

2010-5004

United States Court of Appeals
for the
Federal Circuit

THERESA CEDILLO and MICHAEL CEDILLO,
(as Parents and Natural Guardians of), MICHELLE CEDILLO

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

*Appeal from the United States District Court of Federal Claims
in 98-VV-916, Judge Thomas C. Wheeler.*

**BRIEF OF *AMICI CURIAE* ELIZABETH BIRT CENTER
FOR AUTISM LAW AND ADVOCACY, *et al.* IN SUPPORT
OF APPELLANTS AND IN FAVOR OF REVERSAL**

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BRIEF OF *AMICI CURIAE* OF PETITIONERS-APPELLANTS

STATEMENT OF INTEREST OF *AMICI CURIAE*

The twenty-three organizations that have signed this amicus brief have a strong interest that this case be decided impartially. A full list of the amici is attached as Exhibit A. Many of the organizations, like Elizabeth Birt Center for Autism Law and Advocacy, advocate for the rights of people with autism. Others, like Autism One, educate and serve families dealing with autism. Still others, such as the Autism Research Institute, fund scientific research on autism. Many of the

organizations advocate for the ethical principle of informed consent for vaccination, as every vaccination decision carries the risk of injury or death. Still other organizations focus on the risks of mercury in medicine. The amici sought and received the consent of all parties to file this brief.

SUMMARY OF ARGUMENT

As organizations, we represent or serve the one and a half million people in the United States who have an autism spectrum disorder.¹ Autism is the fastest growing developmental disorder in the country and includes: (1) impairments in social interaction, (2) impairments in verbal and non-verbal communication, and (3) stereotypical restricted or repetitive patterns of behavior and interests.² For decades, the autism prevalence was four to five per ten thousand children.³ In December 2009, the Centers for Disease Control announced that the rate among eight-year olds is now 110 per ten thousand, or approximately one percent of all

¹ It is estimated that 1.5 million people in the U.S. are living with autism spectrum disorders based on the current Centers for Disease Control (CDC) prevalence rate and the 2000 census. *See, e.g.*, Autism Society of America, What is Autism: Facts and Stats, http://www.autism-society.org/site/PageServer?pagename=about_what_is_factsstats (last visited Jan. 22, 2010).

² *Id.* (citing autism as fastest-growing disorder); *Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968, 7 (Fed. Cl. 2009) (citing clinical definition of autism spectrum disorder).

³ CDC, Autism and Developmental Disabilities Monitoring Network, <http://www.cdc.gov/features/countingautism> (last visited Jan. 22, 2010).

U.S. children.⁴ As Dr. Thomas Insel, Director of the National Institute of Mental Health and Chair of the Interagency Autism Coordinating Committee said in light of these new numbers, "There is no question that there has got to be an environmental component here."⁵

The Omnibus Autism Proceeding (Omnibus) offered a public forum in which to present and probe theories of vaccine-induced autism. The Special Masters in the *Cedillo*, *Snyder* and *Hazlehurst* test cases,⁶ however, failed in their fundamental judicial duty to provide an impartial forum for these cases.

We believe that Special Master Hastings and the Court of Federal Claims failed to do justice. We file this amicus brief in support of Petitioner Michelle Cedillo on three grounds: (1) Michelle met her burden under the *Althen* causation standard; (2) the Court of Federal Claims deprived Michelle of due process; and

⁴ CDC, Prevalence of Autism Spectrum Disorders – Autism and Developmental Disabilities Monitoring Network, United States, 2006, <http://www.cdc.gov/mmwr/PDF/ss/ss5810.pdf> (last visited Jan. 22, 2010).

⁵ David Kirby, *Rising Autism Numbers -- Leading Federal Official Says "No Question" That Environmental Exposures Are A Factor*, Huffington Post, Dec. 19, 2009, http://www.huffingtonpost.com/david-kirby/rising-autism-numbers_b_397978.html (accompanied by transcript).

⁶ *Cedillo*, 2009 WL 331968; *Hazlehurst v. Sec'y of HHS*, 2009 WL 332306 (Fed. Cl. 2009); *Snyder v. Sec'y of HHS*, 2009 WL 332044 (Fed. Cl. 2009).

(3) it deprived her of equal justice, as it has compensated many petitioners in similar circumstances.

Michelle Cedillo's first "test case" in the Omnibus is not just about Michelle and her admirable family. It is a "test case" for the Vaccine Injury Compensation Program (Program) itself. Congress established the Program to provide compensation to those injured by vaccines "quickly, easily, and with certainty and generosity."⁷ Congress intended the Program to create presumptions for "on-table" vaccine injuries that the Program would compensate administratively. The reality is adversarial litigation where special masters "protect" the national vaccine program rather than apply the law.

Michelle's case exemplifies the conflict of interest in the Program between compensating victims and protecting the vaccine program. We saw this conflict vividly when Special Master Hastings abandoned his judicial role to opine that Michelle's case was "one-sided," that her doctors were "*very wrong*," and that her doctors "are guilty...of gross medical misjudgment."⁸ This is not the language of an impartial judge. We look to this Court to review the record with neutrality and in accordance with the law.

⁷ H.R. Rep. No. 99-908, at 18 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6354.

⁸ *Cedillo*, 2009 WL 331968 at 135.

