No. 14 - _____

In the
# Supreme Court of the United States

HARRY TEMBENIS and GINA TEMBENIS,
Administrators of the Estate of ELIAS TEMBENIS,
deceased,

*Petitioners,*

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

*Respondent.*

On Petition for a Writ of Certiorari
to the U.S. Court of Appeals for the Federal Circuit

## PETITION FOR WRIT OF CERTIORARI

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## QUESTION PRESENTED

Under §300aa-15(a) of the National Childhood Vaccine Injury Act of 1986 ["the Vaccine Act"], 42 U.S.C. §300aa-1, *et seq*., "compensation awarded ... to a petitioner under Section 300aa-11" for "vaccine-related injury or death ... shall include" the following:

> In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

42 U.S.C. §300aa-15(a)(3)(B).

**The Question Presented is:**

**Whether the right to receive compensation provided by §300aa-15(a)(3)(B) is extinguished when the injured vaccinee dies before a decision awarding such compensation is rendered?**

## PARTIES TO THE PROCEEDING

The parties to the proceeding below were Petitioners Harry and Gina Tembenis, administrators of the estate of Elias Tembenis, their late son. They were Appellees before the U.S. Court of Appeals for the Federal Circuit and petitioners/legal representatives of their son in proceedings under the Vaccine Act. *See* 42 U.S.C. §300aa-11(b)(1)(A). Respondent, the Honorable Kathleen Sebelius, the Secretary of Health and Human Services, was Appellant below.

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## OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit reversing the Court of Claims' decision is reported at 733 F.3d 1190 (Fed. Cir. 2013). PA2a.[1] The opinion of the U.S. Court of Claims sustaining the Special Master's award and denying the Motion for Review is reported at 2012 U.S. Claims LEXIS 1359 (Fed. Cl. Oct. 19, 2012). PA22a. The opinion of the Special Master awarding Petitioners $1,084,955.61 in damages is unpublished but available at 2012 U.S. Claims LEXIS 1047 (Fed. Cl. July 31, 2012). PA29a. The Special Master's Ruling on Compensation for Lost Earnings of Elias Tembenis is unpublished but available at 2011 U.S. Claims LEXIS 2200 (Fed. Cl. Oct. 26, 2011). PA35a. The Special Master's Decision on Entitlement to Compensation is unpublished but available at 2010 U.S. Claims LEXIS 950 (Fed. Cl. Nov. 29, 2010). PA51a.

## JURISDICTION

The U.S. Court of Appeals for the Federal Circuit rendered its opinion and entered its judgment on October 28, 2013. PA20a. Jurisdiction in this Court, therefore, exists under 28 U.S.C. §1254(1).

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[1]All reference to the attached Petitioners' Appendix use the prefix "PA."

## FEDERAL STATUTE INVOLVED

This case involves the interpretation and scope of 42 U.S.C. §300aa-15. The entire subsection is set forth in the Appendix [PA89a]; however, its most salient provisions for this case are set forth here.

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(a) General rule. Compensation awarded under the Program to a petitioner under [42 USCS §300aa-11] for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part shall include the following:

* * *

(2) In the event of a vaccine-related death, an award of $ 250,000 for the estate of the deceased.

* * *

(3)(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

* * *

(d) Types of compensation prohibited. Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

## INTRODUCTION

In its opinion, the Federal Circuit has conditioned the award of adequate compensation for children and adults injured by vaccines on who wins a ghoulish race: a glacial bureaucracy or the Grim Reaper. By depriving grieving parents of the statutory right to recover projected lost earnings when a child who has suffered vaccine injuries dies while his vaccine claim is pending, the court rewards the very governmental agency responsible for the inexcusable (and increasing) delays in its vaccine compensation program at the direct expense of those whom Congress designed the program to benefit. The court's opinion contravenes the plain language of the Vaccine Act, the express intent of Congress, bedrock common law principles, and its own prior opinions. There will be no inter-circuit conflicts to temper this decision as the Federal Circuit hears all vaccine appeals. Resolution of this issue, therefore, must come from this Court.

As an infant, Elias Tembenis suffered catastrophic injuries after receiving a vaccination. He died at age 7 from those injuries while waiting for the National Vaccine Injury Compensation Program ["Vaccine

Program"] to process his claim. It had been four years. Yet his parents would wait five more to receive a final award. PA29a. When they did, the Secretary of Health and Human Services ["HHS"] challenged the court's $659,955.61 award for Elias' lost future earnings because Elias had not lived to see that final judgment. PA37a. The Special Master rejected the Secretary's arguments. PA50a. The Federal Circuit, however, agreed with the Secretary and denied that portion of the award. PA19a.

A writ of certiorari is warranted here because the meaning and scope of §300aa-15(a)(3)(B) is a recurring question of national importance. Because the Vaccine Act specifically provides for compensation even when a vaccine-injured child or adult dies, it is certain that many other injured children and adults will die before filing or while their claims under the Vaccine Act are pending and that their deaths will also be held to preclude an award to their representatives of lost future earnings, ordinarily the largest portion of most such awards. Unfortunately, the risk of recurrence is increasing because delays in the Vaccine Program are growing exponentially. For example, HHS' *goal* for *average* processing time in 2008 was 1,422 days, nearly four years. *See infra* note 7.

The Federal Circuit's opinion also deprives devastated families of important statutory rights. The Vaccine Act is clear and unambiguous that compensation for vaccine-related injuries or death "shall include" both actual and projected lost earnings. *See* 42 U.S.C. §§15(a) and 15(a)(3). Nothing in the Act makes any combination of such compensation elements mutually exclusive. Moreover, the Federal Circuit has long held that compensation under the Act is not

contingent upon the actual, post-injury life of the injured child. *See, e.g., Edgar v. Sec'y of HHS*, 989 F.2d 473, 477 (Fed. Cir. 1993). Indeed, the Secretary has already conceded that, had Elias lived, he would have been entitled to a $659,955.61 award for lost future earnings. As a result, the Federal Circuit's opinion denying such compensation will also serve to deprive other families like Elias' of valuable statutory rights.

Without review, the Federal Circuit's opinion will also enshrine in the Vaccine Act very disparate treatment of children and adults who have suffered the same vaccine-related injuries depending on when and if their claims are resolved and when and if they die before that occurs. This disparate treatment would also include those who suffered vaccine injuries but died of something else as well as adults who die before their vaccine claims are filed or resolved.

A second reason for granting the petition is that the Federal Circuit's opinion's is fundamentally inconsistent with other opinions of that court. Although the panel attempted to distinguish Elias' case on its facts, the distinctions it made were largely meaningless and cannot be squared with the consistent rationale undergirding prior opinions of that Circuit on compensation under the Vaccine Act.

Tracking the plain language of the Vaccine Act, the Federal Circuit has consistently permitted a deceased child's representative to seek *both* recovery of compensation for vaccine-related *injuries* under §300aa-15(a)(1), (3), and (4), and a *death* benefit under §300aa-15(a)(2). This is due, in part, to the Federal Circuit's full embrace of the notion that remedial statutes, like the Vaccine Act, are to be construed liberally. By contrast, the Federal Circuit's decision

here rejects this interpretation in favor of one that views the statutory death benefit as the alternative to and award of projected lost earnings under a strict and selective construction of the Vaccine Act.

Finally, the Federal Circuit's interpretation of 42 U.S.C. §300aa-15(a)(3)(B) is fatally-flawed and implausible. First, it interprets the Vaccine Act to measure impaired earning capacity from the *date of the award*, not the date of vaccine-related injury. While there is no uniform rule in all states for all tort claims as to when the *endpoint* occurs in a calculating lost future earnings or even whether they are to be awarded to a decedent's family, there is an "American rule" as to when such calculations begin – with the injury. Thus, without a word from Congress, the First Circuit has abandoned this long-standing rule in favor of the one prevailing in England. Worse, the court has imposed this new rule based on an obvious misreading and wholesale amendment of the Vaccine Act.

In interpreting §300aa-15(a)(3)(B) against the backdrop of tort schemes which have no application to a *compensation* program – and which this Court held to be preempted by that compensation program in *Bruesewitz* – the Federal Circuit has also ignored the plain language of the Vaccine Act. Its first omission is the most obvious: the lack of any indication in the plain language or structure of the Act that would make any combination of elements of compensation mutually exclusive.

Second, the panel ignored Subsection *15(b)*'s express provision for *both* a death benefit and actual and projected lost earnings for injuries suffered before the Vaccine Act was passed. Third, the panel mischaracterized the nature of the compensation

afforded under the Vaccine Act using inapposite tort principles. Having painted itself into an inappropriate corner, the court found that the Special Master's interpretation of §300aa-15(a)(3)(B) somehow affords a double recovery. The court, however, ignored Subsection 15(d)(2), which expressly defines the nature of compensation for lost actual and future lost earnings under the Vaccine Act and which destroys the legal basis, if any, for the panel's conclusion. Moreover, the language of that Act, its legislative history, and its interpretation by other circuit courts reveals that Congress more likely embraced, rather than eschewed, the award both of future lost earnings and of a death benefit.

For all of these reasons, the Petition should be granted.

## STATEMENT OF THE CASE

Although vaccines are safe for the vast majority of people to whom they are administered, it is and has always been the case that a small number of people will be gravely injured by any vaccine and a few will die as the result of those injuries. *See Schafer v. American Cyanamid Co.,* 20 F.3d 1, 4 (1st Cir. 1994); H.R. REP. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. Elias Tembenis was one of those inevitable few.

On December 26, 2000, Elias, then a healthy 4-month old, received the Diphtheria-Tetanus-acellular-Pertussis ["DTaP"] vaccine. PA59a. Within hours, he suffered catastrophic injuries and his first seizure. PA50a-61a. Because of his injuries and recurring seizures, Elias was diagnosed with seizure

disorder, Pervasive Developmental Disorder, and developmental delay. PA63a.

In 2003, seeking "simple justice"[2] and compensation for his vaccine-related injuries, Elias and his parents began their long journey through the courts and administrative agencies when they filed a petition for compensation in the National Vaccine Injury Compensation Program ["NVICP"]. PA52a.

Unfortunately, Elias was unable to complete that journey. On November 16, 2007, Elias went into bradycardiac arrest during a seizure. PA65a. The next day, his parents, faced with a child with no neurologic functioning and massive organ failure, made the agonizing choice to withdraw aggressive life support. *Id.* Six minutes later, Elias Tembenis died from his vaccine-related injuries. *Id*. Eight years later, the journey Elias and his parents began is still incomplete.

*The Vaccine Act*

In the mid 1980's, thousands of American families faced a long, hard slog through the tort system or endless settlement negotiations with vaccine manufacturers to obtain any compensation for vaccine-related injuries. Even then, "no recovery may be available. Yet futures have been destroyed and mounting expenses must be met." H.R. REP. No.

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[2]In describing the purposes of the Act at the time of its passage, Dr. Martin Smith, Chairman, American Association of Pediatrics, assured parents it would provide "simple justice to children." *See Compensating Vaccine Injuries: Are Reforms Needed?: Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Resources,* 106th Cong. (1999).

99-908, at 6, *reprinted in* 1986 U.S.C.C.A.N. at 6347. At the same time, some vaccine manufacturers threatened to abandon this field of therapy because of the threat of lawsuits seeking compensation for mounting vaccine-related injuries. *See Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1374 (Fed. Cir. 2009); H.R. REP. No. 99-908, at 6.

Responding to these concerns, Congress created a no-fault insurance program that "postpones actions in state court by requiring plaintiffs to pursue remedies under the NCVIA before attempting a tort claim in state court." Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L. J. 351, 355 (2001). Under this compensation programs, awards were to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. REP. No. 99-908, at 3. In this fashion, Congress could "[c]reate a compensation system that is speedy and generous enough to dissuade petitioners from going into court." H.R. REP. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313, 2313-365; H.R. REP. No. 99-908, at 26 ("vaccine-injured persons will now have an appealing alternative to the tort system").

A critical issue in any vaccine claim is the question of causation. Unlike other drugs, vaccines do not act directly on a disease process or condition. Instead, vaccines attempt to stimulate the immune system to produce antibodies that protect against a disease *from which the patient does not yet suffer*. *See Toner v. Lederle Labs.,* 779 F.2d 1429, 1430 (9th Cir. 1986). The "bank-shot" nature of vaccines then makes proving that the vaccine stimulated other, dangerous reactions very difficult. In recognition of that scientific fact, the

Vaccine Act provides two mechanisms to obtain benefits: table claims and causation-in-fact claims. In a table claim, a claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table within a prescribed period is afforded a presumption of causation. 42 U.S.C. §§300aa-11(c)(1)(C)(I); 300aa-14. "He need not prove fault. Nor, to prove causation, need he show more than that he received the vaccine and then suffered certain symptoms within a defined period of time." *Schafer v. American Cyanamid Co.,*20 F.3d 1, 3 (1st Cir. 1994) (citing §§300aa-13, 300aa-14).

Like almost 90% of the participants in the NVICP today, however, Elias asserted *off*-Table claims. PA53a; *see* Peter H. Meyers, *Fixing the Flaws in the Federal Vaccine Injury Compensation Program*, 63 ADMIN. L. REV. 785, 790 & n.19 (Fall 2011) (quoting former Chief Special Master, Gary J. Golkiewicz). As a result, he and virtually all other petitioners in the program could not avail themselves of Congress' key enticement to seek compensation in the NVICP rather than in the courts. Instead, to prove his claims, Elias and his family had to establish that but for his vaccination, he would not have been injured, and that his vaccination was a substantial factor is bringing about his injury. *Shyface v. Sec'y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). They did. PA51a.

*Proceedings Below*

To seek compensation for vaccine-related injuries, victims and/or their representatives must first bring their claims in the Court of Federal Claims. *See* 42 U.S.C. §300aa-12. To that end, Elias Tembenis,

through his father and legal representative, Petitioner Harry Tembenis, filed a petition in the U.S. Court of Federal Claims on December 16, 2003. PA52a; *Harry Tembenis, parent of Elias Tembenis, a minor*, No. 03-2820V, in the in the United States Court of Federal Claims, Office of Special Masters (Dec. 16, 2003). On November 13, 2008, the caption was amended to name Harry and Gina Tembenis, as administrators of Elias' estate, as Petitioners. *Id.*

The Special Master convened an entitlement hearing on October 23, 2009, and, on November 29, 2010, issued a decision finding that the DTaP vaccine administered to Elias had caused his injuries and untimely death and that Petitioners were entitled to compensation under the Vaccine Act. PA51a.

In determining the amount of compensation to be awarded, all parties agreed that Petitioners were entitled to a total of $175,000.00 for Elias' pain and suffering and past unreimbursable expenses, pursuant to 42 U.S.C. §300aa-15(a)(1)(B) and (a)(4). PA29a. The parties also agreed that Petitioners were entitled to the $250,000.00 death benefit under §300aa-15(a)(2) since Elias' death was found to be vaccine-related. PA29a. The parties disagreed, however, as to whether Petitioners were entitled to any compensation for Elias' impaired earning capacity, measured by his projected loss of future earnings, under §300aa-15(a)(3)(B). PA37a.

On October 26, 2011, the Special Master ruled that Elias' estate was entitled to compensation for his Elias' lost earnings. PA35a. The Special Master stated:

> The Circuit has indicated that all the forms of compensation set forth in § 15(a) are available in the case of a deceased petitioner, and the

> statute specifically provides in section 15(a)(3)(B) for compensation to minor children. *See Zatuchni*, 516 F.3d at 1322 (stating 'that recovery under § 300aa-15(a)(1) through 4 is permitted' following the death of the vaccinee). On its face, the statute does not discriminate between stricken vaccines who die as children and those who perish in adulthood. . . .In sum, the plain language of section 15(a)(3)(B), in addition to the decisions in *Zatuchni* and *Edgar*, forecloses the interpretation advocated by the Secretary.

PA42a.

On July 31, 2012, the Special Master issued his opinion awarding Petitioners a lump sum payment of $1,084,955.651 in compensation for Elias' vaccine-related injuries and death. PA29a. This award consisted of a death benefit of $250,000.00 [§300aa-(a)(2)]; past unreimbursable expenses and actual pain and suffering in the amount of $ 175,000.00 [§300aa-(a)(1)(A) & a(4)]; and lost future earnings of $659,955.61 [§300aa-(a)(3)(B)]. PA29a.

On October 19, 2012, on Motion for Review, the Court of Federal Claims sustained the Special Master's Decision awarding $1,084,955.61. PA22a. In the court's opinion, Senior Judge Merow held: "As the language of section 15(a)(3)(B) '[i]s clear and fits the case, the plain meaning of the statute will be regarded as conclusive.'" PA28a (citing *Norfolk Dredging Co. v. United States,* 375 F.3d 1106, 1110 (Fed. Cir. 2004); *Hall v. United States*, 677 F.3d 1340, 1345 (Fed. Cir. 2012).

The Secretary appealed to the Federal Circuit which reversed the Court of Federal Claims' decision

awarding compensation for lost future earnings.[3]

In holding that compensation for lost future earnings is limited to claimants who are alive at the time a judgment awarding compensation is entered, the court started with the assumption that lost future earnings are determined as of the *date of that judgment*. Plugging that assumption into the plain language of §300aa-15(3)(B), the court reasoned that

> when the claimant dies before compensation is awarded, there is no reasonable expectation that the claimant would attain age 18. We thus conclude that the most natural reading of subsection (a)(3)(B) is to limit the eligibility for lost future earnings to persons who are alive at the time the compensation award is made.

PA10a.

In making its assumption, the panel expressly relied upon 42 U.S.C. §300aa-13(b)(1) which the court believed required it to measure lost future earnings based on the condition of the child at the time of the award. As discussed below, Subsection 13(b)(1) requires a special master to consider the injured person's current condition only "in evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report or summary" in the context of determining whether an injury or death is vaccine-related or not and thus whether *any* compensation is due. *Id.* The statute does not discuss how one calculates the amount of any award. *Id.*

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[3] PA2a. The Secretary did not dispute the Special Master's award of past pain and suffering, actual unreimbursable expenses, or the statutory death benefit. *See* PA37a. As a result, those awards were not and are not part of this appeal.

The court also attempted to explain its decision by applying principles from tort law and engaged in a lengthy discussion as to whether the compensation sought for lost future earnings would qualify as damages in a survival action or one for wrongful death. In concluding that recovery under subsection (a)(3)(B) is "analogous to recovery under a survival statute," because it allegedly addresses recovery of amounts necessary for the victim's sustenance, while recovery of the statutory death benefit "aligns to a wrongful death statute," PA13a, the court concluded that an award of both would amount to double recovery. *Id.* It did so even though Subsection 15(d)(2) states that compensation under Subsection 15(a)(3)(B) is not solely for "[t]he health, education, or welfare of the person who suffered the vaccine-related injury..." and the families of decedents under the Vaccine Act are permitted to bring separate suits for their own injuries outside of the NVICP. *See, e.g., Schafer*, 20 F.3d 1. The court did not discuss either legal impediment to its interpretation of Subsection 15(a)(3)(B).

The Federal Circuit panel also addressed contrary authority in prior, apposite, Federal Circuit decisions. Distinguishing these cases on their facts alone, the court did not address their common rationale, grounded in a plain reading of Subsection 15(a), which provides that compensation "shall include" four elements and made no combination of those elements mutually exclusive.

From the denial of compensation for lost future earnings and the Federal Circuit's judgment of October 28, 2013, Petitioners now seek a writ of certiorari.

## REASONS FOR GRANTING THE PETITION

This Court should grant the petition for writ of certiorari for three reasons:

### I. THE MEANING AND SCOPE OF 42 U.S.C. §300aa-15(a)(3)(B) IS A RECURRING QUESTION OF NATIONAL IMPORTANCE

#### A. The Question Presented Will Recur if Not Resolved by This Court Now

The Vaccine Act created a program to award compensation in the event of vaccine-related injury or death. 42 U.S.C. §300aa-10(a). Thus, the Vaccine Act expressly authorizes the legal representatives of a person who dies from vaccine-related causes to file or pursue a pending petition seeking compensation for his death. 42 U.S.C. §300aa-11(b)(1)(A). In addition, the Act has also been interpreted to permit a legal representative to seek and recover compensation when a deceased person was *injured* by a vaccine but *died* from something else.[4]

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[4] *See, e.g., Figueroia v. Sec'y of HHS*, 715 F.3d 1314, 1317 (Fed. Cir. 2013). The Court explained:

> It is not disputed that a claim for injury compensation under the Vaccine Act survives the injured person's death and may be asserted by the personal representative of the estate in most situations, including (1) when the petition is filed before death by an injured individual who subsequently dies from non-vaccine-related causes; (2) when the petition is filed before death by a vaccine-injured individual who subsequently dies from vaccine-related causes ... and (3)

There is, therefore, a great likelihood that other vaccine-injured children and adults will die before their claims are filed or processed and compensation awarded to them under the Vaccine Act. If the Federal Circuit's opinion is not reviewed and reversed by this Court now, their deaths will be held to bar their legal representatives from receiving compensation for loss of future earnings, one of only four types of possible compensation under the Vaccine Act. *See* 42 U.S.C. §300aa-15(a)(3)(B). Under the Federal Circuit's rationale, this would be true whether their deaths were vaccine-related or not, and whether or not their estates receive a death benefit. *See* 42 U.S.C. §300aa-15(a)(2) (death benefit available only for vaccine-related death).

