United States Court of Appeals for the Federal Circuit

LAURA OLIVER, AND, EDDIE OLIVER, JR., PARENTS AND LEGAL REPRESENTATIVES OF E.O., III,
Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2017-2540

Appeal from the United States Court of Federal Claims in No. 1:10-vv-00394-EDK, Judge Elaine Kaplan.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

CLIFFORD JOHN SHOEMAKER, Shoemaker and Associates, Vienna, VA, filed a combined petition for panel rehearing and rehearing en banc for petitioners-appellants.

DANIEL ANTHONY PRINCIPATO, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, filed a response to the petition for respondent-

appellee. Also represented by JOSEPH H. HUNT, C. SALVATORE D'ALESSIO, CATHARINE E. REEVES, HEATHER L. PEARLMAN.

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

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

PER CURIAM.

O R D E R

Appellants Laura Oliver and Eddie Oliver, Jr., parents and legal representatives of E.O., III, filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by the Secretary of Health and Human Services. The petition for rehearing and response were first referred to the panel that heard the appeal, and thereafter referred to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 16, 2019.

FOR THE COURT

January 9, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

United States Court of Appeals for the Federal Circuit

LAURA OLIVER AND EDDIE OLIVER, JR., PARENTS AND LEGAL REPRESENTATIVES OF E.O., III,
Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2017-2540

Appeal from the United States Court of Federal Claims in No. 1:10-vv-00394-EDK, Judge Elaine Kaplan.

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

I write in dissent, for the court's ruling conflicts with the terms and the premises of the Vaccine Act. Here, baby Oliver ("E.O."), within hours of his 6-month well-baby DTaP vaccinations, experienced fever and seizures, followed by more seizures and encephalopathies and developmental injuries. The government's position is that the Vaccine Act is not available to E.O. because of his genetic makeup. This ruling is legally and scientifically

incorrect. It has important implications for national vaccine immunization programs, for scientific study now suggests that previously unexplained vaccine injury is related to genetic makeup. En banc attention is warranted.

The National Childhood Vaccine Injury Act of 1986

It had long been known that a small percentage of childhood vaccinations have led to grave injury and permanent disability, as discussed in the legislative record:

> Childhood vaccines are essential to maintain the health of our society. They have been invaluable weapons against the dread diseases that used to kill or injure hundreds of thousands of children every year: polio, measles, pertussis, diphtheria, tetanus, rubella, mumps, and smallpox. But while these vaccines have brought the gift of life and health to millions, there are a very small number of children every year who are injured by unpredictable side effects of the vaccines through no fault of their own or the vaccine manufacturers.

132 Cong. Rec. S17,343–02 (1986) (statement of Sen. Kennedy). The House Report reiterated the concern for unforeseeable injury flowing from compulsory vaccinations:

> While most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured.
>
> . . . .
>
> . . . But it is not always possible to predict who they will be or what reactions they will have. And since State law requires that all children be immunized before entering school, most parents

> have no choice but to risk the chance—small as that may be—that their child may be injured from a vaccine.

H.R. Rep. No. 99-908, at 4–6 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6345–46.

The legislative record states that about one half of one percent of children each year experience vaccine-related injury;[1] and with four million births each year in the United States, this is about 20,000 vaccine injuries per year.[2] The record referred to the withdrawal of vaccine manufacturers in the United States:

> [A] major vulnerability is the unresolved public policy problem of liability for unavoidable injury in mass immunization programs. The specter of high and uncertain damage awards contributes to driving manufacturers out of vaccine production . . . .

Examination of the Task Force Report on the Vaccine Pertussis: Before the Comm. on Labor & Human Res., 98th Cong. 3 (1983) (statement of Sen. Hawkins) ("S. Hrg. 98-350"). It was reported that "there is only one pharmaceutical manufacturer in the entire United States for 19 types of vaccine products and no U.S. manufacturer of 11 other vaccine products." *Id.* Congress also recognized the concern for children whose "futures [had] been destroyed"

---

[1] *To Amend the Public Health Service Act to Provide for the Compensation of Children and Others Who Have Sustained Vaccine-Related Injury, and for Other Purposes: Hearing on S. 2117 Before the Comm. on Labor & Human Res.*, 98th Cong. 21 (1984) ("S. Hrg. 98-1060").

[2] Joyce A. Martin et al., *Births: Final Data for 2017*, 67 National Vital Statistics Reports 1, 3 (2018), https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_08-508.pdf.

by vaccine-related injury and whose "mounting expenses must be met." H.R. Rep. No. 99–908, at 6 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

Thus the Vaccine Act was developed as a no-fault system to compensate "vaccine-injured persons quickly, easily, and with certainty and generosity." *Id*. at 3. The Act is supported by payments to the Vaccine Injury Compensation Trust Fund, 26 U.S.C. § 9510, funded by a tax of "75 cents per dose of any taxable vaccine." 26 U.S.C. § 4131(b)(1).

