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 FOR PETITIONERS-APPELLANTS

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Cedillo v. HHS

No. 2010-5004

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Ronald C. Homer certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Theresa Cedillo and Michael Cedillo, as Parents and Natural Guardians of, Michelle Cedillo

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Kevin P. Conway
Sylvia Chin-Caplan

11 3 09
Date

Signature of counsel

Ronald C. Homer
Printed name of counsel

Please Note: All questions must be answered

cc: _____

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STATEMENT OF RELATED CASES

No appeal of this case has been before any other court. However, *Hazlehurst v. Sec'y of HHS*,[1] also a "test case" in the Vaccine Program's Omnibus Autism Proceeding ("OAP"), is pending before this court.

[1] 88 Fed.Cl. 473 (USCFC 2009), *appeal docketed*, (Fed. Cir. 2010) (No. 03-654; renumbered No. 2009-5128).

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I. JURISDICTION

This Court has jurisdiction to review the judgment of the United States Court of Federal Claims under 42 U.S.C. § 300aa-12(f).[2] The United States Court of Federal Claims issued its final judgment on August 7, 2009. A168. A Notice of Appeal was docketed with this Court on October 7, 2009, within the time period allowed by § 12(f). A194.

[2] The Vaccine Act, which established the Vaccine Injury Compensation Program, is located at 42 U.S.C. § 300aa-1 *et seq.* Individual sections to the Act will include only the section number.

II. STATEMENT OF THE ISSUE

Whether the United States Court of Federal Claims erred in upholding the findings of fact and rulings of law made by the special master.

III. STATEMENT OF THE CASE

A. Nature of the Case

The petitioner, Michelle Cedillo ("Michelle"), alleges a measles-mumps-rubella ("MMR") vaccine substantially contributed to her inflammatory bowel disease ("IBD"), brain damage, and autism. She filed a claim in the Vaccine Program seeking compensation for her injuries. A special master dismissed her petition, the Court of Federal Claims affirmed, and Michelle now appeals to this Court.

B. Course of Proceedings and Disposition of the Court Below

On December 9, 1998, at four years of age, Michelle filed a petition alleging that an MMR vaccine caused brain damage. A171. By 2001, Michelle and the respondent had each filed an expert report, and her case was ripe for hearing. A173-A174. In July of 2002, however, the Chief Special Master initiated the OAP.[3] He did so in response to a flood of petitions filed by autistic children.[4]

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[3] A499-A506. The docket of the OAP, or "Autism Master File" is *available at* http://www.uscfc.uscourts.gov/node/2718. A495–A498.

[4] As of April 23, 2008, 4,900 autistic children have filed claims. *See* A547-A554.

Initially intending to file civil lawsuits against vaccine manufacturers,[5] these children discovered they were required by law to first process their claims in the Vaccine Program.[6] Michelle, who is autistic, joined the OAP.

In 2007, Michelle volunteered to be the first "test case" in the OAP to determine whether the MMR vaccine caused her injuries.[7] In June of 2007, Michelle's evidence[8] was presented to a panel of three special masters ("the

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[5] The civil "tort" theory was that it was negligent for vaccine manufacturers to use Thimerosal (i.e. ethyl mercury) as a preservative in childhood vaccines. Michelle, for example, during her first few months of life, was injected with 100 times the Environmental Protection Agency's safety level for mercury exposure for adults. A259-A262.

[6] The Vaccine Act requires a person with a vaccine-related injury to file a petition in the Vaccine Program before proceeding in either state or federal court. § 11(a)(2)(A). Civil plaintiffs with autism who have filed in state and federal courts have been routinely directed to the Vaccine Program in accordance with § 11(a)(2)(B). *See*, for example, *Owens v. American Home Products Corp.,* 203 F.Supp.2d 748 (S.D. Tex. 2002).

[7] Two additional test cases followed. *See Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332258 (USCFC Spec. Mstr. Feb. 2009); 88 Fed.Cl. 473 and *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (USCFC Spec. Mstr. Feb. 2009). The *Hazlehurst* appeal is before this Court. Colten Snyder chose to abandon his appeal to file a civil action.

[8] Michelle's evidence consisted of her medical records, affidavits, written and oral opinions of a toxicologist, an immunologist, a gastroenterologist, a microbiologist, a molecular biologist, a pediatric neurologist, biochemists, and extensive scientific literature in support of these opinions.

Tribunal").[9] A182-A183. She presented evidence that: (1) she was born healthy; (2) had normal development and met all milestones; (3) received the recommended childhood vaccinations, including twelve (12) Thimerosal containing vaccines ("TCVs");[10] (4) the TCVs damaged her immune system; (5) the subsequent MMR vaccine further damaged her immune system; (6) she experienced fevers in excess of 105 degrees due to the MMR vaccine; and (7) she was unable to clear the measles virus ("MV") contained in the MMR vaccine due to her immune deficiency. In consequence, Michelle demonstrated, the MV persisted and replicated.[11] This was proven by a Unigenetics ("the O'Leary lab") test result that found Michelle's gut tissue positive for vaccine-strain measles virus years after the inoculation. A220. The persisting MV, Michelle showed, caused her IBD, inflammation in her brain, and autism. In further support of her theory, Michelle presented her medical records, showing that her treating physicians documented

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[9] During the years 2002 through 2006, Special Master George L. Hastings, Jr. managed the OAP. On January 11, 2007, however, the Chief Special Master assigned two (2) additional special masters, Denise K. Vowell and Patricia E. Campbell-Smith, to assist Special Master Hastings. Subsequently, over Michelle's objection, the special masters decided they would hear and consider, as a group, all of the evidence in Michelle's case, but that only Special Master Hastings would write the decision. *See* A531-A546. Special Master Vowell was assigned to conduct the hearing in *Snyder* and Special Master Campbell-Smith was assigned to *Hazlehurst.*

[10] Thimerosal consists of 49.6% ethyl mercury.

