19-5657

CRGNA

No. 19 -____

In The Supreme Court of the United States

W.R. III, A MINOR, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, HEATHER ROGERO and WALTER ROGERO II,

Petitioner - Appellant,

v

ALEX AZAR II, SECY. OF HEALTH & HUMAN SERVICES

Respondent-Appellee.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit



PETITION FOR A WRIT OF CERTIORARI CORRECTED

REV. HEATHER D. ROGERO

Counsel of Record

DR. WALTER A. ROGERO, II

990 Northpointe Drive

Mountain Home, AR 72653

WRLegal@outlook.com

918-527-6125

AUG 21 2019

QUESTIONS PRESENTED

The Rehabilitation Act of 1973, Section 504¹ based on the 14th Amendment, protects the rights of children with disabilities from *unequal treatment* and *disability discrimination* in federal programs, like the no-fault National Vaccine Injury Compensation Program (NVICP), within The National Childhood Vaccine Injury Compensation Act of 1986 (NCVIA); §§300aa-1 to -34.

Both lower Federal Courts found and published from medical records and medical opine; that a child claimed, suffered, was diagnosed, and still suffers a medical injury of encephalopathy; § 300aa–14(b)(3)(A), after his DTaP; § 300aa–11(c)(1)(C)(ii)(II), his theory opined by expert treating physician. Under § 300aa–13(a)(1)(A)³, his published Court preponderance, defined as "proof of actual causation" by this Court in Shalalah v. Whitecotton, equipoises his compensation.

Federal Circuit found the master received medical records; records including several instances where the child's own *treating physicians*, his neurologist and neurogeneticist at Children's National in D.C. who diagnosed him as having *both* encephalopathy, ICD 348.3 *and* autism, ICD 299.0 on the *same* treatment dates, documented his regression after May DTaP, *and* medical exams of contemporaneous acute encephalopathy criterion, as defined by The Act.

Agreed by both parties is government opine that the child's diagnoses are encephalopathy and subsequent autism diagnoses, and in terms of differentiating between his autism and encephalopathy, his autism is a sequela; 42 CFR § 100.3(d)(3)⁴ of encephalopathy, opining his autism did not cause his encephalopathy, and his vaccination is causally unrelated to autism, both medically and legally as sequela, the master found autism was not a claim and was a sequela. Federal Circuit denied preponderance and compensation, on a "basis" the child also had a subsequent sequela, an autism disability; applying § 300aa–13(a)(1)(B) contrary to this Court's interpretation⁵.

Autism disability is a protected class of over 3.5 million U.S. citizens, (Buescher, 2014). A contention of unequal treatment on the basis of autism disability in a federal program contains questions of national significance warranting this Court's supervisory review:

- (1) Whether Court of Appeals *conclusion*, that *Rogero* had not established by a preponderance of the evidence between his encephalopathy and his DTaP vaccination, is in accordance with 42 U.S.C. § 300aa–13(a)(1)(A) and The Rehabilitation Act, when the Court published *findings* from preponderance evidence, every required matter of § 300aa–11(c)(1)?
- (2) Whether Federal Circuit contravened § 300aa–13(a)(1)(B) as interpreted by this Court in Shalalah v. Whitecotton, subsequently violating The Rehabilitation Act, Section 504?

¹ "No ... individual with a disability in the United States ... by reason of ... his disability ...be denied the benefits of, or be subjected to discrimination under any *program* ... conducted by any Executive agency" [NVICP is conducted by HRSA under HHS, See 45 C.F.R. 84 & 85.]

² Diphtheria-Tetanus-Pertusis combined vaccines

³ Section 300aa-13(a)(1) states, in relevant part:(a) Compensation shall be awarded under the Program to a petitioner if the special master or court **finds** on the record as a whole-(A) that the petitioner has demonstrated by a *preponderance* (medical records or opine) of the evidence the matters required 42U.S.C. §300aa-11(c)(1).

⁴ 42 CFR § 100.3(d)(3): Sequela means a condition which was actually caused by a condition [encephalopathy] listed in the Vaccine Injury Table.

⁵ The Secretary may rebut a prima facie case by proving that the injury [encephalopathy] was in fact <u>caused 'by</u> factors unrelated to the administration of the vaccine § 300aa-13(a)(1)(B). If the Secretary fails to rebut, the claimant is entitled to compensation. 42 U.S.C. §300aa13(a)(1) Shalala v. Whitecotton, 514 U.S. 208 (1995).

PARTIES TO THE PROCEEDING

Petitioners (appellants) are W.R. III, a minor by and through his parents and next friends, Rev. Heather D. Rogero and Dr. Walter A. Rogero II.

Respondent (appellee) is Alex A. Azar II, in his official capacity as Secretary of Health and Human Services

CORRECTION

Pursuant to the June 18, 2019 Supreme Court letter requesting signature page to fit within Rule 33.2(b), this corrected version of the petition is respectfully submitted for timely filing in response for USC13 No. 2018-1684.

In The Supreme Court of the United States

No.	***

W.R. III, A MINOR, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, HEATHER ROGERO and WALTER ROGERO II,

Petitioner - Appellant,

vs.

ALEX AZAR II, SECY. OF HEALTH & HUMAN SERVICES

Respondent- Appellee

CERTIFICATE OF INTEREST NOT APPLICABLE

NOW COMES BEFORE this Honorable Court, pursuant to Rule 29.6, attorney of record is Pro Se for appellant, HEATHER ROGERO and WALTER ROGERO II, Parents of W.R. III, a minor and certificate of interest is not required for Pro Se Appellants.

The represented party and real party are HEATHER ROGERO and WALTER ROGERO II, Parents of W.R. III, a minor.

The corporate disclosure statement required by Rule 26.1 does not apply as there are no corporations involved in this appeal.

The appellants are the attorney of record.

/s/ Heather D. Rogero Heather D. Rogero /s/ Walter A. Rogero II Walter A. Rogero II

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OTHER AUTHORITIES

129 A.L.R. Fed. 1 (Originally published in 1996), and 39 A.L.R. Fed. 2d 155, July 27, 2009; "B Causation in Fact of Injury by Vaccine, § 23[b] Burden of proof—Table Injuries not
manifested within requisite time"
Buescher AVS, Cidav Z, Knapp M, Mandell DS. Costs of Autism Spectrum Disorders in the United Kingdom and the United States. JAMA Pediatr. 2014;168(8):721–728.
doi:10.1001/jamapediatrics.2014.210
Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures Recommendations of the Immunization Practices Advisory Committee (ACIP) MMWR 40(RR10);1-28, Publication date: 08/08/1991
Mary Holland, Louis Conte, Robert Krakow, and Lisa Colin, <i>Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury</i> , 28 Pace Envtl. L. Rev. 480 (2011). Available at:
https://digitalcommons.pace.edu/pelr/vol28/iss2/616
NIH, U.S. National Library of Medicine, Medical Encyclopedia, "Focal Neurological Deficits" "Causes" include "injury" https://medlineplus.gov/ency/article/003191.htm

PETITION FOR A WRIT OF CERTIORARI

Petitioner, W.R III. et al. respectfully prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals' for the Federal Circuit below.

OPINIONS & ORDERS BELOW

The Opinion and Judgement of the U.S. Court of Appeals for the Federal Circuit appears at *App. 1a* (Sept. 12, 2018), reported at USC13 No. 2018-1684. The U.S. Court of Appeals for the Federal Circuit Order Denying Judicial Notice (Jan. 16, 2019) *App. 15a* and Denying Panel and *En Banc* Rehearing (Jan. 18, 2019); *App. 16a*. Order denying stay is **App. 18a** (Jan. 25, 2019). The U.S. Court of Federal Claims Order Denying Motion for Review and Affirming the Decision, (Jan. 12, 2018) at *App. 19a*, and Entitlement Decision *Rogero v. Sec'y of HHS*, No. 11-770V, U.S. Claims LEXIS 1200, 2017 is WL 4277580 (Fed. Cl. 2017) Denying Compensation at *App. 21a*.

JURISDICTION

The Judgment of the United States Court of Appeals for the Federal Circuit was entered on September 12, 2018, 18-1684 *App. 1-13, Judgement at 14*. Petitioner's timely Combined Petition for Panel and *En Banc* Rehearing was denied on Jan 18, 2019, *App. 16-17a*.

Subsequent to denial, Petitioner's Request for Relief of Judgement to resolve by RCFC 60, of 11-770 V (Fed. Cl. 2017) was denied on March 4, 2019, 2019 WL 1551732, from Federal Court of Claims that held that parents failed to establish that judgment was void 60(b)(4) when only considering RCFC 59 grounds, overlooking fundamental rights violations of equal protection under RCFC 60(b)(6). On April 9, 2010, 2019 WL 1873569 Federal Claims denied relief of judgement overlooking meritorious grounds of equal protection of the laws under RCFC/FRCP 60 (b)(6) and (d)(1) and did not exercise discretion under RCFC 60 (d)(1). On May 10, 2019, Federal Circuit denied recovery, misapprehending that opined "evidence" is the Federal Claims findings that determined W.R. eligible for compensation under § 300aa—13(a)(1), discretion again was not exercised for grounds of fundamental rights violations under RCFC 60 (b)(6) nor was (d)(1) addressed, making this fundamental rights case ripe for this Court's review.

Chief Justice granted Petitioner's application for an extension of time to file the petition for a writ of certiorari on April 2, 2019 to and including June 17, 2019, Application No. 18A989. Petitioner timely filed. The court requested a correction. Within is the timely filed correction.

The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

Applicable provisions and precedents appear in the appendix to this petition at App. 107a.

STATEMENT OF THE CASE

The Rehabilitation Act of 1973, Section 504⁶ has a basis in the 5th Amendment and Equal Protection Clause of the 14,th protects W.R. from *unequal treatment* and *disability discrimination* in The National Vaccine Injury Program (NVICP); within The National Childhood Vaccine Injury Compensation Act of 1986 (NCVIA), 42 U.S.C. §§ 300aa-1 to -34 on the basis that his autism disability, not a claim, ICD 299.0, is a *subsequent* behavioral diagnosis to his vaccine-related encephalopathy injury claim diagnoses, ICD 348.3, opined by both parties' agreed experts, and adjudicative fact found and published by the special master, inconsistent to his conclusions.

This case is straightforward, involving this Court's supervisory review of Federal Circuit's application of section § 300aa–13(a)(1) in NVICP harming W.R., previously interpreted by this Court's precedent *Shalalah v. Whitecotton*, where it held that Federal Circuit "erroneously construed" § 300aa–13(a)(1)(B). Under Section (A), because the federal courts found W.R.'s *preponderance* evidence and medical theory of his DTaP causal to encephalopathy, and published proof of every required factor from "medical opine or medical record" for compensation, W.R. is determined eligible for compensation as interpreted by § 300aa–13(a)(1)(A) and *Althen*. Under Section (B), as interpreted by this Court and *Althen*, the Secretary opined differentiating W.R.'s diagnoses: an encephalopathy and subsequent autism; a sequela; § 100.3(d)(3), legally ruling out defeating prima facie as defined by this Court's interpretation of § 300aa–13(a)(1)(B); that his autism did not *cause* his encephalopathy failing to rebut prima facie actual causation of the public preponderance. The master also found autism is sequela of his encephalopathy, and not a claim.

Federal Circuit affirmed rejecting *preponderance* standard evidence and compensation; on a "basis" the child *also* had a subsequent autism disability. Chief Justice Warren stated, "as this Court has recognized, *discrimination may be so unjustifiable as to be violative of due process.*" *Bolling v Sharpe* (1954). The child, after 8 years, is still without a Decision on the merits⁷ of his claim, on the legitimate preponderance standard, under the "Vaccine Act".

Petitioner, W.R III. et al. requests a writ of certiorari issue to review the Federal Circuit's construction of the Vaccine Act's section § 300aa–13(a)(1), for making and defeating prima facie

⁶ "No ... individual with a disability in the United States, ..., shall, ... by reason of ... his disability, ..., be denied the benefits of, or be subjected to discrimination under any *program* ... receiving federal... assistance or under any *program* ... conducted by any Executive agency" [NVICP is conducted by HRSA See 45 C.F.R. 84.4 & 85.21]

⁷ Federal Circuit affirmed a special master may adjudicate his own opinion and conclusions absent showing the claim of this case on *Althen* Prongs App. *106a* and reject published preponderance from evidence of his claim.

case, as interpreted by this Court in *Shalalah v. Whitecotton*, but unlike that case, with simple preponderance standard for causation under § 300aa–11(c)(1)(C)(ii)(II), to determine if a child was discriminated on the basis of a causally unrelated to vaccination sequela disability in a federal program, unlike 94 similarly situated cases, adding insult to injury by denying due recovery his life care, violating Section 504 of the Rehabilitation Act, as it relates to HRSA.

The Federal Circuit found that Petitioner W.R. III, and his parents, "filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, ... at 42 U.S.C. §§ 300aa-1 to -34. They [and public findings of medical experts and medical records diagnoses] alleged that W.R. suffered ... encephalopathy, caused ... by [DTaP] vaccinations [his preponderance medical theory in findings] that he received before his second birthday." "On May 4, 2010, W.R. received a DTaP vaccine" App. 2-3a, suffered and was diagnosed with medical encephalopathy App 5a, claimed encephalopathy as injury, App. 9a, and continues to suffer from this medical injury condition. App 5a Federal Circuit found that W.R. had two distinct diagnoses from different diagnostic criterion: medical encephalopathy App. 5a and a behavioral autism App. 12a, diagnosed by board certified pediatric neurologist who acutely knows the difference in diagnoses, unlike a special master absent board certification in pediatric neurology. The courts found W.R. has "continued to suffer" the medical condition of encephalopathy with permanent focal neurological signs, and is "tragically disabled," and also a different diagnoses of subsequent autism sequela, legally irrelevant in Rogero, evidenced by the master's findings, both party's experts, treating neurologist's medical records, and the master even finding in affidavit we hold it is medically impossible for vaccines to cause autism, by the definition causal.

This Court defined encephalopathy from statute 42 U. S. C. §300aa–14(b)(3)(A) in Shalalah v. Whitecotton, 514 U.S. 268 (1995), like Federal Circuit's Whitecotton v. HHS, Nos. 92-5083, 93-5101 (Fed. Cir. 1996) as "any significant acquired ... injury to, ... the brain with permanent focal neurological signs". And is vaccine-related, §300aa–33(5) with focal neurological signs, unlike autism. The Vaccine Injury Table lists encephalopathy in association with the DTaP (Diphtheria-Tetanus-Pertussis vaccines) as "resulting from the administration of the vaccine" § 300aa–14(a). Encephalopathy is vaccine-related injury in this case.