Infant E.O.'s seizures and fever appeared the evening of his DTaP vaccinations. The government argues and the court holds that Vaccine Act compensation is not available because E.O. has a genetic mutation that might injure him at some time. This ruling negates the purpose of the Vaccine Act, for E.O. was required to be vaccinated and he was injured thereby. He is directly within the letter and the purpose of the Vaccine Act.

E.O's vaccine injury is typical of the vaccine injury that necessitated the Vaccine Act

On April 9, 2009 E.O. received his six-month well-baby check-up. His pediatrician administered the requisite DTaP vaccine (diphtheria-tetanus-acellular pertussis). That evening he was observed with seizures and a fever, and was taken to the emergency room. The record details his tragic history of seizures, encephalopathies, and developmental disabilities.

After E.O.'s reaction to the DTaP vaccine, his parents obtained an analysis of his DNA. It was found that E.O. has a mutation of the SCN1A gene—a mutation that has been found to sometimes be associated with an epileptic condition called "Dravet syndrome." The government's position is that it is irrelevant whether the vaccine triggered E.O.'s adverse reactions, for this mutation alone could have led to injury.

The government's theory is not that E.O.'s genetic mutation contributed to his injury, for that would invoke the "preexisting condition" provision of the Vaccine Act. *See* 42 U.S.C. § 300aa-33(4). Rather, the government's theory is that E.O.'s mutation would itself have caused the injury he experienced; on this reasoning, the government argued that the Vaccine Act does not apply to E.O.'s injury. The Chief Special Master and the courts agreed.

Despite record evidence that 20–30% of persons with Dravet syndrome do not have the SCN1A mutation, *see* Anne M. McIntosh et al., *Effects of Vaccination on Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9(6) Lancet Neurol. 592–98 (2010), my colleagues refused to consider the data that over half the persons with the SCN1A mutation do not experience Dravet syndrome, for these data were published after the Special Master's decision. *See* Valentina Cetica et al., *Clinical and Genetic Factors Predicting Dravet Syndrome in Infants With* SCN1A *Mutations*, 88(11) Neurology 1037 (2017) (reporting that "[w]e observed 123 different SCN1A mutations" and that they "could not predict with high confidence Dravet syndrome vs milder phenotypes" and "outcome is not predetermined by genetic factors only.").

Nonetheless the government argues, and my colleagues affirm, that E.O. would have been gravely injured due to his SNC1A mutation—that it is his "destiny"—and that it is irrelevant that the DTaP vaccinations initiated the seizures and their consequences. However, this is precisely the event at which the Vaccine Act is aimed, lest concerned parents withhold vaccinations, and concerned manufacturers cease production of vaccines.

Advances of science provide hope for avoiding vaccine injury—not grounds for avoiding compensation for vaccine injury

The Vaccine Act and its compensation program are of national importance, and immunizations are increasing.

A child born today may receive up to 25 vaccinations by the age of 18 months—three doses of hepatitis B; three doses of rotavirus; three doses of diphtheria, tetanus, and acellular pertussis; four doses of influenza type B; four doses of pneumococcal conjugate; three doses of inactivated poliovirus; one dose of influenza; one dose of measles, mumps, and rubella; one dose of varicella; and two doses of hepatitis A.[3]

The Vaccine Act places some injuries on a presumptive injury Table, and other injuries require evidence that the subject "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine . . . ." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). "Aggravation" refers to a preexisting condition. *See id.* at § 300aa-33(4) ("The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.").

The role of genetic knowledge in the vaccine compensation program requires deeper understanding than the "destiny" pejorative that removed E.O. and others from the program despite the direct relation between vaccination and injury. Recent years have seen powerful advances in knowledge. The Human Genome Project, starting in 1990, involved scientists around the world in identifying and sequencing all three billion base pairs (approximately 25,000 genes) that constitute the human genome.[4] This took 13 years and about $2.7 billion dollars.[5] Today

---

[3] https://www.aap.org/en-us/Documents/immunization-_schedule2018.pdf.

[4] https://report.nih.gov/NIHfactsheets/ViewFactSheet. aspx?csid=45.

[5] https://www.genome.gov/11006943/human-genome-project-completion-frequently-asked-questions/.

genetic analysis can be completed in a few days or hours, and mechanization is continually adding speed and reducing cost.

With new analytic resources, and the ever-increasing importance of immunizations, many scientific studies have been directed to these aspects. A review states: "Just until recently, the idea of genetics influencing the response to vaccine exposure began to be further explored." John Castiblanco & Juan-Manuel Anaya, *Genetics and Vaccines in the Era of Personalized Medicine*, 16 Current Genomics 47, 49 (2015). These authors state:

> A vaccine generally improves immunity to a particular disease upon administration by inducing specific protective and efficient immune responses in all of the receiving population. The main known factors influencing the observed heterogeneity for immune responses induced by vaccines are gender, age, co-morbidity, immune system, and genetic background.