[11] Replication: "[a]utoreproduction or duplication, as in mitosis or cellular biology." STEDMAN'S ELECTRONIC MEDICAL DICTIONARY (Lippincott Williams & Wilkens, 27th ed. CD-ROM, 2000), or *available at* http://www.stedmans.com/section.cfm/45.

her normal development, then immediately and consistently associated her injuries with, and only with, her MMR vaccine. She also provided the testimony of her mother, Theresa Cedillo, and expert testimony supported by hundreds of scientific articles.[12]

In response, the respondent presented the opinions of seventeen (17) expert witnesses, all of whom denied that vaccines can contribute to autism. On February 12, 2009, Special Master Hastings dismissed Michelle's petition. A105. In so doing, he "concluded that the evidence was overwhelmingly contrary to [Michelle's] contentions." A1.[13] Michelle moved for reconsideration. A192; *see*

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[12] Michelle argued that her burden is simply to show that the MMR vaccine harmed her. However, the court and the respondent hoped that the decision would have wide application with respect to other autistic children in the OAP. For this reason, Michelle chose a theory that implicated the TCVs as well as the MMR vaccine, which does not contain Thimerosal. She alleged that TCVs damaged her immune system. This, in turn, prevented her immune system from clearing the injected measles virus and allowed it to persist, replicate, and cause her IBD and autism. To meet her burden, Michelle argued that she did not need to prove that the TCVs harmed her. She needed only to show that her MMR vaccine harmed her. In this regard, as the Court of Federal Claims has noted, petitioners "are merely required to show that the vaccine in question caused them injury. . . ." *Kelley v. Sec'y of HHS*, 68 Fed.Cl. 84, 100 (USCFC 2005).

[13] In a 143 page decision, the special master found TCVs do not harm the immune system (A14); Michelle's immune system was not damaged (A20); the O'Leary lab result was not reliable (A23-A24); MMR vaccine does not cause autism (A52); autism is due to a malformation of the brain during the *prenatal*, not *postnatal*, period (A58-A59); Michelle was autistic *before* she received the MMR (A75); the MMR vaccine cannot cause chronic gastrointestinal problems (A79); Michelle does not have IBD (A90); Michelle's treating physicians did not offer substantial evidence that her MMR vaccine harmed her (A99-A100); and Michelle failed all three prongs of the *Althen* test. (A104); *Althen v. Sec'y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005). The *Hazlehurst* and *Snyder* decisions, issued the same day, dismissed the petitions for the same reasons.

A458-A478. She argued that new evidence not available at the time of her hearing was worthy of his consideration.[14] When the special master denied her motion, Michelle moved for review by the Court of Federal Claims in accordance with § 12(e). A192. She argued that the special master had not only refused to consider her medical records, her mother's testimony, her expert testimony, and relevant scientific literature, but also had completely ignored the substantial concessions made by the *respondent's* experts and new evidence filed with her motion for

[14] In her motion, Michelle reminded the special master that she only had 30 days to move for review of his lengthy, science-laden decision. She asked him to withdraw it, even temporarily, to consider new evidence that had emerged in the 20 months since the hearing. A460-A461. She filed a new textbook chapter edited by the respondent's expert Dr. Zimmerman that provided overwhelming support for Michelle's medical theory and her proposed mechanism of injury. In stark contrast to the findings of the special master, the textbook demonstrates that it is now the scientific consensus that *post-natal* environmental factors can cause autism; that the critical period is the first two post-natal years; that the immune and gastrointestinal systems are implicated; that symptoms of autism may be triggered by infections or *immunizations;* and that autopsies show *neuroinflammation* in the brains of autistic persons. *See* A461-A472. In addition, Michelle filed compelling new evidence with respect to the reliability of the O'Leary lab, a new study that included labs from Columbia University, the *respondent's* Centers for Disease Control, and *Dr. O'Leary's* lab. All three labs studied the gut tissue of autistics. *All three successfully recovered measles RNA.* Once again, in direct contrast to the harsh criticism of the special master (A23-A52), this proved that the O'Leary lab's operating techniques were valid. A472-A473. Michelle also advised the special master that his conclusion that the O'Leary Lab was unreliable was based, in large part, on the testimony of the respondent's expert, Dr. Rima, in *Snyder.* Michelle filed the affidavit of Dr. Ronald Kennedy, who demonstrated that Dr. Rima had made a major mathematical calculation error with respect to a critical aspect of her lab result. A477; *See* A491. Finally, Michelle submitted updated medical records conclusively demonstrating, again contrary to the findings of the special master, that Michelle indeed has IBD. A475-A476. The special master denied the motion three (3) days after it was filed. A192; A492-A494.

reconsideration. On August 6, 2009, the Court of Federal Claims denied her motion. A167. Michelle now requests further review by this Court.

IV. STATEMENT OF FACTS

Michelle was born healthy on August 30, 1994. A216. She received an MMR vaccine on December 20, 1995. A228. At that time, she had a good appetite and slept well. A206. No problems were noted. A206. Seven days later, however, "[Michelle] developed a fever. . .that would spike up to 105 or over and then come back down with Tylenol and then go back up, come back down." A263. Michelle's mother was told "a very bad flu [was] going around. . . ." A263. Michelle's high fever returned. The January 6, 1996 pediatric notes stated, "105.7° today. Started with cough yesterday. Gagging to point of vomiting. Tylenol at 8:30 am. . . .[Assessment]: sinusitis vs. flu." A205. The note also reports that Michelle "**had fever and rash last week, 1 week after MMR**." A205 (emphasis added).

On March 15, 1996, Michelle's pediatrician stated, "[r]ash to face & neck [times] 2 ½ weeks. Walking, runs. **Talking less since ill in Jan[uary]**. . . ." A205 (emphasis added).

During the subsequent months, Michelle did not improve. On May 2, 1997, at the age of thirty-three (33) months, Dr. William Masland, a neurologist, wrote:

> [Michelle's] neonatal period was unremarkable. She started crawling about nine months and walking at 16 months. She also was using

> single words at the time, **at 16 months she developed a fever of 105+, that lasted for four days. This occurred two weeks after immunization. The fever went down, stayed away for a week and then recurred to 104 to 105 degrees for three or four days. Since then she lost her ability to verbalize and has continued with repetitive movement**. When I saw her she was relatively unresponsive to verbal stimuli. . . .**It would appear that there was some neurological harm done at the time of the fevers. Whether this was a post-immunization phenomenon or a separate occurrence, would be very difficult to say**. . . .**Given the overall history**, **it would appear the neurological problem now is dependent upon the febrile episodes and is not a structural or systemic problem, such as a chromosomal abnormality or one of the inborn errors of metabolism.**

A221 (emphasis added).

On May 20, 1997, Michelle was examined for suspected speech and/or language delay. The report stated, "**Michelle was said to have reached the major developmental milestones on time up to the age of sixteen months when she received vaccinations for measles, mumps, and rubella. At that time, she suffered two high fevers. . . .**" A198 (emphasis added).