⁸ Encephalopathy is an injury "set in the table" even when the "onset or significant aggravation of which did not occur within the time period set forth in the Table" See plain language of §300aa-11(c)(1)(C)(ii)(II), which requires simple preponderance on *Althen* Prongs for prima facie.

This Court defined that "autism is a neurodevelopmental disorder" and found it as a "disability" defined by statute in *Endrew F. v. Douglas County School Dist. RE-1*, No. 15-827, 580 U.S.S.C. (2017), (798 F. 3d 1329, (----)). This Court, like the Act, distinguished that encephalopathy is not a neurodevelopmental disorder of autism, like medical experts and treating physicians in this case (See p. 36 at (2) and 37 at (3)-(4)), proving Federal Circuit's Decision on a basis of autism is discriminatory, and denied W.R. equal access to the Act's definition of §300aa–14(b)(3)(A) in his own medical records from Children's National in D.C. where his own treating physicians identified him as having both encephalopathy and an autism in the same visit date, including his neurologist, Dr. Civetello, his neurogeneticist, Dr. Gropman, clear evidence he was denied impartial procedural due process of his claim. The Federal Circuit (and Federal Court of Claims) continues to contravene these same sections: § 300aa–13(a)(1) both (A) and (B), of the Vaccine Act impermissibly heightening "causation-in-fact" preponderance standard like treatment of W.R.'s claim, this Court found treatment in Shalalah v. Whitecotton, as "erroneous construing".

Since this Court first granted certiorari in 1995, *Shalalah v. Whitecotton* to review and address the Court of Appeals' construction of The Vaccine Act's requirements for making and rebutting a prima facie case of encephalopathy associated with Diphtheria-Tetanus-Pertusis "hold[ing] that the court *erroneously construed* the provisions defining a prima facie case under the Act" the need for review has only continued, this time construing it in such a way as to cause review for disability discrimination, violating W.R.'s fundamental right to liberty of an impartial Decision in NVICP protected by The Rehabilitation Act and 14th Amendment, contravened The Vaccine Act's definition, and decided inconsistent with this Court and precedents.

A difference is the statutes between *Rogero*, 300aa-11(c)(1)(C)(ii)(II) for "Table Injuries not manifested within requisite time¹⁰", and *Whitecotton* 300aa-11(c)(1)(C)(i) for onset timing within 72 hours. Congress specifically authorized two statutes for encephalopathy recovery. They

⁹ §300.8 (a)(1) Child with a disability ... "autism", 42 U.S. Code § 15009 - Rights of individuals with developmental disabilities (a)(4)(b) CLARIFICATION The rights of individuals with developmental disabilities ... shall be considered in addition to any constitutional or other rights otherwise afforded to all individuals. (Pub. L. 106–402, title I, § 109, Oct. 30, 2000, 114 Stat. 1692.).

¹⁰ 129 A.L.R. Fed. 1 (Originally published in 1996), and 39 A.L.R. Fed. 2d 155, July 27, 2009; "B Causation in Fact of Injury by Vaccine, § 23[b] Burden of proof—Table Injuries not manifested within requisite time".

both use the exact wording, "injury, or condition set forth in the Vaccine Injury Table " and "but which was caused by a vaccine in the [Table]" The onset timing is different.

Federal Circuit stated why W.R. was denied due process on his claim with his public preponderance evidence of his encephalopathy from DTaP, and is illegitimate and erroneous "[H]e has [also] been definitely diagnosed with an autism" App. 12a opined of Dr. Wiznitzer, who materially also opined W.R.'s motor development was caused by "linked", and "is" his encephalopathy, and his autism was "later", his report documenting when and where W.R. had encephalophic neurodegeneration - after his May 2010 DTaP, from his contemporaneous medical records, infra., proving the masters decision was "wholly arbitrary" treatment of a party of one.

Materially, all of W.R.'s permanent focal neurological signs are motor injuries in his neurology records, diagnosed by his neurologist, and the government conceded his motor injury is encephalopathy (and excluded from autism diagnostic criterion explained in hearing), his encephalopathy and chronic encephalopathy are not his autism. Court of Appeals "basis" of autism is wholly arbitrary. § 300aa–13(a)(1)(B) requires the Secretary prove the cause of encephalopathy (motor injuries), and HHS opined "in this case" his behavioral autism was "later" and "subsequent" and a "sequela" of encephalopathy, 42 CFR § 100.3(d)(3), 11 the government failed defeating prima facie. Federal Circuit's basis of autism is equipoise to and qualifying as disability discrimination by the federal courts in NVICP. Any autism basis, under § 300aa–13(a)(1)(B), is discrimination in Rogero. The special master published a Chief Special Master's quote, "the sequelae [of the encephalopathy] may include autism or autistic-like symptoms." Federal Circuit's reason so far departed from this Court's precedent interpretation of § 300aa–13(a)(1)(B), in Shalalah v. Whitecotton, and precedents requiring intervening review, his undisputed encephalopathy is a vaccine-related injury and NCVIP is a vaccine injury program.

W.R. contends with direct proof of evidence of both lower Federal Court's published verifiable adjudicative findings in *Rogero*, in textual context of statutory and precedent text, *findings* that were denied impartial due process and not upheld by Federal Circuit, substantiated with additional citations to the record.

This Court in *Bruesewitz v. Wyeth*, Inc., 131 S. Ct. 1068, No. 09–152 (2011), described the monetary loss from the unequal treatment of harm to W.R.in §300aa–15(a) which is significant for

¹¹ 42 CFR § 100.3(d)(3): Sequela means a condition which was actually caused by a condition [encephalopathy] listed in the Vaccine Injury Table

this Court to review for injustice, for loss of W.R.'s eligible life care of substantial sum in similarly situated compensated cases, for children harmed, like W.R., in a designated fund for "compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering" and excludes cost of his permanent disability and extensive 8 year toll on W.R.'s family seeking equal justice under the law.

W.R. is one of 3.5 million U.S. citizens with autism disability in a protected class, and direct public evidence of unequal "irrational and wholly arbitrary" treatment by the government on illegitimate basis of autism disability in a federal program is one of national significance, this Court's supervisory power is duly appropriate. Allegations to this effect were argued first in Federal Court of Claims on Motion for Review of precluding an *entire class* of petitioners on the basis of having a causally unrelated to vaccination autism disability, a fundamental rights issue, and on Appeal of procedural due process and unintentional autism disability discrimination raised to U.S. Court of Appeals for the Federal Circuit, now ripe for this Court's supervisory review.

Agreed¹² between both parties' experts¹³ in court and substantiated by HHS Counsel's filing quoting W.R.'s medical experts, and medical records are that:

- (1) WR's Medical Theory is his 4th DTaP causal to his encephalopathy with focal neurological signs § 300aa-14(a)(b)(3), causation in fact, with Althen Prongs, opined by his treating expert MD and others for prima facie. Acute onset evidence criteria; loss of aware of his environment and loss of eye contact (is found in his contemporaneous medical record exam in June 2010) for onset timing under § 300aa-11(c)(1)(C)(ii)(II) as defined by Judge Dyk in binding Pafford, (Fed. Cir. 2006).
- (2) W.R. suffered and still suffers the claim encephalopathy ICD 348.3, manifested by motor injury; Cranial Nerve 7 injury severely affecting his tongue and speech articulation to be unintelligible to others, but "talkative with approximations", and low muscle strength. His legal onset symptoms, opined by his MD, and filed by HHS.
- (3) W.R. also suffered a behavioral autism disability, ICD 299.0, "later" than his encephalopathy manifested by repetitive movements, that is not a claim.
- (4) In this case, encephalopathy has a subsequent sequela of autism, a "secondary" diagnosis. Autism is also *not* part of the medical theory because it is legal sequela, 42 CFR § 100.3(d)(3), and *causally unrelated* to vaccination.

¹² Citations to evidentiary record and findings are within Petition, infra.

¹³ Both lower Federal Court's public *conclusions* contradict both parties agreed experts medical opine, and the lower Federal Courts *verifiable adjudicative findings* are agreed with both parties, proof is within, *infra*.

Congress *specifically* authorized compensation for W.R. under § 300aa-11(c)(1)(C)(ii)(II), his *preponderance* warranting this Court's review, especially since in the public domain. W.R. and his family respectfully pray this Superior Court grants review, not only for him, but on behalf of all other Americans with causally unrelated to vaccination autism, who have a right to impartial treatment in federal programs, regardless of their disabilit[ies], since Section 504 of The Rehabilitation Act was enacted in 1973 by Congress.

A. Legal Framework

- 1. Since 1868, the 14th Amendment's Equal Protection Clause, protects W.R.'s fundamental rights providing a constitutional basis for The Rehabilitation Act of 1973, Section 504¹⁴, (Pub. L. 93–112, 87 Stat. 355), the first disability civil rights law prohibiting discrimination against citizens with disabilities, such as autism¹⁵ including federal programs, i.e. National Vaccine Injury Compensation Program, (NVICP) that ensures W.R., a citizen, with both differentiated and diagnosed vaccine-related encephalopathy as defined by §300aa–14(b)(3)(A) and causally unrelated to vaccination subsequent autism, the right of liberty to a Decision free from abuse of discretion and legal error with accurate and impartial procedural due process on the merits of his claim and relevant evidence applied to §300aa–11(c)(1).
 - a. Section 504 of the Rehabilitation Act: "No otherwise qualified individual with a disability in the United States ... shall, solely by reason of her or his *disability*, be excluded from the participation in, be *denied the benefits* of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. 16"
 - b. Under Sec. 504, is The National Vaccine Injury Compensation Program receiving federal assistance is conducted by HRSA under HHS, and mandated that discrimination is prohibited on the basis of disability under 45 CFR §§ 84.4 and 85.21.
 - c. Chief Justice Warren in *Bolling v Sharpe* (1954), addressed discrimination violating constitutional rights: "The Fifth Amendment, ... does not contain an equal protection clause as does the Fourteenth Amendment ... But the concepts of equal protection and due process, both stemming from our American ideal of fairness, are not mutually exclusive. The "equal protection of the laws" is a more explicit safeguard of prohibited unfairness than "due process of law," and, therefore, we do

¹⁴ Section 504 includes programs that are conducted by HHS & HRSA, or receive funding, See, regulation at 45 CFR Parts 84 and 85.

¹⁵ §300.8 (a)(1) Child with a disability ... "autism", 42 U.S. Code § 15009 - Rights of individuals with developmental disabilities (a)(4)(b) CLARIFICATION The rights of individuals with developmental disabilities ... shall be considered in addition to any constitutional or other rights otherwise afforded to all individuals. (Pub. L. 106–402, title I, § 109, Oct. 30, 2000, 114 Stat. 1692).

¹⁶ The NVICP program exists due to statute of NVICA and HHS, DOJ, and Federal Court of claims receive appropriate Trust Fund amount annually 26 U.S. Code §9510.

not imply that the two are always interchangeable phrases. But, as this Court has recognized, discrimination may be so unjustifiable as to be violative of due process."

2. In 1986, Congress enacted The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), and the National Vaccine Injury Program¹⁷ ("Vaccine Program") 42 U.S.C.A. §§ 300aa-1 et seq., a new title to the Public Health Service Act of 1986, §§ 2101 et seq., 2114(a), creating "a new system for compensating individuals who have been injured by vaccines routinely administered to children." "Congress became concerned that tort liability and related costs might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market, and that normal tort litigation might leave many sufferers of vaccine-caused injuries uncompensated." Id. at 1307 (citing H.R. Rep. No. 99–908, at 1, 4, 6–7 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6345, 6347–48).

Under 42 U.S.C.A. §§ 300aa-1 et seq., W.R.'s claim of vaccine-related encephalopathy injury causal from DTaP vaccine, under §300aa-11(c)(1)(C)(ii)(II), requires *preponderance* standard:

A. Encephalopathy § 300aa-14(b)(3)(A) is an injury in the Vaccine Injury Table associated with DTaP vaccine; §300aa-14(a), defined as "vaccine-related injury" ... "associated with one or more of the vaccines set forth in the Vaccine Injury Table"; §300aa-33(5). "The term "encephalopathy" means any significant acquired ... injury to... the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs 19, ... The neurological signs and symptoms of encephalopathy ... may result in various degrees of permanent impairment..." See §300aa-14(b)(3)(A).

Congress enacted *two specific* statutes for *encephalopathy* injury, for onset both inside *and* outside Table timing of 72 hours, specifically authorized by Congress, *both as injury "set forth in Table"* under The Act. Not relevant to *Rogero* is §300aa–11(c)(1)(C)(i), and relevant by medical record and opine is §300aa–11(c)(1)(C)(ii)(II), a "table injury not manifested within requisite time" a "injury ... set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period

¹⁷ The Vaccine Act created the National Vaccine Injury Compensation Program ("VICP"), through which claimants can petition for compensation for vaccine-related injury or death. See 42 U.S.C. § 300aa–10(a). In doing so, the Act established a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269, 115 S. Ct. 1477, 131 L.Ed.2d 374 (1995).

¹⁸ H.R. Rep. No. 99-908 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

¹⁹ §100.3 (c)(3)(i)(A)(1) defines "neurologic findings referable to the CNS: Focal cortical signs" [such as diagnosed speech articulation disorder]; "cranial nerve abnormalities" [W.R.'s diagnosed CN7 injury]; ... or cerebellar dysfunction" [diagnosed hypotonic gait].

²⁰ See, specifically 129 A.L.R. Fed. 1 (Originally published in 1996), and 39 A.L.R. Fed. 2d 155, July 27, 2009; "B Causation in Fact of Injury by Vaccine, § 23[b] Burden of proof—Table Injuries not manifested within requisite time".

set forth in the Table but which was caused by a vaccine referred to in subparagraph (A), requiring demonstration of *preponderance* standard. (*Encephalopathy* is distinctly differentiated from §300aa–11(c)(1)(C)(ii)(I)) injuries "not set forth in Vaccine Injury Table" under §300aa–11(c)(1)(C)(ii)(I), law that was incorrectly applied absent a claim in *Rogero*.