The risk that a person who has sustained a vaccine injury will die while his or her claim is being processed grows with each passing year. In passing the Vaccine Act, Congress expressed its intention that its vaccine compensation program grant awards to those injured "quickly, easily, and with certainty and generosity." H.R. REP. 99-908, at 3, *reprinted in* 1986 U.S.C.C.A.N. at 6344. If it ever did, the program no longer works that way.

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> when the petition is filed after death by the estate of a vaccine-injured individual who dies of vaccine-related causes...

*Id., citing Griglock v. Sec'y of HHS*, 687 F.3d 1372, 1374-75 (Fed. Cir. 2013); *Zatuchni v. Sec'y of HHS*, 516 F.3d 1312, 1321, 1323 (Fed. Cir. 2008). The Court went on to hold that a claim may also be asserted when the petition is filed after the death of a vaccine-injured individual who died of non-vaccine related causes. 715 F.3d at 1324-25.

According to investigations undertaken by the Government Accounting Office ["GAO"],[5] processing vaccine claims takes far longer than anyone ever expected. Less than 15 percent of claims initially filed in the program were processed within one year or less.[6] Instead, almost 40 percent of claims took from two to five years to process and another almost 20 percent took more than five years. *Id.* At the time of the report, some cases had been pending for *eight years or more* and remained open. *Id*.

The unacceptable delay identified by GAO has only gotten worse over time. *See* Meyers, *supra*, at 805. The actual *average* claims processing time in 2005 was 894 days. The government's aspirational *target* for 2008 grew to an average of 1,422 days, nearly four years.[7] Petitioners' journey through the NVICP began with

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[5] *See* F.R.E. 201(b)(2). This Court is requested to take judicial notice of the facts relating to the operations of the NVICP described here.

[6] U.S. Gov't Accounting Office, GAO/HEHS-00-8, *Vaccine Injury Compensation Program Challenged to Settle Claims Quickly and Easily* (1999), at 2. Although this Court has noted that the NVICP ostensibly imposes a 240-day time limit for processing claims, 42 U.S.C. §300aa-12(d)(3) (cited in *Bruesewitz v. Wyeth* LLC, 131 S. Ct. 1068, 1073 (2011)), the significant delays described have rendered that deadline illusory.

[7] U.S. Dep't of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation, *National Vaccine Injury Compensation Program Strategic Plan* (April 2006) at 7-9, *available at* http://webcache.googleusercontent.com/search?q=cache:http://www.hrsa.gov/vaccinecompensation/strategicplan406.pdf.

filing in 2003. Elias Tembenis died in 2007. Compensation was finally awarded in *2012*. PA29a.

The persistence of significant delays in the NVICP means that there is a substantial likelihood that a significant number of other vaccine-injured children and adults will also die before their claims are finally resolved in the NVICP.

Because the question presented is thus certain to recur and to impact significantly the lives of a growing number of participants in the NVICP, it is an issue of critical national importance warranting the grant of a writ of certiorari.

### B. The Federal Circuit's Opinion Robs Devastated Families of Important Statutory Rights

Under the Vaccine Act, compensation awarded to one who, like Elias Tembenis, was injured by a vaccine, or his personal representative "shall include" actual and projected unreimbursable, vaccine-related expenses and actual and projected lost earnings. *See* 42 U.S.C. §300aa-15(a)(1) & (3). PA89a-90a. In addition, damages for actual and projected pain and suffering, capped at $250,000.00, may also be recovered. *See* PA90a [§300a-15(a)(4)]. Finally, if the injured person ultimately dies from vaccine-related causes, his estate may recover a death benefit of $250,000.00. PA91a [§300a-15(a)(2)]. These amounts are reduced before payment to the net present value of the element, including pain and suffering, then are paid in a lump sum. PA93a [§300a-15(f)(4)(A)]. In fact, the cap on pain and suffering must be applied *before* the amount is further reduced to net present value. *See McAllister v.*

*Sec'y of HHS,* 70 F.3d 1240, 1242 (Fed. Cir. 1995). Other than attorney's fees, PA92a [§300a-15(e)], there is no other kind of compensation available to estates, representatives, or victims under the Vaccine Act.[8]

What this means is that, in the case of a child injured by a vaccine, the largest element of damages, by far, will almost certainly be lost earnings. That is the case here. Under the special master's award, the Court awarded the estate the death benefit of $250,000.00, *combined with* past unreimbursable expenses *and* actual pain and suffering of $175,000.00, and lost future earnings of $659,955.61, which had already been reduced to net present value. PA29a.

Neither the Federal Circuit nor the Secretary has ever contended that, had Elias lived until judgment was entered here, his personal representatives, Petitioners Harry and Gina Tembenis, would have been denied the full panoply of compensation available for vaccine injury under the Vaccine Act, including lost future earnings. Moreover, even the panel conceded that, in that event, such an award of lost future earnings "[*i*]s *not contingent upon the petitioner living to 18*, and the petitioner does not have to wait until age 18 to receive the lump sum." PA11a (emphasis supplied); *see Edgar,* 989 F.2d at 477. Instead,

> The fact that a vaccine-related death followed a vaccine-related injury in a particular case does not alter the fact that certain expenses

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[8]The Vaccine Act specifically prohibits the award of punitive or exemplary damages and, except for death benefits and lost wages, compensation "for other than the health, education, or welfare of the person who suffered the vaccine-related injury..." within the NVICP. PA91a-92a [§300a-15(d)].

> were incurred, wages lost, or pain and suffering endured in the interim, and these damages are no less related to or caused by a vaccine-related injury within the meaning of subsections (a)(1), (3), and (4) simply because the vaccine-injured person in question is no longer living.

*Zatuchni,* 516 F.3d at 1318-19; *Figueroia,* 715 F.3d at 1318 (quoting *Zatuchni*).

This view is consistent with the long-standing rule that losses attributable to an injury must be measured by the victim's *pre-injury* life expectancy. Although the particular cause of action and state may determine the *endpoint* at which one cuts off recovery for actual or projected lost earnings, there is considerable agreement in the United States as to the point at which one *begins* to measure such compensation.

For example, in *Sea-Land Servs. v. Gaudet*, 414 U.S. 573, 594 (1974), *abrogated by statute on other grounds*, *Miles v. Apex Marine Corp.*, 498 U.S. 19, 31 n.1 (1990), this Court explained:

> Under the prevailing American rule, a tort victim suing for damages for permanent injuries is permitted to base his recovery 'on his prospective earnings for the balance of his life expectancy *at the time of his injury undiminished by any shortening of that expectancy as a result of the injury*...'[9]

By barring the legal representatives of children

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[9] *Id.* (quoting 2 F. Harper & F. James, LAW OF TORTS §§ 24.6 at 1293-94 (1956)) (emphasis in original), *cited in Edgar,* 989 F.2d at 477; RESTATEMENT (SECOND) OF TORTS §924, cmts. d,e (1979).

and adults who were injured by vaccines but died before their claims were resolved from recovering compensation for lost future earnings resulting from that injury, the Federal Circuit has deprived them of a significant statutory right. Whether that deprivation was warranted by 42 U.S.C. §300aa-15(a)(3)(B) is, therefore, a recurring issue of national importance that merits the grant of a writ of certiorari here.

### C. Under the Federal Circuit's Opinion, Vaccine-Injured Persons With Identical Injuries Are Not Treated the Same

Sadly, the opinion of the Federal Circuit enshrines in the Vaccine Act very disparate treatment for similarly-situated people depending upon how long it takes their claims to be processed and when and if they die before they are awarded compensation. In fact, even genetically-identical twins, injured by the same vaccine on the same day, whose parents filed petitions for them under the Vaccine Act on the same day, who have the same life expectancy and potential earnings, and who suffered the same catastrophic side effects on the same day, would not be treated equally.

Under this scenario, if one twin dies from her vaccine-related injuries on the day before judgment is entered under the Vaccine Act, but the other, who was put on life support, manages to stay alive until the judgment is entered but dies the next day, the parents, as legal representatives of both, would receive a capped death benefit for the first twin but uncapped lost future earnings for the second. Under the Federal Circuit's decision then, the economic value of one identical twin's life would be substantially greater than that of the

other even though both suffered the same vaccine-related injury and death.

The Federal Circuit's decision also leaves those who have suffered severe vaccine-related injuries but die of something else with little compensation save actual expenses and capped, past pain and suffering. Because they would receive no death benefit, the economic value of their life under the Vaccine Act would arguably be zero.

While the panel's decision turned, in part, on the alleged double recovery that would result if one could recover both compensation for lost earnings, under Subsection 15(a)(3)(B), and a death benefit, under Subsection 15(a)(2), the court's second rationale, based on its reading of Subsection 15(a)(3)(B) to exclude the dead, would apply equally to bar recovery of lost earnings by the personal representatives of those injured by vaccines but killed by something else. Once again, those whose claims are processed within their lifetimes would receive projected lost earnings. The representatives of those who had the misfortune to die while waiting for a decision would not even though the two individuals suffered exactly the same injuries, had the same life expectancy at the time of injury, and the same prospective earnings.

Moreover, such disparate treatment is not confined to children. Subsection 15(a)(3(A), which addresses the lost earnings of adults, largely parallels Subsection 15(a)(3(B) with regard to future earnings. Thus, the rationale used to justify barring recovery of projected lost earnings where the vaccine-related injury results in death will apply equally to those who are *over* 18 and seeking lost future earnings. The only difference is that they might receive some *past* lost earnings.

Finally, the court's use of the date of judgment as the touchstone for calculating damages for future lost wages will place even living claimants on unequal footing. While the court's opinion speaks only to awards made to estates of lost future earnings, the rationale for its decision – that lost earning capacity is assessed as of the time of award – would mean that the earning capacity of even severely-injured but living children and adults would be assessed on the basis of their current, and not their pre-injury, condition. Thus, in a case like *Edgar,* where the child was in a coma, her future earnings, assessed on the date of judgment, would effectively have been zero as well. That is not at all what that court found. 989 F.2d at 477 ("economic losses attributable to an injury must be measured by the victim's pre-injury life expectancy"). Nothing in the Vaccine Act justifies this disparity or the cruel irony of giving the government a heftier discount the longer its delays an injured child's recovery.

Conversely, nothing in the Act would justify measuring lost future earnings for those who are alive from the date of the injury and those who have died from the date of judgment. In either event, the Federal Circuit's opinion does not treat similarly-situated parties the same.

The Federal Circuit has already flatly rejected just this kind of disparate treatment in a similar vaccine case. *See Figueroia*, 715 F.3d at 1318. In holding that the vaccine-related injury claims of a decedent who died from non-vaccine-related causes survived his death, the *Figueroia* court explained:

> If two individuals received the same vaccine on the same day, experienced the same nonfatal complications, and sought identical

> compensation, but died of accidents within days of one another—one the day before filing a petition, and the other the day after—the estate of the person who had not yet filed could recover nothing, while the other estate would receive the maximum injury benefit allowable under the Act. *This makes no sense...It is illogical to attribute to Congress a purpose to deny some claimants compensation while allowing compensation for others who suffer identical vaccine-related injuries.*

*Id.* (emphasis supplied). Nevertheless, only months later, the panel here restored equally nonsensical dichotomies.

Children who have been injured by vaccines are already members of a blessedly exclusive but exceptionally unfortunate club. Their misfortune should not be compounded by making the compensation their families receive for their injuries and death contingent upon either the persistence of a pulse or the efficiency of the NVICP. For these reasons, the question presented is a recurring question of national importance warranting a grant of the petition for writ of certiorari here.

## II. THE FEDERAL CIRCUIT'S OPINION IS FUNDAMENTALLY INCONSISTENT WITH OTHER OPINIONS OF THAT COURT

For almost 25 years, the Federal Circuit has interpreted Subsection 15(a) of the Vaccine Act to permit a deceased child's or adult's legal representative to seek *both* compensation for vaccine *injuries* pursuant to §300aa-15(a)(1),(3), and (4) and a *death* benefit

under §300aa-15(a)(2).[10] The *Zatuchni* court explained:

> [I]t is in no way inconsistent with the text of 42 U.S.C. §300aa-15(a) to award compensation under subsections (a)(1), (3), and (4) for damages that 'resulted from' or were sustained 'by reason of' a vaccine-related *injury in addition to* the death benefit provided for under subsection (a)(2) '[i]n the even of a vaccine related death'... To the contrary, it is the reading of §300aa-15(a) that most naturally flows from its text and structure.

516 F.3d at 1319 (emphasis supplied). This view that a claim for vaccine injury is not extinguished by the death of the injured child or adult and may be asserted by a representative in tandem with a claim arising from his vaccine-related death is ordinarily justified both on grounds that the plain language and structure of the Vaccine Act and, in particular, §300aa-15(a) & (b), demand it, *see, e.g., Zatuchni*, 516 F.3d at 1319-21, but also because it is warranted by this Court's long-standing presumption that remedial statutes are to be construed liberally.[11]

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[10] *See, e.g.*, *Figueroia*, 715 F.3d at 1323; *Griglock,* 687 F.3d at 1375 (denying recovery on limitations grounds but reaffirming that death benefit and lost future earnings are not "exclusive of the other" under the Vaccine Act); *Zatuchni*, 516 F.3d at 1318 (death benefit is not exclusive remedy).

[11] *See Cloer v. Sec'y of HHS*, 675 F.3d 1358, 1362 (Fed. Cir. 2012), *aff'd*, 133 S. Ct. 1886 (2013) (citing *Atchison, Topeka, & Santa Fe Ry. Co. v. Buell*, 480 U.S. 557, 561-62 (1987)); *Figueroia*, 715 F.3d at 1317; *see also Peyton v. Rowe*, 391 U.S. 54, 65 (1968) (citing the "canon of construction that remedial statutes should be liberally construed"). At least one circuit judge has found that this

Despite this clear consensus and directive from the Federal Circuit, a rump line of cases has stubbornly persisted in the Court of Federal Claims. Under these cases, a claim for vaccine injury is held not to survive the death of an injured child. Thus, the death benefit provided by Subsection 15(a)(2), and attorneys fees under Subsection 15(e), are held to be the exclusive remedies available to personal representatives or estates under the Vaccine Act.[12] The Court in *Sheehan* explained this rationale:

> This holding is governed by binding precedent which mandates a strict interpretation in favor of the United States of any statutory waiver of sovereign immunity. (citations omitted) Moreover, the statutory scheme for the

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interpretation is also mandated by federal common law. He explained:

> The issue of survivorship is among the background legal principles for which judicial gap filling is appropriate. The Supreme Court has impliedly held, and eight circuits have explicitly held, that federal common law determines survivorship where the statute is silent as to the issues.

*Zatuchni*, 516 F.3d at 1328-29 (Dyk, J., concurring in the result and dissenting from the majority opinion) (citing *United States v. NEC Corp*., 11 F.3d 136,137 (11th Cir. 1993) (extends rule to claims against the United States)).

[12] *See, e.g*., *Clifford v. Sec'y of the HHS*, 2002 U.S. Claims LEXIS 209 (Fed. Cl. July 30, 2002); *Cohn v. Sec'y of HHS*, 44 Fed. Cl. 658 (1999); *Vijil v. Sec'y of HHS*, 1993 U.S. Claims LEXIS 48 (Fed. Cl. May 7, 1993); *Sheehan v. Secretary of HHS*, 19 Cl. Ct. 320, 320-21 (Cl. Ct. 1990); *but see Andrews v. Sec'y of HHS*, 33 Fed. Cl. 767 (1997) (court awarded pain and suffering damages in addition to the death benefit).

> national vaccine injury compensation program, as well as the legislative history, compels the court to limit petitioner's award to death benefits and attorneys fees.

*Id.* at 320-321. Indeed, this Court has recognized that the sovereign immunity canon may apply to the Vaccine Act. *Sebelius v. Cloer*, 133 S. Ct. 1886, 1895 (2013). However, this Court was also quick to note that "such canons and policy arguments come into play only 'to the extent that the Vaccine Act is ambiguous.'" (Citation omitted). These 'rules of thumb' give way when 'the words of a statute are unambiguous,' as they are here." *Id.*

Prior to this case, no Federal Circuit panel had fully embraced the "exclusive remedy"/strict construction interpretation of Subsection 15(a) as applied to claims for vaccine-related injury and death, even though the court had long acknowledged the potential application of the sovereign immunity canon in vaccine cases. *See, e.g.*, *Zatuchni*, 516 F.3d at 1323, n. 13; *Schumacher v. Sec'y of HHS*, 2 F.3d 1128, 1135 n.12 (Fed. Cir. 1993); *but see Childers v. Sec'y of HHS*, 1999 U.S. Claims LEXIS 76, 85 (Fed. Cl. Mar. 26, 1999) (petitioner entitled to lost earnings even after court construed the statute strictly in government's favor). To the contrary, by the time the Federal Circuit panel issued its opinion in this case, the Circuit had permitted recovery of a death benefit in a variety of permutations involving every other compensation provision in Subsection 15(a), including 15(a)(3). In fact, the Government here did not even contest the award of a death benefit, along with actual pain and suffering and expenses in this appeal. PA5a.

Unable to distinguish the consensus interpretation of Subsection 15(a), reaffirmed in *Zatuchni* and *Edga*r, the panel chose to attempt to distinguish such cases on their facts. As a result, the court focused on the fact that *Zatuchni* involved a claim under §300aa-15(a)(3)(A) for actual lost earnings, *see* 516 F.3d at 1315, while the court ignored the fact that *Zatuchni*'s rationale clearly applies with equal force to claims for *projected* lost earnings. That court had held:

> if a petition is properly filed by a person who suffered a vaccine-related injury, but that person dies of vaccine-related causes while her claim is pending, § 300aa-11(b)(1)(A) does not prevent -- directly or by implication -- the legal representative *of the estate of such a person from requesting each of the categories of compensation listed in § 300aa-15(a)* after they have been properly substituted for the deceased petitioner.

*Id.* at 1321 (emphasis supplied).

Because it holds that projected lost earnings are not available here, the panel's opinion is fundamentally inconsistent with the predominant, consensus rationale running through *Zatuchni* and other Federal Circuit cases cited here. That alone should justify review. The likelihood that two opposing lines of cases, distinguished continually by their facts, will take root in the Federal Circuit as they have in the court of claims, however, means that it is up to this Court to provide direction now. Without it, there will be chaos in the Courts of Federal Claims as judges and Special Masters try to reconcile these inconsistent directives from the same court and issue their rulings with fairness and predictability. Thus, further "percolation"

of this issue is unlikely to benefit this Court and would probably make the situation worse.

## III. THE FEDERAL CIRCUIT'S INTERPRETATION OF 42 U.S.C. §300AA-15(A)(3)(B) IS FATALLY FLAWED AND IMPLAUSIBLE

### A. The Federal Circuit Improperly Measures Lost Future Earnings Under the Vaccine Act Based on a Child's Condition on the Date *of the Award*

The lynchpin of the Federal Circuit's decision here is its determination that lost earnings in cases of vaccine-related death must be calculated by assessing what earnings would be projected *as of the date the award is made*. PA10a. Because no earnings can reasonably be projected for one who is already dead by that date, the court held that no compensation for lost future earnings was authorized under the Vaccine Act in that event. PA10a-11a.

As suggested above, in making this novel determination, the court abandoned the traditional "American rule" that one measures prospective lost earnings by "the balance of his life expectancy *at the time of his injury* undiminished by any shortening of that expectancy as a result of the injury."[13] While there is considerable disagreement and confusion among the

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[13] *See Sea-Land Servs. v. Gaudet*, 414 U.S. at 594; *In re Joint Eastern & Southern Dist. Asbestos Litig.*, 726 F. Supp. 426, 429-30 (E.D.N.Y. 1989) (citing cases adopting the American rule in a broad cross-section of states); RESTATEMENT (SECOND) OF TORTS, § 924, cmt. d (1979).

states as to the *endpoint* of such calculations in survival actions as compared to actions for wrongful death and in actions brought by living victims as opposed to grieving families, there is little disagreement in the United States as to when the calculation *begins* – with the injury. In fact, the only country that embraces the rule the Federal Circuit has employed here is Great Britain.[14]

Nothing in the language of the Vaccine Act itself or its legislative history evinces Congress' intent to depart so dramatically from this traditional and broadly-adopted principle. While this divergence may not constitute a technical "conflict" with other circuit courts and state high courts for this Court's purposes, it may well be such a departure "[f]rom the accepted and usual course of judicial proceedings...as to call for an exercise of this Court's supervisory power." SUP. CT. R. 10(a).