FACTUAL AND PROCEDURAL BACKGROUND

A. The Evidence Shows That Michelle's Vaccines Injured Her.

Michelle Cedillo was born a healthy baby girl on August 30, 1994. Like other children born in the U.S. at that time, she received twelve mandated vaccines containing ethyl mercury.⁹ Each of these vaccines contained at least 25 micrograms of mercury, grossly exceeding the Environmental Protection Agency's maximum daily adult exposure for methyl mercury, a related form of mercury, of 0.1 microgram per kilogram per day (there are no safety standards for ethyl mercury).¹⁰ At fifteen months, on December 20, 1995, Michelle received the Measles-Mumps-Rubella (MMR) vaccine.¹¹ Seven days later, Michelle developed a fever that reached over 105 degrees.¹² She also developed a rash within the same

⁹ Pet. Br. at 4.

¹⁰ National Research Council, *Toxicological Effects of Methylmercury* 11 (National Academic Press 2000), available at http://www.nap.edu/openbook.php?record_id=9899&page=R1 (citing the Environmental protection agency's guideline of 0.1 microgram per kilogram per day). Thus a baby weighing approximately five kilograms at two months should not receive more than .5 micrograms of mercury on the day of a doctor's visit. At the two-month visit, infants like Michelle routinely received 62.5 micrograms of mercury, or 125 times the EPA limit. Later studies suggested that "the accepted reference dose should be lowered to between 0.025 and 0.06 micrograms per kilogram per day," meaning that the exposure at the two-month visit could be as high as 500, rather than 125, times the recommended level. Steven G. Gilbert & Kimberly S. Grant-Webster, *Neurobehavioral Effects of Developmental Methylmercury Exposure*, 103 *Environmental Health Perspectives* 135 (supp. 6) (1995).

¹¹ Pet. Br. at 7; A228.

¹² *Id.*; A263.

week. By March, 1996, Michelle's pediatrician noticed that she was less verbal and continued to have a rash.¹³ By July, 1997, doctors concluded that Michelle's course of development had changed completely and that she appeared autistic.¹⁴ Since that time, Michelle has suffered many severe medical problems — autism, mental retardation, life-threatening seizures, inflammatory bowel disease, uveitis, partial blindness and arthritis. Michelle cannot talk, cannot walk unassisted and cannot care for herself. She requires round-the-clock care.

In 1998, at age four, Michelle's parents filed a petition in the Program, alleging that the MMR vaccine harmed her. In 2002, the Chief Special Master of the Federal Court of Claims initiated the Omnibus to hear the nearly 5,000 claims of children who alleged that their vaccines caused autism. In June 2007, Michelle and her family courageously agreed to have Michelle's case be the first "test case." Michelle's lawyers argued that Michelle's MMR vaccine and thimerosal-containing vaccines together contributed to her autism. Michelle presented extensive evidence to support her causation theory.

On February 12, 2009, a decade after Michelle filed, Special Master Hastings dismissed her petition. He then dismissed Michelle's motion for

¹³ *Id.*; A205.

¹⁴ Pet. Br. at 8-9; A199-A203.

reconsideration based on new scientific evidence that supported Michelle's causation theory.¹⁵ On March 13, 2009, Michelle filed for review with the Court of Federal Claims. On August 6, 2009, Judge Wheeler affirmed Special Master Hastings' decision.¹⁶ Michelle now asks this Court to reverse the decisions of the Special Master and Court of Federal Claims below.

B. Congress Intended the Vaccine Injury Compensation Program to Decide Claims Quickly, Easily, and with Certainty and Generosity.

The National Vaccine Injury Compensation Act of 1986 (the Act) created the Program to ensure the vaccine supply, improve vaccine safety and to generously compensate vaccine victims. The tort system was not compensating vaccine-injured children or ensuring a reliable vaccine supply.¹⁷ The vaccine program itself was at risk.¹⁸

To ensure compensation, the Act removed civil litigation's requirement that the victim prove causation.¹⁹ Rather, the Program would presume causation based on certain criteria, such as a temporal relationship between vaccination and

¹⁵ Pet. Br. at 5-6; A492-A494.

¹⁶ *Cedillo v. Sec'y of HHS*, 89 Fed.Cl. 158 (2009).

¹⁷ H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6347.

¹⁸ *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994). *See also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007).

¹⁹ 42 U.S.C. 300aa-13(a)(1).

symptoms specified in a “Vaccine Injury Table.” The Act makes clear that the Program does not require petitioners to prove that the vaccine was defective or that the injury was avoidable. The Table’s purpose was to ensure that the compensation process would remain administrative rather than litigious.

If the Vaccine Injury Table contains a particular presumptive injury, the burden of proof shifts to the government to demonstrate that the injury was “unrelated to the administration of the vaccine.”²⁰ For “off-table” injuries, a petitioner must show that the vaccine more likely than not caused the injury.²¹ The Act also contemplates that the Secretary of Health and Human Services (HHS) should add new vaccine injuries to the Table as new vaccines are mandated.²²

C. The Decisions Against Michelle Below Illustrate How the Vaccine Program Is Failing to Fulfill its Mission.

The Program has not fulfilled its mission to compensate vaccine injury victims like Michelle. Had the Cedillo family filed its claim three years earlier, in 1995, the Program presumptively would have compensated her for encephalopathy, according to the Vaccine Injury Table. By administrative fiat,

²⁰ 42 U.S.C. 300aa-13(a)(1)(B).

²¹ 42 U.S.C. 300aa-13.

²² H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6361.

however, HHS removed this presumption from the Table in March 1995, forcing Michelle and others to prove causation.²³ Although Judge Plager, in his dissent in *Terran*, eloquently explained how those changes violated the U.S. Constitution, he did not carry the day.²⁴ Although Congress itself considered Michelle's injury compensable, Michelle's family has yet to receive one penny for vaccine injury.

The overwhelming majority of cases filed in the Program lose;²⁵ only eighteen percent prevail.²⁶ It is hard to imagine that more than eighty percent of cases fail to meet the liberal compensation standards Congress set to ensure public trust in the Program.