Id. at Abstract. And "[t]he effect of the genetic status, in defining the response generated directly or indirectly with an innate or adaptative immune response, has been demonstrated across multiple viral vaccines (e.g., smallpox, influenza, measles, rubella, and mumps)." *Id.* at 47.

The scientific literature describes new fields called "vaccinomics" and "adversomics," directed to understanding and predicting how an individual will respond to a vaccine, as further summarized by GA Poland et al., *Personalized Vaccinology: A Review*, 38 Vaccine 5350, (2018). Poland et al. earlier wrote, in *Heterogeneity in Vaccine Immune Response: The Role of Immunogenetics and the Emerging Field of Vaccinomics*, 82 Clinical Pharmacol Ther. 653 (2007):

> this new golden age of vaccinology has been termed "predictive vaccinology," which will predict

> the likelihood of a vaccine response or an adverse response to a vaccine, the number of doses needed and even whether a vaccine is likely to be of benefit (i.e., is the individual at risk for the outcome for which the vaccine is being administered?).

Id. at Abstract. *See also* Jennifer A. Whitaker et al., *Adversomics: A New Paradigm for Vaccine Safety and Design*, 14 Expert Review Vaccines 935 (2015):

> [T]he field of vaccine adversomics is in its infancy. At this time, these technologies are not being used clinically. The first step in advancing this science is to use adversomics research techniques to understand the mechanisms behind adverse events that have a causal relationship with immunization . . . . The precise mechanisms of adverse reactions associated with vaccines are not well understood. Understanding the molecular/genetics/proteomics level (i.e., adversomics) involvement, specifically how genetics (genomics and transcriptomics) impact the development of vaccine adverse reactions, may aid in the design of newer and safer vaccine candidates.

Id. at 939.

Rebecca E. Chandler, *Harm Caused by Vaccines Might Vary Between Individuals*, 358 British Medical Journal (Online) (2017), refers to:

> A growing number of publications in the literature describe links between [adverse events following immunization] and individual variation. . . . [including] the discovery of genetic variants associated with an increased risk of febrile convulsions after the measles, mumps, and rubella and smallpox vaccines.

There's much more. The government's theory that the mere existence of E.O's SCN1A mutation doomed him to a

lifetime of seizures and disability—although no sign appeared until the night of his DTaP vaccination, has been overtaken by science. The court's ruling is a misapplication of knowledge and a distortion of the Vaccine Act.

En banc action is required, to correct our precedent in view of advances in knowledge

I am optimistic that advances in science may reduce the 20,000 new vaccine injuries per year, by providing predictability and preventive capability. Meanwhile, the court has erred in removing vaccine-injured children from access to the Vaccine Act if they are found to have a genetic mutation. Several decisions of this court have accepted this flawed premise.

In *Snyder v. Sec'y of Health & Human Servs.*, 553 F. App'x 994, 1004 (Fed. Cir. 2014), this court held that "the evidence supports a finding that the SCN1A gene mutation was, more likely than not, the sole cause" of the seizure disorders that occurred upon vaccination. This over-simplification has been discredited, *see Cetica, supra.* Until legislative attention brings the statute into conformity with advancing science it befalls the court to do our best to get it right.

In *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1368 (Fed. Cir. 2013), although the infant experienced a prolonged seizure the day after the DTaP vaccination, and continued to experience seizures and convulsions, this court affirmed the Special Master's finding that "the SCN1A gene mutation was the sole substantial cause of Deribeaux's seizure disorder and developmental delays." However, the wealth of scientific knowledge between then and now teaches that a "sole" cause is rare indeed.

In *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373 (Fed. Cir. 2012), *rehearing denied*, 690 F.3d 1380, 1382 (Fed. Cir. 2012), this court held that a mutation was

solely responsible for the child's seizures that were initiated by the vaccination.

In all of these cases, there was a direct cause-and-effect relation between vaccination and the seizure response, yet the court held that the vaccination did not bring the injury within the Vaccine Act. This is a case of "a little knowledge" producing an over-simplification of extraordinarily complex relationships, while contravening the purposes of the Vaccine Act: to share the burden of vaccine injury, while preserving the development and manufacture of vaccines.

* * *

The government argued that E.O. would have been gravely injured independent of his six-month vaccinations. This is not only contrary to the statute; it is also contrary to the scientific evidence, for it is conceded that E.O.'s DTaP vaccinations triggered an immediate reaction of seizures and fever, followed by more seizures, encephalopathies, and ensuing disability.

The only difference between this case and a compensable case was that E.O.'s parents had his DNA analyzed. Modern science is starting to explain what had previously been inexplicable. In retrospect, had E.O.'s mutation been known before his routine six-month vaccination, the vaccination might not have occurred. But DNA analysis before vaccination is not compulsory—vaccination is compulsory.

We should rehear en banc, to apply the Vaccine Act in accordance with its purpose. From the denial of reconsideration, I respectfully dissent.