

No. 12-937

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**In the Supreme Court of the United States**

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JENNIFER STONE, ET AL., PETITIONERS

*v.*

KATHLEEN SEBELIUS, SECRETARY OF  
HEALTH AND HUMAN SERVICES

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*ON PETITION FOR A WRIT OF CERTIORARI  
TO THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT*

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**BRIEF FOR THE RESPONDENT IN OPPOSITION**

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### QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, establishes a no-fault compensation scheme for persons injured as a result of receiving certain vaccines. The Act provides that compensation cannot be awarded unless “the special master or the court finds on the record as a whole \* \* \* that there is not a preponderance of the evidence that the [person’s injury or condition] is due to factors unrelated to the administration of the vaccine.” 42 U.S.C. 300aa-13(a)(1)(B). The question presented is as follows:

Whether the court of appeals erred in holding that the record evidence supports the special master’s finding that genetic mutations were the sole cause of the injuries for which petitioners seek compensation.

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## **OPINIONS BELOW**

The opinion of the court of appeals (Pet. App. 1a-29a) is reported at 676 F.3d 1373. Opinions of the United States Court of Federal Claims (CFC) (Pet. App. 47a-72a, 73a-88a) are reported at 98 Fed. Cl. 719 and 99 Fed. Cl. 187, respectively. A related opinion of the CFC (Pet. App. 89a-100a) is reported at 95 Fed. Cl. 233. Another related opinion of the CFC (Pet. App. 39a-42a) is unreported. Relevant decisions of the special master are not reprinted in the appendix to the petition for a writ of certiorari or published in the *Federal Claims Reporter*, but are available at 2011 WL 1135878, 2011 WL 836992, 2010 WL 3735705, and 2010 WL 1848220.

## **JURISDICTION**

The judgment of the court of appeals was entered on April 26, 2012. A petition for rehearing was denied on

August 27, 2012 (Pet. App. 31a-33a). On November 19, 2012, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including January 24, 2013, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

#### STATEMENT

1. To stabilize the vaccine market and provide compensation for vaccine-related injuries and deaths, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 U.S.C. 300aa-1 *et seq.* The Vaccine Act created the National Vaccine Injury Compensation Program (Compensation Program), see 42 U.S.C. 300aa-10(a), which provides compensation for vaccine-related injuries and deaths through a no-fault system “designed to work faster and with greater ease than the civil tort system.” *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)). A person alleging a vaccine injury (or the legal representative of such a person) may file a petition for compensation in the CFC, naming the Secretary of Health and Human Services as respondent. *Ibid.* A special master of the CFC then issues a decision on the petition. *Ibid.*; see 42 U.S.C. 300aa-11, 300aa-12(d). The decision is subject to deferential review exclusively by a judge of the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(e)(1), (2)(B) and (f).

The Compensation Program covers categories of vaccines that have been formally recommended for routine administration to children by the Centers for Disease Control and Prevention, 42 U.S.C. 300aa-14(e). The claimant must show by a preponderance of the evidence that she received a vaccine listed on the Vaccine Injury

Table (Table), 42 C.F.R. 100.3, and suffered a corresponding injury listed on the Table, or in the case of an injury not listed on the Table, that her injury “was caused by” a listed vaccine. 42 U.S.C. 300aa-11(c), 300aa-13(a). Compensation cannot be awarded unless the special master or the court finds “on the record as a whole \* \* \* that there is not a preponderance of the evidence that the [injury or condition] is due to factors unrelated to the administration of the vaccine.” 42 U.S.C. 300aa-13(a)(1)(B).

2. Petitioners Jennifer and Gary Stone claim that administration of the diphtheria tetanus acellular pertussis (DTaP) vaccine to their daughter Amelia substantially caused her to develop a seizure disorder known as Severe Myoclonic Epilepsy of Infancy (SMEI). Pet. App. 3a. Petitioner Scott Hammitt makes the same claim with respect to his daughter Rachel. *Ibid.* SMEI is not listed on the Vaccine Injury Table as an injury associated with the DTaP vaccine. See 42 C.F.R. 100.3.

Amelia Stone received a DTaP vaccination in late August 2001, when she was four months old. One day later, she experienced a febrile seizure. In late September 2001, she suffered a second febrile seizure. No evidence of brain damage was found after either seizure. After experiencing additional seizures, Amelia was diagnosed with SMEI. Genetic tests revealed that Amelia has a mutation in her SCN1A gene that is associated with SMEI, rather than a “normal phenotype.” Pet. App. 4a.

Rachel Hammitt received her second dose of DTaP vaccine—along with polio, hepatitis B, Haemophilus influenzae type B, and pneumococcal conjugate vaccinations—in mid-March 2004, when she was four months old. Pet. App. 4a. Rachel suffered a febrile seizure that

evening but suffered no brain damage as a result of that seizure. *Id.* at 4a-5a. Rachel experienced a second febrile seizure in April 2004. *Id.* at 5a. She later experienced intermittent seizures, leading to a diagnosis of SMEI. Genetic tests revealed that Rachel has a mutation in her SCN1A gene that is associated with SMEI, rather than a “normal phenotype.” *Ibid.*

3. The special master ultimately found in separate proceedings that petitioners failed to establish that their children were entitled to compensation because the record showed that the SCN1A gene mutations were the sole cause of Amelia’s and Rachel’s SMEI. 2011 WL 836992, at \*3; 2011 WL 1135878, at \*10. The CFC affirmed on separate appeals. Pet. App. 47a-72a, 73a-88a.