On July 21, 1997, Karlsson Roth, Ph.D., a developmental psychologist, examined Michelle and recorded:

> She was discharged home at 24 hours of age, feeding and growing well. She has never had an episode of otitis media. She has been very healthy with the exception of one cold. **This child had a MMR at around 15 months of age, after which she had two separate bouts of high fevers from 103 to 105. This was then followed by a mild fever, after which the youngster began to cut eight teeth at once. This child also has had a rash around her mouth which followed this episode, and the parents got an air purifier and/or humidifier which seems to have helped. The child took only liquids for three**

> **weeks, and it was after this time that they noticed a complete change in her development**. . . .**Michelle appears to meet criteria for a diagnosis of Autism**. . . .

A199-A204 (emphasis added).

On August 6, 1997, Michelle's measles titer tested positive. A218-219.

That day, Dr. Sudhir Gupta, an immunologist, observed:

> 3 [year old] young girl (1st child) born full term. Normal delivery 8 lbs, normal reflexes. **Developed normal. She received her MMR at 16 month - 2 days later fever of 105° F. No infection was found. This followed by rash on the face and trunk. Then she stopped talking. She became afraid of strangers**. . . .Impression:
> ? Autism. . . .

A195-196 (emphasis added).

On August 7, 1997, Dr. Ira Lott, a pediatric neurologist, wrote:

> **Until about 15 months of age, Michelle was described as entirely normal. At that time she had multiple single words, perhaps as many as 10. She then had an 'MMR immunization' followed by a viral illness with high fever. It was then noted that she had lost her words**. . . .

A222-A223 (emphasis added).

On October 31, 1997, Dr. Gupta wrote to Michelle's parents:

> [W]e have done the immunological testing that shows that Michelle has **almost** normal immune functions. . . .As far as vaccination is concerned, vaccinations can be postponed based on the laboratory data that shows that Michelle has significant amounts of antibodies to various vaccines that she is supposed to get**. Based on that, she could get medical exception to the vaccination requirements of the school system**.

A217 (emphasis added).

Catherine Brown of the San Diego State University Communications Clinic examined Michelle on May 28, 1998. She stated:

> **After her measles-mumps-rubella (MMR) vaccination at 17 months Michelle developed a high fever and was ill for some time. Following that incident, Michelle's behavior changed dramatically and communication development has not progressed since that time. . . .*Summary and Conclusions*[:] Michelle** demonstrates a severe delay in both language comprehension and language production secondary to moderate-severe autism.

A224-A225 (emphasis added).

B.J. Freeman, Ph.D., performed a neuropsychiatry exam on May 13, 1999. The report stated:

> **The parents reported that language development was normal until approximately fifteen months of age. At that time, she received her 'MMR immunization' and soon after evidenced significant delays in language development including loss of single words previously obtained** . . . .

A226-A227 (emphasis added).

In 2000, Michelle participated in a several-month study at the Southwest Autism Research Center. On October 29, 2000, Dr. Cindy Schneider, Medical Director,[15] wrote the following detailed report:

> Michelle received her first and only MMR vaccination on December 20, 1995, at the age of 15 3/4 months. . . .She was seemingly in good health at the time of vaccination. . . .Michelle was seen again on

[15] Dr. Schneider, board certified in obstetrics and gynecology, is a specialist in autism. *See* A210-212. Although she was not a paid expert, her report was filed in support of Michelle's petition. *See* A207-A209.

> January 6, 1996. She was reported to have had a fever of 105.7. . . . Note is made of a fever and rash the previous week, which was one week post-vaccination. . . .**In summary, Michelle Cedillo's records support that the first evidence of illness occurred approximately one week following MMR vaccination. This fever was associated with a rash, gagging, vomiting, and profound changes in cognitive awareness and developmental skills. This acute encephalopathy resulted in a complete loss of language as well as the development of multiple gastrointestinal symptoms, which plague Michelle to this day. This presentation is consistent with autistic enterocolitis, a condition associated with chronic gastrointestinal inflammation, constipation, and autistic regression. . . .There is increasing evidence that this is an autoimmune disease characterized by anti-epithelial antibodies as well as the presence of vaccine-strain measles RNA. It is my medical opinion that Michelle not only suffers from the neurological devastation of autism, but also the chronic gastrointestinal disease associated with it. Both conditions, in all probability, resulted from MMR vaccination.**

A207-A209 (emphasis added).

On January 31, 2002, an O'Leary lab report was **positive for measles virus**. A220 (emphasis added).

V. STANDARD OF REVIEW

The Federal Circuit may review "findings of fact and conclusions of law of the United States Court of Federal Claims. . . ." § 12(f). In this regard, the Federal Circuit has stated, questions of law are to be reviewed "under the 'not in accordance with law' standard." *Munn v. Sec'y of HHS*, 970 F.2d 863, 870, n.10 (Fed. Cir. 1992). When reviewing legal issues, the Federal Circuit stated, it need pay no deference whatsoever to decisions below concerning such conclusions of law. Thus, "[i]ssues of law-constitutional imperatives, statutory construction,

procedural requirements-come to us for decision with little if any deference owed to or expected by the forums below." *Id*. at 870.

VI. SUMMARY OF THE ARGUMENT

In 1988, vaccine manufacturers threatened to stop making vaccines due to the cost of adverse verdicts and the defense of lawsuits. Congress responded by establishing a federal vaccine compensation program. It did so to encourage manufacturers to continue making existing vaccines and to develop new ones. Under the federal program, vaccine-injured persons are prohibited from filing civil lawsuits until they have processed their claims in the Vaccine Program. Although injured persons do retain the right to sue if dissatisfied with the Program, congress made "post-Program" civil lawsuits more difficult by requiring multi-phased trials and by limiting theories of liability against manufacturers.

Congress also sought to limit civil lawsuits by making the federal program an attractive alternative to contentious, costly, extended civil litigation. Thus, congress created an informal, speedy, generous, "no fault" program with relaxed evidentiary standards.[16] Congress declared that discovery would be the exception, not the rule, unlike in the onerous civil litigation system. To date, the Program has

[16] The Program is funded by a special tax on each vaccination. At this time, the fund has in excess of $3.1 billion dollars available to compensate injured persons. The fund is expected to grow by $200 million this fiscal year. *See* TREASURYDIRECT, *available at* www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm.

been successful. People have been compensated for a wide variety of injuries. Manufacturers, protected from lawsuits, have continued making vaccines and have developed several new ones.

