Id.* at *41 (emphasis added). The Special Master's analysis of the second *Althen* prong therefore depends on J.B. having a defective or underdeveloped brainstem. But notably, the autopsy did not examine or section J.B.'s arcuate nucleus or other medullary areas to determine whether J.B. had any such brainstem abnormality. *Id.* at *7, *30–31. The Special Master found that the Petitioners had proven by a preponderance of the evidence that J.B. had a brainstem abnormality based, in part, on statistical evidence that a brainstem defect is found in 50–70% of SIDS cases and Dr. Miller's testimony that, based on this statistical evidence, J.B. likely had the defect. *See id.* at *32.

The Special Master also found that Petitioners had established the temporal requirement of the third *Althen* prong. *See id.* at *42. The Special Master therefore found in favor of the Petitioners. *Id.* at *42–43.

D

The government sought review of the Special Master's decision in the Court of Federal Claims. The Court of Federal Claims reversed the Special Master, finding "as a matter of law that the Special Master erred in ruling for Petitioners, and in finding that Petitioners had met their burden of proof as established by applicable statutes and case law." *Boatmon*, 138 Fed. Cl. at 567; *see also id.* at 571

(faulting the Special Master's "improper application of the standard of proof required in vaccine cases").

The Court of Federal Claims reviewed four decisions by three other Special Masters that considered Dr. Miller's theory of vaccination causation in other SIDS cases and "uniformly found that the evidence presented by Dr. Miller to prove his theory of vaccine causation was not persuasive." *Id.* at 571.[2] Despite acknowledging that "[a] Special Master is not bound to follow the opinions of other Special Masters," the Court of Federal Claims criticized the Special Master for "ma[king] no acknowledgement of the other cases reaching opposite conclusions and ma[king] no attempt to distinguish the instant case from any of the others." *Id.*

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[2] *See Jewell v. Sec'y of Health & Human Servs.*, No. 11-138V, 2016 WL 5404165, at *13 (Fed. Cl. Spec. Mstr. Aug. 29, 2016) ("[T]here is insufficient evidence in the record to support Petitioner's argument that vaccines should be included among Dr. Kinney's 'exogenous stressors' as a potential causal factor in the pathogenesis of SIDS."); *Copenhaver v. Sec'y of Health & Human Servs.*, No. 13-1002V, 2016 WL 3456436, at *18 (Fed. Cl. Spec. Mstr. May 31, 2016) ("[T]he Copenhavers have not presented a persuasive basis for finding that vaccinations can cause SIDS."); *Lord v. Sec'y of Health & Human Servs.*, No. 12-255V, 2016 WL 806818, at *14 (Fed. Cl. Spec. Mstr. Feb. 9, 2016) ("Petitioners have failed to show that their interpretation of the Triple Risk Model, as it relates to vaccines, is a sound and reliable medical theory."); *Cozart v. Sec'y of Health & Human Servs.*, No. 00-590V, 2015 WL 6746616, at *13 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) ("[T]hey failed to show that their interpretation of the Triple Risk Model, as it relates to vaccines, is a sound and reliable medical theory.").

The Court of Federal Claims determined that the Special Master erred by accepting Dr. Miller's theory because it was not "supported by a 'sound and reliable' medical or scientific explanation" because it has "not been accepted by any other experts in the field of SIDS research." *Id.* at 571–72 (quoting *Knudsen*, 35 F.3d at 548). In doing so, the Court of Federal Claims invoked *Daubert* and criticized Dr. Miller's theory for not having "been subjected to peer review and publication." *Id.* at 572 (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993)). According to the Court of Federal Claims, by accepting Dr. Miller's unsupported theory, the Special Master "applied a standard so low as to constitute clear error." *Id.*

The Court of Federal Claims reversed the Special Master, concluding that "having found that Petitioners failed to satisfy *Althen* Prong One, the Court also finds that they have not presented a persuasive basis for finding that the vaccinations caused J.B.'s death, as required under *Althen* Prong Two." *Id.*

The Petitioners appealed the Court of Federal Claims' decision. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

II

A

In Vaccine Act cases, we review the Court of Federal Claims' decision *de novo*. *LaLonde*, 746 F.3d at 1338. In so doing, we apply the same standard that the Court of Federal Claims applies in reviewing the special master's decision. *Id.* We review factual findings under the arbitrary and capricious standard, and we review legal rulings to determine whether they are not in accordance with law. *Id.* at 1339. "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." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357,

1360 (Fed. Cir. 2000). And "[b]ecause we review the trial court's legal determination that the special master acted in a manner not in accordance with law *de novo*, we effectively review the special master's decision under the same standard." *Althen*, 418 F.3d at 1277–78.