The government has not taken steps to advance vaccine safety or expand presumptions for injury compensation, as the 1986 Report recommended.²⁷ While 46 doses of nine new vaccines have been added to the Centers for Disease Control

²³ 60 Fed. Reg. 7678 (Feb. 8, 1995). *See also Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1374 (2009).

²⁴ *Terran v. Sec'y of HHS*, 195 F.3d 1302, 1319 (Fed. Cir. 1999)(Plager, J., dissenting) (majority sustaining that the Act does not violate Constitutional separation of powers principles)

²⁵ As of December 2009, 13,237 petitions have been filed and 2,387 have been compensated, or approximately 18%. *See* Health Resources and Services Administration, National Vaccine Injury Compensation Program Statistics Report (Dec. 2, 2009), *available at* <http://www.hrsa.gov/vaccinecompensation/Docs/StatisticsReport.pdf>.

²⁶ *Id.*

²⁷ H.R. Rep. No. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 6361.

vaccine schedule,²⁸ only one new symptom has been added to the table of injuries.²⁹ In other words, while there are more than twice as many chances for vaccine injury today, HHS has not updated the presumptions for compensation.

The Program has failed to meet two of Congress' three objectives. It has failed to compensate injured children quickly, easily and with certainty and generosity. It has failed to advance vaccine safety. But it has protected the vaccine program by insulating industry from liability. Michelle had no choice but to bring her claim for compensation to the Program.

STANDARD OF REVIEW

This Court reviews the decisions below to determine if they were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."³⁰ The Court applies a *de novo* standard, owing no deference either to the special master

²⁸ Nine new federally recommended vaccines have been added to the schedule since 1986: hepatitis B, rotavirus, *haemophilus influenzae* type b, pneumococcal, influenza, varicella, hepatitis A, meningococcal, human papillomavirus. Those that existed before 1986 were diphtheria, tetanus, pertussis, measles, mumps, rubella and inactivated poliovirus. See Centers for Disease Control and Prevention, Recommended Immunization Schedules for Persons Aged 0 through 6 Years and 7 Through 18 Years, available at <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm>.

²⁹ Health Resources and Services Administration, Vaccine Injury Table, available at <ftp://ftp.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf>, indicating the addition of anaphylaxis within four hours of the hepatitis B vaccine.

³⁰ 42 U.S. C. 300aa-12(e)(2)(B).

or the trial court on questions of law.³¹ As to facts, this Court must reverse factual findings for clear error.³²

ARGUMENT

I. Because Michelle Proved Her Case, This Court Should Reverse.

This Circuit established a petitioner's burden of proof in *Althen* and has upheld it in *Capizzano* and *Andreu*.³³ It requires a petitioner prove

(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.³⁴

The reason for this lower burden than in civil court is "to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."³⁵

³¹ *Whitecotton v. Sec'y of HHS*, 81 F.3d 1099, 1106 (Fed. Cir.1996).

³² *Hines v. Sec'y of HHS*, 940 F.2d 1518, 1524 (Fed. Cir. 1991).

³³ *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (affirming the Court of Federal Claims' reversal of the special master's denial of a claim for injury caused by a tetanus toxoid vaccine because petitioner proved causation by a preponderance of the evidence); *Capizzano v. Sec'y of HHS*, 440 F.3d 1317 (Fed. Cir. 2006) (reversing decisions below denying compensation from the hepatitis vaccine under the *Althen* standard); *Andreu v. Sec'y of HHS*, 569 F.3d 1367 (Fed. Cir. 2009) (reversing decisions below denying compensation from the DPT vaccine under the *Althen* standard).

³⁴ *Althen*, 418 F.3d at 1278.

³⁵ *Id.* at 1280.

Dr. Marcel Kinsbourne, a pediatric neurologist, outlined the medical theory for Michelle's case.³⁶ He testified that the science of autism has shifted radically in recent years, moving away from the static, genetic theory that HHS's experts defended. The contemporary model is one of ongoing disease that involves the brain, gut and immune system based on gene-environment interaction. Dr. Kinsbourne opined that Michelle's MMR vaccine led to the persistent presence of vaccine-strain measles virus, causing neuro- and gastrointestinal inflammation. He opined that Michelle's genetic vulnerability interacted with mercury-containing vaccines and the MMR to allow the measles virus to replicate and persist.³⁷ He concluded his report:

To forego an integrated causation and argue that these elements are distinct and unrelated leaves the three cardinal elements (gut disease, brain disease, and measles vaccine virus infection) unexplained. It is not credible that the concurrent presence of all these elements is mere coincidence.³⁸

Special Master Hastings and Judge Wheeler rejected Dr. Kinsbourne's theory and found that Michelle had not met any of the three prongs of the *Althen* test.³⁹ We argue below that the decisionmakers below were biased

³⁶ A597-98.

³⁷ *Id.*

³⁸ *Id.* at 20.

³⁹ *Cedillo*, 2009 WL 331968 at 39; *Cedillo*, 89 Fed.Cl. at 171.

and failed to follow the law of this Circuit. For these reasons, this Court should reverse.

A. The Court of Claims Failed to Criticize the Partisan Tone of the Special Master's Decision.

The Special Master's limited role is "to apply the law."⁴⁰ His role is not to displace the Court of Federal Claims or to chastise petitioner, her lawyers or experts. His role is to "aid judges in the performance of specific judicial duties."⁴¹ Special Master Hastings abandoned this role to opine that Michelle's case was "one-sided," that her doctors were "*very wrong*," and that her doctors "are guilty...of gross medical misjudgment."⁴²

We find the tone of Special Master Hastings' decision offensive. We can only understand the virulence of his tone as an attempt to intimidate future petitioners from bringing claims, to intimidate lawyers from representing them, and to intimidate medical and scientific experts from testifying. This attempt to silence the autism community on the vaccine-autism connection is "*very wrong*," to quote the Special Master himself.