The panel attempted to justify its radical new rule by reliance upon a single phrase it misappropriated from 42 U.S.C. §300aa-13(b)(1). *See* PA11a-12a. A review of that provision, however, reveals that the court has simply cut a sentence in half, removed one phrase from its proper context, applied it to another to which it has no application at all, and, in the process, completely rewritten the statute.

As an initial matter, Subsection 13(b) addresses matters to be considered in awarding any compensation at all, not how that compensation is to be

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[14] *See Gaudet*, 414 U.S. at 595, n.32 (discussing the "English" rule), *citing Oliver v. Ashman*, [1961] 3 W. L. R. 669 (C. A.); John G. Fleming, *The Lost Years: A Problem in the Computation and Distribution of Damages*, 50 CALIF. L. REV. 598, 600 (1962).

calculated. Thus, Subsections 13(b)(1) and (2) specifically address medical diagnoses and coroner's reports which would reveal whether an injury or death was vaccine-related or not. The statute then provides: "*in evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary*, the special master or court should consider the entire record and the course of the injury, disability, illness or condition until the date of judgment of the special master or court." §300aa-13(b). In its opinion, the court has simply read out the highlighted phrase and improperly applied the remainder to Subsection 15(a).

It should be clear that nothing in Subsection 13 actually authorized the panel to alter so radically the traditional touchstone used to calculate lost future earnings. *McAllister,* 70 F.3d at 1243, offers no support because *McAllister's* discussion of §13(b)(1) took place in the context of awarding damages for past and future *pain and suffering*, not lost earnings, when medical records of the sort discussed in that provision would arguably be relevant. Moreover, the court in *McAllister* similarly misread §13(b)(1).

Using the traditional and widely-accepted benchmarks applicable where, as here, the statute is silent, Elias' prospective lost earnings should have been projected and his lost earning capacity and life expectancy determined *from the date of this vaccine injury*, not the date of any award. Using the proper measure then, Subsection 15(a)(3)(B) can easily and properly be read to permit an award of lost future earnings. Because the court excluded such compensation from the award here, the petition should be granted.

### B. The Federal Circuit Ignored Subsection 15's Plain Language and Mischaracterized the Nature of the Compensation It Provides

The second reason why the Federal Circuit's opinion is fatally flawed is the panel's misinterpretation of §300aa-15(a)(3)(b). The court ignored the plain language of §§15(a), 15(b), and 15(d)(2) and mischaracterized the nature of lost future earnings.

Under 42 U.S.C. §300aa-15(a), compensation awarded to a petitioner, such as Harry and Gina Tembenis here, for "a vaccine-related injury or death" "shall include" actual and projected unreimbursable expense, PA89a [§300aa-15(a)(1)], "in the event of a vaccine-related death, an award of $250,000.00 for the estates of the deceased, PA90a [§300aa-15(a)(2)], actual and projected lost earnings, PA90a-91a [§300aa-15(a)(3)], and actual and projected pain and suffering. PA91a [§300aa-15(a)(4)]. There is no language in Subsection 15(a) that in any way evinces Congress' intention to make any combination of these elements mutually exclusive.

This reading is confirmed by Subsection 15(b) which addresses claims relating to vaccine injuries that occurred before the passage of the Vaccine Act. In the case of *either* vaccine-related injury or death, the statute permits but does not require awards of actual expenses and a death benefit under Subsection 15(a)(1)(A) and (a)(2), a capped amount for actual and projected lost earnings under Subsection 15(a)(3), pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(b)(1)-(3). There is nothing in the statute or

legislative history or the Federal Circuit's opinion to explain why Congress would have awarded both a death benefit *and* lost projected earnings to those with pre-Vaccine Act injuries but denied such awards to those who suffered post-Vaccine Act injuries.

Despite the unambiguous language of the statute, the court held that §§15(a)(2) and (a)(3)(B) were nevertheless mutually exclusive and that any award of the future lost earnings would somehow impermissibly duplicate the death benefit awarded here.

In reaching a result so contrary to the plain language of the statute, the court mistakenly mischaracterized lost future earnings under Subsection 15(a)(3)(B). This error is grounded in two flawed assumptions. The first is that a death benefit will always be available when lost future earnings are sought. Because Elias' death was vaccine-related, his estate is entitled to seek a death benefit. *See* 42 U.S. 300aa-15(a)(2). However, the rationale of the court's decision here would apply with equal force to those who seek lost future earnings for injured vaccinees who died from something else. They are not entitled to seek a death benefit. *Id*. As a result, the court's assumption that a death benefit will always be available as an alternative remedy is misplaced.

The court's second flawed assumption is that loss of projected future earnings is somehow personal to the deceased under the Vaccine Act or is "compensation for lost wages which would have otherwise provided the income necessary to sustain the [injured] person." PA8a,14a (citing *Sarver v. Sec'y of HHS*, 2009 U.S. Claims LEXIS 776, 28 (Fed. Cl. Nov. 16, 2009)). Because it concluded that such "compensation for lost future earnings of a deceased would only benefit the

estate, not the deceased," the court held that such damages are not recoverable by a personal representative after the death. PA14a.

In reaching this conclusion, the court relied upon tort treatises but ignored the plain language of the Vaccine Act itself. Under Subsection 15(d)(2), compensation under the program cannot include, "*except with respect to compensation payments under paragraphs (2) and (3) of subsection (a) of this section*, compensation for *other than* the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which compensation is paid." (Emphasis supplied). The language of the Act is, therefore, crystal clear that both lost actual and projected earnings under Subsection 15(a)(3) are not considered *by Congress* to be solely for the benefit of the deceased under the Vaccine Act or a substitute for wages. As a result, the court's determination that an award of lost future earnings here somehow would permit a double recovery crumbles.

Moreover, the court's assumption that Congress was concerned about "double" recovery in enacting the Vaccine Act is suspect. In fact, a more generous recovery may have been *intended* since it was not certain that a death benefit would always be available to the representatives of a vaccine-injured child who died from something else. Moreover, in continually expressing its desire to make the program "generous," it is hard to imagine Congress was concerned that the parents of a dead child might somehow get a "windfall."

Instead, it is likely that Congress intended to build a certain amount of "generosity" into the NVICP. This notion is supported by other decisions in the Federal and other circuits in which these courts agreed that a

parent could recover *both* loss of consortium tort damages from a state court and compensation for her vaccine-injured child from the Vaccine Court. *See Abbott v. Sec'y of HHS*, 1992 U.S. Cl. Ct. 473, *rev'd on other grounds*, 27 Fed. Cl. 792 (1993); *Schafer,* 20 F.3d at 6; *Massing v. Sec'y of HHS*, 926 F.2d 113,1135-36 (1993).

The court's reliance on state tort schemes to buttress its decision is also misplaced. The Vaccine Act did not adopt a tort scheme: it created a compensation program. *See, e.g., Deribeaux v. Sec'y of HHS*, 717 F.3d 1363, 1365 (Fed. Cir. 2013) (Vaccine Act created a program "[t]hrough which claimants can petition the Court of Federal Claims to receive compensation for vaccine-related injuries or death"). Thus the court's reference to tort schemes, particularly those that provide for separate claims for "support," is misdirected.

For all of these reasons, the court issued an opinion that is fatally-flawed and fundamentally incorrect. Review by writ of certiorari and reversal is thus warranted here.

## CONCLUSION

For the reasons stated, the Petition should be granted.

Respectfully submitted,

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JANUARY 24, 2014

# APPENDIX

# APPENDIX

# APPENDIX A

United States Court of Appeals
for the Federal Circuit

HARRY TEMBENIS AND GINA TEMBENIS, ADMINISTRATORS OF THE ESTATE OF ELIAS TEMBENIS, DECEASED,

Petitioners-Appellees,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellant.

2013-5029

Appeal from the United States Court of Federal Claims in No. 03-VV-2820, Senior Judge James F. Merow.

Decided: October 28, 2013

JOSEPH PEPPER, Conway, Homer & Chin-Caplan, P.C., of Boston, Massachusetts, argued for petitioners-appellees. On the brief was RONALD C. HOMER.

MICHAEL E. ROBINSON, Attorney, Commercial Litigation Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for the respondent-appellant. With him on the brief were STUART F. DELERY, Principal Deputy Assistant Attorney General, and MICHAEL S. RAAB, Attorney. Of counsel was RYAN D. PYLES, Attorney.

Before O'MALLEY, CLEVENGER, and TARANTO, Circuit Judges.

CLEVENGER, Circuit Judge.

This is a National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") case. *See* 42 U.S.C. § 300aa-1 *et seq*. The question before us is whether the estate of a petitioner who dies prior to judgment is entitled to compensation for lost future earnings. The United States Court of Federal Claims ("Claims Court") answered in the affirmative. *Tembenis v. Sec'y Health & Human Servs*., No. 032820V (Fed. Cl. Oct. 19, 2012) ("Trial Op."). Because eligibility for future lost earnings under § 300aa15(a)(3)(B) requires the person suffering from a vaccine-related injury to survive the compensation judgment, we reverse.

## BACKGROUND

When he was approximately four months old, Elias Tembenis received a Diptheria-Tetanus-acellular-Pertussis ("DTaP") vaccine. Elias developed a seizure disorder shortly afterwards, and his parents, Harry and Gina Tembenis, filed a Petition for Vaccine Compensation on his behalf. While the petition was

pending, Elias died as a result of his seizure disorder at the age of seven. The caption of the case was then amended to name Harry and Gina Tembenis, administrators of Elias' estate, as petitioners.

The Tembenis' petition proceeded, and, in 2010, a special master determined that the DTaP vaccine caused Elias' epilepsy and resulting death. *Tembenis v. Sec'y of Health & Human Servs.*, No. 03-2820V, 2010 WL 5164324 (Fed. Cl. Spec. Master Nov. 29, 2010). The Secretary of Health and Human Services ("Secretary") and the estate agreed that the Secretary would pay the $250,000 death benefit under § 300aa-15(a)(2) and would also pay$175,000 for actual pain and suffering and past unreimbursable expenses under §§ 300aa-15(a)(1) and (a)(4). The parties did not agree, however, on whether Elias' estate was entitled to recover future lost earnings under § 300aa-15(a)(3)(B). The special master, after receiving briefing from the parties on this issue and relying on our decisions in *Zatuchni v. Sec'y Health & Human Servs.*, 516 F.3d 1312 (Fed. Cir. 2008), and *Edgar v. Sec'y of Health & Human Servs.*, 989 F.2d 473 (Fed. Cir. 1993), determined that the estate was entitled to future lost earnings. *Tembenis v. Sec'y Health & Human Servs.*, No. 03-2820V, 2011 WL 5825157 (Fed. Cl. Spec. Master Oct. 26, 2011).

The Secretary reserved her right to challenge the future lost earnings award, but proffered the sum of $659,955.61 as a measure of the lost earnings. The petitioners agreed, and the special master awarded petitioners a lump sum payment of $1,084,955.61, the sum of the$425,000 in uncontested awards and the

$659,955.61 in contested future lost earnings.[1]

The Secretary subsequently filed a Motion for Review with the Claims Court, limited to the question of whether the Tembenis estate is entitled to any future lost earnings award. The Secretary made no challenge to the special master's causation finding or to the awards of the death benefit, pain and suffering, and past unreimbursable expenses. The Claims Court also read our decisions in *Zatuchni* and *Edgar* to support recovery for lost future earnings for a child who died as a result of his vaccine judgment was entered, and thus affirmed the special master's future lost earnings award. Trial Op. at 2-3.

The Secretary now appeals to our court, again arguing that an estate cannot recover lost future earnings under § 300aa-15(a)(3)(B) when the person injured by a vaccine dies before entry of a compensation judgment. We have jurisdiction under 42 U.S.C. § 300aa-12(f), and, as this is purely a question of statutory interpretation, we review the decision of the Claims Court *de novo*, *Locane v. Sec'y Health & Human Servs.*, 685 F.3d 1375, 1379 (Fed. Cir. 2012). Before this case, no compensation award under the Vaccine Act had allowed future lost earnings for the estate of a deceased petitioner. The interpretive question before the court is thus one of first impression.

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[1] Our court has already affirmed the award of $425,000 in uncontested damages. *See Tembenis v. Sec'y Health & Human Services*, No. 2013-5029 (Fed. Cir. May16, 2013) (order granting partial summary affirmance to petitioners-appellees).

## DISCUSSION

Congress enacted the Vaccine Act to stabilize the vaccine market and facilitate compensation for vaccine-related deaths and injuries. *See Lowry v. Sec'y Health & Human Servs.*, 189 F.3d 1378, 1381 (Fed. Cir. 1999). Among other things, the Vaccine Act established the National Vaccine Injury Compensation Program, see 42 U.S.C. § 300aa-10(a), which provides compensation for vaccine-related injuries or death 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 injured by a vaccine, or his or her legal representative, may file a petition for compensation in the Claims Court, naming the Secretary as respondent. A special master then "makes an informal adjudication of the petition," *Bruesewitz*, 131 S. Ct. at 1073, subject to further review by a judge of the Claims Court and our court, *see* 42 U.S.C. § 300aa-12(e)(2) and (f).

The Vaccine Act provides several forms of compensation to those who show that they were injured by a vaccine. *See* 42 U.S.C. §§ 300aa-15(a)(1) through (a)(4). Because the different forms of compensation under § 300aa-15(a) are interrelated, we consider each to determine if subsection (a)(3)(B) is restricted as the Secretary asserts.

Under subsection (a)(1), a vaccine-injured person may recover both past and predicted "actual unreimbursable expenses" which result from the vaccine-related injury. § 300aa-15(a)(1). This includes a vast array of expenses, such as those "for diagnosis,

medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary." *Id*. at § 300aa-15(a)(1)(B)(iii). An award under (a)(1) is intended to alleviate the financial burden of the petitioner's medical treatment. The estate of a person who is dead at the time of the award can recover past expenses, but obviously has no future treatment-related expenses. *Zatuchni,* 516 F.3d at 1318-19.

Subsection (a)(4) allows recovery for "actual and projected pain and suffering and emotional distress from the vaccine-related injury." 42 U.S.C. § 300aa-15(a)(4). An award under (a)(4) ameliorates, to some extent, the injured person's pain and suffering. As under subsection (a)(1), when a claimant is deceased at the time of a compensation award, the estate can recover for pain and suffering and emotional distress from the time of the injury until the date of death. *See Zatuchni*, 516 F.3d at 1318-19. Taken together, both (a)(1) and (a)(4) are attempts to make the injured person whole.

Similarly, subsection (a)(3) is also designed for a compensatory purpose. Under (a)(3), a vaccine-injured person may recover lost earnings. Subsection (a)(3) provides:

> (A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18and whose earning capacity is or has been impaired by reason of

> such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.
> (B) In the case of any person who has sustained a vaccine-related injury before attaining the age of18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

42 U.S.C. § 300aa-15(a)(3). Recovery for past and future lost earnings is compensation for the lost wages which would have otherwise provided the income necessary to sustain the person. *See Sarver v. Sec'y Health & Human Servs*., No. 07-307V, 2009 WL 8589740, at *10 (Fed. Cl. Spec. Master Nov. 16, 2009).

Subsection (a)(3) treats those over 18 differently from those under 18. Persons over 18 may recover both "actual and anticipated" lost earnings. §300aa-15(a)(3)(A). By allowing recovery for actual as well as anticipated future earnings, subsection (a)(3)(A) contemplates that a person who was injured by a

vaccine after attaining the age of 18could have entered or remained in the workforce. The lost earnings award is tailored to the individual "in accordance with generally recognized actuarial principles and projections." *Id*. Actual lost earnings are available to an estate and may be recovered for the time between the injury and the date of death. *Zatuchni*, 516 F.3d at 1315. Anticipated lost earnings are available to those who are alive at the time of the award and are expected to suffer from a lost earning capacity going forward, but death terminates any anticipation of future lost earnings.

For persons under 18, subsection (a)(3)(B) sets forth another inquiry. In order to be eligible for lost earnings, the minor must have an injury: (1) which is vaccine-related; (2) which impaired the minor's earning capacity; and (3) which is "of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond." 42 U.S.C. § 300aa-15(a)(3)(B). In other words, the court asks how the vaccine-related injury will affect the person's earning capacity when he or she reaches age 18. If the court concludes that a minor is indeed suffering a vaccine-related injury, which impairs his or her earning capacity, and the minor's earning capacity is likely to remain impaired at age 18 and beyond, the court awards an amount "determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector . . . as determined by the Secretary." *Id*. A person who is injured before 18 is only eligible for "compensation after attaining the age of 18." *Id*. In other words, subsection (a)(3)(B) only allows recovery of future lost earnings.

Because the statutory language does not expressly require that a claimant injured by a vaccine before the age of 18 be alive to receive future lost earnings, the appellees argue that no such restriction should be read into the statute. But the words of the statute also do not expressly state that an estate can recover for future lost earnings of a decedent. An interpretive issue thus exists within the statute. The Secretary fairly states the issue as whether compensation for lost future earnings under subsection (a)(3)(B) is limited to claimants who are alive at the time a judgment of compensation is entered.

The statute refers to the impairment of future earnings capacity, not to the termination of such capacity, and thus assumes that the claimant has some potential capacity to earn. "Impaired" thus points to the diminished earnings capacity of a living person, not the hypothetical earning capacity of a deceased person. It is presumed that a person who is alive at the time a future lost earnings compensation award is made would have had an earning capacity as of age 18 but for the vaccine-related injury. The statute thus predicts future lost earnings to compensate for life beyond the age of 18. Where a claimant is deceased, however, the same prediction cannot rationally be made. Subsection (a)(3)(B) presupposes an expectation of future earnings to be received after attaining the age of 18. When the claimant dies before compensation is awarded, there is no reasonable expectation that the claimant would attain the age of 18. We thus conclude that the most natural reading of subsection (a)(3)(B) is to limit the eligibility for lost future earnings to persons who are alive at the time the compensation award is made.

Our interpretation of subsection (a)(3)(B) is in harmony with subsection (a)(3)(A), which as noted above provides compensation for loss of earnings for persons injured by a vaccine after attaining the age of 18 in two categories, actual and anticipated. An anticipated loss of future earnings for a person over age 18 looks beyond previous actual earnings to the future, a prediction that cannot reasonably be made if the claimant is deceased at the time the prediction is made. Entitlement to an award of future lost earnings depends upon the claimant being alive at the time the compensation judgment is entered.

Aside from the language of subsection (a)(3)(B) itself, other sections of the Vaccine Act support our interpretation. Another subsection of § 300aa-15, subsection (f)(4)(A), directs payment to be made "on the basis of the net present value of the elements of the compensation . . . in a lump sum." When awarding lost future earnings to a living minor, the special master calculates"the present value of the expected future stream of earnings that has been lost." *Edgar*, 989 F.2d at 476. The award is not contingent on the petitioner living to 18, and the petitioner does not wait until age 18 to receive the lump sum. *Id*. at 477. However, a deceased petitioner has no post-18 "expected future stream of earnings" to be awarded. The present value of the expected future stream of earnings is zero.

Looking beyond § 300aa-15, 42 U.S.C. § 300aa13 (b)(1) instructs the special master to consider "the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court" when awarding compensation. *See also McAllister v. Secretary of Health & Humans Services*, 70 F.3d 1240, 1243 (Fed. Cir.

1995) (interpreting § 300aa-13(b)(1) to require the special master to take any changes in the petitioner's condition into account when awarding damages). Awarding the petitioners both lost future earnings and a death benefit would contravene § 300aa-13(b)(1). In order to award lost future earnings, the special master would have to consider Elias' injury up to a point just prior to his death. That snapshot of Elias' condition would not entitle Elias to a death benefit. Instead, to receive the death benefit, the special master would have to consider the course of Elias' injury to a point post-death. Essentially, the Tembenis' are asking that the special master take two snapshots of Elias' condition: one just prior to death and one just after death. This approach would contradict § 300aa-13(b)(1) and *McAllister*, both of which require the special master to consider "the entire record and course of the injury" up to the date of compensation judgment. *See also Sarver*, 2009 WL 8589740 at *8-9.

The last form of compensation available under the Vaccine Act is the so-called death benefit under § 300aa-15(a)(2). *Id*. ("In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased."). This fixed amount is for the benefit of the person's estate. *See Figueroa v. Sec'y Health & Human Servs*., 715 F.3d 1314,1323-24 (Fed. Cir. 2013) (explaining the legislative history of § 300aa-15(a)(2)). Obviously, a person who is alive at the time of the award cannot recover under (a)(2). Subsection (a)(2) is the only type of compensation that is not designed to reimburse or replace an injured person's own losses arising from his or her vaccine-related injury. Put simply, except for the death benefit of $250,000, under the Vaccine Act's entitlements to compensation, no

element of future damages survives a claimant's death.