B

We first address the flaws in the Court of Federal Claims' analysis. We then turn to the reasons we affirm its ultimate conclusion and judgment.

1

Much of the Court of Federal Claims' analysis focused on the fact that the Special Master's decision in this case was contrary to other Special Masters' decisions in other cases addressing the issue of vaccination causation in SIDS deaths. The Court of Federal Claims faulted the Special Master for "ma[king] no acknowledgement of the other cases reaching opposite conclusions and ma[king] no attempt to distinguish the instant case from any of the others." *Boatmon*, 138 Fed. Cl. at 571. It concluded that the Special Master's "departure from the conclusions of other Special Masters can only be explained by improper application of the standard of proof required in vaccine cases." *Id.*

To the extent the Court of Federal Claims required that special masters cite and distinguish the decisions of other special masters, it was incorrect. As the Court of Federal Claims itself acknowledged, "[a] Special Master is not bound to follow the opinions of other Special Masters." *Id.*; *see also Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998) ("Special masters are neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand."), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999). The government also acknowledges this on appeal. Appellee's Br. 18 n.1 ("The decisions of other special masters . . . are not binding

precedent."); *id.* at 22 ("[S]pecial masters' decisions are non-binding."). By extension, special masters are not required to distinguish non-binding decisions of other special masters. That is, in part, because "[c]ausation in fact under the Vaccine Act is . . . based on the circumstances of the particular case." *Knudsen*, 35 F.3d at 548.

The Petitioners also argue that the Court of Federal Claims improperly invoked *Daubert* in rejecting Dr. Miller's theory of causation. Appellants' Br. 25; Reply Br. 8–9. To the extent the Court of Federal Claims' opinion suggests that that *Moberly*'s requirement for a "reputable medical or scientific explanation" requires that the special master apply *Daubert* and that *Daubert* requires "peer review and publication," *Boatmon*, 138 Fed. Cl. at 572, that was incorrect. Special masters *may*, but are not required to, analyze expert testimony according to *Daubert*. *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338–39 (Fed. Cir. 2010) ("We have previously held that Special Masters may look to the *Daubert* standards in evaluating expert testimony."); *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) ("Thus, the Special Master did not err in analyzing the proffered testimony according to *Daubert*.").

The Petitioners also contend that the Court of Federal Claims erred in "wield[ing] one *Daubert* factor"—whether the theory at issue has been subjected to peer review and publication—"as dispositive of the reliability of [the] evidence." Appellants' Br. 26. The *Daubert* factors are "meant to be helpful, not definitive," and all factors "do not . . . necessarily apply even in every instance in which the reliability of scientific testimony is challenged." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999); *see also Daubert*, 509 U.S. at 594–95 ("The inquiry envisioned . . . is, we emphasize, a flexible one."). While special masters may use the *Daubert* framework to evaluate the reliability of expert testimony, we reject any suggestion from the Court of

Federal Claims that such testimony must meet each *Daubert* factor to be reliable. *See Terran*, 195 F.3d at 1316.

In sum, we reject any implication from the Court of Federal Claims' decision that special masters must cite and distinguish the decisions of other special masters, that they must apply *Daubert* in assessing expert testimony, or that each *Daubert* factor must be satisfied.

2

The Court of Federal Claims was correct, however, in determining that the Special Master erred by lowering the standard of proof for causation. Under the proper standard, Petitioners failed to meet their burden to prove by a preponderance of evidence that vaccinations can and did cause or contribute to J.B.'s death from SIDS.

a

In off-Table cases like this one, it is the petitioners' burden to prove actual causation by a preponderance of the evidence. *Moberly*, 592 F.3d at 1322. The Vaccine Act "relaxes proof of causation for injuries satisfying the Table[,] . . . but does not relax proof of causation in fact for non-Table Injuries." *Id.* (quoting *Grant*, 956 F.2d at 1148). A petitioner must provide a "reputable medical or scientific explanation" for its theory. *Id.* While it does not require medical or scientific certainty, it must still be "sound and reliable." *Knudsen*, 35 F.3d at 548–49.

The Special Master deviated from the correct "reputable," "sound and reliable" standard and articulated a lower "reasonable" standard. *See Special Master Decision*, at *30 ("[P]etitioners must show by a preponderance of the evidence a *reasonable theory* as to how the vaccine could cause the harm at issue." (emphasis added)); *id.* at *39 ("Accordingly, [P]etitioners have satisfied the requirement of *Althen* Prong One by presenting a *reasonable explanation* of how the vaccine could cause or substantially contribute to the child's death." (emphasis added)); *id.* at *40 ("Dr.