⁴⁰ *Althen*, 418 F.3d at 1280.

⁴¹ *Id.* (citing *La Buy v. Howes Leather Co.*, 352 U.S. 249, 256 (1957)).

⁴² *Cedillo*, 2009 WL 331968 at 135.

The Court of Federal Claims had an obligation to criticize this unacceptable departure from judicial demeanor. We are disappointed that Judge Wheeler failed even to note the inappropriate tone of the Special Master's ruling. We look to this Court to restore our confidence that the Program will not only uphold the law but will uphold the impartiality and dignity of the judiciary.

B. The Special Master Ruled Against Michelle to Preserve the 'Integrity of the Vaccine Program.'

In March 2008, in an address to the Advisory Commission on Childhood Vaccines, Chief Special Master Golkiewicz explained the conflict of interest special masters apparently perceive in their roles. He stated:

We all know from the legislative history, Congressman Waxman, a primary architect of the Program, stated at several Congressional hearings, the purpose of the Program is to promote receipt and production of vaccines by protecting manufacturers and administrators from liability, but also to compensate those who suffer a vaccine-related injury.

However, Congressman Waxman also articulated *a competing policy concern*. I call it *protecting the vaccine's integrity*, and that is that vaccine does not cause every injury that follows immunization. There's a tension between these two objectives, a tension that affects dramatically the litigation of the cases, the parties' arguments and ultimately who wins.⁴³

⁴³ Gary Golkiewicz, Chief Special Master, U.S. Court of Federal Claims, Presentation to the Advisory Commission on Childhood Vaccines (Mar. 6-7, 2008), *available at* <http://www.hrsa.gov/vaccinecompensation/GolkewiczTranscript.htm>; A566-A575.

Chief Special Master Golkiewicz stated the view that decisions to generously compensate vaccine-injured victims may undermine public faith in the harmlessness of vaccines. Chief Special Master Golkiewicz suggests that special masters experience a tension between the law, which requires them to compensate victims for injuries proven more likely than not, and the executive and legislative ‘policy concern’ to ‘protect vaccine’s integrity.’

Chief Special Master Golkiewicz’s comments ring true. This Court has recognized special masters’ divided loyalties in many recent decisions, including *Althen*, *Capizzano* and *Andreu*. In these decisions, this Court has rejected their attempts to make petitioners’ burden of proof unattainably high, apparently in order to ‘protect vaccine’s integrity.’

Instead of applying the law as Congress and this Circuit have established, Special Master Hastings acceded to the Program’s ‘competing policy concern’ to dismiss a claim for legitimate vaccine injuries. This Court should hold special masters and the Court of Federal Claims below accountable to the law, not an extra-legal ‘competing policy concern.’

C. Because “Autism” is Legally Taboo, Special Master Hastings Ruled in Favor of Policy, Not Law.

The Special Master and the Court of Claims perhaps denied Michelle’s petition because one of her vaccine-induced injuries was called “autism.” While special masters have compensated many cases in which the petitioners’ injuries included autism, these awards, in name, were for mental retardation, acute disseminating encephalomyelitis (ADEM) resulting in Pervasive Developmental Delay/Not Otherwise Specified (PDD/NOS) and autistic-like symptoms with an underlying mitochondrial disorder.⁴⁴

To rule in Michelle’s favor is to reaffirm that vaccines are not harmless, and that they do sometimes cause adverse reactions. ‘Competing policy concerns’ are Congress’ headaches, not this Court’s.

Under Article III of the Constitution, this Court enjoys true independence from executive and legislative policy, perhaps unlike the special masters and judges below. The judges of this Court enjoy life tenure and insulation from the other branches of government precisely to give them the ability to make decisions based solely on law. We look to this Court to provide the kind of searching *de*

⁴⁴ Pet. Br. 23-25, n.39 & 44-47.

novo review that it has provided in recent vaccine cases, such as *Althen*, *Capizzano* and *Andreu*.

D. Affirming the Rulings Below Will Potentially Push 5,000 Cases of Vaccine Injury into the Civil Tort System, Defeating the Purpose of the Vaccine Act.

If this Court affirms the decisions below, nearly 5,000 Omnibus cases will potentially enter the civil justice system. Those cases ultimately pose the risk of staggering judgments against manufacturers. Congress' rationale for the Program was to provide an appealing alternative to civil litigation for plaintiffs. If the Program fails to offer deserved compensation to Michelle, it will be hammering a nail into its own coffin. Existing and potential future petitioners will see that filing in the Program is merely a stopover on the way to civil court. Congress did not intend this, nor is it in the best interests of the 'integrity of vaccines.' Only a decision based on law, acknowledging that Michelle met her burden under *Althen*, will serve the interests of justice.

E. Michelle's RNA Measles Biopsy Results Are Reliable.

The preponderance of the evidence favors reliance on the O'Leary test results which show the continued existence of the measles virus in Michelle's gut.

HHS attempts to discredit the O'Leary lab results primarily on the basis of Dr. Bustin's testimony. But Dr. Bustin, HHS's expert, did not in fact discredit them.⁴⁵ Preponderant evidence supports the reliability of the lab results.