For Michelle, however, the Program has not been a success.[17] It has been a disaster. For Michelle, the program has not been generous. It has not been speedy. It has not been informal. For her, the rules and due process were suspended. For her, fairness was jettisoned. Indeed, Michelle has been treated far differently than any of the thousands of petitioners who have preceded her. In a typical vaccine case, for example, each party has one expert witness. In Michelle's case, however, seventeen (17) experts rendered opinions against her. A typical trial lasts one (1) day. In Michelle's case the respondent presented testimony against her for twenty-one (21) days. In a typical trial, petitioners need to persuade only one (1) special master. Michelle, however, unlike any petitioner before her, had to persuade a

[17] Unfortunately, Michelle did not file her petition until 1998. Had she filed it before 1995, the respondent may well have *conceded* that she suffered an "on-Table" encephalopathy presumptively caused by the MMR vaccine. In this regard, the Vaccine Table presumes an MMR vaccine causes an encephalopathy if the onset of symptoms occurs within "5-15 days" after the vaccine. § 14. Prior to 1995, the word encephalopathy was interpreted as any general type of brain injury. In 1995, however, the respondent attached unattainable conditions to the term "encephalopathy." *See* § 14, Qualifications and Aids to Interpretation, (2) Encephalopathy. In *Andreu v. Sec'y of HHS*, 569 Fed.3d 1367, 1374 (Fed. Cir. 2009), this Court found this fact relevant.

Tribunal of special masters, a judge of the Court of Federal Claims, and the Federal Circuit.[18]

Why was Michelle treated differently? The answer is apparent. It is because she alleges that vaccines caused her *autism*. In this regard, some background is appropriate. Prior to the inception of the Vaccine Program in 1988, children received seven vaccines in three shots, the diphtheria-pertussis-tetanus ("DPT"), the MMR, and the polio vaccines. Since then, however, new vaccines have been developed. American school-aged children now are required by law to receive not only the MMR, DPT, and polio vaccines, but also the hepatitis A ("hep A"), hepatitis B ("hep B"), varicella, rotavirus, *haemophilus influenzae* ("Hib"), and pneumococcal vaccines. Since 1988, there also has been an explosion in the number of American autistic children. Indeed, Michelle is only one of 5,000 autistic children who allege the unthinkable - that vaccines have contributed to their autism.

Unfortunately for Michelle and the other autistic children, this issue is highly newsworthy. Indeed, Michelle's case has been repeatedly reported by every major newspaper, television station, radio station, and magazine in the country. In Michelle's view, this publicity caused the respondent great concern that the public

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[18] The Chief Special Master announced at the outset that Michelle could not be compensated without the blessing of the Federal Circuit. *See* A499-A506.

would question the safety of vaccines, thereby posing a threat that immunization rates would fall. In Michelle's view, due to the publicity given to her case, she became a threat to our national immunization policies. In her view, she was denied compensation because she is a messenger. She was denied compensation because she is autistic.[19]

In Michelle's view, the Tribunal ignored not only her considerable, albeit circumstantial, evidence that a persisting vaccine-strain measles virus caused her IBD, her brain damage, and her autism, but also ignored the very substantial *concessions* by the *respondent's* experts supporting her theories of injury. In Michelle's view, they did so because of the intense national publicity her case has received. In Michelle's view, they did so to assure the American public that vaccines are safe. They did so because they view their roles as protectors of the integrity of our nation's vaccines. However, Michelle submits, this is the role of the respondent, *not* a special master or a Tribunal of special masters.

In an address to the Advisory Commission on Childhood Vaccines ("ACCV") in March of 2008, the Court of Federal Claims Chief Special Master Gary J. Golkiewicz recognized that the interplay of various competing policy

[19] To persuade a British Court to release the expert reports of Drs. Bustin, Rima, and Simmonds (but **not** the claimants corresponding expert reports), the respondent threatened the Court that American immunization rates would fall unless Michelle's claim was defeated. *See generally* Sayers v. Smithkline Beecham Plc, (2007) EWHC 1346 (QB), 2007 WL 2041770.

considerations plays a considerable role in defining the Vaccine Program's causation standard. He stated:

> [D]epending on your respective goal, the standard of causation [in the Vaccine Program] could look very different. . . .It's important to understand whether you're promoting a policy based standard of causation or a traditional tort based standard. . . .If you believe that the causation standards are correctly tort based, you may take issue with several of the recent Federal Circuit opinions discussing the appropriate causation standard to apply in vaccine cases. . . .If you believe the causation standard should be policy based, you have to determine what your primary policy objective is.
>
> 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.

A566-A575.

In Michelle's view, the Tribunal, to protect vaccine integrity in a very public case, chose to impose upon Michelle an unattainable standard of proof. To protect the vaccine's integrity, they rejected ***all*** of Michelle's credible evidence, rejected ***all*** of the respondent's substantial concessions, and blindly accepted the conclusions of the respondent's seventeen experts. In so doing, Michelle submits,

the Tribunal members shirked their roles as impartial jurists, denied Michelle the fundamental fairness required by the Vaccine Rule 8(b)(1),[20] ignored congressional intent in establishing the Vaccine Program, and rejected the Federal Circuit's interpretation of that intent. For Michelle's special master to have done so in his decision, and for Judge Wheeler to have affirmed, was arbitrary, capricious, an abuse of discretion, and not in accordance with law. Sadly, if upheld by this Court, the result will drive thousands of autistic children into the civil arena — precisely the result congress sought to avoid.[21]

VII. ARGUMENT

A. Purpose of the Vaccine Program

Prior to the Vaccine Program, civil lawsuits against vaccine manufacturers abounded. In 1988, due to the crippling costs of litigation, vaccine manufacturers threatened to stop making vaccines, the nation's health programs were threatened, and a crisis ensued. To address these concerns, congress established the Vaccine

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[20] Vaccine Rule 8(b)(1) requires special masters to exercise "fundamental fairness" when considering evidence.

[21] Prior to 2001, infants like Michelle were administered vaccines containing the preservative Thimerosal (i.e. ethyl mercury) on 10 separate occasions. Although the special master and Judge Wheeler characterized this as a small amount, *each injection* contained amounts ***30 times the Environmental Protection Agency's safe level for adults***. This gross error by manufacturers, now corrected, will surely form the basis for hundreds of suits by autistic children whose claims are not resolved in the Vaccine Program. A576-A577.

Program. Congress hoped the Program would lessen the number of lawsuits against manufacturers and promote the "development of both new and improved vaccines. . . ." H.R. Rep. No. 99-908, 99th Cong., 2d. Sess., page 4 (1986). It also hoped to create "a new system for compensating individuals who have been injured by immunizations routinely administered." *Id*. at 3. Such awards, congress intended, would "be made to vaccine-injured persons quickly, easily, and with certainty and generosity." *Id*. at 18.