Miller has presented a *reasonable* and persuasive theory." (emphasis added)); J.A. 674 (Dr. Miller explaining a "*plausible mechanism* whereby such infants, presumptively including [J.B.], can die from the indirect effects of the vaccine" (emphasis added)). These articulations of the standard are incorrect as a matter of law.

We have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard. *Moberly*, 592 F.3d at 1322 (rejecting a "more relaxed standard" of whether the condition was "likely caused" by the vaccine and reiterating that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard"); *see also LaLonde*, 746 F.3d at 1339 ("However, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (quoting *Moberly*, 592 F.3d at 1322)).

By the Special Master's and Dr. Miller's own assessment, Dr. Miller's theory is only "plausible." *See, e.g.*, *Special Master Decision*, at *21 ("[Dr. Miller] testified that, based on the literature, there is a *scientifically-plausible* mechanism for vaccinations acting as the extrinsic risk factor in SIDS in much the same way as a mild infection." (emphasis added)); *id.* ("[Dr. Miller] concluded that the mechanism [underlying his theory] is *plausible*." (emphasis added)); J.A. 670 (Dr. Miller stating in his report that "it is *medically plausible* that this case of SIDS was related to these vaccinations" (emphasis added)). The Special Master erred in allowing a theory that was at best "plausible" to satisfy the Petitioners' burden of proof.

b

The Special Master also erred in determining that Petitioners' theory that vaccinations can be an exogenous risk factor under the Triple Risk Model is a sound and reliable medical theory as required by *Althen* prong one.

First, Petitioners have not shown that their theory that vaccinations can be an exogenous stressor under the Triple Risk Model of SIDS is a sound and reliable medical theory. It would be an extension of the Triple Risk Model to include vaccination-induced cytokine activity in the list of exogenous stressors as Dr. Miller proposes. Dr. Miller himself concedes that, outside of Vaccine Act litigation, vaccinations have not been identified as an exogenous stressor for SIDS. *See Special Master Decision*, at *21 (Special Master noting that Dr. Miller "acknowledged that there is not wide recognition, or a generally accepted theory, that vaccinations are an exogenous stressor [for SIDS]"). Dr. Miller was unable to identify any other medical professional who identified vaccinations as exogenous stressors under the Triple Risk Model. *See* J.A. 161–62 (Dr. Miller testifying that, other than experts in Vaccine Act cases, no one in the medical community has asserted that vaccines are more likely than not an external risk factor for SIDS). "Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. *Daubert* is not required, *see Terran*, 195 F.3d at 1316, but reliability and reputability are, *Moberly*, 592 F.3d at 1324; *Knudsen*, 35 F.3d at 549. Here there is nothing more than the assertion of Dr. Miller. The Special Master erred in adopting an unsound and unreliable theory that constitutes a significant extension of the Triple Risk Model in the absence of any indicia of reliability.

Second, the Petitioners failed to show by a preponderance of the evidence that vaccinations cause cytokines to provoke an abnormal brainstem serotonin response or otherwise cause or contribute to a SIDS death. When asked at oral argument to identify what material in the record shows how the *function* of cytokines, not just the *presence* or *expression* of cytokines, affects the brain and supports Dr. Miller's theory, the Petitioners replied that there are

animal studies and in vitro studies that show that cytokines cross the blood brain barrier and interfere with the central nervous system. *See* Oral Arg. at 37:12–39:28, No. 2018-2333, http://www.cafc.uscourts.gov/oral-argument-recordings. The Petitioners stated that "it is almost ubiquitous in the literature that cytokines from a peripheral insult, including infection, *vaccination*, can and do cross the blood brain barrier." *Id.* at 37:29–37:39 (emphasis added). The Petitioners specifically identified Frøen[3] (J.A. 736–40), Brambilla[4] (J.A. 600–07), and Stoltenberg[5] (not included in the Joint Appendix but referred to in the record) for support. None support Dr. Miller's proposed theory.