First, there is uncontested evidence that Dr. O'Leary is a highly-respected, pioneering scientist in polymerase chain reaction (PCR) testing. He leads a laboratory at Trinity College in Dublin, Ireland and led the Unigenetics laboratory from which Michelle received test results. Both Special Master Hastings and Judge Wheeler noted his positive reputation.⁴⁶

Second, Drs. Bustin and Rima, HHS experts who testified on the O'Leary lab results, were experts in previous hearings in the United Kingdom on a potential MMR-autism link. Vaccine manufacturers paid them handsomely for that service, so their strong positions should be gauged accordingly.

Third, in the U.K. litigation, Dr. Bustin visited the O'Leary laboratory and inspected its laboratory notebooks. Those notebooks, however, are sealed in the U.K. proceeding, and Michelle's lawyers could not inspect them, despite many efforts to do so. It is impossible to assess Dr. Bustin's testimony without the

⁴⁵ *Id.* at 28-31, particularly n.56; A363-A367.

⁴⁶ *Cedillo*, 2009 WL 331968 at 46; *Cedillo*, 89 Fed.Cl.158 at 169.

underlying evidence. This Court should disregard his testimony without the complete documentation it is allegedly based on.

Fourth, while Dr. Bustin was critical of the procedures at the O'Leary lab, he did not contest the accuracy of the results when a substantial inflammation level was detected, showing "high copy numbers." Dr. Bustin stated that his dispute was with the lab's ability to detect minimal inflammation levels, indicated by "low copy numbers."⁴⁷ Dr. Bustin conceded that Michelle's lab results showed a substantial inflammation level.⁴⁸

Fifth, two reputable, independent laboratories replicated O'Leary's PCR lab results for substantial inflammation levels. HHS's experts inadvertently introduced evidence that both Dr. Finbar Cotter's London laboratory and Dr. Michael Oldstone's U.S. laboratory replicated the O'Leary lab results, the standard for reliability in science.⁴⁹ An affidavit from Dr. Kennedy submitted with the motion for reconsideration further confirmed that the only discrepancy was limited to "low copy numbers"⁵⁰ for minimal inflammation levels.

⁴⁷ *Cedillo v. Sec'y of HHS*, No. 98-916V, Transcript of Proceedings ("*Cedillo* Transcript"), June 8, 11-15, 18-22, 25-26, 2007; A365.

⁴⁸ A366.

⁴⁹ Pet. Br. at 31, n.56, 32 & 42.

⁵⁰ *Id.* at 33, n.59; A491.

Sixth, the O'Leary lab books that Dr. Bustin used as the basis for his testimony showed that the O'Leary lab used positive and negative controls. In these lab books, Dr. Bustin could point to a single episode of contamination.⁵¹ Yet experts for both parties acknowledged that contamination occurs in every laboratory. Special Master Hastings had no factual basis to conclude that contamination in the O'Leary lab was "rampant."⁵²

Special Master Hastings rejected the O'Leary test results, citing three reasons: (1) the laboratory failed to publish any sequencing data to confirm the validity of its testing, (2) other laboratories were unable to replicate the findings of the O'Leary lab in the Uhlmann study, and (3) the D'Souza group found that the Uhlmann primers used to detect measles RNA were "nonspecific."⁵³

These reasons are unpersuasive. While it would be desirable to have a laboratory publish its sequencing data, it is unreasonable to require it. As to the second and third reasons, petitioner's expert Dr. Hepner testified that the Afzal and D'Souza studies do not cast doubt on Michelle's gut biopsy results.⁵⁴ Those studies evaluated blood, not gut tissue, from subjects without gastrointestinal

⁵¹ A363.

⁵² *Cedillo*, 2009 WL 331968 at 36.

⁵³ *Id.* at 46.

⁵⁴ *Id.* at 45-47.

dysfunction. It is irrelevant to Michelle's case that other labs could not replicate blood samples from the O'Leary lab.

The Special Master also concluded that Michelle failed to prove that the measles virus RNA, if detected, was vaccine-strain measles virus rather than wild type.⁵⁵ This is inaccurate, however, because Michelle presented direct evidence that the O'Leary lab used allelic discrimination to distinguish vaccine-strain measles. The lab results not only showed the existence of measles RNA, but showed that it was indeed vaccine-strain.⁵⁶

Michelle submitted further compelling evidence of the reliability of the O'Leary lab results in her motion for reconsideration. She submitted a new study on the recovery of measles RNA from the gut tissue of autistic children. The multi-center Hornig study,⁵⁷ relying on laboratories at *HHS's own* Centers for Disease Control, Columbia University and Dr. O'Leary's laboratory at Trinity College were all concordant in finding measles RNA in one clinical subject and one control, again showing the O'Leary laboratory's reliability.⁵⁸ This study on

⁵⁵ *Id.* at 51.

⁵⁶ A449.

⁵⁷ A484-A489; A472-A473.

⁵⁸ *Id.*

gut tissue provides a far more meaningful comparison than the Afzal and D'Souza blood studies the Special Master cited.

In short, Michelle has submitted compelling evidence that her gut biopsy contained vaccine-strain measles RNA. Special Master Hastings rejected this evidence, and Judge Wheeler showed great deference.⁵⁹ To find that the lab evidence was unreliable was an abuse of discretion.

Accepting that the gut biopsy results were reliable, it follows that Michelle met her burden under the first prong to advance a persuasive medical theory causally connecting the vaccination to her injury.

F. Michelle Has Shown a Logical Sequence of Cause and Effect Between Her MMR Vaccine and Her Injuries.

Michelle met the first and third prongs of the *Althen* burden of proof. Having done so, “the second prong can be met through medical opinion testimony.”⁶⁰ This Court has concluded that “treating physicians are likely to be in

⁵⁹ *Cedillo*, 2009 WL 331968 at 59; *Cedillo*, 89 Fed. Cl. at 171.