Prior to enacting the Vaccine Act, congress also recognized the uncertainty of the existing science about whether vaccines were even capable of causing serious injuries. However, congress realized, this "uncertainty" of the science did not stop civil lawsuits against vaccine-manufacturers. At the same time, congress was loath to pre-empt all rights to file civil litigation against vaccine manufacturers. For this reason, congress balanced these competing interests and established a permissive standard of proof that would encourage the resolution of cases in the Vaccine Program. Thus, an excerpt from the legislative history of § 13 states:

> The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.[22]

[22] Due to this stated congressional intent, courts have held that "close questions of causation must be resolved in favor of the petitioners." *McClendon v. Sec'y of*

Shyface v. Sec'y of HHS, 165 F.3d 1344, 1351 (Fed. Cir. 1999) (citing H.R. Rep. No. 99-908 at 18)**.**

B. Sufficiency of Evidence Necessary to Prove a Vaccine Program Claim

This Court has addressed the sufficiency of evidence necessary to prove a Vaccine Program claim. In *Althen v. Sec'y of HHS*, the Court described a petitioner's burden as simply providing: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." 418 F.3d at 1278. Commenting on the quantity and quality of proof necessary, the Court stated: "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof [as to] how vaccines affect the human body." *Id*. at 1280. Indeed, the Court said, due to the very absence of direct scientific evidence in this field, congress encouraged "the use of circumstantial evidence" and envisioned that "close calls regarding causation [would be] resolved in favor of injured claimants." *Id*. In *Capizzano v. Sec'y of*

HHS, 24 Cl.Ct. 329, 334 (USCFC 1991); s*ee also Althen*, 418 F.3d at 1280.

HHS,[23] the Federal Circuit commented upon the evidentiary value of the recorded statements of a petitioner's treating physicians. This Court determined:

> *Althen III* explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.' 418 F.3d at 1280; *see also* 42 USC § 300aa-13(a)(1).

Capizzano, 440 F.3d at 1326.

C. Past Vaccine Program Awards

i. Introduction

During the past decade, the publicity afforded to the issue of whether vaccines can cause autism has been intense. In Michelle's view, due to this publicity, both the respondent and the special masters feared that a finding in her favor would drive down immunization rates. For this reason, to protect the integrity of vaccines, Michelle's case, a so-called "test" case, was treated far differently than other vaccine program petitioners. Disregarding the Federal Circuit's recent decisions in *Althen* and *Capizzano*, the Tribunal instead invoked standards from *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[24] and found all of Michelle's evidence unreliable. For her special master to do so, Michelle submits, was fundamentally unfair. She was entitled to equal treatment.

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[23] 440 F.3d 1317 (Fed. Cir. 2006).
[24] 509 U.S. 579 (1993).

There is no direct scientific proof, Michelle concedes, that vaccines cause autism. As the Federal Circuit noted in *Althen*, the field is "bereft" of science in this area. 418 F.3d at 1278. However, she submits, substantial *circumstantial* evidence, albeit indirect evidence, supports such a link. Indeed, Michelle says, similar circumstantial evidence, preponderant evidence, consisting of the statements of treating physicians in medical records, expert opinions, scientific literature, and concessions by the respondent's experts, has been sufficient to support compensating a wide variety of injuries in the Program. In this regard, Michelle is sure, each of the respondent's seventeen experts in her case would deny that vaccines are capable of causing any of the below-cited injuries. There is simply no scientific proof. However, Michelle submits, all of the below petitioners were compensated in the Vaccine Program because of the Program's relaxed standards of proof. All were compensated because they, like she, presented preponderant evidence, legally sufficient evidence, that a vaccine injured them.

ii. <u>Vaccine Program Awards</u>

Medical records, affidavits, expert testimony, and scientific articles, all based on circumstantial evidence alone, have established that vaccines have caused:

- Optic neuritis and acute-disseminated encephalomyelitis caused by tetanus vaccine;[25]
- Multiple sclerosis ("MS") caused by tetanus vaccine;[26]
- MS due to hep B vaccine;[27]
- Transverse myelitis ("TM") due to hep B vaccine;[28]
- Guillain-Barré Syndrome ("GBS") due to hep B vaccine;[29]
- Chronic inflammatory demyelinating polyneuropathy ("CIDP") due to hep B vaccine;[30]
- CIDP due to tetanus vaccine;[31]
- Intractable seizures due to DPT vaccine[32] and diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccine;[33]

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[25] *Althen*, 418 F.3d 1274.

[26] *Rogers v. Sec'y of HHS*, No. 94-89V (USCFC 2000).

[27] *Werderitsh v. Sec'y of HHS*, No. 99-310V, 2006 WL 1672884 (USCFC 2006).

[28] *Stevens v. Sec'y of HHS*, No. 99-594V, 2006 WL 659525 (USCFC 2006).

[29] *Peugh v. Sec'y of HHS*, No. 99-638V (USCFC Order dated April 21, 2006).

[30] *Gilbert v. Sec'y of HHS*, No. 04-455V, 2006 WL 1006612 (USCFC 2006).

[31] *Kelley*, 68 Fed.Cl. 84.

[32] *Andrews v. Sec'y of HHS*, 33 Fed.Cl. 767 (USCFC 1995).

[33] *Paulmino v. Sec'y of HHS*, No. 03-2190 (USCFC 2006).

- Death due to DPT vaccine;[34]
- Scarring due to DPT vaccine;[35]
- Hemolytic anemia due to DPT vaccine;[36]
- TM due to DTaP vaccine.[37]

In one case relevant to Michelle, a special master determined that a DPT triggered familial hemophagocytic lymphohistiocytosis ("FLH"), an inherited immune deficiency.[38]

The MMR vaccine, special masters have found, was the legal cause of the following off-Table *neurological injuries***:**

- Acute disseminating encephalomyelitis ("ADEM");[39]
- TM with resulting paraplegia;[40]

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[34] *Shyface*, 165 F.3d 1344.

[35] *Blankenship v. Sec'y of HHS*, No. 01-273V (USCFC 2002).

[36] *Brown v. Sec'y of HHS*, No. 99-044V, 2000 WL 1207255 (USCFC 2000).

[37] *Herkert v. Sec'y of HHS*, No. 97-518V, 2000 WL 141263 (USCFC 2000).

[38] *Gall v. Sec'y of HHS*, No. 91-1642V, 1999 WL 1179611 (USCFC 1996).

[39] *Tufo v. Sec'y of HHS*, No. 98-108V, 2001 WL 286911 (USCFC 2001).

[40] *Lodge v. Sec'y of HHS*, 92-697V, 1994 WL 34609 (USCFC 1994).

- TM;[41]
- GBS;[42]
- Seizure disorder;[43]
- Attention deficit disorder, encephalopathy, learning disabilities, and behavioral problems;[44]
- Mental retardation in a child who became autistic;[45]
- ADEM and resulting Pervasive Developmental Delay/Not Otherwise Specified ("PDD/NOS");[46]

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[41] *Rodriguez v. Sec'y of HHS*, 67 Fed.Cl. 409 (USCFC 2005).