In the Frøen study, a first group of piglets was given IL–1ß (a pro-inflammatory cytokine that is released during infection), a second group was given nicotine, a third group was given nicotine and the cytokine, and a fourth control group was given a placebo. J.A. 736. Apnea, defined as a deprivation of airflow for greater than five seconds, was induced by artificial means on each group of piglets. J.A. 737. The study found that nicotine worsened autoresuscitation after apnea and that it was further aggravated when combined with cytokines. J.A. 737–38. The study did not show

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[3] J. Frederik Frøen et al., *Adverse Effects of Nicotine and Interleukin–1β on Autoresuscitation After Apnea in Piglets: Implications for Sudden Infant Death Syndrome*, 105 Pediatrics (April 2000).

[4] D. Brambilla et al., *Interleukin–1 Inhibits Firing of Serotonergic Neurons in the Dorsal Raphe Nucleus and Enhances GABAergic Inhibitory Post-Synaptic Potentials*, 26 Eur. J. Neuroscience 1862 (2007).

[5] Lauritz Stoltenberg et al., *Changes in Apnea and Autoresuscitation in Piglets After Intravenous and Intrathecal Interleukin–1β Injection*, 22 J. Perinatal Med. 421 (1994).

that cytokines alone caused any spontaneous apneas before the first induced apnea. J.A. 738.

The Stoltenberg study is not included in the Joint Appendix but was considered by the Special Master. Stoltenberg, also conducted on piglets, was similar to Frøen and showed that exposure to cytokines may prolong artificially induced apnea. *See Special Master Decision*, at *16. Dr. McCusker opined that the Frøen and Stoltenberg studies, performed on very young piglets, have limited relevance to what happens in living human infant brains. *See id.* at *26. Fundamentally, neither the Frøen nor the Stoltenberg study examined the effects of vaccinations and neither show that vaccinations can produce the kind of cytokine activity in the brain that Dr. Miller theorizes.

Brambilla, a study conducted on rat brains in vitro, looked at the effect of exposure to IL–1ß on the firing of serotonin neurons and GABAergic neurons in the dorsal raphe nucleus in the medulla. J.A. 600–01. The researchers euthanized the rats, removed and sectioned the brains, bathed them with IL–1ß, stimulated them, then observed the firing of the neurons. J.A. 601. The study found that IL–1ß suppressed the firing of the serotonin neurons and increased the firing of the GABA neurons. J.A. 604. Dr. McCusker opined that the Brambilla study, performed on rat brains in petri dishes, does not reflect what happens in a living vulnerable infant in a crisis situation. *See Special Master Decision*, at *26.

In our view, these studies do not provide support for Dr. Miller's proposed theory because they do not show that that cytokine activity is capable of impacting the brain's 5–HT system in the manner Dr. Miller claims or that vaccinations are capable of producing such cytokine activity in the brain.

For these reasons, the Petitioners have failed to show by a preponderance of the evidence that Dr. Miller's theory

that vaccinations can be exogenous stressors for SIDS is a sound and reliable medical theory of causation.

c

The second prong of *Althen* requires that the petitioner show by a preponderance of the evidence "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. Here, because the Petitioners failed to present a sound and reliable theory of how vaccinations can cause SIDS, they have also failed to show that vaccinations caused or contributed to J.B.'s death from SIDS.

Additionally, on the second *Althen* prong, the government argues that the Special Master erred by "conclud[ing] based on statistical evidence alone that J.B. did in fact have a brainstem vulnerability." Appellee's Br. 24–28. The Special Master's determination that the Petitioners satisfied the second *Althen* prong depended on his conclusion that J.B. had a brainstem abnormality. *See Special Master Decision*, at *32. In reaching this conclusion, the Special Master relied, in part, on what he regarded as a concession by Dr. McCusker that J.B. must have had a brainstem abnormality. *See id.* The testimony in question was Dr. McCusker's statement that "the brain problem that -- according to the triple-risk theory, the brain problem must exist." J.A. 272 ll. 21–22. The Special Master took this to be an admission by Dr. McCusker that the brain problem must have existed *in J.B.'s case*. *Special Master Decision*, at *22 ("Dr. McCusker agreed that 'according to the Triple Risk theory, the brain problem must exist [in J.B.'s case].'" (alteration in original) (quoting J.A. 272)). Notably, the "[in J.B.'s case]" was the Special Master's addition and was not part of Dr. McCusker's testimony. The Special Master relied on this "admission" in adopting Dr. Miller's theory.

The government strongly contests that Dr. McCusker's testimony was a concession that J.B. had the brainstem abnormality. In fact, the government has contested whether

J.B. had a brainstem abnormality throughout this case. *See Boatmon*, 138 Fed. Cl. at 571 ("Respondent maintains that the Special Master impermissibly found, based on statistical evidence alone, that J.B. had a defective brainstem making him vulnerable to vaccines under the Special Master's extension of the Triple Risk Theory."); Appellee's Br. 24–28; Oral Arg. at 26:21–27:29.