4. The court of appeals affirmed in a consolidated decision. Pet. App. 1a-29a. The court held that the special master’s denial of compensation was not “arbitrary [or] capricious,” 42 U.S.C. 300aa-12(e)(2)(B), in light of the trial record, which contained no support for petitioners’ theory that the initial febrile seizures experienced by Amelia and Rachel after their DTaP vaccinations affected their “susceptibility to seizures in the future,” Pet. App. 19a, but instead revealed “a number of factors cumulatively demonstrat[ing] that the gene mutation was responsible for both children’s SMEI,” *id.* at 21a.

The court of appeals noted that because “the special master determined in both cases that the SCN1A gene mutation was the sole, substantial cause \* \* \* for the SMEI” and “that the DTaP vaccine played no role whatsoever in either child’s SMEI, \* \* \* he did not engage in a superseding cause analysis, nor did he need to.” Pet. App. 17a-18a (brackets and internal quotation marks omitted). The court explained that “[t]he superseding cause analysis presupposes that the first fac-

tor”—*i.e.*, the vaccine—“was causally related to the injury”; because “here, the initial factor [wa]s found to have no causal relationship to the ultimate injury,” the superseding cause analysis “has no role to play” in this case. *Id.* at 18a (internal quotation marks omitted).

5. The court of appeals denied petitioners’ petition for rehearing en banc. Pet. App. 33a. Judge Newman dissented from the denial of rehearing en banc, expressing the view that Amelia’s and Rachel’s seizures following their DTaP vaccinations “marked the onset of the course of illness for both,” and that it should not be a bar to compensation that the “mutation in the SCN1A gene of each infant \* \* \* could have eventually produced the disorder.” *Id.* at 36a; see *id.* at 34a-38a.

#### ARGUMENT

The court of appeals correctly held that the record evidence supports the special master’s factual findings that genetic mutations were the sole causes of the seizure disorders for which petitioners seek compensation. Because the court’s factbound decision is correct, further review is not warranted.

Petitioners seek Vaccine Act compensation for Amelia’s and Rachel’s SMEI, contending that the girls’ seizure disorders were caused by administration of the DTaP vaccine. Pet. App. 3a, 29a n.1. Because SMEI is not listed on the Vaccine Injury Table as an injury associated with the DTaP vaccine, to obtain compensation, petitioners were required to show that the girls’ SMEI “was caused by” the vaccine, 42 U.S.C. 300aa-11(c), 300aa-13(a), and to counter any evidence that the SMEI was “due to factors unrelated to the administration of the vaccine,” 42 U.S.C. 300aa-13(a)(1)(B). There is no dispute that both children have mutations in their SCN1A genes, and that those mutations are associated



with SMEI. Pet. App. 4a, 5a. Petitioners principally argue that the court of appeals failed to follow “established rules for assessing responsibility under circumstances in which two or more factors contribute to the cause of a single injury.” Pet. 17. They assert that their case presents the legal question of whether “a child’s genetic susceptibility to a vaccine injury should prevent that child from receiving compensation for that vaccine injury.” Pet. i.

Those arguments, like Judge Newman’s dissent from the denial of rehearing en banc, fundamentally misconceive the factual findings affirmed in the decision below. As the court of appeals explained, its decision rested on the special master’s well-supported finding that “the only harm caused by the DTaP vaccination in each case was the single, isolated, initial febrile seizure,” and that the SMEI instead “was triggered by the SCN1A gene mutation alone.” Pet. App. 18a-19a; see *id.* at 21a; 42 U.S.C. 300aa-13(a)(1)(B). To be sure, petitioners alleged that the initial febrile seizures experienced by Amelia and Rachel after their DTaP vaccinations caused brain damage, affecting their “susceptibility to seizures in the future.” Pet. App. 19a. But medical records before the special master showed “no indication of brain damage or any other continuing effect” from the initial febrile seizures. *Ibid.* (Amelia); *id.* at 4a-5a (Rachel). Petitioners’ expert witness in fact acknowledged that “he had simply ‘inferred’ that the children had suffered brain damage from the fact of their initial seizures,” and that “there was no clinical manifestation of the inferred brain damage in either case.” *Id.* at 6a.

Based on the record evidence and on petitioners’ inability to identify any “clear error of fact committed by the special master,” the court of appeals held that the

special master's findings were not "arbitrary or capricious." Pet. App. 19a; see 42 U.S.C. 300aa-12(e)(2)(B). Petitioners state that they do not challenge "the facts on which" the court of appeals based its decision, only "the law created by the decision below." Pet. 19. But the reasoning and conclusions of the court of appeals are specific to the factual record of these cases. As the court of appeals explained, petitioners' arguments below (like their arguments in this Court) presuppose that a vaccine "was causally related to the injury." Pet. App. 18a. But those arguments and the legal principles to which petitioners advert have "no role to play where, as here, the [vaccine] is found to have no causal relationship to the ultimate injury." *Ibid.*

#### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted

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