- 42 CFR § 100.3(d)(3) "Sequela means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table." Autism is sequelae caused by encephalopathy in some Federal Claims compensated case laws, and causally unrelated to vaccination.
- B. Under §300aa-13(a)(1). Preponderance Standard for vaccine-related encephalopathy for compensation, is simple preponderance standard, proof of causation, or prima facie, is proved when petitioner's evidence demonstration is "substantiated by medical records or medical opinion" and "compensation shall be awarded under the Program if the special master or court finds on the record as a whole-" the factors under section §300aa-11(c)(1).
 - I. Vaccine Rules of the United States Court of Federal Claims, RCFC, Appx. B, VR 8(b)(1) mandates "the special master must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties" and VR 3(b)(1) "the special master is responsible for ...including taking such evidence as may be appropriate "of "documents, affidavits, or oral testimony" VR 8(b)(2):
 - a. §300aa-14(b)(3)(B) Mandates even if there is no preponderance for "encephalopathy ... If at the time a judgment ... for a vaccine-related injury it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table". And "the court [not the special master] shall consider the entire medical record".
 - b. 42 U.S.C. §300aa-11(c)(1)(C)(ii)(II) is a simple preponderance, not scientific certainty for W.R.'s vaccine-related encephalopathy, §300aa-33(5) requiring Althen Prongs. Althen, relied on by Court of Appeals holds it is "inconsistent with the Vaccine Program" to require proof of a scientific mechanism; like aluminum, an ingredient working as an adjuvant inside a DTaP.
 - C. §300aa-13(a)(1)(B) held by this Court in Shalala v. Whitecotton held, "The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused by "factors unrelated to the administration of the vaccine ..."). If the Secretary fails to rebut, the claimant is entitled to compensation. 42 U. S. C. §300aa-13(a)(1) (1988 ed. and Supp. V)."
- 3. In 1995, this Court first examined the Vaccine Act; Shalala v. Whitecotton, 514 U.S. 68. There, this Court "granted certiorari to address the Court of Appeals' construction of the Act's requirements for making and rebutting a prima facie case. Because we hold that the court erroneously construed the provisions defining a prima facie case under the Act, we reverse without reaching the adequacy of the Secretary's rebuttal". And held that the court erroneously construed the provisions defining a prima facie case under the Act. And "The Act defines encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain" 42 U.S.C. 300aa-14(b)(3)(A) and lists the condition on the Vaccine Injury Table in association with the DPT [DTaP] vaccine". "The table lists the

- vaccines covered under the Act, together with particular injuries or conditions associated with each one. 42 U. S. C. §300aa–14 (1988 ed., Supp. V)."
- 4. In 2000, this Court has also recognized successful equal protection claims brought by a class-of-one, where the court found "irrational and wholly arbitrary treatment" could be the basis for an equal protection case, when treated differently from others similarly situated. *Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000) (per curiam) applying to legislative and regulatory action.
- 5. In 2011, this Court stated also in case of a disabled child after diphtheria-tetanus-pertussis vaccine, that "To stabilize the vaccine market and facilitate compensation, Congress enacted the NCVIA in 1986. The Act establishes a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." Shalala v. Whitecotton, 514 U. S. 268, 269 (1995)" and "Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects" establishing "unavoidability" of vaccine injuries for some. Dissent by Justices Sotomayor and Bader-Ginsburg stated that "unavoidable" side effects are created by vaccines defending the rights of children like W.R. that "Congress intended to leave the courthouse doors open for children who have suffered severe injuries ..." like encephalopathy in Breusewitz v. Wheyth 562 U.S. 233 (2011).
- 6. In 2017, this Court defined that autism is a disability by statute and that "autism is a neurodevelopmental disorder" voting 8-0 in *Endrew F. v. Douglas County School Dist. RE-1*, No. 15-827, 580 U.S.S.C. (2017), (798 F. 3d 1329, (----)),
 - Like *Endrew F.*, *Rogero's* autism disability discrimination contentions are also based on a disability act, The Rehabilitation Act of 1973, whereas *Endrew F*. was based on violation of Individuals with Disabilities Education Act (IDEA).
 - B. <u>Undisputed Material Facts & Court Findings of § 300aa-11(c)(1)</u>
 That Determined Eligibility for Compensation Under of § 300aa-13(a)(1)(A)

I. Background

(1) The adjudicating master found W.R. was born "healthy" in September 2008 App. 35a, and Chief Special Master's RULING App. 29a (ECF 36 at 2-3) states "medical record demonstrates that [W.R.] experienced reactions to multiple [DTaP] vaccinations, which is evidence of challenge/rechallenge²¹" proof [for Prong Two], "two of his treating physicians as well as his genetic counselor, document ... alleged injuries ... vaccine-related... "vaccine-injured" ... 2010" and that "special masters must consider the relevant and reliable evidence' Vaccine Rule 8(b)(1)." In Rogero, the master ignored the RULING before adjudicating.

²¹ "A rechallenge event occurs when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine. The chief special master stated that this evidence of rechallenge constituted "such strong proof of causality" "logical sequence of cause and effect" (rechallenge). Capizzano I, 2004 U.S. Claims LEXIS 149, at *59.", Capizzano v. HHS, 44p F. 3d 1317, 1326 (Fed. Cir. 2006).

a.Re-challenge Proof Found [Adverse Effects are Erroneously Mischaracterized by the Decision as Developmental Regression for the Reader. Regression is only after 4th DTaP]. The master found medical records of W.R.'s adverse reaction diagnoses subsequent to each of his four DTaP sets (diphtheria/tetanus/pertussis vaccines), diagnosed and opined as distinct adverse effects matching those listed in the DTaP prescribing medical literature filed, Ex. 63 in full, App 114a-115a in part. (See App. 35a, 44a, 49a CR Federal Circuit at App. 4a), filed as Rechallenge proof from medical record diagnoses. After 1st DTaP he suffered "severe eczemic eruption²²" HHS counsel agreed, "W.R. had skin eruptions following his first parenteral administrations and a systemic reaction with eczema and atopic dermatitis following ... allergic reactions in his medical records" Tr. 139, hospitalized for bronchiolitis after the 2nd, and digressed on his motor but not speech or social milestones after the 3rd and diagnosed with claim injury encephalopathy (with acute onset symptoms and cranial nerve 7 with tongue, speech, and face) after the 4th. The DTaP prescribing information²³ and treating expert medical opine determined these as adverse effects from DTaP, Tr. 87-88, 181.

II. Material Court Findings of Preponderance of Claim & Theory; § 300aa-11(c)(1):

1. § 300aa-11(c)(1)(A) & § 300aa-11(c)(1)(B)(I). W.R. Received the Alleged DTaP in USA from medical records.

The Federal Circuit determined from the master's public *findings* W.R. received his alleged 4th DTaP in May 2010²⁴ in Arlington, VA, USA, a vaccine set in the Vaccine Injury Table: "on May 4, 2010, W.R. received a DTaP vaccine. *Id.* at 20." *App. 3a* "on May 4, 2010, at his appointment with Barbara Stevens, M.D.²⁵" [in Arlington, VA] *App. 4a*

2. § 300aa-11(c)(1)(C)(ii)(II). Federal Court Published Findings demonstrate W.R.'s Medical Theory of DTaP causal to Encephalopathy from Expert Medical Opine Quoting Contemporaneous Medical Record under § 300aa-11(c)(ii)(II)

Both lower Courts determined W.R. sustained a condition of encephalopathy; an injury is set forth in the Vaccine Injury Table, listed, and alleged as caused by DTaP, on all 3 Althen Prongs for actual causation, as interpreted by Althen and Pafford relied on by Federal Circuit in the Decision, App. 6a, and never analyzed in a public Decision on preponderance standard.

²² 42 U.S. Code § 300aa for ACIP, published "that certain non-encephalitic reactions are predictive of more severe reactions with subsequent doses", "pertussis vaccine ...caused acute encephalopathy resulting in permanent brain damage" "The only contraindication to tetanus and diphtheria toxoids is a history of a neurologic or severe hypersensitivity reaction" Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures Recommendations of the Immunization Practices Advisory Committee (ACIP) MMWR 40(RR10);1-28, Publication date: 08/08/1991 https://wonder.cdc.gov/wonder/prevguid/m0041645/M0041645.asp#Table_4 A

²³ Adverse Reactions: Immune System Disorders: Hypersensitivity" "Skin Disorder" "Erythema", "Rash" "bronchiolitis" "CONTRAINDICATION" for future DTaP: "Hypersensitivity" and "encephalopathy" (Pet. Ex. 63 at 3-4 8, 11 or Fed. Cir. Appx. 41-45) App. 114a-115a applicable pages

²⁴ Medical record **prior to this DTaP document eye contact was listed as a strength** on exam, smiley, giggling in response to activities, sustained attention and interaction before DTaP at 16.5 months, Ex. 34 at 4. And Ex. 34 at 4, 44, 68, Tr. 527-528 saying, mama, dada, and book, independently pointing and waving Pet. ECF 183 at 1-6, Ex. 34 at 45.

²⁵ MD also documented her opine of withholding the other two vaccines due and repeat adverse effect of skin eruptions when seen 3 days later. Pet. Ex. 5 at 5-6.

- a. §300aa-11(c)(1)(C)(ii)(II). The Federal Circuit found the Master found W.R. was diagnosed with medical encephalopathy [ICD 348.3] on exam *App.-5a*, the injury claimed *App. 9a*, by pediatric neurologist at Children's National in D.C., an injury in the Vaccine Injury Table *App. 9a* under §300aa-11(c)(1)(C)(ii)(II). His neurologist contemporaneously documented on that exam "lost pointing and waving after shot 5/10" [DTaP] "vaccine-injured" with focal neurological signs of encephalopathy found on exam "CN7 [cranial nerve 7] facial symmetry decreased NL fold on right", little stares", "regression" "pointing back" "low tone", "toe walks" "needs [labs: mitochondrial testing] also documented a second psychiatric "autism" [ICD 299.] on behavior (Pet. Ex. 9 at 153-157). By treating expert, Tr. 38, his pediatrician documented in 2010, "Vaccines; did not have MMR, positive regression after DTaP" Ex. 6 at 53-54.
- b. ***The master found preponderance expert medical opine, §300aa-13(a)(1)(B) of his Medical Theory of DTaP causal to Encephalopathy App. 49a:²⁶ Expert Treating MD, Dr. Megson, quoting medical records diagnoses²⁷ and "specifically pointed to the "pertussis" portion of the DTaP vaccination administered to W.R. at 19-months of age" ... "opining that that vaccination caused ... encephalopathy' (Id.) and [manifested by] "progressive hypotonia," "motor delays," [speech disorder of oromotor] "dyspraxia," and "encephalopathy." (Ex. 104, p. 9 of 10.)" "after his DTaP vaccination at 19 months of age" [quoting neurology medical record diagnoses]. (Also See FN 26)
- c. §300aa-13(a)(1). The master found legal Encephalopathy Onset in May 2010, as defined by The Act²⁸ for timing under §300aa-11(c)(1)(C)(ii)(II). Evidence as defined by RCFC, App. B, VR 8(b), of acute encephalopathy *loss of eye contact*, specifically "twenty-seven days after W.R.'s DTaP vaccination of May 4, 2010 ... unable to get W.R. to make eye contact" (Tr. 531-532)" *App. 48a*, "staring spells" and "spacy presentation" *App. 45a*, and

²⁶ Master also found all MD's opining (using the medical records conceded by the master) the 19-month DTaP causal, Decision App. 71a, Harvard trained Pediatric Neurologist, Dr. Goh, MD ... after his 19-month DTaP vaccination ... opinion that W.R.'s case points to [Ex. 150 states "vaccine-related neurological injury citing Dr. Civetello's records, EFC 188 at 35 via] "mitochondrial impairment exacerbated by vaccination." (Ex. 150, p. 1.) App. 60a "Dr. Goh, soon after the 19-month DTaP vaccination, W.R. had a regression of language and other skills (Ex. 150, p. 2.)", App. 74a, Dr. Palevsky, MD "[a]t 19 months, [W.R.] received ... DTaP ... [s]oon, he regressed, and lost speech." "encephalopathy." (Ex. 243, p. 4-5)" App. 59a Dr. Seneff "regression" following 19-month DTaP" "encephalopathy" (Ex. 88 at 2, 5)." App. 74a,

²⁷ Expert Dr. Megson, MD used contemporaneous medical records from June 8 & 15th, 2010 of Dr. Panitz, MD first exam after the DTAP compared to former records for her opine of legal encephalopathy as defined by §100.3(c)(2)(i)(B), #(2) at §100.3(d)(4)(i) and (iii), Ex. 6 at 3-4 "it documents the loss of skills that were documented previously that he had [in records]" Tr. 73, documented on exam: "without eye contact", "not aware of environment." And Encephalopathy as defined by focal signs § 300aa–14(b)(3)(A): "hypotonic gait¹⁶", distorts his cheeks and makes "unusual guttural vocalizations", but no specific words, word approximations, or signs, "does not point or use other gestures". W.R.'s history includes babbling but unable on exam, making guttural sounds, [A loss of babbling with inflection in record before DTaP in medical record in April saying, mama, dada, and book words, and independently pointing and waving in records Ex. 34 at 45, See Pleading ECF 183 at 1-6, FN 24, 36].

²⁸ §100.3(c)(2)(i)(B), #(2) at §100.3(d)(4)(i) and (iii) are legal criteria for onset of encephalopathy

loss of awareness of his surroundings in May, he found "W.R. would not turn head to sound, or engage" (Ex. 276 p. 13 #56)" of Affidavit, *App. 46a*, and from medical records W.R. "to occasionally seem to have unresponsive episodes" *App. 74a* "assessed W.R. as "having assessment of "other convulsions." (Ex. 28p. 14.) 'In that medical record'" *App. 75a* - all confirmed on MD examination in early June.

HHS Agreed, filing concession of W.R.'s medical opine evidence of Medical Theory by Expert Treating MD, Dr. Megson quoting W.R.'s medical records (See FN 20, 23). HHS filed Expert Dr. Megson opine: "contended that W.R. suffered a developmental regression and encephalopathy including, inter alia, loss of eye contact, awareness of his surroundings, pointing, waving, and saying mama/dada ["ongoing"] in the month after the May 4, 2010 DTaP vaccine. Pet. Ex. 104 at 10; see also Tr. at 22-23." And HHS filed "In this case ...W.R. suffered an encephalopathy that was caused-in-fact by the vaccines [Diphtheria, Tetanus, and Pertusis] he received, and that his ...neurodevelopmental [autism is] sequelae [§100.3(d)(3)] of that encephalopathy" HHS ECF 177 at 21, 10, Pet. Ex. 104 at 10, He became withdrawn, couldn't imitate words anymore, hypotonic gait He lost pointing, waving, saying "mama" and "dada" and stopped imitating words, Tr. 22-23. HHS conceded acute encephalopathy criteria, ECF 177 at 6, from medical record "unresponsive episodes." After May 2010 DTaP. See FN 24 & 27.

