

United States Court of Appeals
for the Federal Circuit

JENNIFER STONE and GARY STONE,
Parents and Next Friends of,
AMELIA STONE, a Minor,
Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN
SERVICES,
Respondent-Appellee.

2011-5109

Appeal from the United States Court of Federal
Claims in case no. 04-VV-1041, Senior Judge Lawrence S.
Margolis.

SCOTT R. HAMMITT,
as the Legal Representative of his Minor Daughter,
RACHEL HAMMITT,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN
SERVICES,
Respondent-Appellee.

2011-5117

Appeal from the United States Court of Federal Claims in No. 07-VV-170, Judge Thomas C. Wheeler.

ON PETITION FOR REHEARING EN BANC

RICHARD GAGE, Richard Gage, P.C., of Cheyenne, Wyoming, filed a consolidated petition for rehearing en banc for petitioners-appellants in appeal no. 2011-5109. With him on the petition was CURTIS R. WEBB, of Twin Falls, Idaho, for petitioner-appellant in appeal no. 2011-5117.

ALEXIS B. BABCOCK, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, filed a response for respondent-appellee in appeal no. 2011-5109. With her on the response was ALTHEA W. DAVIS, Senior Trial Counsel for respondent-appellee in appeal no. 2011-5117; STUART F. DELERY, Acting Assistant Attorney General, RUPA BHATTACHARYYA, Director, MARK W. ROGERS, Deputy Director, GABRIELLE M. FIELDING, Assistant Director, and CATHARINE E. REEVES, Assistant Director.

Before RADER, *Chief Judge*, NEWMAN, LOURIE, SCHALL*, BRYSON, LINN, DYK, PROST, MOORE, O'MALLEY, REYNA, and WALLACH, *Circuit Judges*.

PER CURIAM.

NEWMAN, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

* Judge Schall participated in the decision for panel rehearing.

O R D E R

A consolidated petition for rehearing en banc was filed by the Petitioners-Appellants, and a response thereto was invited by the court and filed by the Respondent-Appellee. The petition for rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and the response were referred to the circuit judges who are authorized to request a poll of whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

- (1) The petition of Petitioners-Appellants for panel rehearing is denied.
- (2) The petition of Petitioners-Appellants for rehearing en banc is denied.
- (3) The mandate of the court will issue on September 4, 2012.

FOR THE COURT

August 27, 2012
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

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NEWMAN, *Circuit Judge*, dissenting from denial of the petition for rehearing en banc.

These consolidated cases raise an important new principle, one that is fundamental to the Vaccine Act, and that could not have arisen but for recent advances in genetic science.

Amelia Stone and Rachel Hammitt were healthy infants, and developing normally until they received their second vaccinations for Diphtheria-Tetanus-acellular Pertussis ("DTaP"), after which both experienced seizures. The government conceded that the seizures were a result of the vaccination. These events were followed by additional seizures and developmental delays, eventually diagnosed as Severe Myoclonic Epilepsy of Infancy ("SMEI"), also known as Dravet's Syndrome, a severe seizure disorder that appears during the first year of life and is characterized by febrile and other types of seizures, including myoclonic seizures, cognitive impairment, developmental delays in language and motor skills, and hyperactivity. See *Snyder v. Sec'y of HHS*, 102 Fed. Cl. 305, 310 n. 16 (Fed. Cl. 2011).

The Secretary conceded that the seizures triggered by the vaccinations marked the onset of the course of illness for both previously healthy infants. Secretary's brief in *Stone v. HHS*, filed Oct. 27, 2012, at 17. The Special Master stated that ordinarily, there would be no issue as to entitlement to compensation under the Vaccine Act. See *Stone v. HHS*,

2010 WL 1848220, at *7 (Special Master Report that “the undersigned finds that petitioners would have likely demonstrated entitlement to compensation if respondent had not demonstrated that Amelia’s SMEI was caused by the genetic mutation located in her SCN1a gene”) (quoted in Secretary’s brief 10). Nevertheless, the Special Master and the Court of Federal Claims denied Vaccine Act relief on the ground that causation had not been shown. They held that a DNA mutation in the SCN1A gene of each infant, which the government’s experts testified appeared to be associated with the seizure disorder of both claimants, could have eventually produced the disorder.

These claimants plainly met the conditions for Vaccine Act compensation, as summarized in *Althen v. Sec'y of HHS*, 418 Fed. 3d 1274 (Fed. Cir. 2005):

Concisely stated, [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. If [a petitioner] satisfies this burden, she is entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Id. at 1278 (internal citation omitted). The Vaccine Act was enacted because it was known that some small percentage of vaccine recipients will inevitably have highly adverse reactions, no matter how pure the vaccine. Legislative testimony emphasized that "approximately one dose of DPT

vaccine in 310,000 will cause a severe adverse reaction," and that "[o]ther vaccines also cause problems in some recipients." 131 Cong. Rec. 6456 (1985).

The statistical record shows that: "Millions of children are immunized yearly and of these, a small percentage have adverse reactions, of which the most serious are retardation and death." 132 Cong. Rec. 30121 (1986). Senator Kennedy observed that "[i]n some cases, vaccination has meant death or disease because of reactions that we do not fully understand and which are probably unavoidable," and that "there are contraindications to the administration of even the safest vaccines." *National Childhood Vaccine Injury Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. 4 (1985). Assistant Secretary for Health Edward N. Brandt testified that "properly manufactured and administered vaccines can, on occasion, cause unavoidable damage," and that:

Although the occurrence of adverse events following immunization can be minimized, it cannot be eliminated entirely. Thus, there will always be a small number of individuals who are harmed by the vaccines that protect our society.

Vaccine Injury Compensation: Hearings on H. R. 5810 Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce, 98th Cong. 61-62 (1984). Advances in genetic science are helping to explain these observations.

Meanwhile, the situation is precisely that for which the statute was enacted. These seriously disabled petitioners are squarely within the purpose of the Vaccine Act, and fully entitled to the compensation provided by statute. From the denial of compensation, I respectfully dissent.