Our analysis of the different forms of compensation available under § 300aa-15(a) is consistent with tort law principles. Generally, the estate of a person who dies may seek compensation on two related fronts. First, compensation under a wrongful death statute is designed to compensate the survivors or the estate of the deceased for losses they have sustained. Second, the estate may also pursue, under a survival statute, damages which the decedent could have recovered had he lived. *See* 1 Speiser & Rooks, RECOVERY FOR WRONGFUL DEATH § 1:13; RESTATEMENT (SECOND) OF TORTS § 925 & cmt. a. (1979).

Thus, "[i]n a survival action, a claim for lost earnings embraces only the earnings lost up to the time of death." Speiser & Rooks at § 1:14, *citing Jones v. Flood*, 716 A.2d 285 (Md. 1998); *see also* RESTATEMENT (SECOND) OF TORTS § 926 & cmt. a. (1979) ("Under statutes providing for the survival or revival of tort actions . . . the death of the injured person limits recovery for damages for loss or impairment of earning capacity, emotional distress and all other harms, to harms suffered before the death."). Future lost earnings are then recovered under a wrongful death statute. *See* RESTATEMENT (SECOND) OF TORTS § 925 cmt. b. (1979).

Applying these concepts to the Vaccine Act, compensation under §§ 300aa-15(a)(1), (3), and (4) is analogous to recovery under a survival statute, while § 300aa-15(a)(2) aligns to a wrongful death statute. The recovery under §§ 300aa-15(a)(1), (3), and (4) is specific to the injured person, while 15(a)(2) is an award "for the estate of the deceased." *Id.* § 300aa-15(a)(2). As

explained above, an estate recovers all past damages under the survival statutes to compensate for losses personal to the deceased. Compensation for lost future earnings of a deceased would only benefit the estate, not the deceased. Thus, when the vaccine-injured person dies as a result of the vaccine before a compensation judgment is made, an estate's recovery of both the set $250,000 death benefit under §300aa-15(a)(2) and future lost earnings under §300aa-15(a)(3)(B) would be duplicative, whereas an estate's recovery of a death benefit and actual lost earnings would not.

This interpretation is also consistent with the availability of recovery under other federal tort liability schemes. For example, the Jones Act, 46 U.S.C. § 30104, which incorporates the Federal Employers' Liability Act ("F.E.L.A."), 45 U.S.C. § 51 et seq., provides that a seaman's right of action for injuries due to negligence survives to the seaman's personal representative. However, the Supreme Court in *Miles v. Apex Marine Corp*., determined that the estate of a deceased seaman could not recover lost future earnings because it would "be duplicative of recovery by dependents for loss of support in a wrongful death action." 498 U.S. 19, 35 (1990). The court went on to note that "the considered judgment of a large majority of American legislatures is that lost future income is not recoverable in a survival action." *Id.; see also Michigan Central R.R. v. Vreeland*, 227 U.S. 59 (1913) (interpreting F.E.L.A.).

The petitioners argue that our interpretation of § 300aa-15(a)(3)(B) conflicts with our prior decisions in *Zatuchni* and *Edgar*. *Zatuchni*, 516 F.3d 1312; *Edgar*, 989 F.2d 473. As noted above, both the special master

and the Claims Court understood *Zatuchni* and *Edgar* to support lost future earnings compensation in this case. We do not agree. Both *Zatuchni* and *Edgar* are fully consistent with our interpretation of § 300aa-15(a)(3).

In *Zatuchni* we held that an estate may recover boththe death benefit under § 300aa-15(a)(2) and "compensation . . . for [] vaccine-related injuries during [the injured person's] lifetime, including actual expenses incurred, pain and suffering, and lost income between the time of the vaccination and [] death." *Zatuchni*, 516 F.3d at 1315 (emphasis added). In *Zatuchni,* the petitioner, Ms. Snyder, who was forty-five years old when she received the measles, mumps, and rubella vaccine at issue, died asa result of her vaccine-related injury while her petition was pending. *Id*. at 1314. We rejected the Secretary's argument that Ms. Snyder's estate could recover no more than the death benefit under § 300aa-15(a)(2), and awarded recovery for past expenses and losses incurred by Ms. Snyder before her death. *Zatuchni*, as executrix of the estate, sought compensation for actual amounts that Ms. Snyder would have earned, absent her vaccine-related injury, during the period between her injury in 1992 and her death in 2005. This limited past earnings recovery is consistent with the *Zatuchni's* rationale for allowing an estate to recover compensation in addition to the death benefit—to make the estate of the deceased whole. *Zatuchni*, 516 F.3d at 1318-19 ("Put simply, the fact that a vaccine-related death followed a vaccine-related injury in a particular case does not alter the fact that certain expenses were incurred, wages lost, or pain and suffering endured in the interim, and these damages are no less related to

or caused by a vaccine-related injury within the meaning of subsections (a)(1), (3), and (4) simply because the vaccine-injured person in question is no longer living."). Thus, in *Zatuchni* our analysis was limited to whether an estate could recover past lost earnings, not future lost earnings.

In *Edgar*, we were asked to evaluate the calculation of the amount of lost future earnings awarded by the Claims Court. 989 F.2d at 473. At the time of her compensation award, Jamie Edgar, approximately age 9, was, as a result of her vaccine-related injury, "in a coma and depend[ed] entirely on hospital staff for her continued care and well-being." *Id.* at 475. The special master found that Jamie's lost earnings due to her impairment aggregated to $1,649,119.51 over her expected work-life. *Id.* The Claims Court affirmed the special master's award of $127,048.00 for lost future earnings, which represented the price of an annuity[2] which was contingent on two conditions: (1) no payments would be made if Jamie died before reaching the age of 18, and (2) payments under the annuity would cease on Jamie's death, even if the full amount of $1.6 million had not been paid. *Id.* We rejected this conditional approach, because "nothing in [§ 300aa15(a)(3)(B)] permits the compensation award to be contingent upon the child reaching age 18. In addition, nothing in [§300aa-15(a)(3)(B)] authorizes the amount of compensation to be contingent upon the actual,

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[2]Under the Vaccine Act, future earnings damages are reduced to their net present value and the special master may order the purchase of an annuity for the benefit of the petitioner. *See* 42 U.S.C. § 300aa-15(f)(4)(A).

post-injury life of the injured child." *Id*. at 477.

The circumstances of Jamie in *Edgar* and Elias in the case before us are both tragic, but there is a key difference: Jamie was alive, albeit in a coma, at the time of her award, and Elias was not. As the circumstances stood, Jamie had a foreseeable need for earnings to provide for her continued living, even if she may never actually recover from her coma and if she may not actually live to the age of 18, while Elias, being deceased, has no similar foreseeable need. On the other hand, Jamie was not entitled to the death benefit under § 300aa-15(a)(2), however unlikely her survival may be from the coma, while Elias' estate has recovered under that subsection. Moreover, *Edgar* was limited to the question of calculating the net present value of a lost earnings award, not whether the petitioner was entitled to the award in the first place. *Edgar* neither mandates nor prohibits future lost earnings in this case.

* * *

The Vaccine Act involves a number of compromises made by Congress in creating the program. In exchange for reduced standards of proof and less adversarial proceedings, the Vaccine Act sets the death benefit at $250,000, without requiring proof of actual wrongful death damages. 42 U.S.C. § 300aa-15(a)(2). Nonetheless, the $250,000 amount set in 1986 may no longer be an appropriate amount for a death benefit. The original version of the Vaccine Act adopted in November 1986 included a provision which would have adjusted the death benefit for inflation. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 2118, 100 Stat. 3743 (1986). That provision was repealed in December 1987. *See* Omnibus Budget

Reconciliation Act of 1987, Pub. L. No. 100-203, Title IV, § 4303(d)(2)(B), 101 Stat.1330 (1987). Attempts have also been made to increase the death benefit. *See* National Vaccine Injury Compensation Program Improvement Act of 2002, H.R. 3741, 107th Cong. § 3 (2002) (increasing death benefit from $250,000 to $300,000); Improved Vaccine Affordability and Availability Act, S. 2053, 107th Cong. § 207 (2002) (increasing death benefit to $350,000).[3] In a 2002 hearing, Congressman Burton opined that his proposal "increased the amount of death benefits from 250,000 to 300,000, and it hasn't been increased for more than a decade. Inflation alone would require that change . . . ." Continuing Oversight of the National Vaccine Injury Compensation Program: Hearing before the H. Comm. on Gov't Reform, 107th Cong. 140 at 76 (2002) (statement of Rep. Dan Burton, Chairman H. Comm. on Gov't Reform). We cannot disturb the legislative choices Congress made in adopting this compensation scheme. Arguments for increasing the death benefit available under the Vaccine Act are properly addressed Congress.

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[3]Other similar bills have been introduced. *See* National Vaccine Injury Compensation Program Improvement Act of 2003, H.R. 1349, 108th Cong. § 3 (2003) (increasing the death benefit to $300,000); National Vaccine Injury Compensation Program Improvement Act of 2005, H.R. 1297, 109th Cong. § 3 (2005) (same); National Vaccine Injury Compensation Program Improvement Act of 2008, H.R. 6391, 110th Cong. §3 (2008) (same); National Vaccine Injury Compensation Program Improvement Act of 2009, H.R. 2459, 111th Cong. § 3 (2009) (same).

## CONCLUSION

The Tembenis estate has received compensation under §§ 300aa-15(a)(1), (a)(2), and (a)(4). Because the Vaccine Act precludes an award of future lost earnings toan estate of a petitioner who dies prior to the compensation judgment, we reverse the decision of the Claims Court allowing the Tembenis estate to recover lost future earnings under § 300aa-15(a)(3)(B).

REVERSED

## COSTS

No costs.

## APPENDIX B

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

**NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION**

OPINION FILED AND JUDGMENT ENTERED:
10/28/2013

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

No costs were taxed in this appeal.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT
/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk

cc: Ronald C. Homer
Ryan D. Pyles
Michael S. Raab
Michael E. Robinson

13-5029 - Tembenis v. HHS
United States Court of Federal Claims, Case No. 03-VV-2820

## APPENDIX C

HARRY TEMBENIS and GINA TEMBENIS, administrators of the estate of ELIAS TEMBENIS, deceased, *Petitioners*, v. SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES, *Respondent*.

No. 03-2820 V

UNITED STATES COURT OF FEDERAL CLAIMS

October 19, 2012, Filed

COUNSEL: Ronald C. Homer, Boston, MA, for petitioners.

Ryan D. Pyles, Lisa A. Watts, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent. With him on the briefs were Stuart F. Delery, Assistant Attorney General, Rupa Bhattacharyya, Director, Vincent J. Matanoski, Acting Deputy Director and Catharine E. Reeves, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC.

Merow , Senior Judge.

This National Childhood Vaccine Injury case was initiated on December 16, 2003, when Harry Tembenis

filed a Petition for Vaccine Compensation on behalf of his son, Elias Tembenis. (ECF No. 1.) This was followed by an Amended Petition (ECF No. 14) alleging that a Diptheria-Tetanus-acellular-Pertussis ("DTaP") vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that led to his death on November 17, 2007, when he was seven years old. The caption of the case was amended on November 13, 2008, to name Harry and Gina Tembenis, administrators of Elias' estate, as petitioners.

The special master proceeded to determine that the DTaP vaccine Elias received on December 26, 2000, was the cause of his epilepsy and resulting death. *Tembenis v. Sec'y of HHS*, No. 03-2320 V, 2010 U.S. Claims LEXIS 950, 2010 WL 5164324 (Nov. 29, 2010). The parties were able to reach agreement on damages comprising the $250,000 death benefit (42 U.S.C. § 300aa-15(a)(2)), and $175,000.00 for actual pain and suffering and past unreimbursable expenses (42 U.S.C. § 300aa-15(a)(4)). Agreement could not be reached on recovery of lost future earnings pursuant to 42 U.S.C. § 300aa-15(a)(3)(B). The special master, after receiving briefing from the parties, issued a comprehensive ruling concluding that the plain language of 42 U.S.C. § 300aa-15(a)(3)(B) provides that damages be awarded to petitioners for the lost wages that could have been anticipated had Elias survived to adulthood and beyond, based on the severity of his injury following vaccination. *Tembenis v. Sec'y of HHS*, No. 03-2820V, 2011 U.S. Claims LEXIS 2200, 2011 WL 5825157 (October 26, 2011).

Following the special master's ruling, respondent maintained her position opposed to an award of future

lost earnings to Elias' estate but proffered the sum of $659,955.61, agreed to by petitioners, for lost earnings, reserving the right to seek review of the special master's ruling, granting damages of $1,084,955.61 which includes the $659,955.61. (Resp't's Proffer 2, ECF No. 77.) The Special Master's Decision (ECF No. 78), filed July 31, 2012, awarded petitioners a lump sum payment of $1,084,955.61.

Respondent filed a Motion for Review asserting that "[t]he Special Master erred in ruling that the estate of a child who died as the result of a vaccine-related injury is entitled to the child's prospective lost earnings." (Resp't's Mot. for Rev. 1, ECF No. 79.) Petitioners' Response concludes "the Special Master's Ruling that Elias' estate is entitled to compensation for his lost earning capacity rests on the plain language of § 15(a)(3)(B) as well as binding Federal Circuit decisions, and is therefore not contrary to law."[1] (Pet'rs' Resp. 21-22, ECF No. 83.).

Upon analysis of 42 U.S.C. § 300aa-15(a)(3)(B), the special master's October 26, 2011 ruling, and the briefs submitted by petitioners and respondent. It is concluded that the special master's ruling is correct, with the result that pursuant to 42 U.S.C. § 300aa-12(e)(2)(A) the July 31, 2012 decision is sustained.

The statutory provision at issue, 42 U.S.C. § 300aa-15(a)(3)(B) provides: (B) In the case of any

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[1]Petitioners have also filed a separate "Motion for Partial Summary Affirmance" seeking an "Order authorizing the payment of the uncontested portions of compensation, as awarded by the Special Master." (Pet'rs' Mot. 5, ECF No. 84.) Respondent opposes this motion. (ECF No. 85.).

person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

Respondent bases her position opposed to recovery of lost earnings compensation on the fact that Elias, a minor, died as a result of his vaccine-related injury, before he obtained an award. (Resp't's Brief 3-4, ECF No. 79.)[2] This position is adopted in a prior ruling by another special master. See Sarver v. Sec'y of HHS, No. 07-307V, 2009 U.S. Claims LEXIS 776, 2009 WL 8589740 (Nov. 16, 2009).[3]

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[2]Respondent also argues that awarding compensation for lost earnings would duplicate the $250,000 statutory award for death under 42 U.S.C. § 300aa-15(a)(2). (Resp't's Brief 9-10, ECF No. 79.) This position is foreclosed by the ruling in *Zatuchni v. Sec'y of HHS*, 516 F.3d 1312 (Fed. Cir. 2008).

[3]While adopting the position that the vaccinee's death precludes compensation for lost earnings, the special master in *Sarver* recognized the restrictive nature of the ruling stating:

> The result in this case may appear to be arbitrary in that if Erica had lived until there was a decision awarding the Sarvers compensation for Erica's vaccine-caused illness, the Sarvers could legitimately

Contrary to the respondent's position and the ruling in *Sarver*, section 15(a)(3)(B) plainly states that a vaccinee's injury, serious enough so that it could be anticipated to cause impaired earning capacity at age 18 and beyond calls for recovery of compensation for lost earnings.

The special master expressed the matter in her ruling as follows:

> (1) As in *Zatuchni*, the plain and natural meaning of section 15(a)(3)(B) contradicts the Secretary's arguments. The provision states that if a vaccinee's injury is severe enough that it could be anticipated to cause a person at age 18 to suffer lost wages, compensation should be awarded. *See Edgar v. Sec'y of Dep't of Health & Human Servs.*, 989 F.2d 473 (Fed. Cir. 1993), (holding that compensation for loss of earnings may not be diminished in the event of the vaccinee's premature death). There is no requirement, express or implied, that a vaccinee must actually survive to age 18, or be found likely to survive, to obtain compensation.

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> claim (and probably be awarded) compensation for Erica's loss of earning capacity pursuant to section 15(a)(3)(B). It is only because Erica has died that the Sarvers are precluded from receiving this compensation. The fact that Erica's death, itself, was caused by the vaccine may seem to increase the unfairness. Certainly, the Sarvers[‘] claim for compensation has a compelling emotional component.

2009 U.S. Claims LEXIS 776, 2009 WL 8589740 at *10.

(2) The Secretary's interpretation does not give effect to the plain meaning of the words Congress used and the context in which they appear. The language concerning 'anticipation' must be read in conjunction with the language concerning the "severity of the injury" suffered and the lost earning "capacity." Instead, the Secretary isolates the phrase "impaired earning capacity at age 18," to conclude that a child who does not survive to age 18 should receive no compensation for lost earnings. This distorts the provision by omitting key concepts. The statute on its face requires that in the case of a minor vaccinee the severity of the injury must be considered at the time of the award to anticipate loss of earning capacity. The language does not imply that survival to the age of 18 must be anticipated.

The Secretary's interpretation also distorts the plain meaning by adding to the words a concept that Congress did not include – the necessity for actual lost earnings. The Secretary argues, "Because Elias' death at age seven years effectively forecloses the possibility of him ever having suffered an actual loss of earning capacity, petitioners are not entitled to receive an award for his lost earnings under the statute." Resp't Br. at 5 (emphasis in original). When Congress meant to restrict the compensation available under section 15(a) to amounts actually incurred, it said so explicitly. *See* §§ 300aa-15(a)(1)(A) and (B) (compensating for "actual unreimbursable expenses"). One must assume, therefore, that

> omission of the word "actual" from the text of section 15(a)(3)(B) was deliberate.

2011 U.S. Claims LEXIS 2200, 2011 WL 5825157, at *2 (Oct. 26, 2011).

As the language of section 15(a)(3)(B) "[i]s clear and fits the case, the plain meaning of the statute will be regarded as conclusive." *Norfolk Dredging Co.,* 375 F.3d at 1110; *Hall v. United States*, 677 F.3d 1340, 1345 (Fed. Cir. 2012). That is also the circumstance present here, the plain meaning is conclusive, and it is **ORDERED** that Respondent's Motion for Review is **DENIED** and the Special Master's Decision awarding compensation of $1,084,955.61 is **SUSTAINED** with judgment to be so entered.[4]

/s/ James F. Merow
James F. Merow
Senior Judge

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[4]Absent the filing of a Petition for Review pursuant to 42 U.S.C. 300aa-12(f) which would then place the matter in the United States Court of Appeals for the Federal Circuit, petitioners will obtain payment of the full amount. Their Motion for Summary Affirmance (ECF No. 84) has, with this Order, become moot and is, therefore, **DENIED**.

## APPENDIX D

HARRY TEMBENIS and GINA TEMBENIS, administrators of the estate of ELIAS TEMBENIS, deceased, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.

No. 03-2820V

UNITED STATES COURT OF FEDERAL CLAIMS
July 31, 2012, Filed
NOTICE: NOT FOR PUBLICATION

COUNSEL: Ronald C. Homer , Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioners.

Ryan D. Pyles , U.S. Dep't of Justice, Washington, D.C. for Respondent.

OPINION
OFFICE OF THE SPECIAL MASTERS

DECISION[1]

[1]In accordance with Vaccine Rule 18(b), Petitioners have 14 days to file a proper motion seeking redaction of medical or other information that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Redactions ordered by the special master, if any, will appear in the document as posted on the United States Court of Federal Claims' website.

LORD, Special Master

On December 16, 2003, Petitioner Harry Tembenis filed a petition on behalf of his son, Elias Tembenis, seeking compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 et seq. (2006). Petitioner filed a "Short-Form Autism Petition for Vaccine Compensation," and joined the Omnibus Autism Proceeding ("OAP"). On August 27, 2008, Petitioner filed a notice to proceed separately from the OAP, and he also filed an amended petition that alleged that a Diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that eventually led to his death. On November 13, 2008, the caption was amended to name Harry and Gina Tembenis, as administrators of Elias's estate, as Petitioners. An entitlement hearing was convened on October 23, 2009, and a decision finding Petitioners entitled to compensation issued on November, 29, 2010.

On July 26, 2012, Respondent filed a Proffer on Award of Compensation setting forth all items of compensation to which the parties agreed should be awarded to Petitioners. Based upon the record as a whole,I find the Proffer reasonable and that Petitioners are entitled to an award as stated in the Proffer. Pursuant to the Proffer, attached as Appendix A, the Court awards Petitioners:

> **A lump sum payment of $1,084,955.61, representing the estate benefit ($250,000.00), past unreimbursable expenses and actual pain and suffering ($175,000.00), and lost future earnings**

**($659,955.61) in the form of a check payable to Petitioners as administrators/ executors of the estate of Elias Tembenis.**

The Court thanks the parties for their cooperative efforts in resolving this matter. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the Clerk is directed to enter judgment accordingly.[2]

**IT IS SO ORDERED**.
/s/ Dee Lord
Dee Lord
Special Master

**RESPONDENT'S PROFFER ON AWARD OF COMPENSATION**

**I. Items of Compensation**

**A. Estate Benefit**

Section 15(a)(2) of the Vaccine Act provides for the following compensation: "In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased." 42 U.S.C. § 300aa-15(a)(2). Pursuant to this section, respondent proffers that petitioners should be awarded $250,000.00. Petitioners agree.