⁶⁰ *Andreu*, 569 F.3d at 1375.

⁶⁰ *Andreu*, 569 F.3d at 1375.

the *best position* to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.”⁶¹

The decisions below found that Michelle had not shown the logical sequence that the second prong requires. But they err; Michelle has met her burden through testimony from numerous treating physicians, all of whom note the close timing between her injury and the MMR.⁶² The only purpose of noting this connection is to show medical significance. If a close connection in time were irrelevant, presumably Michelle’s doctors would have left it out.

Capizzano holds that treating physician testimony best fills the gap between the first and third prongs.⁶³ For the Special Master to decide that the HHS experts -- who never examined Michelle and who had contact only with the cold record more than a decade later -- were more credible than Michelle’s treating physicians was capricious. Again and again, Special Master Hastings pointed to HHS’s experts being more “credible.”⁶⁴ But as this Court has established, a

⁶¹ *Id.* (quoting *Capizzano*, 440 F.3d at 1326) (emphasis added).

⁶² See Pet. Br. 7-11.

⁶³ *Capizzano*, 440 F.3d at 1326.

⁶⁴ See, e.g., *Cedillo*, 2009 WL 331968 at 67-68, 81, 107, 111 and n.95.

Special Master may not “cloak the application of an erroneous legal standard in the guise of a credibility determination and thereby shield it from appellate review.”⁶⁵

The Special Master attempted to raise the burden of the second prong beyond this Court’s standard as in *Capizzano*. While the Special Master declared that this case is “one-sided” for the government, the evidence suggests that this is a close case to be decided in the injured party’s favor. This Court requires a logical sequence of cause and effect -- nothing more and nothing less.

Michelle has established that mercury can suppress immunity, including from HHS’s own expert pediatric neurologist, Dr. Andrew Zimmerman.⁶⁶ She has also established that measles can lead to inflammation, including in the brain and gut. She provided evidence of two brain disorders arising from wild-type measles infection.⁶⁷ She has provided ample evidence of multiple inflammatory conditions that developed after the MMR vaccine – inflammatory bowel disease, uveitis, arthritis and autism. Both Michelle’s and HHS’s experts regard autism as neuroinflammation.⁶⁸ She has provided evidence that her gut biopsy containing

⁶⁵ *Andreu*, 569 F.3d at 1379.

⁶⁶ A479-A483 contains relevant excerpts from *Autism: Current Theories and Evidence*, ed. by Dr. Zimmerman (2009).

⁶⁷ Pet. Br. 49.

⁶⁸ A229-A233 & A479-A483.

measles RNA is reliable. Michelle has met her burden to bridge the gap between theory and timing. She has made a *prima facie* case showing a causal sequence by a preponderance of the evidence. The burden of proof should have shifted to HHS, and it has failed to advance any alternative explanation.

G. The Testimony of Michelle's Treating Physicians and Family Are More Credible than HHS's Experts.

Dr. Krigsman's testimony, which the Special Master injudiciously disparaged, strongly supports the logical sequence that Michelle presents. Michelle's theory is not implausible or incorrect simply because medicine has failed to describe it. This Court should not allow the decisions below to "impermissibly rais[e] a claimant's burden under the Vaccine Act and hinder 'the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.'"⁶⁹

The Court of Claims also affirmed the Special Master's disregard for the testimony of Michelle's parents and family members. It is the role of the special masters to assess credibility, and Special Master Hastings repeatedly stated his

⁶⁹ *Capizzano*, 440 F.3d at 1324.

respect for the Cedillo family.⁷⁰ Despite this stated admiration, he failed to give weight to the detailed contemporaneous insights of Michelle's family, violating pediatric medicine's first rule, to "listen to the mother."

II. Because Michelle Did Not Receive Fundamental Due Process Below, this Court Should Reverse.

A. Congress Never Contemplated or Authorized the Omnibus Nature of This Proceeding.

The Petitioners' Steering Committee agreed to present a "test case" to Special Master Hastings on January 9, 2007. But Special Master Golkiewicz subverted that proposal to create a three-member committee of special masters to review "general causation evidence."⁷¹ The Petitioners' Steering Committee strenuously objected.⁷² While in theory each special master would decide the three MMR-thimerosal test cases separately, one only need look at the decisions in *Cedillo*, *Snyder* and *Hazlehurst*, issued on the same day, with the same results, and with the same tone, to see that the committee decided the general and specific causation issues in lock step.

⁷⁰ *Cedillo*, 2009 WL 331968 at 134.

⁷¹ See OAP Autism Update, January 19, 2007; A531-A538.

⁷² Pet. Br. 27-28; A539-A546.

An aggrieved party should not face three trial court judges. Michelle should not have had to contend with HHS entering specific causation testimony into the *Snyder* hearing without notice and without the opportunity to confront the expert. In effect, Michelle had the burden to persuade three factfinders in three different hearings. This was a burden that no other petitioner in the Vaccine Program has ever faced, and it is one that violates the “fundamental fairness” requirement of Vaccine Rule 8. The three-member committee that the Chief Special Master created was arbitrary, does not accord with law, and this Court should reverse.

B. Special Master Hastings Abused His Discretion in Favoring the HHS and Prejudicing Michelle in Procedural Matters.

Special Master Hastings permitted HHS to admit two technical expert reports from Dr. Stephen Bustin four days before trial without notice.⁷³ HHS introduced this crucial evidence at the eleventh hour, although HHS had years to obtain it and share it with Michelle’s lawyers. In effect, the Special Master sanctioned a legal ambush, overwhelming Michelle’s lawyers on the eve of trial with new, prejudicial evidence. Michelle’s lawyers requested a continuance, which Special Master Hastings denied. The time Special Master Hastings offered

⁷³ Pet. Br. 28-31 (citing A374-A404).

later in the hearing could not remedy the procedural harm that had already occurred.