- d. The master found medical record evidence of encephalophic regression, losing 12 months of skills after DTaP by July 8 *App. 40a*: On January 27, 2010, at 16.5 months *before the 19-month DTaP*, "his social and emotional skills were estimated to be between 12-18 months of age" On July 6, 2010, after the 19-month DTaP "evaluations to assess his then-present levels (Ex. 4, 73-86.)" *App. 43a* (Ex. 4 at 83-85) on July 6, 2010, "social and emotional skills at 6 months" 12 months loss of skills. HHS Dr. Wiznitzer also documented regression, *See* post hearing brief ECF 183 at 4-6. Medical record, Ex. 22, also documents on July 8 W.R. was "disoriented all spheres- level 3" when level 5 was coma, signed by MD and found permanently disabled.
- 3. The Master found Mrs. Rogero's Affidavit Testimony²⁹ is from Medical Records, App. 46a: "Mrs. Rogero's Affidavits listed selective language from certain of W.R.'s medical records¹⁷ in order to describe W.R.'s condition before and after his DTaP vaccination of May 4, 2010; she alleged, in essence, that W.R. was able to perform many tasks prior to this May 2010 vaccination that he subsequently lost after that vaccination" ..."... lost pointing. waving, turning to his name, and his ability to vocalize different sounds" (Ex. 276, p. 10 #51). substantiated in medical records and quoted by experts; FN 24 & 27.

²⁹ Court of Appeals found the contemporaneous medical records of encephalopathy onset in Opening Brief, terming them "met criteria for encephalopathy as defined by the Table" [for All 3 Althen Prongs for actual causation] but sanctioned erroneous conclusions inconsistent to this verifiable finding, i.e., it is erroneous conclusion of "facts alleged that did not appear in W.R.'s contemporaneous medical records" App. 7a, when the master conceeds here they are from "medical records", and in opinion "credit contemporaneous medical records over assertions" App. 11a when allegations and medical records are the same wording, Both the Master and Respondent's former attorney on Appeal contradicted the contemporaneous medical records and neither substantiated their erroneous factual assumptions, when required preponderance was already published in the masters opinion, even without these specific records.

- 4. The Master found autism is not a claim and can be caused by encephalopathy injury as sequela, 42 CFR §100.3(d)(3)³⁰. App. 105a, that "[T]his case is about encephalopathy that was caused by the vaccinations (combined DTaP: Diphtheria, Tetanus, and Pertusis) [in which] the sequelae [of the encephalopathy] may include autism or autistic-like symptoms." (E.g., Pet. Post-Hearing Brief, filed 8-19-16, pp. 1-2.)". [Quoting a Chief Special Master of Federal Claims Court read from former Counsel Shoemaker]
 - (1) *HHS Agreed*. Dr. Cetaruk opined "in this case," "in terms of differentiating between W.R.'s autism and encephalopathy" that W.R.'s "symptoms were encompassed by the diagnosis of encephalopathy with a subsequent autism" opining affirmatively "autism can be sequelae of encephalopathy" Tr. 768-769. HHS's Dr. Wiznitzer opined that W.R.'s motor development is encephalopathy with later autism, Tr. 820.
 - (2) Rogero Experts Agreed: Dr. Mikovits "ASD is not an infrequent sequela of encephalopathy" Ex. 236 at 5 Dr. Ratajczak, that autism in terms of encephalopathy is one of the sequelae, Tr 628.
- 5. The Master found why Petitioner's Did Not Allege W.R.'s Subsequent Autism as a Claim: Affidavit evidence "it would be impossible for vaccination to cause autism" App. 44a-45a (The special masters adds his own incorrect factual inferences around this fact) See context at (Ex. 276 at 20 #90; 23-24): Rogero: "In the very medical definition of 'causality or causation' it would be impossible for vaccination to cause autism." (And lists from the medical record he has both Encephalopathy and autism diagnoses). And that he would not have autism "diagnostic label until after his 2nd birthday" App. 74a at his follow up in October 2010 is circumstantially medical record proof of documented increase in eye contact from June exam in medical record of acute onset time period.
- 6. § 300aa-11(c)(1)(D)(i). The master found from neurology record in 2013, 3 years later, W.R. continued to suffer with a medical neurological "chronic encephalopathy manifested by speech disorder oral motor dyspraxia, hypotonia, and motor delays." App. 100a and neurodevelopmental autism App. 5a
- 7. Because W.R. also has a subsequent autism with different diagnostic criterion than encephalopathy, and is a disability categorically covered by The Rehabilitation Act, Section 504, W.R. is entitled to the Act's discriminatory protections of unequal treatment in The National Vaccine Injury Compensation Program on the basis of his autism disability.
- 8. Today, W.R. is 10, severely disabled with two disabilities, (1) encephalopathy [now static chronic] manifested as permanent focal neurological signs (motor issues, server articulation disorder from the cranial nerve 7 injury affecting his tongue, low tone, hypotonic gait), requires constant 1:1 attendant care for severe impulsivity issues for safety and ongoing intensive rehabilitative speech, occupational therapy, and physical therapy. He is totally dependent on others for his needs. (2) None of which match symptoms or criterion of his repetitive behavior and social impairment of his secondary behavioral autism disability.

C. Related Litigation

There is no related litigation other than the lower two federal courts on this case.

³⁰ 42 CFR §100.3(d)(3) legally defines sequelae as caused by an injury in the table.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW IS UNCONSTITUTIONAL AND INCONSISTENT

The U.S. Court of Appeals for the Federal Circuit affirmed a Decision against a child with undisputed encephalopathy with manifestations of permanent neurological focal signs §300aa–14(b)(3)(A), diagnosed by treating board-certified pediatric neurologist at Children's National in D.C. from 2010-2016+, alleged causal by his May 2010 DTaP received in Arlington, VA and documented in 2010 by pediatrician and neurologist of positive regression after May DTaP in medical records; his Medical Theory opined by his medical experts in Court findings, and expert treating physician quoting the contemporaneous medical records of medical exam after May DTaP constituting the legal definitions of vaccine-related encephalopathy defined by Congress §300aa–33(5), acute encephalopathy onset as defined in the Act, outside requisite table time, satisfying preponderance in public findings of §300aa–11(c)(1)(C)(ii)(II), an injury set in the Table, for actual causation, with *Althen* Prongs.

Under Section 504 and the Equal Protection Clause, in VICP, under The NCVIA of 1986, "equal" in this case refers to access and the right to be treated equally on his claim injury of encephalopathy from DTaP and medical theory, and not be denied impartial due process on a legally unsupported basis because he also had a subsequent to encephalopathy autism sequela, causally unrelated to DTaP. Court of Appeals treatment of affirmed erroneous conclusions is irrational and wholly arbitrary treatment, especially when the government's medical experts opined his encephalopathy injury caused his subsequent and later autism disability; sequelae, is disability discrimination on a "class of one" inside a protected class of over 3.5 million Americans with autism disability, (Buescher, et. al 2014) deserving of this Court's supervisory scrutiny.

The unequal treatment of Petitioner's claim was unlike 94 similarly situated compensated cases of vaccine-related brain injury (encephalopathy or encephalitis); §300aa-33(5), with subsequent symptoms of autism or sequela.

As initial matter, overlooked by Federal Claims, HRSA oversees NVICP, and is legally prohibited from discriminating on a basis of autism evident in the statement below, as are special master and judges. HRSA's statement in *Pace Environmental Law Review*³¹ reveals the special

³¹ Mary Holland, Louis Conte, Robert Krakow, and Lisa Colin, *Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine Induced Brain Injury*, 28 Pace Envtl. L. Rev. 480 (2011). Available at: https://digitalcommons.pace.edu/pelr/vol28/iss2/6

master's discriminatory treatment of W.R.'s claim affirmed by Federal Circuit because as the special master publicly found, it was irrelevant that he also has subsequent behavioral autism:

"We have compensated cases in which children exhibited an encephalopathy, or general brain disease. *Encephalopathy may be* accompanied by a medical progression of an array of symptoms including *autistic behavior*, *autism*, or seizures." – David Bowman (HRSA)

Likewise, the rejected public preponderance of verifiable adjudicative evidentiary findings of the Federal Court of Claims of encephalopathy associated with DTaP are direct evidence of disability discrimination proven when he was mandated to consider "relevant" and "appropriate" evidence in RCFC, VR 8(b)(1) and 3(b)(1) for *Rogero*, in a RULING prior to his adjudication. To have considered them, they would have been on *Althen* prongs proving they did or did not meet preponderance, as defined by Judge Dyk in *Pafford*. In *Rogero*, direct evidence is relevant and appropriate preponderance was not considered because these claim findings are absent *Althen* public causation analysis adjudication.

Thus, W.R.'s encephalopathy³² claim was unequally treated unlike 94 similarly situated cases of compensated children with acquired encephalophic brain injury³ 42 U.S.C. § 300aa–14(b)(3)(A) following a vaccine in the Table and also had causally unrelated to vaccination autism or autism symptoms as sequelae of encephalopathy, *Pace Environmental Law Review* lists 83 of those compensated cases that were confirmed to *also* have *causally unrelated* to vaccination autism, as symptoms or sequela, or diagnoses like *Wright*.

An additional 11 found are: *Andreu v.* HHS, 569 F.3d at 1382, (Fed Cir. 2009), *Banks v.* HHS, No. 02-0738 V (Fed. Cl. 2007), *CHILD DOE/77 v.* HHS, (Fed. Cl. 2010), *Gancz v.* HHS, No. 91178V (Fed. Cl. 2000), *Hoiberg v.* HHS, No. 06-188V (Fed. Cl. 2007), *John Doe 21 v.* HHS, 84 Fed. Cl. 19, 20 (Fed. Cir. 2008), *McDermott (ZANG) v.* HHS, No. 90-550V (1991) 355, *Miucin v.* HHS, No. 90-550 V (1991), *Poling v.* HHS, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cir Spec. Mstr. Jan. 28, 2011), *Richardson v.* HHS, No. 04280V (Fed. Cl. 2009), *Wright v.* HHS, No. 12-423 (Fed. Cl. 2015)

Totaling 94 compensated cases of proof of *irrational and wholly arbitrary treatment* in *Rogero*, W.R.'s case that had no claim injury of autism, like these 94 cases, and some publicly published with autism sequelae.

³² Opined at hearing from medical records by expert treating MD of facial weakness cranial nerve 7 injury and on right, hypotonic gait, onset evidence on medical exam of loss of eye contact and not aware of environment, in contemporaneous 2010 medical records within the month of his May 2010 DTaP with evidentiary photos of his face before and after described in neurology exam on both lower court dockets.

Whereas the Court of Appeals affirmation is premised on unequal arbitrary treatment sanctioning of erroneously construing §300aa–13(a)(1)(A)-(B) public evidence in the Decisions (1) denying W.R.'s fundamental right to his *preponderance*, *found by the Court*, for impartial relevant and appropriate procedural due process on the merits of his claim and medical theory, and (2) impermissibly heightening his legal burden of *preponderance* to requiring *scientific proof of a mechanism*; ingredient in DTaP, denying equal protection of the laws (3) on the discriminatory basis of autism-disability, warrants review under The Rehabilitation Act of 1973, Section 504, in VICP because 94 other similarly situated children with both acquired brain injury *and* autism or autism symptoms and were not denied recovery, *or denied impartial due process*. Respondent's former attorney waived direct response to The Rehabilitation Act contention, instead redirecting Federal Circuit by quoting The Americans with Disabilities Act (ADA), which is irrelevant to this case, it does not protect in NVICP.

This Court stated in Shalala v. Whitecotton, 514 U.S. 208 (1995):

"for injuries and deaths traceable to vaccinations, the Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system H.R. Rep. No. 99-908, pp. 307 (1986) ... and may establish prima facie entitlement to compensation by introducing proof of actual causation... The table lists the vaccines covered under the Act, together with particular injuries or conditions associated with each one. 42 U.S.C. § 300aa-14." This Court made clear a Petitioner, "may establish prima facie entitlement to compensation by introducing proof of actual causation" [interpreted by *Althen* as "preponderance standard" of the Act's medical opine or medical records on *Althen* Prongs].

Congress specifically intended encephalopathy, an injury set in the Table, outside the requisite table time be intentionally compensated under 42 U.S. Code §300aa-11(c)(1)(C)(ii)(II) statutory provision to benefit petitioner, this provision was not so vague or amorphous as to make judicial enforcement difficult or impractical, and the statute imposes a binding mandate on the special master to accurately determine his facts and conclusions of law. Congress created a comprehensive Act and Program in 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34, for enforcing the statute, which implies that it intended to specifically authorize compensation, a right, via fair and accurate analysis by the Court of Petitioner's actual claim. In Binding Pafford, which the Court relied, App. 7a, Judge Dyk explains the appropriate statute at dissenting, and clearly contemplates that causation in fact may be established for encephalopathy set in the table for off Table onset timing cases "without showing the 'medically accepted temporal relationship' listed in the Table." Binding Pafford v. Secretary of Health and Human Services, No. 05-5106 (Fed. Cir.2006).

A. Published Court Findings of Preponderance is Violation of § 300aa-13(a)(1)(A)

42 U.S.C.A. § 300aa-13 (a)(1)(A): "Determination of eligibility and compensation (a)(1) Compensation shall be awarded under the Program to a petitioner if the special master or court <u>finds</u> on the record as a whole... <u>preponderance of the evidence</u> the matters required ... by section 300aa-11(c)(1)." §300aa-13 (a)(1)(B) defines preponderance as the matters substantiated by "medical records or by medical opinion."

The issue is the Federal Circuit violated W.R.'s fundamental right to impartial due process on his claim when the Federal Court erroneously misconstrued § 300aa–13(a)(1)(A) illegitimately rejected his preponderance when affirming a master's *conclusion* that *Rogero* had not established by a preponderance of the evidence a causal connection between his encephalopathy and his DTaP. And proceeded to affirm a master may *reject preponderance* of medical records, and medical opine (and DTaP science on the Docket) in the master's own public findings, *of every factor required in findings* for compensation under § 300aa–11(c)(1) instead of apply the law, of § 300aa–13(a)(1). This Court intervened in 1995 and is needed still in 2019 for the same reason of **misconstruing § 300aa–13(a)(1)**. Proof of necessity is below.

The Federal Circuit concluded, "Rogeros failed to show preponderance of the evidence that W.R.'s [May 4, 2010 DTaP *App. 3a*] vaccinations caused" "his alleged" "encephalopathy". *App. 2a, 14a*. "He rejected the Rogeros' evidence as <u>unpersuasive</u>" *App. 6a*

Federal Circuit "AFFIRMED" App. 13a "rejecting" W.R.'s preponderance and persuasive evidence established, as defined by Althen and The Act, in the special master's verifiable adjudicative findings, infra. Precedent Althen on which the court of appeals relied, App. 6a defined "persuasive" evidence of Medical Theory as

"A persuasive medical theory is demonstrated by "... "evidence in the form of scientific studies <u>or</u> expert medical testimony[.]" Grant, 956 F.2d at 1148." (citing Althen v. HHS, 418 F.3d 1274 (Fed. Cir. 2005)).