**B. Actual Pain and Suffering and Past Unreimbursable Expenses**

Elias Tembenis died during the pendency of this

[2]Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.

case, and evidence supplied by petitioners document their expenditure of past unreimbursable expenses related to Elias's vaccine-related injury. Accordingly, pursuant to *Zatuchni v. HHS*, 516 F.3d 1312 (Fed. Cir. 2008), respondent proffers that petitioner should be awarded past unreimbursable expenses and compensation for Elias's actual pain and suffering in the combined amount of $175,000.00. Petitioners agree.

**C. Lost Future Earnings**

Respondent maintains her position that an award of future lost earnings to the estate of a decedent is neither appropriate under the Vaccine Act, nor under *Zatuchni*. However, the Special Master ruled otherwise in her Ruling on Compensation for Lost Earnings of Elias Tembenis (Ruling), dated October 26, 2011. Accordingly, this proffer for lost earnings was determined in accordance with the Special Master's Ruling made over the objection of respondent, and respondent reserves the right to seek review of that Ruling once the final decision on damages has been issued by the Special Master.

In light of the Special Master's Ruling, respondent proffers that the appropriate amount to be awarded for Elias's lost future earnings is $659,955.61. This amount reflects that the award for lost future earnings has been reduced to net present value. Petitioners agree.

**D. Attorneys' Fees and Costs**

This proffer does not address final attorneys' fees and costs. Petitioners are entitled to reasonable final attorneys' fees and costs, to be determined at a later date upon petitioners filing substantiating documentation.

## II. Form of the Award

The parties recommend that the compensation provided to petitioners should be made in a lump sum payment of $1,084,955.61 in the form of a check payable to petitioners as administrators/executors of the estate of Elias Tembenis.

## III. Guardianship

Petitioners represent that they presently are, or within 90 days of the date of judgment will become, duly authorized to serve as executors or administrators of the Estate of Elias Tembenis under the laws of the State of Massachusetts.

## IV. Summary of Recommended Payments Following Judgment

A. Lump sum paid to petitioners: **$1,084,955.61**
B. Reasonable final attorneys' fees and costs: **TBD**

Respectfully submitted,
STUART F. DELERY
Acting Assistant Attorney General
RUPA BHATTACHARYYA
Director
Torts Branch, Civil Division
MARK W. ROGERS
Deputy Director
Torts Branch, Civil Division
CATHARINE E. REEVES
Assistant Director
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s/ RYAN D. PYLES
RYAN D. PYLES
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DATED: July 26, 2012

## APPENDIX E

**IN THE UNITES STATES COURT OF FEDERAL CLAIMS**
OFFICE OF SPECIAL MASTERS
No. 03-2820V
Filed: October 26, 2011

HARRY TEMBENIS and GINA TEMBENIS, ELIAS TEMBENIS, deceased, Petitioners v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.

Damages: vaccine-related injury; Zatuchni, Duptheria-Tetanus-acellular-Pertussis (DtaP); whether parents of a deceases child may recover for his lost earning capacity; sufficient severity; reasonable anticipation

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, M.A. for Petitioners. Ryan D. Pyles, United States Department of Justice, Washington, D.C. for Respondent.

**RULING ON COMPENSATION FOR LOST EARNINGS OF ELIAS TEMBENIS**[1]

[1]In accordance with Vaccine Rule 18(b), petitioner has 14 days to file a proper motion seeking redaction of medical or other information that satisfies the criteria in 42 U.S.C. §300aa-12(d)(4)(B). Redactions ordered by the special master, if

**LORD**, Special Master.

## I. INTRODUCTION AND SUMMARY

On December 16, 2003, Petitioner Harry Tembenis filed this case on behalf of his son, Elias Tembenis, under the National Childhood Vaccine Injury Act ("Vaccine Act" or "Act").[2] At that time, Mr. Tembenis, as the sole Petitioner, filed a "Short-Form Autism Petition for Vaccine Compensation," and joined the Omnibus Autism Proceeding ("OAP"). On August 27, 2008, Mr. Tembenis filed a notice to proceed separately from the OAP. He also filed an amended petition alleging that a Diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that eventually led to his death on November 17, 2007.[3]

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any, will appear in the decision as posted on the United States Court of Federal Claims' website.

[2]The National Vaccine Injury Compensation Program ("Vaccine Program") Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 et seq. (2010). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

[3]Elias was admitted to the emergency room with a fever and a cough on November 16, 2007. Pet'r Ex. 16 at 2. While there, he suffered a seizure and went into status epilepticus, followed by bradycardiac arrest. *Id*. at 14. On November 17, 2007, due to the absence of any neurologic functioning and overwhelming organ failure, it was decided to withdraw aggressive life support. *Id*. at 36. Elias was pronounced dead six minutes later. *Id*. The immediate cause of death was multisystem organ failure, which

On November 13, 2008, the caption was amended to name Harry and Gina Tembenis, administrators of Elias's estate, as Petitioners. An entitlement hearing was convened on October 23, 2009.

On November 29, 2010, I issued a decision that Petitioners were entitled to compensation. On January 3, 2011, I ordered the parties to file a joint status report within 30 days detailing the parties' efforts to resolve the damages portion of the case. On May 2, 2011, the parties filed a joint status report in which they stated that "there are irreconcilable differences with regard to damages." Joint Status Rep. 1, ECF No. 61. Specifically, the parties were unable to agree on an appropriate amount of compensation for lost wages. *Id.* I ordered briefing on the issue of whether the Act provides compensation for lost earnings of a vaccinee who died in childhood, before receiving an award. Briefing was completed on August 25, 2011, and the matter is now ripe for decision.

The issue presented is purely legal: whether compensation for a deceased, minor vaccinee is provided by section 300aa-15(a)(3)(B):

> In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is

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was a consequence of cardiac arrest, which was a consequence of Elias' seizure disorder. Pet'r Ex. 15 at 393.

> likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

42 U.S.C. § 300aa-15(a)(3)(B).

The Secretary maintains that compensation is not permitted for future lost earnings when a minor vaccinee dies before receiving an award, because it cannot be "anticipated" that such an individual would be likely to suffer impaired earnings at age 18. Resp't Br. at 3. Accordingly, only losses incurred before a vaccinee's decease are allowed, even if the cause of death is vaccination. *Id.* The Secretary maintains that awarding lost earnings to a deceased vaccinee would duplicate the $250,000 statutory award for death in section 15(a)(2). Resp't Br. at 6. The Secretary recognizes that the Federal Circuit in *Zatuchni v. Sec'y of Dep't of Health & Human Servs.*, 516 F.3d 1312 (Fed. Cir. 2008), held that the compensation provided in sections 15(a)(1), (3) and (4) is not duplicative of the death award in section 15(a)(2), but argues that the vaccinee's representative in Zatuchni did not seek, and was not awarded, compensation for "future" lost wages. *Id.* at 9.

(1) As in *Zatuchni*, the plain and natural meaning of section 15(a)(3)(B) contradicts the Secretary's arguments. The provision states that if a vaccinee's injury is severe enough that it could be anticipated to cause a person at age 18 to suffer lost wages, compensation should be awarded. *See Edgar v. Sec'y of*

*Dep't of Health & Human Servs.*, 989 F.2d 473 (Fed. Cir.1993), (holding that compensation for loss of earnings may not be diminished in the event of the vaccinee's premature death). There is no requirement, express or implied, that a vaccinee must actually survive to age 18, or be found likely to survive, to obtain compensation.

(2) The Secretary's interpretation does not give effect to the plain meaning of the words Congress used and the context in which they appear. The language concerning "anticipation" must be read in conjunction with the language concerning the "severity of the injury" suffered and the lost earning "capacity." Instead, the Secretary isolates the phrase "impaired earning capacity at age 18," to conclude that a child who does not survive to age 18 should receive no compensation for lost earnings. This distorts the provision by omitting key concepts. The statute on its face requires that in the case of a minor vaccinee the severity of the injury must be considered at the time of the award to anticipate loss of earning capacity. The language does not imply that survival to the age of 18 must be anticipated.

The Secretary's interpretation also distorts the plain meaning by adding to the words a concept that Congress did not include – the necessity for actual lost earnings. The Secretary argues, "Because Elias' death at age seven years effectively forecloses the possibility of him ever having suffered an *actual* loss of earning capacity, petitioners are not entitled to receive an award for his lost earnings under the statute." Resp't Br. at 5 (emphasis in original). When Congress meant to restrict the compensation available under section 15(a) to amounts actually incurred, it said so explicitly.

*See* §§ 300aa-15(a)(1)(A) and (B) (compensating for "actual unreimbursable expenses"). One must assume, therefore, that omission of the word "actual" from the text of section 15(a)(3)(B) was deliberate.

(3) The Secretary argues further that in no case, whether under section 15 (a)(3)(A) (adult vaccinees) or (B) (minor vaccinees), may future lost earnings be awarded to survivors on behalf of a deceased individual. Such compensation would be duplicative of the award for death in section 15(a)(2). Resp't Br. at 7-8.

*Zatuchni* expressly states, however, that each of the elements of compensation set forth in section 15(a) is available to the successor of a deceased vaccinee.

> [I]f a petition is properly filed by a person who suffered a vaccine-related injury, but that person dies of vaccine-related causes while her claim is pending, § 300aa-11(b)(1)(A) does not prevent – directly or by implication – the legal representative of the estate of such a person from requesting each of the categories of compensation listed in § 300aa-15(a) after they have been properly substituted for the deceased petitioner.

*Zatuchni*, 516 F.3d at 1321 (emphasis added). Although this is *dictum*, no persuasive argument has been presented by the Secretary to overturn the Circuit's stated conclusion in *Zatuchni*.

Accordingly, where, as in this case, a child suffers a severe seizure disorder as a result of vaccination, it certainly can be anticipated that the child's earning capacity will be impaired at age 18. If the child succumbs to his vaccine-related injury, his successors may obtain compensation for his loss of future earnings

pursuant to section 15(a)(3)(B) of the Act.

## II. DISCUSSION

### A. Zatuchni Makes Available All Elements of Compensation To Successors of a Deceased Petitioner.

In *Zatuchni*, a petitioner who alleged a vaccine injury at the age of 45 died before her case was concluded. 516 F.3d at 1314. The question was whether the petitioner's estate could "receive the compensation for medical expenses, lost wages, and pain and suffering provided for under 42 U.S.C. § 300aa-15(a)(1), (3), and (4), in addition to the $250,000 death benefit provided for under § 300aa-15(a)(2)." *Id*. at 1315. The Federal Circuit held that the enumerated elements of compensation were available to the estate of the deceased vaccinee. *Id*. at 1319. "Most important," in the Circuit's analysis, were the text and structure of section 15(a), which lists the death award "alongside" the provisions compensating for lost wages, pain and suffering. *Id*. at 1318. The Court found no evidence in the text of section 15(a) that the death award "is the only compensation that may be paid in a 'death case[.]'" Rather, the language Congress used was "inclusive." *Id*.

Rejecting the Secretary's restrictive interpretation of section 15(a), the Circuit stated that the vaccinee's death did "not alter the fact that certain expenses were incurred, wages lost, or pain and suffering endured in the interim, and these damages are no less related to or caused by a vaccine-related injury . . . simply because the vaccine-injured person in question is no longer living." 516 F.3d at 1319-20. Awarding

compensation in addition to the amount for death is not inconsistent with section 15(a), the Circuit held. "To the contrary, this is the reading of § 300aa-15(a) that most naturally flows from its text and structure." *Id*. at 1319.

Section 15(a)(3)(B) was not specifically addressed in *Zatuchni*, since the vaccinee in that case suffered her alleged injury in adulthood. The reasoning of *Zatuchni* applies, however, in the case of a child vaccinee, no less than an adult. The Circuit has indicated that all the forms of compensation set forth in § 15(a) are available in the case of a deceased petitioner, and the statute specifically provides in section 15(a)(3)(B) for compensation to minor children. *See Zatuchni*, 516 F.3d at 1322 (stating "that recovery under § 300aa-15(a)(1) through (4) is permitted" following the death of the vaccinee). On its face, the statute does not discriminate between stricken vaccinees who die as children and those who perish in adulthood. For the reasons discussed below, I find no persuasive reason to imply the intent to draw such a distinction.

Nor, in light of *Zatuchni*, do I find an occasion to engage in a comprehensive analysis of whether Congress intended to include survivorship among the rights afforded petitioners under the statute. The majority's analysis in *Zatuchni* proceeded under the plain terms of the Act and its structure, without reference to federal or state law. *See Zatuchni*, 516 F.3d at 1321 n.10 (eschewing any attempt "to 'harmonize' the Act with state law," in favor of "follow[ing] the unambiguous language of the Act"). As the Circuit reasoned, the provisions compensating for death are "alongside" those affording other forms of compensation, not separate and distinct from them. *Id.*

at 1320. To construe the statute in accordance with Zatuchni, the same approach used by the Federal Circuit should be adopted. This gives effect to the natural meaning of the words Congress used in the context of section 15(a) as a whole, and comports with the structure and intent of the Act.[4]

*Zatuchni* also counsels against adoption of the Secretary's policy arguments. In particular, the Secretary asserts that Congress's concern about the sufficiency of funds for the NVICP should restrict the recovery by an individual who died as a result of vaccination. Resp't Br. at 5-6. Zatuchni held to the contrary, based on the express legislative history indicating that Congress intended that the Act's provisions be administered with "'generosity[.]'" See *Zatuchni*, 516 F.3d at 1316 (citing and quoting legislative history).

**B. Section 15(a)(3)(B) Supports Awarding Compensation.**

**1. The Statute Provides Compensation For Present Loss of Future, Anticipated Earning Capacity.**

The Secretary questions whether *Zatuchni* applies

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[4]Similarly, the question of sovereign immunity, see Resp't Br. at 10-11, does not arise where, as here, congressional intent to waive it is clear. *See Zatuchni*, 516 F.3d at 1323 (doctrine of sovereign immunity does not "require us to ignore what we see as the plain reading of 42 U.S.C. § 300aa-15(a) . . . ."); "'Clear evidence of legislative intent prevails over other principles of statutory construction[.]'" *Stotts v. Sec'y of Dep't of Health & Human Servs.*, 23 Cl. Ct. 352, 364 (1991) (citing and quoting *Neptune Mutual Ass'n., Ltd. of Bermuda v. United States*, 862 F.2d 1546, 1549 (Fed. Cir. 1988)).

here because Petitioners seek compensation for future, as opposed to actual, incurred loss. Since Elias died as a result of his vaccine injury before he was awarded compensation, the Secretary maintains that the element of compensation for lost earnings is unavailable because Elias cannot possibly suffer lost earnings in the future. The Secretary misconstrues the nature of the loss, which is present loss of the capacity to earn in the future. Elias had a certain capacity to earn in adulthood before he was injured by vaccination; after vaccination, that capacity was impaired. The intent of section 15(a)(3)(B) on its face is not to compensate for actual lost earning capacity, but for the future, "anticipated" loss of the capacity to earn. This intent is embodied in the language Congress used, which requires that a special master determine if the "vaccine-related injury is of sufficient severity to permit reasonable anticipation that [the petitioner] is likely to suffer impaired earning capacity at age 18 and beyond . . . ." § 300aa-15(a)(3)(B).

The phrase "reasonable anticipation" relates as much to severity of the vaccine-related injury as to loss of earnings. Thus, the special master is to determine whether the nature and severity of the minor child's injury is such that impairment of earning capacity in adulthood could reasonably be anticipated. This meaning emerges clearly from the language used in the statute, which must be applied as written. *See Zatuchni*, 516 F.3d at 1321 n.10 (noting the court's obligation to "follow the unambiguous language of the

Act").[5]

That the child in *Stotts* was alive at the time the award was made does not vitiate the significance of the passage quoted above. But see Resp't Br. at 9-10 (attempting to distinguish Stotts). Stotts does not indicate that a child must actually survive until the Section 15(a)(3)(B) directs the special master to consider the age of 18 and beyond as the time period for which future lost earnings should be calculated. The provision construed as a whole does not explicitly or implicitly direct a special master to determine whether the child actually will reach the age of 18, or suffer actual loss of earnings. "It is plainly evident that § 300aa-15(a)(3)(B) [which] provides the special master with the authority to award compensation for impaired earning capacity measured by lost earnings, simply codifies the manner in which they must be calculated, and specifies only that they are to be calculated from the age of 18 if the individual suffered a vaccine-related injury before that time.") *Stotts v. Sec'y of Dep't of Health & Human Servs.*, 23 Cl. Ct. 352 at 365 (1991) (emphasis in original).

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[5]The court in *Stotts* reached the same result using similar reasoning. *Stotts* noted that the compensation is for loss of the "capacity" to earn, not for actual lost earnings. The loss of capacity to earn occurs at the time of the injury; thus the award must be made in anticipation of the loss of earning that will result (based on severity of the injury) over the child's anticipated work life, calculated from the age of 18, regardless of what the child's actual life experience may turn out to be. "Under the plain language of § 300aa-15(a)(3)(B), one could sensibly argue that the vaccine-related injury being compensated is loss of *earning capacity*, not loss of actual *earnings*." 23 Cl. Ct. at 366 n.13 (emphasis in original).

That the child in *Stotts* was alive at the time the award was made does not citiate the significance of the passage quoted above. *But see* Resp't Br. at 9-10 (attempting to distinguish Stotts). Stotts does not indicate that a child must survive until the age of 18 to qualify for compensation. Historically, many children in the NVICP have received compensation for lost earnings without a finding that the victim actually would survive to age 18, and without the Secretary even contending that actual survival to that age was an issue.[6] The happenstance of a vaccinee's death from his vaccine-related injury is merely that – an event without legal significance insofar as application of the statutory provision on lost wages is concerned. *Contra Sarver*, No. 07-307V, slip op. at 10 n.5 (Fed. Cl. Spec. Mstr. Nov. 16, 2009) ("What is required is that the special master reasonably anticipate, when making his (or her) decision about damages, that the person is likely to be alive at age 18 and beyond.")

Similarly, the principle that a special master

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[6] *See, e.g., Holihan v. Sec'y of Dept of Health & Human Servs.*, 45 Fed. Cl. 201 (1999); *Watkins v. Sec'y of Dep't of Health & Human Servs.*, 1999 WL 199057 (Fed. Cl. Spec. Mstr. Mar. 12,1999); *Brewer v. Sec'y of Dep't of Health & Human Servs.*, 1996 WL 147722 (Fed. Cl. Spec. Mstr. Mar. 18, 1996); *Foulk v. Sec'y of Dep't of Health & Human Servs.*, 1993 WL 189960 (Fed. Cl. Spec. Mstr. May 17, 1993); *Kircher v. Sec'y of Dep't of Health & Human Servs.*, 1992 WL 78537 (Cl. Ct. Spec. Mstr. Mar. 23, 1992); *Wasson v. Sec'y of Dep't of Health & Human Servs.*, 1991 WL 20077 (Cl. Ct. Spec. Mstr. Jan. 10, 1991); *Latorre v. Sec'y of Dep't of Health & Human Servs.*, 1990 WL 290313 (Ct.Cl. Spec. Mstr. June 15, 1990); *Clark v. Sec'y of Dep't of Health & Human Servs.*, 19 Ct. Cl. 113 (1989); *Reddish v. Sec'y of Dep't of Health & Human Servs.*, 18 Cl. Ct. 366 (1989); *Beck v. Sec'y of Dep't of Health & Human Servs.*, 1989 WL 250082 (Ct. Cl. Spec. Mstr. Aug. 17, 1989).

should consider all the information available at the time an award is made does not indicate that a deceased child is entitled to no compensation for future lost wages. *See McAllister v. Sec'y of Dep't of Health & Human Servs.*, 70 F.3d 1240, 1243 (Fed. Cir. 1995) (cited in *Sarver*, slip op. at 10) ("[C]ompensation in a Vaccine Act case is ordinarily calculated as of the time of the special master's decision that leads to the final judgment in the case."). *McAllister* means simply that a special master, at the time an award is made, must take into account all the available information concerning the effect of the severity of the vaccinee's injury on his capacity to earn after the age of 18. *McAllister* does not mean that a child who has died before the age of 18 therefore is entitled to no compensation. If *McAllister* offers any guidance regarding the issue presented here, it is that a child who dies as the result of vaccination, based on the severity of his vaccine-related injury, is entitled to 100% compensation for future lost wages, not 0%. *See Rivera v. Sec'y of Dep't of Health & Human Servs.*, 1992 WL 198853, at *5 (Ct. Cl. Spec. Mstr. July 31, 1992) (to take into account diminished life expectancy in awarding annuity "would take unfair advantage of the severity of [vaccinee's] injuries.").[7]

**2. The Secretary's Interpretation Is Not Plausible**.

As set forth by the Secretary in her brief, "Respondent reads section 15(a)(3)(B) . . . as requiring

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[7]This discussion assumes that the victim's death, as in this case, was vaccine-related. If the victim's death were unrelated to vaccination, the amount of compensation would reflect the severity of the vaccine-related injury.

that compensation for a minor's lost wages be based upon the "'reasonable anticipation'" that the claimant "'is likely to suffer impaired earning capacity at age 18 and beyond.'" Resp't Br. at 4. The Secretary contends that the special master must anticipate loss of the capacity to earn when the victim of a vaccine injury actually reaches age18 – meaning that the vaccinee must be found likely to reach the age of 18 in order to qualify for any compensation of future lost earnings.