Similarly, Special Master Hastings and Judge Wheeler erred by admitting and failing to criticize the factually-flawed testimony of Dr. Bertus Rima. Dr. Rima made a calculation error by a factor of 10 on the biopsy results for Colten Snyder in the *Snyder* hearing, arriving at the number 3,400 copies that should have been 340. This miscalculation led Dr. Rima to conclude that the PCR copy numbers for Michelle were “completely and utterly biologically implausible.”⁷⁴ Although petitioner’s expert Dr. Kennedy submitted an affidavit shortly after Special Master Hastings’ decision was published, explaining and correcting Dr. Rima’s error,⁷⁵ Judge Wheeler relied again on Dr. Rima’s conclusion based on the wrong calculation.⁷⁶ Dr. Rima testified in the *Snyder* hearing about Michelle when Michelle’s lawyers were not even present to cross-examine Dr. Rima.⁷⁷ These are clear procedural and factual errors this Court should reverse.

Special Master Hastings also abused his discretion by permitting HHS to use Michelle’s hearing as a venue for smear tactics against Dr. Andrew Wakefield,

⁷⁴ *Cedillo*, 2009 WL 331968 at 51.

⁷⁵ Pet. Br. 33, n.59; A491.

⁷⁶ *Cedillo*, 89 Fed. Cl. at 172.

⁷⁷ Pet. Br. 32-33; A559-A561.

a physician who was not involved in this case. Based on an attenuated connection to Dr. Wakefield, Special Master Hastings admitted the HHS expert testimony of Dr. Chadwick, who had worked in Dr. Wakefield's laboratory in the 1990's.⁷⁸ Dr. Chadwick knew nothing about the O'Leary laboratory, the PCR techniques it used or anything at all about Michelle. His only role in the hearing was to smear Dr. Wakefield. Even in closing argument, HHS's counsel affirmed that "all the strands through these cases come back to him [Andrew Wakefield]. He presented bad science."⁷⁹ This argument is particularly ironic because it is HHS's own pediatric neurologist expert Dr. Rutter who first suggested in the medical literature that vaccines might cause autism.⁸⁰ The Special Master abused his discretion to permit HHS to focus on Dr. Wakefield and to taint Michelle's treating physicians and medical theory by mere association.

And Special Master Hastings' prejudice did not end there. Although the Petitioners' Steering Committee insisted that access to the government's best national vaccine safety data in the Vaccine Safety Datalink (VSD) was essential to

⁷⁸ *Cedillo*, 2009 WL 331968 at 56.

⁷⁹ *Cedillo* Transcript, June 26, 2007, 2898-99 at A599-A600.

⁸⁰ M. Rutter, *Autism and Known Medical Conditions: Myth and Substance*, 35 J. Child. Psychol. and Psychiat. 311-22 (1994) (Dr. Rutter's study of genetic autism excluded children with a "medical condition of probable aetiological [causal] importance." One of the exclusions from his genetic study was of "a child with epilepsy and a temporal lobe focus on the EEG [electroencephalogram] who had an onset following immunization.").

the development of the test cases, Special Master Hastings never agreed to subpoena that critical, taxpayer-financed information to which HHS had access.⁸¹ Furthermore, the Petitioners' Steering Committee sought to obtain documents from vaccine manufacturers in discovery, showing that they had been concerned about mercury in vaccines long before Dr. Wakefield.⁸² Special Master Hastings denied such motions for discovery.⁸³

Similarly, when Michelle's lawyers filed a motion for reconsideration on March 13, 2009 requesting that Special Master Hastings overturn his February 12, 2009 decision in light of important new evidence, the Special Master rejected their motion because it was eight days late.⁸⁴ Through the motion, Michelle sought to introduce (a) evidence of Dr. Rima's mathematical error, (b) the newly available Dr. Hornig article, confirming the reliability of the O'Leary biopsy results, and (c) a new autism textbook edited by Dr. Andrew Zimmerman, HHS's pediatric

⁸¹ Pet. Br. at 30, n.54.

⁸² For example, a vaccine injury plaintiff in civil litigation before the commencement of the Omnibus Autism Proceeding obtained an undated, 7-page 1991 Merck memo: From: "Maurice R. Hilleman WP 26-200B"; To: "DR. DAVID GORDON RY 33-76"; Regarding: "VACCINE TASKFORCE ASSIGNMENT THIMEROSAL (MERTHIOLATE) PRESERVATIVE – PROBLEMS, ANALYSIS, SUGGESTIONS FOR RESOLUTION," indicating that Merck was concerned about cumulative vaccine mercury exposure and had discussed it with the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. Available at <http://www.putchildrenfirst.org/media/1.10.pdf>.

⁸³ Pet. Br. at 30, n.54.

⁸⁴ *Cedillo*, 89 Fed. Cl. at 167.

neurologist expert, strongly supporting four key contentions, namely that: (1) postnatal environmental triggers can cause autism; (2) regressive autism is not purely genetic; (3) scientists now accept the concept of gastrointestinal inflammation in autistic children; and (4) there is an important relationship between the immune system, gastrointestinal disorders and autism.⁸⁵

In December 2009, Dr. Insel, HHS's point person for autism, gave further support for Michelle's theory, saying "[i]t's quite believable to me that there are many children who develop autism in the context of having severe gut pathology, of having autoimmune problems, of having lots of other problems."⁸⁶ He might as well have been speaking about Michelle.