Erroneous is the master *found* W.R.'s experts' medical testimony opining a theory filed in scientific DTaP studies in 2013, a theory causal in the Vaccine Injury Table, proof at p. 30. And egregious because The Act has no "persuasive" standard, it has a "preponderance" standard. *Rogero* is now inconsistent revealing legal errors with the Federal Circuit precedents 24, 26-27.

In short, the special master contravened the Vaccine Act when he heightened petitioner's burden requiring scientific proof of a mechanism, and rejected the entirety of the preponderance standard in the Vaccine Act for W.R., denying his fundamental right to equal access of the Vaccine Act, unlike 94 other similarly situated compensated children who had encephalophic brain injury and causally unrelated autism or symptoms. Federal Circuit affirmed.

Applicable law is under § 300aa-13(a)(1)(A), the Act mandates compensation awarded under VICP to W.R. because the special master and Court found factors of 300aa-11(c)(1) that prove W.R. demonstrated he suffered his claim of encephalopathy from May 2010 DTaP by preponderance evidence from medical opine and medical records, when only one was required.

42 U.S.C.A. § 300aa-13 (a)(1): "Determination of eligibility and compensation (a)(1) Compensation shall be awarded under the Program to a petitioner if the special master or court <u>finds</u> on the record as a whole—(A) that the petitioner has demonstrated by a <u>preponderance of the evidence</u> the matters required ... by section 300aa-11(c)(1)." (italics emphasized) **(B) defines preponderance as the matters substantiated by "medical records or by medical opinion" - § 300aa-13 (a)(1).

**Althen Court defined "preponderance" as substantiated by medical records or medical opine: "statute's language is clear; section 300aa-13(a)(1) instructs that a petitioner must prove causation in fact by a 'preponderance of the evidence,' substantiated by medical records or medical opinion, as to each factor contained in section 300aa-11(c)(1)".

Clear and convincing public proof below evidences the violation of § 300aa–13(a)(1)(A) and denying W.R. fundamental right of access to and due process of § 300aa–13(a)(1)(A) and compensation, because *all* required factors were publicly *found* from petition content rendering Court of Appeals Decision erroneous to conclude *preponderance* of encephalopathy from DTaP was not demonstrated from medical record and medical opine, and harmful to W.R. rejecting due process on his claim, *erroneously* holding that the

"Rogeros failed to show preponderance of the evidence that W.R.'s [May 4, 2010 DTaP *App. 3a*] vaccinations caused" "his alleged" "encephalopathy". *App. 2a, 14a*.

(1) Preponderance Evidence in Court Findings of 300aa-13(a)(1)

Preponderance as defined by the Act and Althen, published by both Federal Courts' Public Findings Determined W.R. Eligible for Compensation under § 300aa-11(c)(1)³³ as determined by § 300aa-13(a)(1)(A) for Actual Causation.

A. §300aa-11(c)(1)(A) -(B)(i)(I). The Court of Appeals determined from the master's findings: W.R. received a vaccine set in the Vaccine Injury Table in the USA:

"on May 4, 2010, W.R. received a DTaP vaccine. *Id.* at 20." *App. 3a* "on May 4, 2010, at his appointment with Barbara Stevens, M.D" [in Arlington, VA] *App. 4a*

³³107a-109a contains text of Section §300aa- 11(c)(1).

B. §300aa-11(c)(1)(C)(ii)(II) Suffered Encephalopathy on all 3 Althen Prongs. Court of Appeals determined W.R. sustained an injury of encephalopathy that is set forth in the Vaccine Injury Table the first symptom or manifestation of the onset did not occur within the time period set forth in the Table but which was caused by DTaP in the Table, as interpreted by Althen and Pafford relied on in the Decision, App. 6a.

Court of Appeals stated, "The Rogeros had to establish causation in fact" *App. 8a* "of the injur[y] claimed, an encephalopathy" *App. 9a*. "Specifically, they had to show, by a preponderance of the evidence, (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278." *App. 9a* and did evidenced in *findings below*.

1. Althen Prong One of Medical Theory by Both Courts Findings. Court of Appeals found petitioner's medical theory: "They alleged that W.R. suffered ... encephalopathy, caused ... by vaccinations [Diptheria-Tetanus-Pertusis] that he received before his second birthday." "On May 4, 2010, W.R. received a DTaP vaccine which the Rogeros have emphasized ... in May 2010" App. 2-3a. Encephalopathy, an injury in the Vaccine Injury Table was diagnosed by "neurologist Lucy Civetello, M.D.", "The records report an 'admitting diagnosis' of "[e]ncephalopathy" App. 5a and "the injur[y] claimed, an encephalopathy". App. 9a

Althen held, "To meet the preponderance standard, she must "show a medical theory causally connecting **the** vaccination and the injury." Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted)."

The special master found petitioner's medical theory of DTaP causing Encephalopathy opined by experts medical opine, satisfying both Althen Prongs One and Two, See infra Prong Two, constituting both a persuasive theory and preponderance as defined by Althen and §300aa-13(a)(1)(B).

The special master found his medical theory of Expert Treating MD, Dr. Megson opine³⁴, App 49a (ECF 188 at 29) "DTaP vaccination administered to W.R. at 19-months of age" ... "opining that that vaccination ... caused '... 'encephalopathy' (Id.) ... (Ex. 104, p. 9 of 10.)" "and after his DTaP vaccination at 19 months of age" App 49-50 (This preponderance, defined by the Act, was also found and published fact by the Federal Circuit and Federal Claims Court of W.R.'s medical records)

- 1. AGREED is DOJ for HHS who filed *Althen* Prongs quoting medical records of medical exam (See FN 24, 27-28, and 35-36), Post Hearing ECF 177 at 21:
 - a. "Dr. Megson contended that W.R. suffered a developmental regression and encephalopathy [INJURY] including, inter alia, loss of eye contact³⁵, awareness of

³⁴Federal Circuit precedent holds "that a special master erred in disregarding probative testimony from a petitioner's treating physicians; Capizzano v. HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), Andreu v. HHS, 569 F.3d at 1375 (2009).

³⁵ Encephalopathy Defined by §100.3(c)(2)(i)(B), #(2) at §100.3(d)(4)(i) and (iii): Decreased or Absent Eye Contact²⁷ in Contemporaneous Medical Record: [eye contact noted as a strength prior to 4th DTaP, Ex. 34 at 4 on exam at 16.5 mo.], After DTaP at 19 months, MD's Panitz, Laguarda, and Kohn,

- his surroundings³⁶, pointing, waving, and saying mama/dada in the month after [TIMING OF §300aa-11(c)(1)(C)(ii)(II)] the May 4, 2010 DTaP vaccine [CAUSAL VACCINE]. Pet. Ex. 104 at 10; see also Tr. at 22-23." (See FN 24 and 27)
- b. [MEDICAL THEORY] "In this case, petitioner's overarching theory ... that <u>W.R.</u> suffered an encephalopathy that was caused-in-fact by the vaccines [Diphtheria, <u>Tetanus</u>, and Pertusis] he received, [AND DISTINGUISHING DISTINCT AUTISM WAS NOT A CLAIM] and that his neurodevelopmental problems [autism] are sequelae [§100.3(d)(3)] of that encephalopathy" ECF 177 at 10.

In short, HHS conceded W.R.'s "persuasive medical theory" by DOJ counsel. Dr. Megson citing medical records for compensation on Althen of petitioner's medical opine evidence quoting the medical exam by Dr. Panitz, MD after May DTaP for compensation for all three Althen prongs below, under § 300aa11(c)(1)(C)(ii)(II). HHS's Dr. Wiznitzer and Dr. Cetaruk confirmed the propriety of his encephalopathy by distinguishing it was not his autism that W.R.'s autism was "later" and "subsequent to" encephalopathy and agreed "sequela" of encephalopathy, Dr. Wiznitzer's report documents loss of abilities, regression, by June 2010, of contemporaneous medical records in 2010 before and after May 2010. (See ECF 183 at 1-6).

c. Althen Prong Two Found by Both Courts Public Findings

- A. Court of Appeals acknowledged W.R.'s contemporaneous *medical records*, preponderance of onset of encephalopathy [for actual causation, onset for Prong Two] from Opening Brief 29-33, as defined by the Act as *acute onset*, with timing for Prong Three, Federal Circuit termed this evidence W.R. "met diagnostic criteria for encephalopathy as defined by the Table" *App. 12a.* Rendering the special master's erroneous diversion on contemporaneous medical records illegitimate, **proof at p. 13 #3**.
 - **B.** Special master's findings of public medical opine of Medical Theory of DTaP causal to his encephalopathy, a persuasive medical theory, satisfying Prong One, Two, and § 300aa-13(a)(1): (experts using medical records found by both Courts)

Pet. Ex. 6 at 4, 28 at 14, 33 at 3, noted finding, on June 8 "Makes requests without eye contact", in July "no good eye contact", and August "minimal eye contact" like affidavits "extremely difficult to get any eye contact" on May 30 Exs. 40 at 7; 41 at 24; 276 at 14.

³⁶ Encephalopathy Defined by §100.3(c)(2)(i)(B), #(2) at §100.3(d)(4)(i) and (iii): "Loss of awareness of his surroundings" Decreased, Absent, or Inconsistent Responses to environment or external stimuli, (ECF 189 at 9): On June 8 by Dr. Panitz, MD "not aware of routines or things in environment" Ex. 6 at 3, on July 8 Disability Assessment referral from Dr. Stevens after DTaP: Dr. Civalozlio, MD "Disoriented-all Spheres" Level 3, level 5 is comatose Ex. 22 at 9, 14 and found disabled (Also see, Tr. 544, Pleadings EFC 183 at 3, EFC 174 at 20), and by Dr. Laguarda for "unresponsive episodes" ICD 780.39 "other Convulsions" Ex. 28 at 13-14 (ECF 189 at 9).

- (1) Expert Treating MD, Dr. Megson, App 49a (ECF 188 at 29) "DTaP vaccination administered to W.R. at 19-months of age" ... "opining that that vaccination ... caused '... 'encephalopathy' (Id.) ... (Ex. 104, p. 9 of 10.)" App 49-50a
- (2) Finding Pediatric Neurologist, Dr. Goh, MD, *App. 60a* (EFC 188 at 51) ... after his 19-month DTaP vaccination ... *App 71a*. (EFC 188 at 40) "Dr. Goh, soon after the 19-month DTaP vaccination, W.R. had a regression of language and other skills (Ex. 150, p. 2.)" [Ex. 150 states "vaccine-related neurological injury citing Dr. Civetello's records]
- (3) Finding Dr. Palevsky, MD, *App 55a*, 74a (EFC 188 at 35, 51) "[a]t 19 months, [W.R.] received his ... vaccine, DTaP . . .[s]oon after that, he regressed, and lost speech." "encephalopathy." (Ex. 243, p. 4-5)"
- (4) Finding Dr. Seneff, and *App. 59a* (EFC 188 at 39) following his <u>19-month DTaP</u> vaccination" "encephalopathy" (Ex. 88 at 2, 5)."

d. Althen Prong Three Found by The Court, § 300aa-11(c)(1)(C)(ii)(II) satisfying timing.

§300aa-13(a)(1) Compensation shall be awarded if the "special master or court finds on the record as a whole ... substantiated by medical opine or medical records" W.R. provided both medical experts quoting the medical record is above.

By May 2010, the master's findings found legal acute encephalopathy from evidence RCFC VR 8(b)(2)³⁷ in Decision "from the "record as a whole"; §300aa-13(a)(1), as defined by the Vaccine Act §100.3(c)(2)(i)(B), #(2) at §100.3(d)(4)(i) and (iii), substantiated by medical records, See FN 35-36 by May 29, 2010: (only 2 are required)

- a. "Loss of awareness of his surroundings" (1) Decision, App. 46 (EFC 188 at 26): "On May 29, 2010 W.R. "would not turn head to sound or engage" (Ex. 276 p. 13 #56)" (2) App. 42a (EFC 188 at 25): On August 18, 2010, medical record "W.R. to occasionally seem to have unresponsive episodes". App. 45a (EFC 188 at 23), "in and out of staring spells" and "appeared 'to be in his own world" (3) App. 46a (EFC 188 at 26): "Affidavits listed selective language from certain of W.R.'s medical records in order to describe W.R.'s condition before and after his DTaP vaccination of May 4, 2010" "lost many abilities that he acquired prior to his DTaP vaccination ... after May 4, 2010 ... lost pointing. waving, turning to his name, and his ability to vocalize different sounds" (Ex. 276, p. 10 #51)"
- b. "Loss of eye contact" (1) Decision, App. 48a (EFC 188 at 28): "[On May 31, 2010], "twenty-seven days after W.R.'s DTaP vaccination of May 4, 2010" ... "unable to get W.R. to make eye contact" (Tr. 531-532). (2) Decision, App. 45a (EFC 188 at 25): "staring spells" and "spacy presentation"
- c. Seizure: (1) App. 46a (EFC 188 at 26): "W.R" experienced a "stiff episode" around September or October of 2011". (in medical record at Ex. 9 at 8).

³⁷ "evidence in the form of documents, affidavits, or oral testimony"

- C. § 300aa-11(c)(1)(D)(i) was determined by both Federal Courts that W.R. suffered the residual effects or complications of encephalopathy for more than 6 months after the administration of the vaccine.
 - 1. Special Master's Decision found in records 3 years later, in 2013:
 - a. From neurology record: "chronic encephalopathy manifested by speech disorder oral motor dyspraxia, hypotonia (motor), and motor delays." (Id. at 77), App. 100a
 - b. That his encephalopathy injury caused his autism; sequelae (Id. at 80). App. 105a
 - c. Neurology record diagnoses quoted: "certain symptoms of W.R. are "characteristic of his encephalopathy ... which progressed in his neurological records to a chronic encephalopathy to a chronic static encephalopathy"; citing Ex. 276 "Id., pp. 19-20, 89" at 24³⁸. App.44a
 - 2. Court of Appeals Decision found, "W.R.'s subsequent medical records indicate that he has 'continued to suffer from an autism spectrum disorder, developmental delays, and other medical conditions [those medical conditions in record are encephalopathy, supra] Id. at 24" App. 5a And "this case involves an individual with undisputed, serious, burdensome, indeed-life-altering medical problems" App. 8a
- **D.** § 300aa-11(c)(1)(E) is stated in the Affidavit, Exs. 40-41, 276 that W.R. has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury.

The Vaccine Act statute mandates W.R. is eligible for compensation under 42 U.S. Code § 300aa–13(a)(1)(A); preponderance for compensation of W.R.'s DTaP causing his encephalopathy was found and publicly published by Federal Court findings above, proof of violating § 300aa–13(a)(1), ³⁹ the special master's findings are Federal Claims findings; FRCP 52(a)(4), and Court of Appeals also "found" preponderance of DTaP causal to encephalopathy. Federal Circuit's Decision did not hold up the special masters relevant factual finding, but erroneous illegitimate conclusions contravening The Vaccine Act & Section 504, harming W.R.