The statute provides compensation to a child whose "vaccine-related injury is of sufficient severity to permit reasonable anticipation" of diminished capacity to earn in adulthood. § 300aa-15(a)(3)(B). Granted that section 15(a)(3)(B) lacks stylistic grace (being one sentence comprised of 11 lines of text), its meaning is nevertheless clear. It incorporates, in the following order, the concepts of "earning capacity," "vaccine-related injury," "sufficient severity," and "reasonable anticipation" of a loss of "earning capacity at age 18 and beyond[.]" *Id.* If these concepts are put together in the order promulgated by Congress, the sentence cannot be read in the way the Secretary has construed it: to permit compensation only for actual lost earnings at and beyond age 18. Instead, it must be read to provide compensation for anticipated future loss during adulthood, based on the severity of a child's present vaccine injury.

Only by isolating certain phrases and removing them from their context can it be asserted that Congress in section 15(a)(3)(B) was "'looking ahead' to an actual loss of earnings," as opposed to a "hypothetical" loss in the future. Resp't Br. at 4 (emphasis in original). As the Circuit noted in *Edgar*, the actual loss of earning capacity at age 18 is not a

prerequisite to compensation. Section 15(a)(3)(B) simply is intended to "prescribe[] a factor to be applied in calculating the total compensation for lost earnings, *i.e.*, it must be presumed that an injured child will not begin working until age 18." *Edgar*, 989 F.2d at 477.

While not "on all fours," because the victim in Edgar was alive at the time of the award, the Circuit's reasoning is pertinent here. The Circuit held that the present value of an annuity awarded to an injured vaccinee could not take into account the possibility of the victim's death before reaching age 18, or before receiving an income stream equal to the amount of projected lost earnings. 989 F.2d at 475-77. The Circuit stated that the Secretary could not substitute "an amount reflecting the cost of an annuity with contingencies [for the annuitant's death]" but was required to furnish "an annuity that does not have those contingencies." *Id*. at 477. The Circuit ruled, "nothing in section 2115 (a)(3)(B) permits the compensation award to be contingent upon the child reaching age 18. In addition, nothing in section 2115(a)(3)(B) authorizes the amount of compensation to be contingent upon the actual, post-injury life of the injured child." *Id.*[8]

In sum, the plain language of section 15(a)(3)(B), in addition to the decisions in *Zatuchni* and *Edgar*, forecloses the interpretation advocated by the Secretary. *See Zatuchni*, 516 F.3d at 1315 (noting that "argument cannot overcome the clear intent expressed

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[8]The Federal Circuit referred to Section 2115(a)(3)(B) of the Public Health Service Act, codified at 42 U.S.C. § 300aa-15(a)(3)(B) (2006).

by the structure and language of the statutory scheme at issue").

## III. CONCLUSION

Respondent agrees that Elias sustained a vaccine injury before age 18, and that his earning capacity would have been impaired had he lived to that age. Resp't Br. at 4. Given these factual concessions, and the conclusion reached herein with respect to the availability of lost earnings to the successors of a child who died due to a vaccine injury, damages should be awarded to Petitioners for the lost wages that could have been anticipated had Elias survived to adulthood and beyond, based on the severity of his injury following vaccination. The appropriate amount of such damages will be determined in future proceedings or by agreement between the parties.

**IT IS SO ORDERED.**

s/Dee Lord
Dee Lord
Special Master

## APPENDIX F

HARRY TEMBENIS and GINA TEMBENIS, administrators of the estate of ELIAS TEMBENIS, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.

No. 03-2820V

UNITED STATES COURT OF FEDERAL CLAIMS

November 29, 2010, Filed

COUNSEL: Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA for Petitioners. Ryan D. Pyles, United States Department of Justice, Washington, D.C. for Respondent.

OPINION
OFFICE OF SPECIAL MASTERS

DECISION ON ENTITLEMENT[1]

[1]The undersigned intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted

LORD , Chief Special Master.

## I. INTRODUCTION AND OVERVIEW

On December 16, 2003, Petitioner Harry Tembenis filed this case on behalf of his son, Elias Tembenis, under the National Childhood Vaccine Injury Act ("Vaccine Act" or "Act").[2] Petitioner filed a "Short-Form Autism Petition for Vaccine Compensation," and joined the Omnibus Autism Proceeding ("OAP"). On August 27, 2008, Petitioner filed a notice to proceed separately from the OAP, and he also filed an amended petition that alleged that a Diphtheria-Tetanus-acellular-pertussis ("DTaP") vaccination administered on December 26, 2000, caused Elias to develop a seizure disorder that eventually led to his death. On November 13, 2008, the caption was amended to name Harry and Gina Tembenis, as administrators of Elias's estate, as Petitioners. An entitlement hearing was convened on October 23, 2009. The final post-hearing brief was filed on October 7, 2010. This case is now ripe for decision.

To receive compensation under the Vaccine Act, a petitioner must prove that either: 1) he suffered a "Table Injury"— that is, an injury falling within the Vaccine Injury Table — corresponding to one of his vaccinations, or 2) he suffered an "off-Table" injury

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invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire ruling will be available to the public. *Id*.

[2]The National Vaccine Injury Compensation Program ("Vaccine Program") comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq*. (2010). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

that was actually caused by or "caused-in-fact" by a vaccine. *See* §§ 13(a)(1)(A), 11(c)(1); *Shalala v. Whitecotton*, 514 U.S. 268, 270, 115 S. Ct. 1477, 131 L. Ed. 2d 374 (1995); *see also* 42 C.F.R. § 100.3(a). In this case, Petitioners have alleged that Elias suffered an off-Table injury.

To prove an off-Table claim, a petitioner must provide evidence, in the form of medical records or reliable medical opinion, to establish "(1) a medical theory causally connecting the vaccination to the injury, (2) a logical sequence of cause and effect showing the vaccination was the reason for the injury, and (3) a proximate temporal relationship between the vaccination and the injury." *Althen v. Sec'y of Dep't of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). A petitioner must show that but for her vaccination she would not have been injured, and that the vaccination was a substantial factor in bringing about her injury. *Shyface v. Sec'y of Dep't of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). The vaccination only must be a substantial factor; it does not need to be the sole factor. *Id.*

The facts of this case can be summarized as follows. Elias received a DTaP vaccine. Within one day, he developed a fever, which led to a complex febrile seizure. Subsequently, Elias developed epilepsy. This fact pattern is commonly seen in the Vaccine Program. *See Nance v. Sec'y of Dep't of Health & Human Servs.*, No. 06-730V, 2010 U.S. Claims LEXIS 608, 2010 WL 3291896, *8 (Fed. Cl. Spec. Mstr. July 30, 2010) (citing cases); *Simon v. Sec'y of Dep't of Health & Humans Servs.*, No. 05-941V, 2007 U.S. Claims LEXIS 187, 2007 WL 1772062 (Fed. Cl. Spec. Mstr. June 1, 2007). Because special masters must base

their decisions on both the particular facts and specific expert opinions in a case, a special master is not bound by other special masters' decisions in different cases; however, although those decisions are not binding, they may be persuasive authority. *See Nance*, 2010 U.S. Claims LEXIS 608, 2010 WL 3291896, at *8.

At a post-hearing status conference, I discussed with the parties the applicability of the decision in *Simon* to this case. In *Simon*, the special master found that a DTaP vaccination caused a febrile seizure, which caused a child's epilepsy and subsequent death. The special master found that "on a probability scale, it is reasonable to conclude that where the vaccine is associated with fever and seizure and the seizure is of a complex nature, in the absence of proof of an alternative cause, it is the vaccine that is legally responsible for a subsequent epilepsy and residual sequela." *Simon*, 2007 U.S. Claims LEXIS 187, 2010 WL 1772062, at *6. Because the record in this case was incomplete as to that theory, I requested additional briefing from the parties after the hearing. The parties agree that the DTaP vaccine can cause a fever, and that a fever sometimes can initiate a seizure. The issues here are whether a vaccine-induced febrile seizure can cause epilepsy, and if it can, whether Elias's initial febrile seizure caused his epilepsy.

Based on the medical literature and expert opinions submitted in this case, I find that Petitioners have established that, in circumstances like Elias's, a complex febrile seizure can lead to epilepsy. Further, Petitioners have established a logical sequence of cause and effect showing that Elias's vaccine-induced complex febrile seizure was a legal cause of his subsequent epilepsy. Although the record shows that

Elias may have suffered from other conditions, unrelated to vaccination, that increased his risk of developing epilepsy, Respondent has not shown that those conditions were at work here. In essence, Respondent's argument is that the vaccination did not cause the epilepsy because, based on the statistics, it is more likely that Elias's epilepsy was caused by a congenital condition than by a vaccine reaction. This fact, alone, is insufficient to negate causation. *See Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35 F.3d 543, 550 (Fed. Cir. 1994) (discussing burden of proving an alternative factor in an on-Table case).

The medical literature shows that some uncertainty exists in the medical community as to the cause of the documented association between a complex febrile seizure and epilepsy. Although Petitioners have not proven that Elias's DTaP vaccination was a medically certain cause of his epilepsy and subsequent death, that is not the standard for causation under the Vaccine Act. In enacting the Vaccine Act, Congress made a deliberate choice not to impose on petitioners the burden of producing conclusive scientific proof that an unlikely event actually occurred. Instead a petitioner must only provide reliable scientific evidence to support vaccine causation. *Moberly v. Sec'y of Dep't of Health & Human Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010). That policy choice guides my decision here.

After carefully evaluating and weighing all of the evidence, I find that Petitioners have satisfied their burden of making a prima facie case under Althen, and that Respondent has failed to prove that Elias's epilepsy and death were caused by an alternative factor. Accordingly, Petitioners are entitled to compensation under the Act.

## II. BACKGROUND

### A. Summary of the Relevant Medical Conditions

The parties' dsagreement largely concerns what types of seizures have a causal relationship with epilepsy and whether Elias had that type of seizure. The parties also disagree over whether Elias suffered from a genetic condition that could have caused his epilepsy. The features and signs of the relevant medical conditions provide a context that is important to understanding the significance of Elias's medical history, which follows.

According to the literature filed by the parties, some types of seizures are associated with an increased risk of epilepsy, while others are not. The three types of seizures relevant to this case are benign febrile seizures, complex febrile seizures, and prolonged febrile seizures.

Febrile seizures are frequent in infancy, and most are termed "benign" because they are not associated with an increased risk of future seizures. Pet' Ex. 42 at 1. Benign febrile seizures last only a few minutes, are followed by little or no postictal state (altered state of consciousness after a seizure), and involve bisymmetrical and tonic or tonic-clonic convulsions. *Id.*[3] The literature submitted by the parties did not discuss simple febrile seizures in detail. Nelson's Textbook of Pediatrics gives a general overview of seizures, which

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[3]Tonic means characterized by continuous tension. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2002) at 1920. Tonic-clonic means both tonic and clonic, or exhibiting both continuous tension of the muscles and alternating muscular contraction and relaxation in rapid succession. *Id*. at 377, 1920.

provides some more background. NELSON'S TEXTBOOK OF PEDIATRICS (Robert Kliegman, M.D., et al. eds., 18th ed. 2007). A simple febrile convulsion usually " initially generalized and tonic-clonic in nature, lasts a few seconds and rarely up to 15 minutes, is followed by a brief postictal period of drowsiness, and occurs only once in 24 [hours]." *Id*. at 2457. Additionally, febrile seizures are rare before nine months of age. *Id*. "Factors that are associated with a substantially greater risk of later epilepsy include the presence of complex features during the seizure . . ., an initial febrile seizure before 12 [months] of age, delayed developmental milestones, or a pre-existing neurologic disorder." *Id*. at 2458.

A complex febrile seizure, however, is not considered benign. The medical literature filed by the parties defined a complex seizure as a seizure with one or more of the following characteristics: more than 15 minutes' duration, more than one seizure in 24 hours, or focal features. Karin Nelson & Jonas Ellenberg, *Prognosis in Children with Febrile Seizures*, 61 PEDIATRICS 720-27, 721 (1978) (Pet'r Ex. 42-G); *accord* C. Huang & Y. Chang, *The Long-Term Effects of Febrile Seizures on the Hippocampal Neuronal Plasticity — Clinical and Experimental Evidence*, 31 BRAIN & DEV. 383-87, 383 (2009) (Resp't Ex. M). A complex initial seizure, along with a family history of afebrile seizures and a preexisting neurological abnormality, has been identified as a risk factor for developing epilepsy. Nelson & Ellenberg, *supra*, at 720. Petitioners argued that the medical literature supports a causal association between a complex initial febrile seizure and epilepsy.

The medical literature also discussed prolonged

febrile seizures, which are a type of complex febrile seizure, and their association with epilepsy. The literature does not, however, provide a clear definition as to what qualifies as a prolonged" seizure; some articles said the seizure must last more than 30 minutes, others said more than 20 minutes, and some, including one filed by Respondent, said more than 15 minutes. *See, e.g., supra*, Huang & Chang, at 383. One specific type of prolonged seizure is "status epilepticus," which is defined as "a continuous series of generalized tonic-clonic seizures without return to consciousness, a life-threatening emergency." Dorland's at 1756. Some studies have found that prolonged febrile seizures can cause brain damage, that such brain damage is visible on an MRI, and that this can lead to temporal lobe epilepsy. Respondent argued that, although complex seizures are associated with epilepsy, only prolonged febrile seizures that cause brain damage have a causal association with epilepsy.

Additionally, Respondent argued that Sotos syndrome could explain Elias's seizure disorder. According to literature submitted by both parties, Sotos syndrome is an overgrowth condition that can be identified by a few cardinal features: a characteristic dysmorphic facial appearance, learning disability, and overgrowth, especially in height and head-size. G. Baujat & V. Cormier-Daire, *Sotos Syndrome*, ORPHANET J. RARE DISEASES 2:36 (2007) (Resp't Ex. C); K. Tatton-Brown & N. Rahman, *Sotos Syndrome*, EUR. J. HUM. GENETICS 15: 264-71, 264 (Pet'r Ex. 31-A). Some other features of Sotos syndrome are advanced bone age, seizures, hypotonia, macrocephaly, and recurrent episodes of otitis media. Baujat &

Cormier-Daire, *supra*, at 2-3.[4] T esting can help identify whether a person has Sotos syndrome. An abnormality of the NSD1 gene occurs in at least 90% of Sotos syndrome cases. Tatton-Brown & Rahman, *supra*, at 268-69. Many persons with Sotos syndrome show specific abnormalities on an MRI. G. Bradley Schaefer et al., *The Neuroimaging Findings in Sotos Syndrome*, 68 AM. J. MED. GENET. 462-65, 463 (1997) (Pet'r Ex. 41) at 463; Baujat & Cormier-Daire, *supra*, at 4.

**B. Facts and Medical History**

Elias was born on August 23, 2000. Pet'r Ex. 13 at 14. Until December 26, 2000, it appears that Elias was a healthy baby. Pet'r Ex. 2 at 12; Harry Tembenis Aff., Aug. 14, 2008, at 1 (Pet'r Ex. 25).

On December 26, 2000, Elias received his second dose of the DTaP vaccine. Pet'r Ex. 2 at 14. Elias's parents recall that there was some swelling around the injection site. Tembenis Aff. at 1-2; Pet'r Ex. 14 at 133 (doctor noted "imm[unization] site red RUE [right upper extremity]"). Early in the morning on December 27, 2000, Elias's parents found him seizing in his crib and took him to the emergency room ("ER"). Pet'r Ex. 14 at 132; Tembenis Aff. at 1-2. The seizure lasted about 15 minutes and was controlled with medication by the doctors in the ER. Pet'r Ex. 14 at 132. Five minutes later, Elias began seizing again with apnea, and according to the timeline in the medical records, the second seizure was stopped when Elias was given

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[4]Otitis media is the inflammation of the middle ear, often caused by a viral or bacterial upper respiratory tract infection. Nelson's at 2634. Hypotonia is a condition of diminished tone of the muscles. Dorland's at 900.

an Ativan IV and oxygen. Id. at 132-33. The medical records are unclear, but the second seizure lasted at least a few minutes, and it could have lasted as long as 15 minutes. Pet'r Ex. 14 at 132-33 (noting that the first seizure was stopped at 4:30 a.m., the second seizure started five minutes later, and the second seizure was stopped at 4:50 a.m.).

The medical records document Elias's condition on admission and his progression. On admission, Elias was cyanotic and actively seizing. *Id.* at 133.[5] His temperature was approximately 102 degrees. *Id*. at 132 (102 degrees); *id*. at 135 (102.3); *id*. at 139 (101.7). It was noted that Elias had no rash. *Id.* at 132. Elias's seizures involved bilateral arm twitching, with eyes rolled back with right side deviation. *Id*. at 139. He was in the postictal phase for about 30 minutes, with shallow breathing, posturing, and grunting. *Id.* Elias was admitted to the pediatric intensive care unit for monitoring. *Id*. at 133.

The neurology consult on December 27, 2000, noted that Elias had returned to baseline. *Id*. at 147. Dr. Paul Marshall was the consulting doctor. *Id*. at 121. The assessment was "[questionable] febrile seizure vs. seizure disorder vs. reaction to pertussis component of DTaP." *Id*. at 148. Dr. Marshall noted that, "The prolonged seizure [and] the young age (< 6 months) required additional circumspection re: question of chronic anticonvulsant." *Id*. at 138. Elias had a very high white blood cell count, which suggested that the seizure was related to fever from infection rather than

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[5] Cyanotic means a bluish discoloration of the skin, usually indicating a lack of oxygen in the blood. Dorland's at 455.

fever from immunization. *Id*. Elias was administered ceftriaxone as a prophylactic, to be discontinued if bacterial cultures came back negative. *Id*. at 139.[6] Elias had no symptoms of an upper respiratory infection. *Id*. A CT scan of Elias's head and an EEG were normal. *Id*. at 139-40.

On December 28, 2000, the parents reported that Elias seemed to be completely himself. *Id*. at 143. Although the bacterial cultures came back negative, ceftriaxone was continued to rule out sepsis. *Id*. at 142. A handwritten note described Elias's condition as "s/p [status post] prolonged sz [seizure] assoc[iated] with fever [at] 4 [months of] age." *Id*. at 143. The note also stated that given the high "WBC [White Blood Cell count], this is more likely [secondary] to infection than simply a febrile rx [reaction] to his immunizations." *Id*. Later that day, it was found that Elias had otitis media, and he was to continue on ceftriaxone to treat it. *Id*. at 144. Elias was discharged on December 29, 2000, with instructions to continue using phenobarbitol and to follow up with Dr. Marshall in one month. *Id*. at 121.

On January 29, 2000, Elias saw Dr. Marshall for a follow up visit. Dr. Marshall noted that the etiology of the seizure was uncertain, and he was concerned about a possible association with Elias's DTaP vaccination. Pet'r Ex. 2 at 62-63. Dr. Marshall recommended not giving the next DTaP dose until a follow up EEG was completed. *Id*. He noted that Elias's height was under the 75th percentile, weight was above the 95th

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[6]Ceftriaxone is an antibiotic that is effective against a wide range of bacteria. Dorland's at 315.

percentile, and head circumference was above the 95th percentile. *Id*. Dr. Marshall also observed that Elias's father's head circumference was above the 95th percentile for adults. *Id*.

On February 6, 2001, Elias was admitted to the hospital again for seizures. The seizure lasted for approximately 20-25 minutes. Pet'r Ex. 14 at 327. When the seizure started, Elias's eyes rolled up and to the right and he had jerking of the right arm, but these focal aspects generalized to tonic-clonic movements of all four extremities. *Id*. at 327-28, 332. Elias's mother reported that he was afebrile when the seizure started, and the medical records noted that there was a question as to DTaP's role in causing the first seizure. *Id*. at 325. The diagnosis was status epilepticus. *Id*. at 328. Elias was discharged on February 7, 2001. *Id*. at 332. An undated, handwritten note in Dr. Marshall's records stated that, after Elias's February 6, 2001 seizure, his epilepsy was almost definitively established. Pet'r Ex. 2 at 63.