Far from being "junk science," as HHS's lawyers so frequently accused, Michelle's scientific theory has become the new consensus. Dr. Insel's remarks that there is "no question" that environmental triggers play a role and that autism is related to gut pathology and autoimmunity are simply irreconcilable with HHS's litigation position in this case. It was an abuse of discretion for the Special Master and Judge below to reject Michelle's motion for reconsideration showing strong new scientific support from *HHS's own experts* for Michelle's medical theory.

⁸⁵ See Pet. Br. at 52; A479-A483.

⁸⁶ Kirby, *supra* note 5.

Time after time, Special Master Hastings used the procedural informality of the forum against Michelle. The decisions to admit the Bustin and Rima testimony, to permit endless testimony about Dr. Wakefield, to deny crucial discovery for petitioners and to hold Michelle's lawyers to strict unilateral time limits -- these are examples of the steeply tilted playing field over which Special Master Hastings presided. Because he and Judge Wheeler abused their discretion, this Court should reverse. While any one of these procedural violations might be harmless, this Court should look at the totality of the circumstances and reverse.

IV. Because Michelle is a Victim of Unequal Justice, this Court Should Reverse.

Except for the "autism" label, Michelle's case is quite similar to many other MMR cases that the Program has compensated. Either HHS has conceded or Special Masters have ruled favorably for many MMR-induced *neurological* injuries, including ADEM; transverse myelitis; Guillain-Barre Syndrome; seizure disorder; mental retardation leading to autism; ADEM leading to Pervasive Developmental Delay/Not Otherwise Specified (PDD/NOS) and "autistic-like symptoms" in a child with an underlying mitochondrial disorder.⁸⁷ She has presented preponderant circumstantial evidence from treating physicians, medical

⁸⁷ Pet. Br. 23-25, n.39 & 44-47.

experts, scientific literature, opposing experts and laboratory results. Michelle has submitted legally sufficient evidence while HHS has provided no alternative explanation of any kind.

Michelle is now fifteen years old. She currently receives public assistance in a variety of forms. She will more than likely continue to need substantial public assistance for the rest of her life. Thus there is no question about whether Michelle will require government assistance; the only question is where it will come from and whether it will be enough. Since the Act's inception, the Vaccine Trust Fund has accumulated over \$3.1 billion.⁸⁸ This Trust Fund's sole purpose is to compensate vaccine-injured victims for irreparable harm. The funds in the Trust are not HHS's funds; they are funds collected from consumer-financed taxes on vaccines. Michelle has paid her fair share into this collective insurance pool and now seeks the relief to which she is entitled.

To force Michelle and her family to scrounge for scarce government resources to pay for Michelle's vaccine injuries is not only irrational, it is profoundly unjust. 'Policy concerns' that sanction the denial of compensation for

⁸⁸ Balance in the Vaccine Injury Compensation Trust Fund 75X8175 as of September 2009 was greater than \$3.1 billion. *See* <ftp://ftp.publicdebt.treas.gov/dfi/tfmb/dfivi0909.pdf>.

legitimate vaccine injuries have no place in any court. They should have no quarter in the Program that Congress created to compensate victims "quickly, easily, with certainty and generosity."

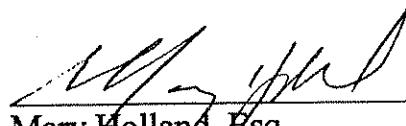
Because the Special Master and Court of Federal Claims elevated misguided policy over law, they denied Michelle the compensation she justly deserves for the catastrophic injuries she suffered. We look to this Court to judiciously apply the law to Michelle's case.

CONCLUSION

This Court should reverse on three grounds: (1) Michelle met her burden under the *Althen* causation standard; (2) the court below deprived her of due process; and (3) the court below deprived her of equal justice.

DATED:

Respectfully submitted,



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EXHIBIT A

Elizabeth Birt Center for Autism Law and Advocacy (EBCALA)
(www.autismone.org/content/elizabeth-birt-center-autism-law-and-advocacy-ebcala)

Age of Autism (www.ageofautism.com)

Autism Action Network (www.autismactioncoalition.org)

Autism Human Rights and Discrimination Initiative
(www.autismwebsite.com/autismdiscrimination)

AutismOne (www.autismone.org)

Autism File USA (www.autismfile.com)

Autism Research Institute (www.autismresearchinstitute.org)

Autism Trust USA (www.theautismtrust.com)

Coalition for Mercury-Free Medicine ([http.mercury-freedrugs.org](http://mercury-freedrugs.org))

Developmental Delay Resources (www.devdelay.org)

Generation Rescue (www.generationrescue.org)

Life Health Choices (www.lifehealthchoices.com)

Maryland Coalition for Vaccine Choice ([http.mdvaccinechoice.wordpress.com](http://mdvaccinechoice.wordpress.com))

Medical Voices Vaccine Information Center ([http.medicalvoices.org](http://medicalvoices.org))

National Autism Association (www.nationalautismassociation.org)

National Vaccine Information Center (www.nvic.org)

New Jersey Coalition for Vaccination Choice ([http.njvaccinationchoice.org](http://njvaccinationchoice.org))

New York Alliance for Vaccination Choice (website in formation)

The Coalition for Safe Minds (www.safeminds.org)

Schafer Autism Report (www.sarnet.org)

Talk About Curing Autism (www.talkaboutcuringautism.org)

Unlocking Autism (www.unlockingautism.org)

Wisconsin Vaccine Information Center ([http.wisvic.org](http://www.wisvic.org))