"our task on appeal ... we must hold up the special master's factual *findings*" *App 8a* (but did not, the Court of Appeals concluded that W.R.) "failed to show by a preponderance of the evidence that W.R.'s [DTaP vaccinations caused [encephalopathy]" injury *App. 13a* and sanctioned "den[ying] compensation" *App. 6a*

The Court of Appeals for the Federal Circuit sanctioned a special master could so far depart violating § 300aa–13(a)(1)(A), U.S. Court Vaccine Rules, and RCFC, Appx. B, 3(b)(1)

³⁸ Some of his neurology records from 2010-2015 that prove he has **both differentiated diagnoses** with different diagnostic criterion of encephalopathy; ICD 348.3, **and** autism; ICD 299.0, are Ex. 9 at 153, Ex. 249, Ex. 102, Ex. 54 at 1, proving Federal Circuit's Decision is erroneous. See also p. 37 at (3) & (4). ³⁹ "Compensation shall be awarded under the Program to a petitioner *if* the special master or court *finds* on the record as a whole—that the petitioner has demonstrated by a preponderance ... section § 300aa-11(c)(1).

& 8(b)(1)⁴⁰, and her own precedents confirming reversible error, overlooked on Appeal, *Rogero* is now inconsistent with below precedents:

"The Special Master cannot manipulate the analysis in a manner calculated to arrive at a conclusion that he or she has already reached" Koehn v, HHS 7773 F. 3d 1239 (Fed. Cir. 2014) A "special master commit[s] reversible error for failing to consider relevant evidence related to [W.R.'s encephalopathy]" Contreras v. HHS, 2015-5097, (Fed. Cir. 2017). Holding, "[B]oth this court and the Court of Federal Claims have a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, "considered the relevant evidence of record" Paluck v. HHS, 78 F.3d. 1373 (Fed. Cir. 2015), quoting Hines ex. rel. Sevier v. HHS, 940 F. 2d 1518, 1528 (Fed. Cir. 1991). And he cannot dismiss so much contrary evidence that it appears that he "simply failed to consider genuinely the evidentiary record before him," Campbell v. HHS, 97 Fed. Cl. 650, 668 (2011).

Federal Circuit so far departed sanctioning a master may "rejec[t] the Rogeros' [preponderance] evidence" [the master's own findings] *App. 6a* in illegality violating W.R.'s right to accurate due process, and the Rehabilitation Act, by denying showing W.R.'s claim on *Althen* prongs as proof of considering evidence.

Althen Court held: "The special master's role is to apply the law. Questions of law regarding the interpretation or implementation of the Vaccine Act are matters for the courts. See La Buy v. Howes Leather Co., 352 U.S. 249, 256, 77 S. Ct. 309, 1 L.Ed.2d 290 (1957) ("The use of masters is to aid judges in the performance of specific judicial duties, as they may arise in the progress of a cause, and not to displace the court.")

The Rehabilitation Act, Section 504 was violated by the Federal Circuit erroneously construing § 300aa–13(a)(1) when sanctioning denying constitutional protection of equal access to § 300aa–13(a)(1) and denying due process on his preponderance, the merits of his claim, when affirming "reject[ing] the Rogeros [preponderance] evidence" *App. 6a* when compensation was denied *App. 14a* And the "irrational and wholly arbitrary" reason?

"[H]e has been [also] definitely diagnosed with an [subsequent] autism" [a sequela] App. 13a A reason equipoise to direct public proof of disability discrimination, denying preponderance standard to his relevant claim in the Program, wholly irrelevant vaccine-related injury trial.

⁴⁰ US Court Vaccine Rules mandate he "consider all 'relevant and reliable' and 'appropriate' evidence, 'governed by principles of fundamental fairness to both parties' and "the special master is responsible for ... including taking such evidence as may be *appropriate*".

(2) Federal Circuit Contravened Section §300aa-13(a)(1)'s Allowance of Medical Opinion and Medical Record as Proof of Preponderance & Medical Theory When Requiring Scientific Proof

Federal Circuit Sanctioned Impermissibly Heightening Claimants Legal Burden from Preponderance to Scientific Proof of a Mechanism, Denying Equal Access to Public Preponderant Medical Theory Violating § 300aa–10 to–34 and 24 years of Precedents.

The treatment received of Court of Appeals' interpretation of the plain language requirement of "medical records or medical opine" of §300aa-11(c)(1)(A) found from simple preponderance proof that "received a vaccine set forth in the Vaccine Injury Table" raises grave constitutional questions of denying equal justice protected by the Equal Protection Clause, by impermissibly requiring W.R., unlike 24 years of cases a heightened legal burden and contravening § 300aa-11(c)(1) and *Althen* on which the Court relied. *App. 6a*

Federal Circuit erroneously sanctioned *inconsistent* to the Vaccine Act: "The special master [required] ...proof (1) ... that "aluminum adjuvants in vaccines can cause neurological injury" (emphasis added) App. 9a and required "to show that aluminum [a mechanism] in vaccines harmed W.R. in any way" App. 12a

Applicable law for actual causation of encephalopathy as defined by Congress is:

- (1) § 300aa-11(c)(1)(A) requiring proof of: "received a vaccine set forth in the Vaccine Injury Table".
- (2) § 300aa-11(c)(1)(C)(ii)(II) requires proof of "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in [The Table].
- (3) Federal Circuit Precedent Knudsen holds inconsistent with Precedent Rogero 11-770V (2017), "The Court of Federal Claims is ... not to be seen as a vehicle for ascertaining precisely how and why DTP ... sometimes destroy the health and lives of certain children ... this research is for scientists ... and doctors the special masters are not 'diagnosing' vaccine-related injuries."

And as interpreted by Precedent Althen Court, relied on by the Federal Circuit in the Decision, in Rogero App. 9a holds for a Medical Theory for § 300aa–11(c)(1)(C)(ii)(II):

⁴¹ Overlooked by Federal Circuit is HHS Dr. Cetaruk, MD, in addressing a possible *mechanism*, not the medical theory. DTaP has aluminum as an ingredient, and he conceded aluminum containing vaccines, i.e. DTaP, can cause encephalopathy, and that encephalopathy is an injury of aluminum toxicity, Tr. 748, 787.

"The burden of a claimant under the National Childhood Vaccine Act is to show by preponderant evidence that the vaccination ... [1] a medical theory causally connecting the vaccination and the injury" Althen (not an ingredient in a vaccination).

Althen, and progenies have also has consistently held for 24 years that for a special master to "require identification and proof of specific biological mechanisms [that is] inconsistent with the purpose and nature of the vaccine compensation program". And "contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof. Althen III, 418 F.3d at 1280 (quoting Knudsen, 35 F.3d at 549)." "We think such an approach is inconsistent with allowing "the use of circumstantial evidence envisioned by the preponderance standard." "In our view, it thus impermissibly raises a claimant's burden under the Vaccine Act and hinders "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants" Capizzano v. HHS, 44p F. 3d 1317, 1326 (Fed. Cir. 2006).

Direct Proof of the Court of Appeals violation of the Vaccine Act requiring proof of a *mechanism* inside the DTaP, not the DTaP vaccine in the Table that is required by The Act is: (1) "The special master found ... the proof (1) did not establish that "aluminum adjuvants [a mechanism] *in* vaccines *can cause* neurological injury," *App. 9a.* The special master specifically identified aluminum as a "mechanism" in the public Decision, and he also identified another possible one; Pertussis Toxoid in the DTaP, both are ingredients in the DTaP W.R. received on May 4, 2010 with the DTaP on prescribing information filed in 2013 lists *both* these ingredients, proving the Federal Circuit's legal error for requiring a mechanism.

The master found the required Medical Theory of DTaP causal to encephalopathy opined by experts and diagnoses from medical records from experts, one is treating MD:

Expert, Dr. Megson, MD App 49a (ECF 188 at 29) "DTaP vaccination administered to W.R. at 19-months of age" ... "opining that that vaccination ... caused '... 'encephalopathy' (Id.) ... (Ex. 104, p. 9 of 10.)" App 49-50, among others, supra at 21-22.

The Federal Circuit found W.R.'s *Preponderance* **Medical Theory** from the special master's findings of medical record (who also found medical opine), constituting preponderance under the Act for *Althen* Prongs:

"They alleged that W.R. suffered ... encephalopathy, caused ... by vaccinations [Diphtheria-Tetanus and Pertusis] that he received before his second birthday." "On May 4, 2010, W.R. received a DTaP vaccine which the Rogeros have emphasized ... in May 2010" App. 2-3a. Encephalopathy, an injury in the Vaccine Injury Table was diagnosed by "neurologist Lucy Civetello, M.D.", "The records report an 'admitting diagnosis' of "[e]ncephalopathy" App. 5a and "the injur[y] claimed, an encephalopathy". App. 9a

Rogero v. HHS 18-1684 (Fed. Cir. 2018) is fundamentally flawed, misconstruing 42 USC §300aa-13(a)(1)(A), See pp. 19-23 for all required preponderance for §300aa-11(c)(1).

Both the Federal Circuit and Office of Special Masters have never so far departed from the Vaccine Act and Congress to have egregiously interpreted DTaP causal to encephalopathy as a Medical Theory is "unpersuasive" before *Rogero*. **Preponderance**, not persuasiveness, is the legal standard under the Vaccine Act, in this regard, misconstruing preponderance, §300aa–13(a)(1). Federal Circuit affirmed the special master's egregious conclusion v, "After thoroughly violating Equal Protection Clause, stating "I have found all of the causation theories [DTaP causal to encephalopathy] advanced in this case to be quite *unpersuasive*." *Special Master Decision* at 47; see id. at 82–83. App. 6a

Contrary to The Act and her own case laws, Federal Circuit has held for a DTaP causal to encephalopathy Medical Theory: A "medical theory causally connecting the vaccination and theory." "a causal connection. "well recognized by the Office of Special Masters." because the Vaccine Injury Table indicates that DTaP vaccines can cause encephalopathy" Paterek v. HHS, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013)⁴² and held by precedent Knudsen court, "it is entirely ... contemplated by the statute, that DTP [DTaP] may cause an encephalopathy", 35 F.3d 543, 549 (Fed. Cir. 1994)

In Federal circuit's own words, the Decision denied W.R. equal access of §300aa-11(c)(1)(A). Both *Althen* and The Vaccine Act requires "vaccine set forth in the Vaccine Injury Table" by medical opine *or* medical records, specifically addressing special masters requiring mechanisms:

That a special master must not "require identification and proof of scientific mechanisms would be inconsistent with the purpose and nature of the vaccine And "contravenes section 300aa-13(a)(1)'s allowance of compensation program". medical opinion as proof, Althen III, 418 F.3d at 1280 (quoting Knudsen, 35 F.3d at 549)." "We think such an approach is inconsistent with allowing "the use of circumstantial evidence envisioned by the preponderance standard." "In our view, it thus impermissibly raises a claimant's burden under the Vaccine Act and hinders "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants" Capizzano v. HHS, 44p F. 3d 1317, 1326 (Fed. Cir. 2006). The petitioner asserting claim under the National Childhood Vaccine Injury Act is not required to prove the case to a level of scientific certainty. National Childhood Vaccine Injury Act of 1986, § 311(a), 42 U.S.C.A. §§ 300aa–11(c)(1)(C), 300aa–14. LaLonde v. Secretary of Health and Human Services, 746 F.3d 1334 (Fed. Cir. 2014) "[I]n a field bereft of complete and direct proof of how vaccines affect the human body," a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery" Althen 418 F. 3d at 1280 (quoting *Knudsen*, 35 F. 3d at 549); *Capizzano*, 440 F. 3d at 1324; see *Duabert*

⁴² Overlooked by Federal Circuit is, "W.R.'s experts [opine] exceeded *Althen* Prongs with his medical records. Applicable case law *Paterek* v. HHS, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013) with his "vaccine-related injury" is also his causal medical theory; because the table indicates DTaP can cause encephalopathy, satisfying *Althen*, Prong One," Opening Brief on Appeal at 27.

v. Merrell Dow Pharms, Inc., 509 U.S. 579, 593 (1993)" (citing Andreu), Moberly, 592 F. 3d at 1325 (Fed. Cir. 2010)."

The Federal Circuit so far departed, also making these precedents inconsistent with Rogero:

"By statute, the Court of Federal Claims is empowered to "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law . . . " 42 U.S.C. § 300aa–12(e)(2)(B). Where ... a special master misapprehends a petitioner's theory of causation, ... the Court of Federal Claims is not only authorized, but obliged, to set aside the special master's findings of fact and conclusions of law. See *Andreu*, 569 F.3d at 1375 (concluding that a special master erred in disregarding probative testimony from a petitioner's treating physicians); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (concluding that a special master "impermissibly raise[d] a claimant's burden under the Vaccine Act"); Althen, 418 F.3d at 1280–81.

Concluding, W.R. was denied equal justice of The Vaccine Act. In Federal Circuit's own Precedents language, *Rogero* Court 18-1684 (Fed. Cir. 2018) erred when they "require[d] identification and proof of scientific mechanisms ... inconsistent with the purpose and nature of the vaccine compensation program". And "contravene[d] section 300aa-13(a)(1)'s allowance of medical opinion as proof", "such an approach is inconsistent with allowing "the use of circumstantial evidence envisioned by the preponderance standard.", "it thus impermissibly raises a [W.R.'s] burden under the Vaccine Act and hinders "the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants" "[I]n a field bereft of complete and direct proof of how vaccines affect the human body," a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery".

Petitioner contends after 24 years of precedents, the Federal Court of Appeals continues to misinterpret these sections of the Vaccine Act requiring "cause-in-fact" and/or scientific certainty proof when publicly finding preponderance for compensation of causal association between DTaP vaccine and encephalopathy under 42 U.S.C.A. § 300aa–11(c)(ii)(II). The Act does not preclude causation in fact from being established by claimant in absence of scientific proof of how an ingredient in a vaccine works, the Act requires only "received a vaccine set forth in the Vaccine Injury Table" 300aa–11(c)(1)(A) in connection with an injury set in the Table under § 300aa–11(c)(1)(C)(ii)(II), Public Health Service Act, § 2113, as amended, 42 U.S.C.A. §§ 300aa–13(a)(1), 300aa-11(c)(1)(A), the Federal Circuit's Decision is erroneous.

Petitioner respectfully submits, nowhere does the entirety of §§300aa-1 to -34 require scientific proof of a *mechanism* of an ingredient in the DTaP for a Medical Theory, §300aa-13(a)(1)⁴³ the appropriate **preponderance** standard, addressed and re-addressed by the lower Federal Courts demands this Court's supervisory power, again. The Court of Appeals decision based on requiring W.R.to prove an elevated evidentiary burden is expressly rejected in *Althen*, and "irrational and wholly arbitrary" to a party of one, to sanction discriminatory procedural due process on a behavioral disability subsequent to his brain injury, violating Section 504.