Elias again was admitted to the hospital for seizures on February 20, 2001. Pet'r Ex. 14 at 275. His temperature on admission was not noted, although he had a slight fever (99-100 degrees) the following day. *Id*. at 280. An EEG performed on February 21, 2001 was normal. Pet'r Ex. 14 at 289. An MRI taken on February 26, 2001 was mostly normal, but the report noted the MRI showed evidence of frontal lobe atrophy of uncertain etiology. Pet'r Ex. 2 at 64. Dr. Marshall was not certain if the atrophy was clinically significant. *Id*. at 65.

In March 2001, Elias did not receive his 6-month (third) DTaP vaccination. *Id*. at 67. Elias was noted to be "an alert, chubby, vigorous, handsome infant." Pet'r

Ex. 20 at 143. His muscle bulk and tone were normal. *Id.*

Elias had seizures with some regularity over the next year. For example, on April 13, 2001, Elias had a febrile seizure. Pet'r Ex. 14 at 410. On August 28, 2001, Elias had a febrile seizure the day after he received pneumococcal and varicella vaccines. *Id.* at 388. In November 2001, Elias was seen because he had a series of afebrile seizures. Pet'r Ex. 2 at 73. In November 2001, Dr. Irina Anselm, Elias's treating neurologist, noted that Elias was a very attractive, non-dysmorphic child. *Id.*

In 2002, doctors observed that Elias displayed signs of other disorders. On January 31, 2002, Dr. Anselm noted that Elias had features of Pervasive Developmental Disorder ("PDD"), which is an autism spectrum disorder. Id. at 45-46. On March 13, 2002, it first was noted that Elias's condition was consistent with Sotos syndrome. Pet'r Ex. 4 at 9.

It appears that Elias may have had Sotos syndrome, but the medical records are not entirely clear on this point. Elias had some physical signs of Sotos syndrome, such as a large head and body. Elias had been diagnosed with PDD and developmental delay. Pet'r Ex. 2 at 22. On April 9, 2002, doctors observed that "he may have an advanced bone age;" Elias, who was 20 months old, had a bone age of 28 months. *Id.* at 75.[7] Elias had recurring otitis media. Pet'r Ex. 6 at 14; Pet'r Ex. 2 at 24. On April 9, 2002, Elias had a genetics evaluation, which found that

[7]The medical records state that the standard deviation for bone age is four months, and note that Elias's bone age was two standard deviations above average. Pet'r Ex. 2 at 75.

Elias's genetics were normal, but the evaluation did not test for the NSD1 abnormalities associated with Sotos syndrome. Pet'r Ex. 2 at 75; Pet'r Ex. 4 at 50.

On the other hand, Elias's condition was not entirely consistent with Sotos syndrome. Although Elias had a large head, Elias's father had a head size in the 95th percentile. And although Elias's head was big, it was not characteristically dysmorphic. Additionally, it appears Elias was a large but proportionally sized baby, rather than just tall as seen in Sotos syndrome. *See* Pet'r Ex. 2 at 36 (on October 21, 2002, height: 57th percentile, weight: 93rd percentile); id. at 62-63 [*19] (On January 29, 2000, height: under the 75th percentile, weight: above the 95th percentile, head circumference: above the 95th percentile).

Despite the uncertainty of the findings, over the next few years the medical records consistently mentioned diagnoses of Sotos syndrome. *See, e.g., id.* at 22, 40-41; Pet'r Ex. 15 at 176. However, two doctors appear not to have accepted entirely the Sotos syndrome diagnosis. On August 29, 2002, Dr. Anselm described Elias as having a history of "possible Sotos syndrome." Pet'r Ex. 2 at 40. On May 8, 2003, Dr. Anselm noted that the "issue with Sotos syndrome is still not settled." *Id.* at 28. The medical records show that Dr. Anselm never stated that she thought Elias had Sotos syndrome. In July 2003, Elias was taken to the Sotos Syndrome Support Association Annual Meeting. Dr. G. Bradley Schaefer, an expert on Sotos syndrome, evaluated Elias, and he diagnosed Elias as having a "Sotos-like" disorder, "possibly just macrocephaly." Pet'r Ex. 28 at 3.

On February 25, 2002, Elias started receiving his DTaP vaccinations again, but the record does not

indicate the reason. Pet'r Ex. 2 at 7, 14. On September 1, 2002, Harry Tembenis wrote a letter to Elias's pediatrician, in which he noted that Elias had experienced almost 40 seizure bouts between his 4 month checkup and his 18 month checkup. *Id*. at 43. In the previous six months, Elias had experienced only two febrile seizure bouts, both caused by ear infections. *Id*.

On March 27, 2003, Elias had surgery to have tubes placed in his ears due to recurring otitis media that was unresponsive to therapy. Pet'r Ex. 6 at 14.

After December 2003, Elias had only occasional seizures. Pet'r Ex. 19 at 22 (note on May 24, 2005, stating that Elias had not had a seizure since December 2003); Pet'r Ex. 20 at 111 (one seizure in January 2006). Elias continued to be developmentally delayed.

On November 16, 2007, Elias went to the emergency room with a fever and a cough. Pet'r Ex. 16 at 12. While there, he had a seizure and went into status epilepticus, followed by bradycardiac arrest. Id. at 14. On November 17, 2007, due to the absence of any neurologic functioning on repeated exams and overwhelming organ failure, it was decided to withdraw aggressive life support. *Id*. at 36. Elias was pronounced dead six minutes later. *Id*. The immediate cause of death was multisystem organ failure, which was a consequence of cardiac arrest, which was a consequence of Elias's seizure disorder. Pet'r Ex. 15 at 393.

**C. Summary of the Parties' Arguments**

Petitioners argued that they have satisfied their burden under the Vaccine Act. They argued that Elias showed no symptoms of a seizure disorder, had a DTaP vaccine that can cause a fever, had a fever that can cause seizures, had a seizure that can cause epilepsy, suffered epilepsy, and died as a result of his epilepsy. In the absence of an alternative cause, Petitioners asserted it was logical to conclude that the vaccine caused the epilepsy and death. Petitioners argued in the alternative that, if Elias were found to have a genetic disorder, the DTaP vaccine significantly aggravated that condition. See Pet'r Post-Hr'g Br., Aug. 27, 2010, at 47.[8]

Petitioners relied on the opinion of Dr. Marcel Kinsbourne. It was Dr. Kinsbourne's opinion that an initial complex febrile seizure can lead to epilepsy.[9] Dr. Kinsbourne described Elias's first seizure as a complex febrile seizure because of the focal nature of the seizure and the occurrence of a second seizure a few minutes

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[8]Because I do not find that Elias had a genetic condition that could explain his seizure disorder, this decision does not further address Petitioners' significant aggravation argument.

[9]Dr. Kinsbourne also presented a theory about the pertussis toxin in DTaP having the same effects as in DTP. Dr. Kinsbourne and Petitioners claimed that the National Childhood Encephalopathy Study ("NCES") on DTP is applicable to DTaP because both vaccines contain a pertussis toxin. I find that application of the NCES DTP studies to DTaP is not warranted by any scientific evidence, and that such application is speculation. Like other special masters who have considered this theory, I do not find it to be reliable. *See Simon*, 2007 U.S. Claims LEXIS 187, 2007 WL 1772062, at *7.

after the first one. He asserted that an initial complex febrile seizure is associated with a greater risk of epilepsy, and that such a seizure can cause epilepsy. Based on the risk factors and the absence of an alternative cause, it was Dr. Kinsbourne's opinion that Elias's epilepsy was caused by his initial seizure, which was caused by Elias's DTaP vaccination. Dr. Kinsbourne supported this theory with literature submitted post-hearing.

Dr. Kinsbourne further opined that the record was unclear as to whether Elias suffered from Sotos syndrome. Although Elias was diagnosed with Sotos syndrome, the record shows that Elias did not show some of the cardinal characteristics of the disorder, and it seems that doctors may have backed away from this diagnosis. *See* Tr. at 46-50. In addition, Elias did not show the characteristic abnormalities of Sotos syndrome on an MRI. Pet'r Post-Hr'g Br. at 28. Even if Elias had Sotos syndrome, however, it would not have changed Dr. Kinsbourne's opinion.

In their post-hearing brief, Petitioners analogized this case to *Sucher v. Secretary of Department of Health & Human Services*, No. 07-58V, 2010 U.S. Claims LEXIS 203, 2010 WL 1370627 (Fed. Cl. Spec. Mstr. Mar. 15, 2010). Petitioners argued that the facts of that case are similar to the facts here, and they noted that the same experts appeared in both cases. In Sucher, the special master found that the petitioner had established that a DTaP vaccination caused the vaccinee to develop a fever and a seizure, and that the seizure caused the vaccinee to develop epilepsy. The vaccinee had her first seizure within 24 hours of a DTaP vaccination, and had two five-minute seizures, followed by several staring and facial twitching

episodes. 2010 U.S. Claims LEXIS 203, [WL] at *3. The diagnosis of those seizures was status epilepticus. *Id.* The special master found that the DTaP vaccine caused a fever; the fever caused a seizure; a complex febrile seizure can lead to epilepsy; the vaccinee's seizure was severe, complex, and prolonged and not short, simple, and benign; the vaccinee had a genetic predisposition to having seizures; and the vaccination was a but for cause and a substantial factor in causing the vaccinee's seizure and subsequent epilepsy. 2010 U.S. Claims LEXIS 203, [WL] at *38-*40.

Respondent contested that Petitioners have satisfied their burden under the Vaccine Act. Respondent argued that Dr. Kinsbourne's opinion was unreliable and ill-adapted to the facts of this case. Under prong 1, Respondent maintained that an association between an initial complex febrile seizure and subsequent epilepsy is observed because many children who have complex febrile seizures also have a pre-existing, underlying brain abnormality. Therefore, a complex seizure does not cause subsequent epilepsy; it is just the first sign of an existing disorder. Respondent's position was that Petitioners cannot prove this is not true. Nonetheless, Respondent has conceded that DTaP can cause a fever, and a fever can cause a seizure.

Even if a complex seizure could cause epilepsy, Respondent argued that it did not do so in Elias's case. Respondent argued that Elias's first seizure was caused by otitis media because it was suspected that Elias's fever may have been due to an infection, and Elias received a diagnosis of otitis media two days after his initial seizure. Additionally, Respondent claimed that Elias did not have the type of seizure that can lead to

epilepsy. Respondent argued that this case is different from cases like Simon and Sucher, because the initial seizure in those cases was diagnosed as status epilepticus and Elias's initial seizure was not. According to Respondent, Elias's epilepsy was more consistent with Sotos syndrome, and thus, there was an alternative explanation for Elias's epilepsy.

Respondent relied on the opinion of Dr. Max Wiznitzer. Dr. Wiznitzer contested that Elias had the type of seizure that can lead to epilepsy. He characterized Elias's seizure as too short to cause permanent brain damage. Dr. Wiznitzer also asserted that Elias's seizure was the result of an underlying brain disease, and the underlying brain disease caused the epilepsy. Dr. Wiznitzer opined that Sotos syndrome was clearly the cause of Elias's epilepsy.

## III. DISCUSSION

### A. Petitioner's Burden of Proof

A petitioner seeking to establish causation-in-fact must show, by a preponderance of the evidence, that but for her vaccination she would not have been injured, and that the vaccination was a substantial factor in bringing about her injury. *Shyface*, 165 F.3d at 1352. Mere temporal association is not sufficient to prove causation in fact; a petitioner must present a medical theory that is supported either by medical records or by the opinion of a competent physician. *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not

medically or scientifically certain.'" *Moberly*, 592 F.3d at 1322 (Fed. Cir. 2010) (quoting *Knudsen*, 35 F.3d at 548-49); *see also Grant*, 956 F.2d at 1148 (medical theory must support actual cause).

The preponderance of evidence standard under the Vaccine Act requires proof that a vaccine more likely than not caused the vaccinee's injury. *Althen,* 418 F.3d at 1279. Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen*, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove her case, and "close calls" regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280.

Respondent may offer evidence of an alternative theory of causation to show that a petitioner has not satisfied an element of her case. *Doe 11 v. Sec'y of Dep't of Health & Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010). When a petitioner bases her case in part on the absence of alternative causes, it is proper for the special master to consider evidence of alternative causes that is presented by Respondent in evaluating whether the petitioner has met her burden of proof. *Id.*

Once the petitioner has met the initial burden of proof, "the burden shifts to the government to prove '[by] a preponderance of the evidence that the petitioner's injury is due to a factor unrelated to the . . . vaccine.'" *de Bazan v. Sec'y of Dep't of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citations omitted). If the petitioner fails to establish a prima facie case of causation, however, the burden does not shift. *Doe 11*, 601 F.3d at 1357-58.

In evaluating whether a petitioner has presented a legally probable medical theory, "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. Assessing the reliability of an expert's opinion in Vaccine Act cases can be challenging, because often there is little supporting evidence for the expert's opinion. *See Althen*, 418 F.3d at 1280 (noting that the "field [is] bereft of complete and direct proof of how vaccines affect the human body"). Consequently, most expert opinion will be an extrapolation from existing data and knowledge. The weight to be given to an expert's opinion is based in part on the size of the gap between the science and the opinion proffered. *Cedillo v. Sec'y of Dep't of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010). A special master is not required to rely on a speculative opinion that "'is connected to existing data only by the ipse dixit of the expert.'" *Synder v. Sec'y of Dep't of Health & Human Servs.*, 88 Fed. Cl. 706, 745, n.66 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)).

**B. Prong 1**

Under *Althen* prong 1, a petitioner must set forth a biologically plausible theory explaining how the vaccine received by the petitioner could cause the injury complained of. *See, e.g., Andreu v. Sec'y of Dep't of Health & Human Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009). This requirement has been interpreted as "can the vaccine(s) at issue cause the type of injury alleged?" *Pafford v. Sec'y of Dep't of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Evidence should be viewed by the preponderance of the evidence standard and "not through the lens of the laboratorian." *Andreu*, 569 F.3d at 1380. Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must

be sound, reliable, and reputable — in other words, the theory need not be scientifically certain, but it must have a scientific basis. *See id.* at 1379-80.

In this case, the parties agree that DTaP can cause a fever, and a fever can sometimes lead to a seizure. Resp't Post-Hr'g Br. at 18. The main point of contention is whether a complex febrile seizure can lead to a seizure disorder or if only a prolonged febrile seizure can. This issue was briefed post-hearing, [*30] and Petitioners have submitted a supplemental report from Dr. Kinsbourne and some supporting medical literature. Respondent has submitted the rebuttal report of Dr. Wiznitzer and some additional literature, which challenged whether the submitted literature supports Dr. Kinsbourne's opinion.

The submitted literature shows that the medical profession recognizes that some classes of febrile seizures are not benign and instead are associated with a greater risk of epilepsy.[10] Although the association with greater risk has been documented, based on the literature in this record, it appears that the source of this risk is not entirely understood. Dubé 2004, *supra*, at 709; Huang & Chang, *supra*, at 383 ("the impact of early-life febrile seizures on the developing brain has

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[10] This was observed in many of the articles filed. *See* Nelson & Ellenberg, *supra* (Pet'r Ex. 42-G); John Annegers *et al.*, *Factors Prognostic of Unprovoked Seizures after Febrile Convulsions*, NEW ENG. J. MED., 316(9):493, 493 (1987) (Pet'r Ex. 42-A); Y. Ben-Ari, *Seizures Beget Seizures: the quest for GABA as a Key Player*, CRIT. REV. NEUROBIOL., 2006;18(1-2):135-44, 140 (Pet'r Ex. 42-B) [hereinafter Ben-Ari 2006"]; Céline Dubé *et al., Serial MRI after Experimental Febrile Seizures*, 56 ANNALS NEUROL. 709-14, 709 (2004) (Resp't Ex. K) [hereinafter "Dubé 2004"].

not been fully resolved"); Nelson & Ellenberg, *supra*, at 720 (there is "uncertainty concerning the magnitude of risks facing children with febrile seizures"). One article stated: "The association between complex febrile convulsions and partial seizures . . . may reflect either a causal association or the presence of preexisting brain disease that is responsible for both the complex febrile seizures and later partial seizures." Annegers, *supra*, at 493. Another stated: "However, in studies in vivo one cannot directly test the hypothesis [that seizures beget seizures] and unravel its underlying mechanism because of the multiple sites at which the event may occur or the agent may act." Ben-Ari 2006, *supra*, at 140.

The discussion in the literature of the hypothesis that a complex febrile seizure can cause epilepsy shows that the theory is accepted by the medical community as one plausible explanation for the increased risk associated with a complex febrile seizure. The articles made clear that the increased risk is associated with a first seizure that is complex, which is a seizure with a long duration, focal features, and/or repeated episodes. *See* Nelson & Ellenberg, *supra*, at 721. Although some studies specifically explored the connection between a prolonged seizure and epilepsy, the articles did not limit causal association to the cases where the initial seizure is prolonged and results in status epilepticus.

Dr. Wiznitzer's opinion is that the submitted literature does not provide statistically significant experimental data showing that a complex febrile seizure can cause epilepsy. Although Dr. Wiznitzer is correct on this point, the literature nonetheless documents that complex febrile seizures are associated with a greater risk of epilepsy, and the medical

community considers Petitioners' theory to be plausible. Petitioners' theory does not need to be directly proven by scientific studies. *Rotoli v. Sec'y of Dep't of Health & Human Servs.*, 89 Fed. Cl. 71, 87 (2009), appeal docketed, 2010-5163 (Fed. Cir. Sept. 24, 2010) (finding that petitioner's theory was legally probable, despite lack of direct proof by scientific studies). Many of the articles Dr. Kinsbourne submitted show that scientists are still studying the association, and that scientists consider a causal relationship to be plausible. *See* Irma Holopainen, *Seizures in the Developing Brain*, 52 NEUROCHEM. INT'L 935-47, 943 (2008) (Pet'r Ex. 42-F) at 943; Céline Dubé *et al., Febrile Seizures: Mechanisms and Relationship to Epilepsy*, 31 BRAIN & DEV. 366-71, 366, 368 (2009) (Pet'r Ex. 42-E) [hereinafter "Dubé 2009"].

Dr. Wiznitzer also opined that the increased risk of epilepsy following a seizure is caused by the presence of an underlying brain disease. The submitted literature confirms that Dr. Wiznitzer's theory is also one considered plausible by the medical community. Thus, the literature shows that both Petitioners' and Respondent's theories are plausible, but this does not cast doubt on the reliability or plausibility of Petitioners' theory. Dr. Wiznitzer's testimony shows only that Petitioners' theory of causation is not medically certain.

Dr. Wiznitzer appears to have interpreted the medical literature as limiting a causal association between a complex seizure and epilepsy to cases where the initial seizure is prolonged. Dr. Wiznitzer noted that some articles, including the Annegers article, discussed how a prolonged seizure can lead to brain cell death and temporal lobe epilepsy. *See* Annegers, *supra*,

at 497; Resp't Ex. J at 1-2 (Dr. Wiznitzer's Supplemental Expert Report). One study found that prolonged febrile seizures can sometimes cause brain damage, and typically, that damage could be seen on an MRI. Dubé 2004, *supra*, at 709. Another study examined whether prolonged febrile seizures, the most common type of early-life febrile seizure, could cause temporal lobe epilepsy. *See* Céline Dubé *et al.*, *Temporal Lobe Epilepsy after Experimental Prolonged Febrile Seizures*, 129 BRAIN 911-22, 911-12, 920 (2006) (Resp't Ex. L) [hereinafter "Dubé 2006"].

The Annegers article, while it discussed how a prolonged seizure can cause epilepsy, did not find that the only way a febrile seizure can lead to epilepsy is through cell death; it only mentioned that cell death/temporal lobe epilepsy is one mechanism that has been explored, and that limited data supported that mechanism. *See* Annegers, *supra*, at 497. The other studies reached much the same conclusion; they merely presented data from murine models showing that prolonged febrile seizures can sometimes cause brain damage and epilepsy, and they did not rule out other mechanisms of causation.

While Dr. Wiznitzer conceded that a seizure that was prolonged and sufficiently severe to cause brain damage could cause epilepsy, he challenged that a seizure of less than 30 minutes could do so.[11] Resp't Ex. J. Dr. Wiznitzer did not contest that a seizure of more than 15 minutes was a risk factor, but he noted

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[11] Elias's first seizure lasted for about fifteen minutes, and he had a second seizure a few minutes after the first one stopped. His second seizure lasted between five and fifteen minutes. Pet'r Ex. 14 at 132-33.

that the medical literature showed no statistically significant increased risk of epilepsy for febrile seizures of less than 30 minutes. For example, for a seizure lasting 30 minutes or more, he stated that Nelson & Ellenberg showed no statistically significant increase in risk of epilepsy, and he opined that, "Obviously a seizure lasting 16-29 minutes would also not be associated with a statistically significant increased risk of subsequent epilepsy." *Id*. at 1.