Aside from this contested testimony, the Special Master's determination that J.B. had a brainstem abnormality rested in part on an assumption based on statistics. J.B.'s autopsy did not examine or section the area required to determine whether he had the brainstem abnormality. *See Special Master Decision*, at *7, *30–31. In the absence of actual evidence, Dr. Miller relied on statistics that a brainstem defect is found in 50–70% of SIDS cases and that, given these statistics, J.B. likely had a defect. *Id.* at *22, *32; *see also* J.A. 107 ll. 6–12 (Dr. Miller testifying that "we make the assumption . . . that based on the statistics . . . it's most likely the physiological abnormality in the 5–HT system, but we don't have proof of that in individual cases"); J.A. 128 ll. 17–23 (Dr. Miller testifying that "it's statistically likely that [J.B.] was one of those [infants with a defective 5–HT system]. I don't have proof of that, but we can assume that"). Notably, we have previously rejected statistical likelihood alone as proof of actual causation. *See, e.g.*, *Knudsen*, 35 F.3d at 550 (rejecting alternative cause theory based on "[t]he bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies").

We conclude that the Petitioners have failed to demonstrate by a preponderance of the evidence a logical sequence of cause and effect showing that the vaccinations J.B. received caused or contributed to his death.

III

We have considered the Petitioners' remaining arguments and find them unpersuasive. The circumstances of

this case are, of course, heartbreaking. However, we cannot allow unsupported, unreliable theories of causation to provide a basis for recovery in off-Table cases under the Vaccine Act. In this case, the Petitioners failed to prove by a preponderance of the evidence that the vaccinations J.B. received can and did cause or contribute to his death. We therefore affirm the judgment of the Court of Federal Claims.

AFFIRMED

COSTS

The parties shall bear their own costs.

United States Court of Appeals for the Federal Circuit

CHASE BOATMON, MAURINA CUPID, PARENTS OF J.B., DECEASED,
Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2018-2333

Appeal from the United States Court of Federal Claims in No. 1:13-vv-00611-TCW, Judge Thomas C. Wheeler.

WALLACH, *Circuit Judge*, joining and concurring.

I join with the majority opinion. I write in concurrence to respond to Judge Newman's dissent.

The Dissent asserts that "the standard of common sense and sound reason" compels finding causation when vaccination is "soon followed by" injury. Dissent Op. 10. The Dissent would obviate the need for a "medical theory" based on "proof of a logical sequence of cause and effect," supported by a "reputable medical or scientific explanation," *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see* 42 U.S.C. § 300aa-13(a)(1) (2012) (requiring proof of causation by a "preponderance of the evidence" for injuries not in the Vaccine Injury Table).

The Dissent believes that, given the "inadequacy of present scientific knowledge," "common sense must suffice." Dissent Op. 10.

Respectfully, an unverified assertion of fact is not common sense; it is a non-cognizable argument. A statement of law without basis in statute or precedent is not sound reason. Refusal to abide by governing law because it offends a judge's sensibilities is not *stare decisis*. I take the unusual step of concurring to respond to a dissent because to leave the Dissent without a response would, in my opinion, be an abrogation of my judicial duty.

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2018-2333

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Newman, *Circuit Judge,* dissenting.

I respectfully dissent, for the court's ruling conflicts with the text and the purpose of the National Childhood Vaccine Injury Act. During a Senate hearing leading to the National Childhood Vaccine-Injury Compensation Act, the Assistant Secretary of the Department of Health and Human Services, testified concerning vaccines:

> Immunization of children is one of the most spectacularly successful preventive health measures available. Through the appropriate use of vaccine, smallpox has been eradicated from the earth. In this country we have also essentially eliminated diphtheria, tetanus, and poliomyelitis as diseases

> of children. We are on the verge of achieving elimination of measles as a native disease and are beginning to intensify our efforts in order to hasten the ultimate elimination of rubella.

National Childhood Vaccine-Injury Compensation Act: Hearing on S.2117 Before the S. Comm. on Labor & Human Res., 98th Cong. 6 (1984) (statement of Edward M. Brandt, Jr., M.D., Assistant Sec'y of Health, Dep't of Health & Human Servs.).