[42] *Tufo,* 2001 WL 286911.

[43] *Freeman v. Sec'y of HHS*, 01-390V, 2003 WL 22424999 (USCFC 2003).

[44] *Blanks v. Sec'y of HHS*, 91-0428V (USCFC 1997)(approved stipulation agreement).

[45] *Freeman v. Sec'y of HHS*, 01-390V, 2003 WL 22424999 (USCFC 2003).

[46] *Banks v. Sec'y of HHS*, No. 02-738V, 2007 WL 2296047 (USCFC 2007). In *Banks*, the special master ruled that PDD/NOS, unlike Pervasive Developmental Delay ("PDD") is not a condition on the autism spectrum. Instead, citing the Yale Child Study Center's Developmental Disabilities Clinic Webpage at http://www.med.yale.edu/chldstdy/autism/pddnos.html, he ruled, PDD/NOS is a condition in which some, but not all, features of autism are identified. It is referred to as "atypical autism." The condition encompasses "cases where there is marked impairment of social interaction, communication, and/or stereotyped behavior patterns or interests, but when full features of autism. . .are not met." *Id*. at 2, n. 4.

- Autistic-like symptoms in a child with an underlying mitochondrial disorder;[47]
- Significant aggravation of an underlying, perhaps genetic, encephalopathy.[48]

In each of the above cases,[49] as in Michelle's case, the respondent's experts flatly denied that a vaccine was capable of causing the injury.[50] Certainly,

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[47] In *Poling ex. rel. Poling v. Sec'y of HHS*, No. 02-1466V, 2008 WL 1883059 (USCFC 2008), the respondent reportedly agreed to compensate Hannah Poling, a child with an underlying mitochondrial disorder, because vaccines caused her autism. *See Vaccine Case Draws New Attention to Autism Debate*, *available at* www.cnn.com/2008/HEALTH/conditions/03/06/vaccines.autism/. Although the Poling family has sought to make the details of the government's concession available to the public, especially to the thousands of autistic children in the OAP, the respondent has fiercely resisted the family's effort. To date, the special master has not ruled on this motion. Michelle has cited the *Poling* case for several reasons. First, the respondent has purportedly conceded, at least in one case, that vaccines *can* cause autism. Second, the *Poling* case highlights the fears of both the respondent and the special masters on Michelle's Tribunal that releasing such information will undermine the integrity of vaccines, lower immunization rates, and cause preventable illnesses to return. Finally, the *Poling* special master's unprecedented refusal to release such government information evidences the Tribunal's overriding objective – to protect the integrity of the vaccines - and explains why Michelle was denied the fundamental fairness granted to other petitioners.

[48] *Wilkerson v. Sec'y of HHS*, 90-0822V, 1998 WL 106132 (USCFC 1998) and *Zeller ex. rel. Zeller v. Sec'y of HHS*, No. 06-120V, 2008 WL 3845155 (USCFC 2008).

[49] Except in *Blanks v. Sec'y of HHS*, 91-0428V (USCFC 1997), where the parties entered into an approved court stipulation agreement.

[50] Indeed, Michelle again states, in all likelihood, none of these petitioners would have survived a *Daubert* hearing in the civil arena. *Daubert* interprets the Federal Rules of Evidence, rules that do not apply, for policy considerations, in the Vaccine Program. *See* Vaccine Rules of the United States Court of Federal Claims, Rule 8(c).

Michelle agrees, there is no "general acceptance" in the medical community that vaccines can cause any one of the above-compensated injuries. Indeed, Michelle concedes, there is no direct scientific proof that any of these injuries were caused by a vaccine. However, each petitioner was successful. Like Michelle, each offered indirect evidence. Each offered preponderant circumstantial evidence. In Michelle's view, each successful petitioner offered evidence similar to her evidence. She was well; she received a MMR vaccine; she suffered symptoms of a brain injury at a medically appropriate time thereafter; her treating physicians suspected that her MMR vaccine caused this injury; and no other likely cause of her injury has been identified. However, Michelle submits, no other case was subjected to such extraordinary publicity. For this reason, Michelle submits, she was not afforded the "fundamental fairness" required by the Vaccine Rules. Instead, she was sacrificed to protect the integrity of vaccines.

D. The Use of a Tribunal to Hear the "General Causation" Issue in Michelle's Case Was Arbitrary, Capricious, an Abuse of Discretion, and Not in Accordance With the Law

On January 9, 2007, the Petitioners' Steering Committee ("PSC") proposed that Special Master George L. Hastings, Jr. hear a "test case."[51] Two days later, on January 11, 2007, the Chief Special Master assigned two new, recently appointed

[51] A507-A528.

special masters, Special Master Vowell and Special Master Campbell-Smith, to assist Special Master Hastings with the autism docket.[52] In this regard, the Chief Special Master stated, "the docket, which to-date has been overseen by Special Master George Hastings, will be divided roughly in equal numbers and assigned to the three special masters for further proceedings." A530. The Chief Special Master further stated:

> With three special masters hearing and deciding the test cases, the OSM is confident that the special masters' decisions discussing the legal and medical issues will educate fully the *Federal Circuit.* . .to issue opinions that guide the special masters in the resolution of the remaining cases.

A530 (emphasis added).

One week later, the Tribunal announced that they would consider, *as a group*, the "general causation evidence" in Michelle's case,[53] but that Special Master Hastings would consider the case-specific evidence alone and make an "independent" decision as to whether Michelle is entitled to compensation. A537. The PSC repeatedly objected to the appointment of the two additional special masters, stating that "multiple decisions by multiple Special Masters addressing nearly identical issues of law, fact, science and medicine. . .will generate

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[52] *See* A529-A530.

[53] At that time, Michelle's case had been selected as the first "test" case to be heard beginning on June 11, 2007. A531-A546.

significant confusion and delay at the appellate level, further slowing progress towards resolving claims in the omnibus." A540.

Having now reviewed the decisions of the special masters and the Court of Federal Claims in her case, as well as the decisions of the special masters in *Hazlehurst* and *Snyder*, Michelle submits that she had the burden of persuading not one but **three** special masters that her MMR vaccine injured her. No other petitioner in the Program's history has been saddled with such a burden. Indeed, no Article III trial court has ever imposed such a burden. To impose it on Michelle was an *ultra vires* act beyond the scope of the authority of the special masters. It violated the "fundamental fairness" requirement of Vaccine Rule 8(b)(1). For this reason, the Tribunal's decision to hear, as a group, the "general causation" evidence in Michelle's individual case was arbitrary, capricious, an abuse of the special masters' discretion, and not in accordance with law.