(3) <u>Federal Circuit Impermissibly Heightening Claimants Legal Burden Beyond</u> <u>Preponderance, Requiring Medical Literature Contravenes 300aa-13(a)(1)</u>

To deny W.R.'s Preponderance for Compensation, Federal Circuit impermissibly heightened W.R.'s legal burden contravening section 300aa-13(a)(1)'s allowance of W.R.'s medical opinion as proof (when his medical records, and his DTaP prescribing literature filed years prior to hearing, see in part, App. 114a). The Court of Appeals sanctioned violating the Vaccine Act when (1) requiring, (2) overlooking Pet. Ex. 63, then (3) erroneously concluding "the Rogeros' experts had "inadequate support in medical literature" App 9a because Althen relied on in the Decision holds,

"by requiring medical literature, it contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof. This prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants. See Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed.Cir.1994) (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program")" Althen

In so doing, Court of Appeals so far departed from the Vaccine Act and this Court's precedent sanctioning that a petitioner's Medical Theory of DTaP causal to encephalopathy publicly found of expert opine, the "causation theor[y]" was "quite unpersuasive" *App. 6a* when only medical opine or medical records were required for preponderance, as required by The Act, and those *findings were found and published by Federal Claims*. Thus, Federal Circuit affirmed Federal Claims can may "reject" *App. 6a* their own findings, because a child *also* had autism disability?

⁴³ 300aa-13(a) "(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and substantiated by medical records or by medical opinion.

The child's preponderance of evidence of expert medical testimony and the relevant scientific DTaP prescribing information, that legally made his evidence "persuasive" "by showing that the vaccination was the reason for the injury[,]"? The Rogeros unequivocally demonstrated that DTaP received on May 4, 2010, could cause encephalopathy injury, W.R. suffered, vaccine-related injury defined by 300aa--33(5)⁴⁴ with expert opine and Glasko Smith Kline pharmaceutical company DTaP Prescribing Information that determined encephalopathy as an adverse effect [Pet. Ex. 63 at 11, Package Insert, Ex. 1 Vaccine Record]. on the docket 3 years prior to hearing, on which the expert MD's relied. See Ex. 63, ECF 33 #9, applicable pages at App. 114a-115a also filed in Federal Circuit appendix. In this regard, the federal courts denied W.R. his fundamental right to the Vaccine Act, his expert MD's opine, his medical records that show both diagnoses on the same day visit, and his filed DTaP prescribing information filed in both courts, because he was diagnosed with an encephalopathy and a subsequent autism is a discriminatory reason on its face.

05/13/2013	<u>33</u>	MEDICAL LITERATURE [Exhibit #56-64] filed by HEATHER
		ROGERO. (Attachments # 9 Exhibit 63,(Shoemaker, Clifford)
		(Entered: 05/13/2013)

Erroneously, the Court erred, DTaP is causally associated to encephalopathy by law. W.R.'s medical literature was not necessary when the Act requires "or" not "both".

This Court stated in Shalalah v. Whitecotton – 514 U.S. 268 (1995), "The Act defines encephalopathy ... 42 U.S.C. §300aa–14(b)(3)(A) and lists the condition on the Vaccine Injury Table in association with the [DTP "DTaP"] vaccine", Supreme Court law with his theory.

Federal Circuit holds, "Petitioner ha[s] established a "medical theory causally connecting the vaccination and theory" because the Vaccine Injury Table indicates that DTaP vaccines can cause encephalopathy, a causal connection "well recognized by the Office of Special Masters." Paterek v. HHS, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013). Precedent Knudsen Court stated, "it is entirely ... contemplated by the statute, that DTP may cause an encephalopathy"

The Master's findings demonstrate petitioner's "persuasive" medical theory" from medical opine and medical record constituting all 3 Althen Prongs of four experts medical opine of DTaP causal to encephalopathy under §300aa11(c)(1)(C)(ii)(II) from medical records, satisfying 300aa-13(a)(1), likewise Federal Circuit acknowledged the contemporaneous medical records of onset and diagnoses of encephalopathy, an injury "set in the Table" for actual causation proof, with onset outside requisite Table time.

⁴⁴ "The term "vaccine-related injury" means an ... injury, condition, ... associated with one or more of the vaccines set forth in the Vaccine Injury Table".

Vaccine Act's legal proof of causation of DTaP to encephalopathy in 42 U.S. Code § 300aa–14(a): "vaccines, the injuries, ... conditions, ... resulting from the administration of such vaccines". "Althen, 418 F.3d at 1278. Because causation is relative to the injury, a petitioner must provide a reputable 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." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548–49 (Fed.Cir.1994).

a. Under §300aa-11(c)(1)(C)(ii)(II), Petitioner's Encephalopathy is an "injury Set in the Table" by Statute, even with Onset Outside Table time, for Proof of Actual Causation Requiring Althen Prongs

Federal Circuit misread the plain language of the text, §300aa-11(c)(1)(C)(ii)(II), for Rogero. Direct proof is the Federal Circuit stated of W.R., that his "encephalopathy" "an injury claimed" "can be a table injury see 42 C.F.R. 100.3" (italics emphasized) App. 9a when Congress enacted law that W.R.'s encephalopathy is an "injury set in the Table". And noticed by this Court in Precedent Shalalah v. Whitecotton, , termed "proof of actual causation" and is in five distinct statutes as "injury set in the Table. Congress specifically authorized recovery for vaccine-related encephalopathy by two statues both inside and outside requisite table timing, and even when the special master fails to find preponderance,

- 42 U.S. Code § 300aa-14(a) INITIAL TABLE The following is a table of vaccines, the <u>injuries</u>, disabilities, illnesses, conditions, and deaths <u>resulting from the administration of such vaccines</u>
- 42 C.F.R. 100.3(a). "In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986 ... the following is a <u>table of vaccines</u>, the <u>injuries</u>, ... <u>resulting from the administration of such vaccines</u>".

II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, **DTaP**, P, DTP-Hib)

B. Encephalopathy or encephalitis

Congress defined encephalopathy "injury" "resulting from the administration of [DTaP]" is an injury "set forth in the Vaccine Injury Table" with the same language in two distinct statutes for encephalopathy. Both statutes state for encephalopathy "injury...set forth in the Vaccine Injury Table", irrespective if onset is within 72 hours under 300aa-11(c)(1)(C)(i) or "table injury not manifested within requisite time" as published in American Law Reports⁴⁵

⁴⁵ See, specifically 129 American Law Reports ALR Fed. 1 (Originally published in 1996), and 39 A.L.R. Fed. 2d 155, July 27, 2009; "B Causation in Fact of Injury by Vaccine, § 23[b] Burden of proof—Table Injuries not manifested within requisite time"

after 72 hours also with plain language of "injury... set forth in the Vaccine Injury Table," requiring simple preponderance on Althen for 300aa-11(c)(1)(C)(ii)(II), like Rogero, onset outside Table time.

42 U.S.C. - § 300aa-11(c)(1)(C)(ii)(II). (Requiring *only* the vaccine and injury for the medical theory, *not* proof of an ingredient as mechanism in the vaccine). Judge Dyk clarified the appropriate statute for this case in binding "Pafford v. HHS, 451 F. 3d 1352, 1355-56 (Fed. Cir. 2006), that the Court of Appeals relied, App. 7a defines vaccine-related encephalopathy outside table timing: "The Vaccine Act specifically authorizes compensation for petitioners who "sustained, or had significantly aggravated, any ... injury [encephalopathy] set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A) [DTaP]" 42 U.S.C. – 300aa-11(c)(1)(C)(ii)(II) (2000)." (emphasis added)

Noted: (§ 300aa–11(c)(1)(C)(i) is irrelevant to *Rogero* and is the encephalopathy statute for onset within hours in requisite Table time, not requiring *Althen* prongs.)

Proof of violating the Rehabilitation Act when sanctioning a legally unsupported basis for autism disability, Congress specifically authorized statute that *even if a special master does not find preponderance* of encephalopathy from DTaP (which he did in *Rogero* but denied impartial due process), it *is still considered* "set in the table", same statutory language used in applicable 300aa-11(c)(1)(C)(ii)(I) for encephalopathy **outside the requisite Table**, *supra*:

§ 300aa-14(b)(3)(B). "...If at the time a judgment is entered ... for a vaccine-related injury ... it is not possible to determine the cause by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record."

Materially, and overlooked by Court of Appeals, they did consider the relevant "medical record" of onset evidence in contemporaneous medical records of encephalopathy with record citations to medical record, in opening brief, but violated 300aa-14(b)(3)(B) because Court of Appeals acknowledged medical record onset of encephalopathy in May 2010, but overlooked the legal error they heightened W.R.'s preponderance medical theory to one requiring scientific proof standard in illegality, stating of his contemporaneous medical records:

"immaterial their contention that W.R. *met diagnostic criteria* for "encephalopathy *as defined in the Table*" *App. 14a* (referring to Opening Brief evidence at 29-33). [which is proof of *Althen* Prong Two, like Dr. Megson opine satisfying all 3 Prongs, and exceeding *Althen* by also proving with medical records].

Which was the basis of expert Dr. Megson's opine in the master's findings, also *filed by* HHS of expert Dr. Megson, MD, *infra*. of "loss of eye contact and loss of awareness of his surroundings, definitions of acute encephalopathy 42 CFR §100.3(c)(2)(i)(B)⁴⁶ for proof of legal encephalopathy onset "set in the Table" as defined by statute § 300aa-11(c)(1)(C)(ii)(II) timing outside Table time, onset timing in May by evidence in the special master's findings.

The justice-function of this Court on correcting constitutional rights violations of accurate and impartial procedural due process of Congressional Acts because the conclusions do not rest solely on the legal rules constitutes this an appropriate case to grant certiorari, so the judgment may reflect the true merits of the case. W.R. has suffered grievous loss and harm, not only of materially for denied due compensation for life needs authorized by Congress, but the heavy toll of warranted litigation on his family. The government function was to correctly apply the Vaccine Act preponderance standard with impartial procedural due process to his claim, with Congress specifically authorizing encephalopathy recovery outside the requisite time on the table, as found by the Court *findings*, not his conclusions contradicting the evidentiary record and claim.

"[T]he decisionmaker's conclusion . . . must rest solely on the legal rules . . . and indicate the [Vaccine Rule require relevant, appropriate] evidence he relied on", Goldberg v. Kelly, 397 U.S. 254, 271 (1970). "Whether any procedural protections are due depends on the extent to which an individual will be "condemned to suffer grievous loss." Joint AntiFascist Refugee Committee v. McGrath, 341 U.S. 123, 168 (1951) (Frankfurter, J., concurring), quoted in Goldberg v. Kelly, 397 U.S. 254, 263 (1970). "[C]onsideration of what procedures due process may require under any given set of circumstances must begin with a determination of the precise nature of the government function involved as well as of the private interest that has been affected by governmental action." Cafeteria & Restaurant Workers Union v. McElroy, 367 U.S. 886, 895 (1961).

The Court of Appeals' sanctioning an erroneous construction of Section § 300aa–13(a)(1) suffers egregious flaw that it cannot justify in the Decision conflicting precedent *Knudsen*:

^{46 &}quot;For ... children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following: (1) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis); (2) A significantly decreased level of consciousness. And clarifies at §100.3(d)(4) Significantly decreased level of consciousness is indicated by the presence of one or more of the following clinical signs: (i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)] which is independent of a seizure and cannot be attributed to the effects of medication; and (3) A seizure associated with loss of consciousness".

"The function of a special master "is not to "diagnose" vaccine-related injuries, but instead to determine based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the petitioner's injury". National Childhood Vaccine Injury Act of 1986, § 311(a), 42 U.S.C.A. § 300aa–11(c)(1)(C)(ii)(II), Andreu, 569 F.3d at 1382 (quoting Knudsen, 35 F.3d at 549).

B. The Federal Circuit Erroneously Construed § 300aa-13(a)(1)(B), Violating The Rehabilitation Act, when Affirming an Unconstitutional Autism Basis⁴⁷

The Federal Circuit again erroneously construed § 300aa-13(a)(1)(B), this time to illegitimately justify alternate causation of autism disability

Court of Appeals affirmed an unconstitutional "basis" *App. 12a* of why a master could adjudicate a subsequent disabilty and sequelae of encephalaopthy injury, only because he has [also] "been diagnosed with autism" *App. 12a* when incorrectly applying the law, an "irrational and wholly arbitrary" reason that violates The Rehabilitation Act Section 504, Vaccine Act, and precedents.

Federal Circuit sanctioned a special master may illegitimately misconstrue § 300aa—13(a)(1)(B) to deny W.R. eligible compensation and impartial procedural due process, denying him the fundamental right to equal access of his found public preponderance and § 300aa—13(a)(1)(B) as interpreted by this Court, and The Vaccine Act. In this regard, Federal Circuit again "erroneously construed the provisions defining a prima facie case under the Act" as found

⁴⁷ Noted is the Federal Circuit also departed from its precedent *Pafford* relied on in *Rogero* Decision. *App. 6a*, Judge Dyk explained two inquiries of showing on *Althen*, were not done by the special master on W.R.'s claim, only alternate one on his conclusions, meaning this is a second reason there is no legal basis for Federal Circuit for affirming alternate causation:

Binding *Pafford* stated, "As we have recognized, the plain language and structure of this provision establish that the petitioner's burden to make prima facie showing of either presumptive or *actual causation* set out in section 300aa-13(a)(1)(A) does not include the burden of proof regarding "factors unrelated" to vaccination set out in section 300aa-13(a)(1)(B) – "[t]hese are two separate inquiries under the statute." Grant, 956 F.2d at 1149 ("The Vaccine Act expressly separates the inquiry for alternative etiologies from the inquiry for causation."). See Pafford v. HHS 451 F.3d 1352, 1355-56 (Fed. Cir. 2006).

Because the Federal Circuit showed he did not [supposedly] "find" preponderance of encephalopathy App. 13a, which is erroneous, because Federal Circuit's Decision (and Federal Claims) shows preponderance of encephalopathy and Medical Theory claim from the master's findings from medical records, supra. What isn't stated by Federal Circuit is that they denied W.R. preponderance standard and due process of his of medical records and medical opine they found and published from Federal Claims findings that determines W.R. eligibility for compensation, as defined by The Vaccine Act of § 300aa-13(a)(1)(A), proof the Panel contravened the Vaccine Act.

by this Court in *Shalalah v. Whitecotton*, 513 U. S. 959 (1994), this time under § 300aa-11(c)(1)(C)(ii)(II) for encephalopathy in *Rogero*. Direct evidence is the Federal Circuit failed to provide *any* statutory basis for sanctioning an illegitimate basis of autism. The only basis left is autism disability discrimination because the government failed to rebut DTaP was not the cause of encephalopathy, and the government opined his autism was not the cause of his encephalopathy, opining autism as subsequent and later than his encephalopathy, even opining autism can be caused by encephalopathy, *infra*.