However, Senator Hatch cautioned, there is "a small but significant public health problem—the incidence of harmful and occasionally even fatal reactions to vaccines administered to children." *Id*. at 2 (statement of Sen. Orrin Hatch, S. Comm. on Labor & Human Res.). Senator Kennedy, a primary sponsor of this legislation, elaborated on the incidence of vaccine injury:

> Even when vaccines are properly manufactured, distributed and administered, there will be a case of paralytic polio which will result from the administration of each 5 million doses of polio vaccine; there will be a serious neurological injury which will result from every 300,000 doses of DTP vaccine, and in rare cases there are severe consequences from the administration of MMR vaccines. These few but important injuries create doubts and fears in our National Childhood Vaccination Programs.

Id. at 3–4 (statement of Sen. Edward Kennedy, S. Comm. on Labor & Human Res.). Senator Kennedy explained the need for legislative action:

> We must be able to assure parents that when their children are the victims of an appropriate and rational national policy, a compassionate Government will assist them in their hour of need.

Id. at 4. Thus, the Vaccine Act provides a system of compensation for children who are injured by vaccine. A legislative Report for an oversight hearing states the guiding principles, including:

> In proposing this legislation, the Committee reiterates its intent that the vaccine injury compensation system be informal, flexible, and expeditious, and that all participants proceed accordingly. The reinvention of the adversarial process will serve neither to compensate injured children nor maintain the stability of the immunization programs of the United States.

H.R. Rep. No. 101-247, at 510 (1989), *as reprinted in* 1989 U.S.C.C.A.N. 1906, 2236.

As discussed in *Knudsen v. Sec'y of Dep't Health & Human Servs.*, 35 F.3d 543 (Fed. Cir. 1994), there has been inadequate medical understanding of the causes of vaccine injury. The *Knudsen* court explained that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation." *Id.* at 549. The court held that compensation is available when vaccine injury is "'logical' and legally probable, not medically or scientifically certain." *Id.* at 548–49. Again in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005), the court recognized the dearth of scientific understanding of vaccine injury, and explained that Congress encouraged "the use of circumstantial evidence" and envisioned that "close calls regarding causation [would be] resolved in favor of injured claimants." *Id.* at 1280.

This precedent conforms to a goal of the Vaccine Act—to foster public confidence and participation in childhood

immunizations—by compensating the rare vaccine injury.[1] Today's decision, denying compensation for a highly probable vaccine injury, does not conform to the statutory purpose.

J.B.'s Immunizations

At J.B.'s four-month well-baby examination, his pediatrician recorded that he was "healthy appearing and cooperative . . . well nourished and well developed." His father stated that J.B. was "smiling and cooing like normal" during the examination. *Boatmon v. Sec'y of Health & Human Servs.*, No. 13-611V (Special Master), 2017 WL 3432329, at *5 (Fed. Cl. July 10, 2017) ("*Special Master Op.*"). The pediatrician administered vaccines for diphtheria-tetanus-acellular-pertussis (DTaP), inactivated polio virus (IPV), haemophilus influenzae (Hib), pneumococcal conjugate (PCV) and rotavirus.

J.B.'s parents testified that later in the day, J.B. began acting abnormally, was not moving as usual, seemed quiet and withdrawn, and had a fever. The next day he was distant and very quiet, would not eat, and had a fever. He

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[1] The Health Resources & Services Administration reports that for the period from January 1, 2006 through December 31, 2017, a total of 3,454,269,356 doses of covered vaccines were distributed in the United States. Health Res. & Servs. Admin. Data & Statistics, *National Vaccine Injury Compensation Program Monthly Statistics Report*, at 3, https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-october-2019.pdf. The HRSA reports that "[f]or petitions filed in this time period, 6,493 petitions were adjudicated by the Court [of Federal Claims], and of those 4,470 were compensated. This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated." *Id.* at 1.

became unresponsive, and his mother called 911 at 2:39 p.m. The record recites the efforts to revive him. At the hospital he was pronounced dead at 4:01 p.m.

A medical examiner conducted an autopsy. The Autopsy Report states that J.B. had no known medical problems and had regular infant care and immunizations. The Report cites the "absence of findings and the reported sleeping position in a child with no anatomic or microscopic significant findings." *Special Master Op.* at *6. The medical examiner classified J.B.'s death as "Sudden Infant Death Syndrome" (SIDS).

SIDS is defined as "the sudden, unexplained death of a baby younger than 1 year of age that doesn't have a known cause even after a complete investigation. This investigation includes performing a complete autopsy, examining the death scene, and reviewing the clinical history." Nat'l Insts. of Health, *What Is SIDS*?, https://safetosleep.nichd.nih.gov/safesleepbasics/SIDS; *see also Special Master Op.* at *7 (quoting James J. Filiano & Hannah C. Kinney, *Arcuate Nucleus Hypoplasia in the Sudden Infant Death Syndrome*, 51 J. Neuropathology & Experimental Neurology 394 (1992)).