E. Michelle Was Denied the "Fundamental Fairness" Required by Vaccine Rule 8(b)(1)

i. <u>The Special Masters' Decision to Allow the Last-Minute Expert Reports and Testimony of Dr. Stephen Bustin Was Arbitrary, Capricious, and an Abuse of Their Discretion</u>

Incomprehensibly, the Tribunal was unfazed by the respondent's last-minute filing of a highly technical, long-existing report of a vaccine manufacturer's expert. In this regard, a critical part of Michelle's evidence is an O'Leary lab result showing the presence of persisting vaccine-strain measles virus in her gut tissue.

A220. The lab had performed similar tests in litigation in England, where claimants also claimed an MMR vaccine caused their autism. Years before Michelle's hearing, a British court permitted Dr. Bustin to inspect the O'Leary lab's notebooks with respect to eight (8) *British* claimants. In June of 2007, as Michelle's trial approached, Dr. Bustin's reports, as well as all expert reports for the claimants and the manufacturers in the British litigation, were under seal by the British Court. *See generally* Sayers v. Smithkline Beecham Plc, 2007 WL 2041770.

Michelle's hearing was scheduled to begin on June 11, 2007. On June 7, 2007, as Michelle's counsel was preparing for the direct testimony of her expert witnesses and for cross-examination of the respondent's experts, the respondent requested permission to file Dr. Bustin's British reports. A181-A182. Although Dr. Bustin's reports were unrelated to Michelle, they were generally critical of the techniques used by the O'Leary lab. At an emergency status conference on Friday, June 8, 2007, three days before her hearing, Michelle's counsel angrily opposed the introduction of these exhibits. A182. First, she argued, the reports addressed the reliability of the O'Leary lab, the single-most critical issue in the case. Next,

they were filed without notice on the eve of trial.[54] To permit these reports into evidence at that time, counsel argued, would be grossly unfair to Michelle, as her counsel and experts had no time to review them, let alone prepare for cross-examination of Dr. Bustin. These reports, counsel argued, were obtained only through the vastly superior financial resources, and combined efforts, of the respondent and the manufacturers. Worse, counsel argued, they were "cherry-picked" from scores of expert reports filed in the British litigation. Michelle's counsel requested a continuance. The Tribunal refused to continue the hearing, permitted the reports to be filed, allowed Dr. Bustin to testify (*see* A418-A448), then relied upon his testimony to dismiss her petition.[55] *See* A105; A181-182.

[54] At this conference, the respondent revealed that these confidential reports were "unsealed" only after an extraordinary, expensive, several-month covert effort. *See generally* Sayers v. Smithkline Beecham Plc, 2007 WL 2041770. Ironically, the petitioners' steering committee has asked Special Master Hastings three years earlier to subpoena these reports from Merck, an American manufacturer, but the special master had ***denied*** the request. In these circumstances, the respondent's surreptitious effort should have been condemned, not rewarded, by the Tribunal.

[55] Michelle was given time to find her own British counsel to seek to unseal other documents. This fact, however, does not cure the prejudice. The playing field was not even. The respondent, for example, had unlimited financial resources, the full assistance of attorneys with the Department of Justice who could counsel them to obtain extra territorial documents, the consent of the vaccine manufacturers, and the ability to hire British attorneys to unseal the Bustin reports.

Michelle invites the Court to review Dr. Bustin's power-point presentation at the hearing.[56] A418-A448. In his reports, Dr. Bustin stated he had the opportunity to examine a small sampling of the O'Leary lab notebooks — notations totally unrelated to Michelle or **any** petitioner in the OAP. In this regard, Michelle says, this small sampling formed the basis for the opinions of *three* British "manufacturers'" experts used by the respondent to attack the O'Leary lab. In sum, the Tribunal allowed highly technical, last-minute evidence, totally unrelated to Michelle, and used it to assist the special master in dismissing her petition, despite the fact that the O'Leary lab notebooks reviewed by these experts have never been unsealed in the British litigation and were unavailable for Michelle to inspect. The Tribunal's reliance on these materials is even more troubling in light of the ample evidence of the lab's reliability at the hearing and in her motion for reconsideration and in the absence of any dispute with respect to Michelle, because

[56] To demonstrate the complexity of this material, Dr. Bustin asked Special Master Hastings at the hearing whether he understood the testimony. Special Master Hastings said "no." A367. In the end, Dr. Bustin, unwittingly, helped Michelle. He attacked another British expert, Dr. Finbar Cotter, whose report the respondent had *neglected* to obtain. Dr. Cotter's lab, Dr. Bustin was forced to concede, had *replicated* the O'Leary lab's results of samples with substantial inflammation levels ("SILs"). A363-A364. For good reason, the respondent also "neglected" to obtain the key reports filed by Dr. O'Leary himself or by his molecular biologist, Dr. Shields.

her biopsy revealed a **substantial inflammation level** ("SIL").[57] *See generally* A458-A478.

ii. The Tribunal's Reliance on the Testimony of Dr. Rima in *Snyder* Was Fundamentally Unfair, Arbitrary and Capricious, an Abuse of Discretion, and Not in Accordance with the Law

At her hearing, Michelle presented *unrebuttable* evidence that the O'Leary lab's test results were reliable with respect to patients, like Michelle, with a SIL. The only dispute concerned O'Leary's test results with minimal inflammation levels ("MILs"). This critical evidence included the testimony of Michelle's experts, the evidence the respondent submitted by Dr. Oldstone, and the dramatic concession by Dr. Bustin. *See* n. 56, *supra*. At the hearing, once again, Dr. Bustin conceded that Dr. Cottor's lab had results consistent with the O'Leary's lab's results with respect to samples with SILs.[58] To "remedy" this problem, at the subsequent *Snyder* hearing, the respondent presented the testimony (and reports) of another British manufacturers' expert, Dr. Bertus Rima. Although Michelle's counsel was not present at *Snyder*, unaware that he would testify against Michelle, and not permitted to cross-examine him, Dr. Rima attempted to rebut this powerful

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[57] A SIL lab result is also referred to as one "with high copy numbers."