Dr. Wiznitzer's opinion overlooked some important aspects of the literature. The Nelson & Ellenberg article stated that, "prolonged duration of febrile seizures was not a major determinant of subsequent epilepsy[;] [m]ore than 90% of children who developed epilepsy after febrile seizures had never had a febrile seizure which lasted as long as 30 minutes." Nelson & Ellenberg, *supra,* at 725-26. Nelson & Ellenberg found, however, that a complex first seizure was associated with an increased risk of epilepsy, and the age of onset was associated with an increased risk of subsequent febrile seizures. *Id*. at 725; *see* Annegers, *supra*, at 497 (reaching same conclusion). Additionally, the literature neither provided a clear definition as to what qualifies a "prolonged" seizure nor limited a causal association with epilepsy to only seizures that are prolonged.

After considering the opinions of Drs. Kinsbourne and Wiznitzer, along with the filed medical literature, I find that Petitioners have presented a biologically plausible theory of causation showing that DTaP can cause a febrile seizure, and that a complex febrile seizure can then cause epilepsy. In doing so, I reach the same conclusion as other special masters who have considered this same question. *See Simon*, 2007 U.S. Claims LEXIS 187, 2010 WL 1772062, at *6. I

recognize that the record shows the existence of some uncertainty as to the precise relationship between a complex febrile seizure and subsequent epilepsy. However, a petitioner is not held to the standard of medical certainty. In this case, Petitioners have satisfied by a preponderance of the evidence prong 1 of *Althen*.

**C. Prong 2**

The second prong of *Althen* requires a petitioner to prove "'a logical sequence of cause and effect show[ing] that the vaccination was the reason for the injury.'" *Andreu*, 569 F.3d at 1374 (quoting *Althen*). The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. Under prong 2 of Althen, petitioners are not required to show "epidemiologic studies, rechallenge, the presence of pathologic markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect . . . ." *Capizzano v. Sec'y of Dep't of Health & Human Servs.*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano*, 440 F.3d at 1325-26; *Andreu*, 569 F.3d at 1375-77 (treating physician testimony).

**1. The Expert Opinions**

Dr. Kinsbourne opined that seizures beget seizures. He opined that the medical community accepts that an initial complex febrile seizure can cause epilepsy, although the precise mechanism of causation is still being studied. He described Elias's first seizure as complex because of the focal nature of the seizure and the occurrence of two seizures back-to-back. Pet'r Ex. 42 (Dr. Kinsbourne's Second Supplemental Report). When epilepsy follows a complex febrile seizure, subsequent seizures are likely to be complex partial seizures. Dr. Kinsbourne opined that Elias "has this type of seizure disorder." *Id.* It was Dr. Kinsbourne's opinion that Elias's complex febrile seizure caused his epilepsy.

To support his position, Dr. Kinsbourne relied on the Nelson & Ellenberg article to show that Elias's initial seizure was of a type that is associated with a greater risk of epilepsy. The authors discussed risk factors for developing epilepsy (afebrile seizures) when the initial seizure is febrile, and also risk factors for having recurring febrile seizures. Nelson & Ellenberg, supra, at 720 (identifying family history of afebrile seizures, preexisting neurological abnormality, and complicated initial seizure as risk factors for epilepsy). The article defined a complex seizure as a seizure with one or more of the following characteristics: more than 15 minutes' duration, more than one seizure in 24 hours, or focal features. *Id.* at 721; *accord* Huang & Chang, *supra*, at 383 (Resp't Ex. M). Although a duration of more than 15 minutes was a risk factor, the article noted that, "Ninety-one percent of children who developed epilepsy following febrile seizures (31 of 34 children) had never had a febrile seizure which lasted

30 minutes or more." Nelson & Ellenberg, *supra*, at 724.

The Annegers article documented the risk factors in developing epilepsy. In addition, Annegers found that age of onset has some influence on the development of subsequent epilepsy. The occurrence of a first febrile seizure before one year of age is weakly associated with an increased risk of epilepsy. Annegers, *supra*, at 497. Dr. Kinsbourne testified similarly at hearing. Tr. at 101.

In response, Respondent argued that otitis media caused Elias's first seizure. Further, Dr. Wiznitzer contested Elias had the type of seizure that can lead to epilepsy. Dr. Wiznitzer characterized Elias's seizure as short, or at least not prolonged, and more characteristic of a benign febrile seizure than a prolonged seizure that can cause temporal lobe epilepsy. Dr. Wiznitzer asserted that the literature provided experimental evidence only for the proposition that a prolonged febrile seizure can lead to temporal lobe epilepsy. He also asserted that Elias's seizure was the result of an underlying brain disease, and the underlying brain disease caused the epilepsy. He contended that the underlying brain disease theory was proposed and established in the Annegers article.

Dr. Wiznitzer contended that the only way the seizure could have caused epilepsy was if the seizure was prolonged and damaged the brain. Based on the medical literature, Dr. Wiznitzer stated that had the seizure caused brain damage and epilepsy, the brain damage would be visible on Elias's MRI. Dr. Wiznitzer stated that Elias does not have any brain damage on his MRI, and therefore, the seizure did not cause brain damage and could not have caused Elias's epilepsy.

**2. The Cause of Elias's Initial Seizure**

Petitioners argued that the DTaP vaccination caused Elias to develop a fever, and the fever caused Elias to have a seizure. Petitioners argued that no other cause for Elias's fever and seizure appears in the record. Respondent claimed Elias's fever and seizure likely were caused by otitis media, which was one of Elias's diagnoses following his initial seizure. Respondent claimed Elias was given cefriaxone for his otitis media. Respondent also stated that the medical records note that Elias had a high white blood cell count, supporting a finding that infection caused the fever.

The record is not clear on whether otitis media preceded the seizures, as it was not until a few days after the seizure that Elias was diagnosed with otitis media. Elias received his DTaP vaccination at his four month well child visit. That record does not document an ear infection, Pet'r Ex. 2 at 12, although the presence of an infection is not always noticed by doctors, *see* Tr. at 85-88 (Dr. Kinsbourne stated that vaccines usually are not given in the presence of an infection, but infections are not always noticed). Further, when Elias was admitted to the hospital for his first seizure, otitis media was not noted in the records, and the records stated that Elias showed no signs of upper respiratory infection.[12] In addition, all of Elias's bacterial cultures taken upon admission to the hospital came back negative. The ER admission record does document, however, that the site of the

[12]An upper respiratory infection frequently accompanies otitis media. *See* Nelson's at 2634.

DTaP injection was red. Pet'r Ex. 14 at 133.

One month after the seizure, Dr. Marshall evaluated Elias's condition. Dr. Marshall noted his concern that the DTaP vaccine might have caused the seizure, but made no mention of the otitis media as a potential cause. Pet'r Ex. 2 at 62-63. Dr. Marshall, who treated Elias in the hospital, knew about the elevated white blood cell count and the otitis media, *see* Pet'r Ex. 14 at 138 (Dr. Marshall noted the elevated white blood cell count suggested seizure was related to infection), but he apparently felt that those facts were not sufficient to rule out DTaP as a causal factor.

Given the uncertainty in the timing of otitis media, and Dr. Marshall's apparent discounting of the significance of the otitis media, I find that otitis media most likely was not the cause of Elias's initial fever. Instead, I find it more likely that Elias's fever and subsequent seizure were caused by his DTaP vaccination.

**3. Type of Initial Seizure: Elias's Initial Seizure Was a Complex Febrile Seizure**

Elias, at four months of age, received his second DTaP vaccination on December 26, 2000. Within 12 hours, he developed a fever, and then started to have a seizure. He was taken to the hospital where doctors stopped his seizure. A few minutes later, he had a second seizure, which was controlled. The seizures had complex features: they lasted for approximately 15 to 20 minutes, they had focal components, and he had two seizures within 24 hours. The December 27, 2000 medical records confirm that the seizure's features were a cause of concern. Pet'r Ex. 14 at 138 (a note by Dr. Marshall stated "The prolonged seizure [and] the young age (< 6 months) required additional

circumspection re: question of chronic anticonvulsant"); id. at 143 (Elias's condition described as "[status post] prolonged [seizure] assoc[iated] with fever"); *Id*. at 133 (attending physician noted concern because Elias was not using his right side and he had right eye deviation); *but see id.* at 139 (progress note stated seizure activity "with bilateral arm twitching, eyes rolled back with [question about] right sided eye deviation").

The features of Elias's two seizures were more like a prolonged complex febrile seizure than a simple febrile convulsion. His seizures satisfied the criteria for a complex seizure specified in the medical literature, and his initial seizure was not like the brief, generalized tonic-clonic seizures that are typically associated with benign febrile seizures. *See* Pet'r Ex. 42 at 1; *see generally* Nelson's at 2457. In addition, Elias showed other risk factors identified in the submitted medical literature. For example, Elias had his first febrile seizure at four months of age, and if an initial seizure occurs before one year of age, that is a risk factor for epilepsy. *See* Annegers, *supra*, at 497.[13] Accordingly, I find that Elias's initial seizure was a

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[13]At hearing, Dr. Kinsbourne testified that seizures that begin in infancy tend to be more severe than ones that do not begin until later. Tr. at 101. The medical literature recognizes the occurrence of a febrile seizure before one year of age as a potential indicator of future problems. *See* Nelson & Ellenberg, *supra* (febrile seizure before one year of age associated with increased risk of future febrile seizures); Huang & Chang, *supra*, at 386 (the authors note that most febrile seizures do not impair global intelligence and memory function, but concerns remain "regarding those children who experience febrile seizures during the first postnatal year, having prior developmental delay, and pre- or peri-natal events").

complex febrile seizure.

The sequelae following Elias's initial seizure also appear to be related to the seizure. Elias developed both recurring febrile seizures and afebrile seizures. *Id.* ("Febrile seizures with focal features, repeated episodes, and long duration were strongly associated with partial unprovoked seizures"); Nelson & Ellenberg, *supra*, at 724 ("The most frequent sequela of an initial febrile seizure was the recurrence of febrile seizures").[14] Some of Elias's subsequent seizures had focal components, although he also had recurring seizures that were generalized tonic-clonic seizures. Dr. Kinsbourne described this as a common sequela to an initial complex febrile seizure, and opined that Elias's epilepsy was caused by his initial seizure. I agree that this constitutes a logical sequence of cause and effect.

Respondent's counterarguments are unpersuasive. Respondent argued that because Elias's seizure was less than 30 minutes, there was no statistically significant risk of developing epilepsy. Although some articles recognize an association between prolonged febrile seizures and temporal lobe epilepsy, prolonged febrile seizures are not the only type of complex febrile seizure to lead to epilepsy. *See* Nelson & Ellenberg, *supra*, at 725-26 (stating that over 90% of children who developed epilepsy after febrile seizures had never had a febrile seizure that lasted 30 minutes or more).

Dr. Wiznitzer maintained that the only way a seizure could cause epilepsy was if it caused visible

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[14]The Nelson and Ellenberg article documents an increased risk of recurring febrile seizures and an increased risk of epilepsy in children who experience complex febrile seizures. Nelson & Ellenberg, *supra*, at 725.

damage to the hippocampus. Dr. Wiznitzer opined that Elias's MRIs showed no signs of deterioration in the temporal lobe, and Dr. Kinsbourne agreed. *See* Tr. at 81-82, 117-19. Nonetheless, because the medical literature does not limit the causal association between a seizure and epilepsy to cases where an MRI shows damage to the hippocampus, the lack of damage does not negate the logical sequence of cause and effect in this case.

**4. Sotos Syndrome**

To cast doubt on whether a petitioner has satisfied her burden of proof, Respondent may offer evidence showing that a petitioner has not satisfied an element of her case. *Doe 11*, 601 F.3d at 1358. Here, Respondent maintained that Sotos syndrome was "a clinically manifest genetic syndrome" that fully explained Elias's seizure disorder. Resp't Post-Hr'g Br. at 22-23.

According to literature submitted by both parties, the cardinal features of Sotos syndrome are: a characteristic dysmorphic facial appearance, learning disability, and overgrowth, especially in height and head-size; other features include: advanced bone age, seizures, hypotonia, and recurrent episodes of otitis media. Baujat & Cormier-Daire, *supra*, at 2-3; Tatton-Brown & Rahman, *supra*, at 264. Although seizures are listed as a feature, the term "seizures" is not further defined, *i.e.*, a single febrile seizure or epilepsy, and neither expert was sure of the incidence of seizures in individuals with Sotos syndrome. *See* Tr. at 50-51, 178.

Dr. Wiznitzer relied on the diagnosis in the medical records. He also pointed to the signs of Sotos syndrome in Elias: large head, developmental delay, hypotonia, a high forehead, and advanced bone age. Tr. at 173.

Under cross examination, Dr. Wiznitzer agreed that Elias did not exhibit the common signs of Sotos syndrome in the neonatal period. Tr. at 160-164. He also conceded that the first mention of hypotonia was when Elias was six years old, but he claimed that "actual assessment of hypotonia is fraught with error," and the lack of mention of hypotonia in the medical records before age six "does not preclude the fact that he might not have had some hypotonia that was missed on exam." Tr. at 174-75. Dr. Wiznitzer also asserted that Elias's February 26, 2001 MRI showed signs of Sotos syndrome, although he appeared to concede that Elias's MRI did not show many of the neuroimaging anomalies that are frequently found in Sotos syndrome. Tr. at 177-78; *see* Baujat & Cormier-Daire, *supra*, at 4; Schaefer *et al., supra*, at 463.

Although Elias exhibited some of the signs of Sotos syndrome, his condition was not entirely congruent with it. Elias was described on numerous occasions as attractive and non-dysmorphic. Elias's overgrowth did not fit the Sotos syndrome pattern; he was big but proportionally so, and he was not abnormally tall at birth. His large head could be explained by ordinary genetics (his father's head was big) or by his autism spectrum disorder. Tr. at 40, 49. Elias had PDD, which resulted in developmental delay, but it does not appear that this necessarily was related to his other conditions. At one time, Elias had advanced bone age, but the literature stated this is a non-specific finding and not limited to persons with Sotos syndrome.

Some medical records stated that Elias had a diagnosis of Sotos syndrome, while others stated that he did not. One of Elias's treating neurologists, Dr. Anselm, did not view the Sotos syndrome diagnosis as

definitive. Pet'r Ex. 24 at 14, 16. And, most pertinently, Dr. Scheaffer, an expert on Sotos syndrome, did not accept Elias's diagnosis of Sotos syndrome, and instead suggested that it was a "Sotos-like" disorder, "possibly just macrocephaly." Pet'r Ex. 28 at 3.

Although a DNA test became available for Sotos syndrome, Elias did not have it performed because insurance would not cover it. Pet'r Ex. 24 at 14. Prior genetic testing revealed no abnormalities. Pet'r Ex. 2 at 75; Pet'r Ex. 4 at 50.

Based on this record, I do not find it more likely than not that Elias had Sotos syndrome. Although he had features of Sotos syndrome and a diagnosis, it appears that doctors eventually decided against the diagnosis. Although it is a close call, I find that a preponderance of the evidence weighs against it.

Even if Elias did have Sotos syndrome, nothing in the record indicates that the seizures associated with it are particularly severe. Respondent argued that Elias's seizures were more consistent with Sotos syndrome, and that Elias did not have the type of seizure that can lead to epilepsy. However, Respondent did not present any evidence regarding the type of seizures typically experienced by someone with Sotos syndrome. Therefore, I am not persuaded that the seizures Elias experienced are of the type that ordinarily occur in persons with Sotos syndrome.

Based on the record as a whole, Petitioners have established a logical sequence of cause and effect. Although Elias suffered from a variety of problems, Petitioners have presented evidence from which I can conclude that, more likely than not, it was the DTaP vaccine that caused Elias's first seizure, and that that seizure led to Elias's epilepsy.

**D. Prong 3**

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. *Pafford*, 451 F.3d at 1358. A temporal relationship between receipt of a vaccine and the alleged onset of symptoms, without more, however, is insufficient to establish a causal relationship in a cause-in-fact case. *Grant*, 956 F.2d at 1148. What constitutes an appropriate temporal association is a question of fact and will vary with the particular theory of causation advanced. *Id.*; *de Bazan*, 539 F.3d at 1352.

Dr. Kinsbourne opined that the fever and seizures occurred within a medically appropriate time frame. Respondent has not contested that 12 hours between vaccination and the onset of seizures is medically reasonable. Additionally, this time frame is consistent with other cases that have considered the same question. *See Simon*, 2007 U.S. Claims LEXIS 187, 2010 WL 1772062. Based on the medical literature and expert opinions, I find that Petitioner has satisfied prong 3.

**E. Evidence of an Alternative Cause**

Once the petitioner has met the initial burden of proof, "the burden shifts to the government to prove '[by] a preponderance of the evidence that the petitioner's injury is due to a factor unrelated to the . . . vaccine.'" *de Bazan*, 539 F.3d at 1352 (citations omitted).

Respondent has not established, by a preponderance of the evidence, that Elias's initial seizure or his subsequent epilepsy was caused by an alternative factor. Although the record shows that Elias had PDD and that he had some symptoms of

Sotos syndrome, Respondent has not established that either condition caused Elias's initial seizure or subsequent epilepsy. The reasons for my finding are clearly set forth in the previous sections, and need not be repeated here.

**IV. CONCLUSION**

Petitioners have satisfied the legal requirements for proving that Elias's December 26, 2000 DTaP vaccination was a legal cause of his epilepsy and death. Respondent has not overcome Petitioners' evidence by proving an alternative cause. Therefore, I find that Petitioners have established entitlement to compensation under the Vaccine Act.

IT IS SO ORDERED.

/s/ Dee Lord
Dee Lord
Chief Special Master

## APPENDIX G

**42 U.S.C. §300aa-15**

(a) General rule. Compensation awarded under the Program to a petitioner under section 2111 [42 USCS § 300aa-11] for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part shall include the following:

(1) (A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which --

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii) (I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 2116(a)(2) [42 USCS § 300aa-16(a)(2)], actual unreimbursable expenses incurred before the date of the judgment awarding such

expenses which–

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $ 250,000 for the estate of the deceased.

(3) (A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm

sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $ 250,000.

(b) Vaccines administered before effective date. Compensation awarded under the Program to a petitioner under section 2111 [42 USCS § 300aa-11] for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $ 30,000, for--

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)[)].

(c) Residential and custodial care and service. The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited. Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related

injury with respect to which the compensation is paid.

(e) Attorneys' fees.

(1) In awarding compensation on a petition filed under section 2111 [42 USCS § 300aa-11] the special master or court shall also award as part of such compensation an amount to cover--

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Claims Court [United States Court of Federal Claims] on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before the effective date of this part, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 2111(a)(5) [42 USCS § 300aa-11(a)(5)] to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this part in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 [42 USCS § 300aa-11] which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation.

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) [42 USCS § 300a-21(a)] to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Claims Court [United States Court of Federal Claims] under section 2112 [42 USCS § 300aa-12] awarding the compensation. Such compensation may not be paid after an election under section 2121(a) [42 USCS § 300aa-21(a)] to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 USCS §§ 901 *et seq*.].

(4) (A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510] in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used,

with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 2121(a) [42 USCS § 300aa-21(a)] shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510], or to the appropriations account from which the funds were

derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable. Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 USCS §§ 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers. No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and--

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits, may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 USCS §§ 1396 *et seq*.].

(i) Source of compensation.

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or

after the effective date of this part shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of the Internal Revenue Code of 1986 [26 USCS § 9510].

(j) Authorization. For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part there are authorized to be appropriated to the Department of Health and Human Services $ 80,000,000 for fiscal year 1989, $ 80,000,000 for fiscal year 1990, $ 80,000,000 for fiscal year 1991, $ 80,000,000 for fiscal year 1992, $ 110,000,000 for fiscal year 1993, and $ 110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

**History:**

(July 1, 1944, ch 373, Title XXI, Subtitle 2, Part A, § 2115, as added Nov. 14, 1986, P.L. 99-660, Title III, Part A, § 311(a), 100 Stat. 3767; Dec. 22, 1987, P.L. 100-203, Title IV, Subtitle D, §§ 4302(b), 4303(a)-(d)(1), (e), (g), 4307(5), (6), 101 Stat. 1330-221, 222, 223, 225; July 1, 1988, P.L. 100-360, Title IV, Subtitle B, § 411(o)(1), 102 Stat. 808; Dec. 19, 1989, P.L. 101-239, Title VI, Subtitle D, § 6601(c)(8), (l), 103 Stat. 2286, 2290; Nov. 3, 1990, P.L. 101-502, § 5(d), 104 Stat. 1287; Nov. 26, 1991, P.L. 102-168, Title II, § 201(e), (f), 105 Stat. 1103; Oct. 27, 1992, P.L. 102-531, Title III, § 314, 106 Stat. 3507; Aug. 10, 1993, P.L. 103-66, Title XIII, Ch 2, Subch B, Part IV, § 13632(b), 107 Stat. 646.)

## APPENDIX H

**42 U.S.C. § 300aa-13(b)**

(b) Matters to be considered.

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record–

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.