The government denied Vaccine Act compensation, and the J.B.'s parents, petitioners, appealed to the U.S. Court of Federal Claims. The Special Master held a trial. The experts from both sides referred to inadequacies in the autopsy, and both sides referred to the absence of understanding of vaccine injury and the causes of sudden infant death. The Special Master discussed the evidence and arguments at length and depth. For example, the Special Master stated that:

> The parties' experts in neuropathology—Dr. Miller for petitioners and Dr. Harris for respondent—reviewed 21 slides from J.B.'s autopsy, including two of J.B.'s brain. Exhibit 13 at 4–5; Exhibit A at 5. The first brain slide is a cross-

> section of pons at the level of the locus coeruleus (the upper pons), and the second slide is of two cingulate gyri with a portion of the adjacent corpus callosum. Exhibit 13 at 5. These brain sections demonstrated no abnormalities. *Id.* However, the medical examiner did not make slides from other parts of the brain, such as the medulla or hippocampus. *Id.* Furthermore, he did not take any photographs of the internal examination. *Id.* The parties' experts agreed that the medical examiner did not collect all of the data necessary to definitively analyze whether J.B. fit the Triple Risk Model of SIDS, introduced in the following section. Tr. 42–43 (testimony of Dr. Miller); Tr. 334 (testimony of Dr. Harris). The experts agreed that they would section considerably more of the brain in a possible SIDS autopsy than the two frontal lobes and one area of the pons that were sectioned in this case. Dr. Harris indicated that usually a SIDS autopsy should include samples of at least ten areas, including the medulla and hippocampus, which can help to show hypoxic ischemic changes as well as epilepsy related changes. Tr. 334. Both experts agreed, however, that in many SIDS cases, brains are not examined with the precision that they would recommend or that Dr. Kinney's group at Harvard did in their studies (introduced in the following section). Tr. 346.

Special Master Op. at *7. The Special Master provided a detailed analysis of all the evidence and argument, in light of the statute and precedent, and stated:

> I have concluded that the petitioners have demonstrated by a preponderance of the evidence that the vaccines can and likely did play a critical role in this child's death by stimulating the production of inflammatory cytokines that suppressed the respiratory response system and caused the

> vulnerable infant to be unable to respond in the normal way to the accumulation of carbon dioxide in his system. Accordingly, petitioners have satisfied the requirement of *Althen* Prong One by presenting a reasonable explanation of how the vaccine could cause or substantially contribute to the child's death.

Id. at *39. The Special Master concluded that:

> The close temporal relationship of the child's death to the receipt of seven vaccines is reasonable and consistent with the theory of neuro-modulation in the arcuate nucleus by the cytokine response to the vaccines.

Id. at *42.

The panel majority, adopting the government's argument, holds that Vaccine Act compensation does not apply because J.B.'s death was not shown to have resulted from the immunizations. The majority states that the cause of death was not the vaccine, but was SIDS. The majority states that "because the Petitioners failed to present a sound and reliable theory of how vaccinations can cause SIDS, they have also failed to show that vaccinations caused or contributed to J.B.'s death from SIDS." Maj. Op. at 18.

However, SIDS is not a cause of death, SIDS is an admission that the cause of death is unknown. The close proximity between vaccine administration to a healthy baby, and fever and death soon thereafter, presents a sufficient relationship among these events to produce a reasonable—likelihood, a prima facie case that the vaccine caused or contributed to the injury.

The prima facie case of vaccine injury

A "prima facie" case is established with "[a] party's production of enough evidence to allow the fact-trier to infer

the fact at issue and rule in the party's favor." *Prima Facie Case*, Black's Law Dictionary 1441 (11th ed. 2019). The prima facie case then shifts the burden of coming forward to the opposing party. *Furnco Const. Corp. v. Waters*, 438 U.S. 567, 577 (1978). The prima facie case "only stands until its weight is met by evidence to the contrary." 9 John H. Wigmore, Evidence § 2487, at 297 (Chadbourn rev. 1981). Wigmore summarizes that:

> A 'prima facie' case so made out need not be overcome by a preponderance of evidence, or by evidence of greater weight; but the evidence needs only be balanced, put in equipoise, by some evidence worthy of credence; and if this be done, the burden of the evidence has been met and the duty of producing further evidence shifts back to the party having the burden of proof, who, if he would win, must not only begin by making out his case, but he must also end by keeping it good. . . . The burden of the evidence, or the duty of going forward with evidence, strictly speaking, means no more than the meeting of a 'prima facie' case or rebutting a presumption, by evidence of equal weight rather than by a preponderance of the evidence.