Applicable laws beyond Althen relied on by Federal Circuit in Rogero are:

- (1) The Rehabilitation Act protects W.R.'s rights in the National Vaccine Injury Compensation Program, conducted by HRSA at 45 CFR § 85.21 45 CFR § 84.4, at *App.111a-113a*. Under the 14th Amendment, W.R. has equal access to § 300aa–13(a)(1)(B) in the Vaccine Act, i.e. 45 CFR § 85.21(a) "No [child with encephalopathy and autism] shall, on the basis of [autism], be excluded from participation in [*Althen* causation analysis under 300aa–11(c)(1) on merits of their claim], be denied the benefits of [determined compensation found by special master's public findings], or otherwise be subjected to discrimination under [NVICP] conducted by [HRSA]."
- (2) This Court's interpretation of § 300aa-13(a)(1)(B) in Shalala v. Whitecotton, 514 U.S. 208 (1995).

 "The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused 'by factors unrelated to the administration of the vaccine...' § 300aa-13(a)(1)(B). If the Secretary fails to rebut, the claimant is entitled to compensation. 42 U.S.C. §300aa-13(a)(1) (1988 ed. And Supp. V)"
- (3) 42 CFR §100.3(d)(3). "Sequela means a condition [autism] or event which was actually caused by a condition [encephalopathy] listed in the Vaccine Injury Table".
- (4) Violates the Vaccine Act 300aa-14(b)(3)(B); even if "it is not possible to determine the *cause* by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table."
- (5) Rules of the U.S. Court of Federal Claims, Appx. B, Vaccine Rules VR 3(b)(1), (8)(b)(1) is violated when sanctioning a special master may "reject" *App. 6a* the "relevant and reliable" and "appropriate" evidence violating fairness to both parties and adjudicate irrelevant and inappropriate causation analysis.

The Government Did Not Rebut W.R.'s Prima Facie Found by The Court

Materially, W.R., as a citizen with his fundamental right of liberty of a Decision free from *irrational and wholly arbitrarily* treatment of his sequela of encephalopathy requires a new Decision based on the merits of his preponderance claim. The special master himself, the Federal Court of Claims, ruled out autism as a factor unrelated under § 300aa–13(a)(1)(B) to have caused his encephalopathy when the Federal court of Claims found and published in Precedent Rogero,

11-770V (2017) that encephalopathy injury may cause autism as sequelae, 42 CFR §100.3(d)(3) as defined in the Vaccine Act, and other compensated case laws with sequela of autism, not a relevant issue to NVICP, that has compensated encephalopathic injury with autism sequela.

(1) The master found: "[T]his case is about encephalopathy that was caused by the vaccinations (i.e. combined DTaP: Diphtheria, Tetanus, and Pertusis) *** [in which] the sequelae⁴⁸ [42 CFR §100.3(d)(3)][of the encephalopathy, § 300aa–14 (b)(3)(A)] may include autism or autistic-like symptoms." (E.g., Pet. Post-Hearing Brief, filed 8-19-16, pp. 1-2.)" [Former Counsel citing a quote from a Chief Special master in U.S. Court of Federal Claims]. App. 105a

Second, under § 300aa–13(a)(1)(B), as defined by this Court in Shalalah v. Whitecotton, the Secretary failed to rebut W.R.'s prima facie, preponderance proof published in public domain, because her expert's opined his autism was later than and causal by his encephalopathy, an injury, Federal Circuit stating their discriminatory on its face reason "that he had autism" is irrelevant, absent legal weight under both The Rehabilitation or The Vaccine Act.

(2) The governments medical expert ruled out W.R.'s autism as the cause of his encephalopathy, ruling it out as a "factor unrelated" as defined by § 300aa—13(a)(1)(B). And did not deny his DTaP did not cause his encephalopathy, (but did file W.R.'s experts opine that DTaP caused his encephalopathy to the Court, supra.)

Relying upon W.R.'s medical records when they opined his autism was "later", "subsequent", and agreed sequelae of encephalopathy. HHS Dr. Cetaruk MD opined, "in this case," "in terms of differentiating between autism and encephalopathy" that W.R.'s "symptoms were encompassed by the diagnosis of encephalopathy with a subsequent autism" opining affirmatively that "autism" can be sequelae of encephalopathy" Tr. 768-769. Dr. Wiznitzer opined that W.R.'s "motor development ... is linked to [caused by] ... encephalopathy" and his autism was "later" Tr. 820.

Federal Circuit is inconsistent with Precedent *Knudsen* Court, pg. 34& 37. In this case, W.R.'s encephalopathy was first, followed by *later subsequent* autism as a sequela of encephalopathy, a combined opine of Dr. Wiznitzer and Dr. Cetaruk, MD for the Secretary in transcript, like the acute encephalopathy evidence the special master recognized being in the same month as his DTaP, May 2010, like his medical exam documents physician findings on exam in early June documenting acute encephalopathy criterion as defined by the Vaccine Act; and in June *at risk* for autism and the MD did not diagnose him then. His encephalopathy was first, autism

⁴⁸ 42 CFR §100.3(d)(3). "Sequela means a condition [autism] or event which was actually caused by a condition [encephalopathy] listed in the Vaccine Injury Table".

subsequent. Precedent *Knudsen Court*, 35 F.3d 543 (Fed. Cir. 1994) interpreted 300aa-13(a)(1)(B) as the unrelated factor has *to cause the encephalopathy*, the government failed to rebut DTaP didn't cause encephalopathy, and genetic tests reveals there was no genetic cause.

"it is entirely plausible and contemplated by the statute, that DTP may cause an encephalopathy at the same time ...something else causes non-encephalophic symptoms or injuries. So long as it has not been shown that the ... unrelated factor <u>caused</u> the encephalopathy ... compensation is not foreclosed."

The Court later stated of *Knudsen*, "In defining the government's burden under section 300aa-13(a)(1)(B), we held that "[t]he government was required not only to prove the existence of an infection (here viral), but also to prove by a preponderance of the evidence

that the particular viral infection present in the child actually caused the table injury

complained of." Id. at 549.

And "[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a **preponderance** of the evidence that a vaccine caused the [petitioner's] injury.' "Andreu, 569 F.3d at 1382 (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed.Cir.1994)). Encephalopathy is vaccine-related injury, and he found preponderance was shown.

Third, Petitioner's experts and treating physician and neurologist agreed with HHS, W.R.'s autism was a secondary diagnoses and sequelae of his encephalopathy.

- (3) **W.R.'s Experts: Treating expert Dr. Megson, MD opined his encephalopathy is his primary diagnosis, agreeing with record of his treating neurologist. (Tr. 37, context is Tr. 35-38) and opined autism was "psychiatric" as also indicated so in neurology records. Dr. Mikovits, PhD "ASD is not an infrequent sequela of encephalopathy" Ex. 236 at 5 Dr. Ratajczak, PhD that autism in terms of encephalopathy is one of the sequelae, Tr 628.
- (4) **W.R.'s Treating Neurologist on both lower Court's Dockets: Treating Neurologist, Dr. Civetello, MD who diagnosed his encephalopathy and differentiated it from his autism from her records, on both courts dockets in letter is: "His primary diagnoses is encephalopathy manifested by oral motor dyspraxia, hypotonia, focal neurologic signs (right side facial weakness) and gross and fine motor delays. Encephalopathy is not a neurodevelopmental or psychiatric disorder but is a primary neurologic disorder. He also has a secondary diagnosis of autism which is separate from his encephalopathy diagnoses" *Also see* some of her five years of records with both diagnoses (Ex. 9 at 153, 154, 156, Ex.102, Ex. 45 at 19, Ex. 249 as examples, also in Fed. Cir. Appx).

Fourth, both parties' counsels determined autism wasn't an allegation in this case, as a sequela of encephalopathy, Tr. 6-10, HHS at ECF 177 at 10. DOJ, and encephalopathy is not a neurodevelopmental disorder as erroneously concluded by the special master, and not a board-certified neurologist, and was erroneously affirmed by Federal Claims, contradicting

the statutory definition Congress expressly wrote, found in this Court's precedent *Shalalah v. Whitecotton*.

Concluding, Federal Circuit again erroneously construed prima facie construction of the Act's recovery and rebuttal as written in the plain language of both §300aa-13(a)(1)(A) & (B), as interpreted by this Court's Precedent, and 24 years of Federal Circuit precedents, so far departing, Court of Appeals affirmed unequal treatment on the basis of autism with direct proof in published findings of his preponderance proved.

Egregiously, Federal Circuit has denied impartial due process on the basis of autism; a subsequent sequela, §100.3(d)(3), of his encephalopathy injury, and medially and legally causally unrelated to any of his vaccinations, both courts even misconstruing sequela as legally defined in the Vaccine Act, contrary to both parties agreed experts. And that autism basis, in light of the published Court preponderance findings, is unequal and unconstitutional, unlike the treatment of at 94 similarly situated compensated children's cases. Federal Circuit's "arbitrary and wholly irrational" treatment requires this Court's supervisory power on behalf of W.R.'s fundamental rights being violated in a federal program to right a constitutional wrong.

C. The Harm Against Petitioner is Vastly Overbroad

The Decision entered in *Rogero* by the Federal Circuit sanctioning unequal treatment of W.R.'s publicly found preponderance and medical theory of DTaP causal to encephalopathy so far departs from two Congressional Acts, invoking contention of discrimination with proof *on the basis of autism disability*, against a child in a federal program. Unconstitutionality, this case extends well beyond the harm to Petitioner, This Court statutorily found autism is a disability in *Endrew F. v. Douglas County School Dist. RE-1.*, a protected class of over 1.5 million children in the U.S. and over 3.5 million total citizens. Thus, this Court has the ripe opportunity to address honoring the fundamental rights of those with autism disability. This case also provides this Court the opportunity to publicly rule that vaccines are *not* medically *or* legally causally related to autism, as *agreed* by both parties of this case, substantiated with the legitimate verifiable adjudicative *findings*, and as enacted by Congress when defining encephalopathy, § 300aa—14(b)(3)(A) with permanent *focal neurological signs*, the Act defines as an *injury*, like NIH⁴⁹,

⁴⁹ NIH, U.S. National Library of Medicine, Medical Encyclopedia, "Focal Neurological Deficits"

[&]quot;Causes" include "injury" https://medlineplus.gov/ency/article/003191.htm (last viewed July 7, 2019)

also defined by this Court. Autism is not a vaccine-related injury, it is a "neurodevelopmental disorder", as held by this Court, sequelae as agreed opine; §100.3(d)(3) and publicly found.

Purposes of Congress are expressly authorized, thus, there is not a rationally related government interest as enacted by statute for compensation of vaccine-related encephalopathy in 42 U.S. Code § 300aa–11(c)(1)(C)(ii)(II). Denying right to The Vaccine Act as written, impermissibly raising legal burden, and denying and accurate and impartial due process and compensation for found preponderance on the basis he has a sequela of autism violates 45 CFR § 85.21(b)(i) VICP cannot "Deny a [child with encephalopathy and autism] the opportunity ... benefit from" determined eligibility for compensation as determined by public Court findings and plain language of §300aa–13(a)(1) for compensation in the NVICP.

This Court has found the substantial harm Federal Circuit's erroneous affirmation on the basis of autism disability and rejecting his legal medical theory have caused, denying W.R.

To "receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses, diminished earning capacity, pain and suffering, ..." National Childhood Vaccine Injury Act of 1986, § 301 et seq., 42 U.S.C.A. § 300aa–1 et seq." *Bruesewitz v. Wyeth*, Inc., 131 S. Ct. 1068, No. 09–152 (2011).

Rogero established by a preponderance of the evidence proven in public findings, that the DTaP vaccination is causally associated with his encephalopathy. His proffered evidence in public findings, which the trial court rejected without showing analysis, provided the requisite showings of his medical theory causally connecting his vaccination and his injury, a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and a proximate temporal relationship between the DTaP vaccination and his encephalopathy injury. There is grave fundamental rights error in the court's conclusion that a subsequent sequela caused by encephalopathy in the master's findings and agreed by both parties' experts was the reason he was denied accurate and impartial procedural due process and equal protection of the law resulting in autism disability discrimination.

II. THE DECISION BELOW IS IN NEED OF REVIEW

Constitutional and equitable principles require this Court's review of how the Federal Circuit erroneous "construed the provisions defining a prima facie case under the Act" when it granted certiorari in 1995, *Shalala v. Whitecotton* to review and address the Court of Appeals' construction of the Vaccine Act's requirements for making and rebutting a prima facie case of encephalopathy associated with Diphtheria-Tetanus-Pertusis. The need for review has only

continued, this time, construing it in such a way as to likely be autism disability discrimination with published court proof warranting this Court's supervisory power.

The Court of Appeals' Decision contravenes Congresses expressed intent of § 300aa–13(a)(1)(A) for recovery and § 300aa–13(a)(1)(B) for rebuttal, for which this Court granted certiorari in 1995. The stakes of this case are indisputably high on contentions of autism disability discrimination in the federal courts. This Court has also granted certiorari to address successful claims brought by a class-of-one, where a petitioner was intentionally treated differently from others similarly situated of "irrational and wholly arbitrary treatment" in *Village of Willowbrook v. Olech*, 528 U.S. 562, 564 (2000) which applies with respect to legislative and regulatory action of The Rehabilitation Act of 1973, Section 504, and The National Childhood Vaccine Injury Compensation Act of 1986, and is warranted again to address "that the court erroneously construed the provisions defining a prima facie case under the Act". *Shalalah v. Whitecotton*, 513 U.S. 959 (1994), this time under statute § 300aa–11(c)(1)(C)(ii)(II).

All considerations present here improperly result in unequal treatment equipoise to autism disability discrimination in the lower federal courts in a federal program to W.R. III, party of one, representative of a protected class of over 3.5 million U.S. citizens, contravening two congressional acts and ultimately violating the fundamental rights of W.R. III protected by the 14th Amendment, warranting to this Court's supervisory review.

CONCLUSION

This petition for a writ of certiorari should be granted.

August 14, 2019

Respectfully Submitted for W.R. IJJ,

Rev. Heather D. Rogero

Counsel of Record

Rev. Dr. Walter A. Rogero II 990 Northpointe Drive Mountain Home, AR 72653

(918) 527-6125

Email: WRLegal@outlook.com