Id.

Here, a prima facie case was established by J.B.'s physiological response within hours of vaccine administration, with death within a day. The petitioners' expert witness opined that an adverse reaction to a vaccine had a critical role in J.B.'s death. The government's expert witness never opined that there was no relation between the vaccine and J.B.'s events; he simply stated that he did not know the cause of J.B.'s death.

Upon provision of a prima facie case, the duty of coming forward with evidence befalls the opponent. Here, not even minimal contrary evidence was offered. The government's expert did not opine that the vaccines could not have been

a factor; he offered no theory to counter J.B.'s observed fever and death. However, the majority holds that since no cause of death was established, it is irrelevant that a vaccine more-likely-than-not caused or contributed to the injury. This reasoning contravenes the legislative purpose to provide an informal, flexible, and fair system.

In *Knudsen*, this court recognized the inadequate medical understanding of vaccine injury, and reasoned that causation need only be "'logical' and legally probable, not medically or scientifically certain." 35 F.3d at 548–49. Additionally, *Knudsen* explained that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation." *Id.* at 549.

Both parties' experts discussed the absence of understanding of infant death that is called SIDS. The parties referred to ongoing studies, such as by Dr. H.C. Kinney, who is described as a leading researcher on SIDS. The parties referred to Dr. Kinney's theory implicating a neurochemical abnormality on the medullary 5-HT system, as was found in some SIDS cases. *See* Kinney, H.C., *Brainstem Mechanisms Underlying the Sudden Infant Death Syndrome: Evidence from Human Pathologic Studies*, 51 Dev. Psychobiol. 223 (2009). Petitioner's expert, Dr. Miller, testified that the sheer cost of conducting a receptor autoradiography and the expertise required, makes receptor autoradiography unfeasible for most medical examiners conducting autopsies. J.A.107.

The goals of the Vaccine Act are to foster public confidence and participation in childhood immunizations by compensating the rare, but serious vaccine injuries. The judicial obligation is to assure administration of the Vaccine Act in accordance with its purpose. "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*, 418 F.3d at 1280.

Here, both sides' experts acknowledged the inadequacy of present scientific knowledge, even as both criticized the medical examiner's autopsy. Meanwhile, common sense must suffice. On the standard of common sense and sound reason, vaccination of a well-baby with seven powerful toxins, soon followed by fever and death, provide a prima facie case of a causal or contributing relationship between the vaccine and these ensuing events, whereby the duty of coming forward with evidence and argument befalls the opponent. Here, the government's expert stated only that he did not know the cause of J.B.'s death.

It is hoped that advances in genetic science, neurological science, and other sciences, will enhance the understanding of vaccine injury, so that even these rare injuries can be foreseen and avoided.[2] Meanwhile, common sense and fair implementation of the legislative purpose are the judicial recourse. Representative Burton remarked on the government's adversarial posture in vaccine injury cases:

> If you talk to families who have been tied up in this system, it sounds like this program has become every bit as adversarial as the tort system it replaced. Cases drag on for 6 or 8 or 10 years.[3]

* * *

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[2] In *Oliver v. Sec'y of Health & Human Servs.*, 900 F.3d 1357 (Fed. Cir. 2018), the record discussed the relation between a newly discovered genetic mutation and vaccine injury in infants found to have the mutation, reporting results suggesting that delay of immunization may avoid injury for infants having that mutation.

[3] The Petitioners' claim was first filed on August 27, 2013.

> Close calls are supposed to go to the families. The Government is not supposed to fight them tooth and nail. Some of these cases don't even look like close calls, and yet the Government fights them for years. That has to stop.

The National Vaccine Injury Program: Is it Working as Congress Intended?: Hearings Before the H. Comm. on Gov't Reform, 107th Cong. 3–5 (2001).

It is the obligation of the courts to assure that the statutory purpose is implemented. Although vaccine injury is sparse, the purpose of the Vaccine Act is to provide compensation in the event of injury that is reasonably attributable to vaccine. The record shows, on undisputed facts that J.B.'s injury and death more-likely-than-not were reasonably attributable to vaccine. My colleagues' ruling ignores the evidence, negates the statutory purpose, and contravenes the policy of supporting public health and well-being. I respectfully dissent.