[58] The special master ignored this evidence. Judge Wheeler blindly accepted his conclusion, finding "no basis" to disturb the special master's conclusion that SILs are irrelevant. A153-A154. This was error.

aspect of Michelle's evidence. Her SIL, he said, was *too* high. It was implausible, he swore, and could only have resulted from contamination in the O'Leary lab. A559-A561. Despite the unfairness of this surprise testimony in *Snyder*, Special Master Hastings relied upon it when he dismissed Michelle's petition. A31-A36. Worse, he rejected her petition for reconsideration even when she pointed out to him that Dr. Rima's opinion was based upon a gross mathematical miscalculation. *See* A492-A494; A491.[59] For him to do so was error. For Judge Wheeler to have permitted him to do so was error.

F. The Special Master Abused His Discretion By Discounting the Opinions of Michelle's Treating Physicians

Michelle's medical records demonstrate that several of her treating physicians associated her illness with her MMR vaccine. These physicians

[59] Dr. Kennedy demonstrated that, in *Snyder*, Dr. Rima had made a division error when he testified that Colton Snyder's copy numbers (i.e. inflammation levels) of 3400 were unbelievably high. A491. When Dr. Rima divided 34,000 by 100, he mistakenly arrived at 3400, when the correct number should have been 340. A491. When Dr. Kennedy used Dr. Rima's formula to calculate Michelle's copy numbers (i.e. inflammation levels), he found them to be "very plausible." A491. Affirming the special master's decision, Judge Wheeler implied that Michelle waived this argument by failing to bring it to the special master's attention sooner. A163. This is grossly unfair and unjust. It was only when Michelle realized the importance that her special master would give this evidence, presented by a **different** expert, in a case by a **different** petitioner, heard by a **different** special master, that she felt the need to respond. In these circumstances, Michelle says, key evidence has been ignored and deference is unwarranted. In any event, Dr. Kennedy's affidavit remains a part of the record. Special Master Hastings commented upon all of the new evidence submitted by Michelle except Dr. Kennedy's affidavit! Judge Wheeler's failure to address this gross omission was clear error.

include: (1) Dr. Daniel Crawford, her pediatrician (A206); (2) Dr. William Masland, a neurologist (A221); (3) Dr. Lisa Shigio, an audiologist (A198); (4) Karlsson Roth, a developmental psychologist (A199); (5) Dr. Sudhir Gupta, an immunologist (A197); (6) Dr. Ira Lott, a pediatric neurologist (A222-A223); and (7) Dr. B.J. Freeman, a neuropsychologist (A226-A227). The special master, however, afforded these records absolutely no probative value. In this regard, Michelle concedes, these doctors did not ***conclude*** that her MMR vaccine had caused her autism. However, they should have been afforded significant probative weight that the vaccine likely harmed her. *Capizzano*, 440 F.3d at 1326. In these circumstances, the special master abused his discretion by affording no weight to the statements of treating physicians in Michelle's medical records. Judge Wheeler's blind acceptance of this finding was error.

G. The Special Master Abused His Discretion By Ignoring Concessions By the Respondent's Expert Witnesses

i. Introduction

The special master rejected the opinions of Michelle's experts who testified that her measles vaccine substantially contributed to her IBD, brain damage, and autism. Instead, he accepted all of the opinions of the respondent's seventeen (17) experts. Michelle did object to the gross unfairness of permitting the highly prejudicial, last minute, technical materials submitted by Dr. Bustin. However, in the end, the respondent's expert evidence was largely supportive of Michelle's

theory. In this regard, Michelle says, in general, experts for the respondent are honest scientists who strongly disagree with the conclusions of the petitioners' experts. This is because there is no direct scientific proof that vaccines can cause *any* serious injury. In the Vaccine Program, however, a petitioner is not required to show direct proof. A petitioner is only required to show *legal* proof — a preponderance of *circumstantial* evidence. For this reason, Michelle welcomed the opportunity to cross-examine the respondent's experts, who invariably conceded important aspects of Michelle's case. The special master, however, relied solely upon the number of the respondent's experts, their obvious qualifications, and their *conclusions* to find against Michelle.[60] However, in so doing, the special master chose to ignore the many concessions of the respondent's experts that supported Michelle's case. In this case, apparently, the special master found the respondent's experts' conclusions *reliable*, but their concessions *unreliable*. For him to have done so was arbitrary, capricious, and an abuse of his discretion. For Judge

[60] In this regard, Michelle points out, the Supreme Court has stated with respect to expert testimony, it is the "methodology underlying the testimony" that must be "scientifically valid. . . ." *Daubert*, 509 U.S. at 592-593. Thus, "[t]he inquiry envisioned. . .is, we emphasize, a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability — of the principles that underlie a proposed submission. . . .not on the conclusions that they generate." *Id*. at 594-595.

Wheeler to have permitted this grossly selective consideration of the record was error. Michelle provides a sampling of these concessions.

ii. Dr. Jeffrey Brent's Concessions

Clearly, immune dysfunction must be present to permit a measles infection to persist. That fact is not in dispute. Michelle presented evidence that, in her case, the TCVs likely damaged her immune system and allowed measles to persist in her gut long after it should have been eliminated from her body. The special master rejected this theory. Indeed, he found no evidence that TCVs can harm the immune system. However, to do so, the special master was required to ignore all evidence that contradicted this conclusion. This included that provided by the respondent's expert toxicologist, Dr. Brent, a toxicologist, who conceded: a large body of literature exists concerning the adverse effects of mercury on the immune system (A384); the effect of organic mercury (contained in TCVs) on the immune system is five times more potent than inorganic mercury (A386); "mercury containing compounds are immunomodulatory" and toxic at very low exposure levels to T-cells (A386); exposures to low concentrations of heavy metals, including mercury, causes "silent" clinical symptoms which upon long term follow-up reveals "clear evidence of tissue or organ dysfunction" (A387-A388); and low doses of mercury can have an inhibitory effect on human T-cells (A390-A392).

It was error for the special master to ignore these concessions and the supporting literature. The special master dismissed the Goth study for being an *in-vitro* study that studied Thimerosal, not ethyl mercury (again, Thimerosal is approximately 50% ethyl mercury). A16-A20. He criticized the Agrawal study. While an *in vivo* study, this study was deficient since it too studied Thimerosal. A16-A20. He ignored the entire body of literature that Dr. Brent conceded showed ethyl mercury has a detrimental effect on all elements of the immune system. *See* A16-A20; A386. It was error for the special master to ignore the vast body of evidence regarding the effects of mercury on the immune system, and then declare that Michelle had failed to prove that mercury exposure can lead to a dysfunctional immune system. In any event, it is not necessary for Michelle to prove that *TCVs* damaged her immune system. It is only necessary for her to show that a dysfunctional immune system, for *any* reason, allowed the vaccine-strain measles virus to harm her.

iii. Dr. Stephen Hanauer's Concessions

Michelle alleges that the persisting vaccine-strain measles virus from her MMR caused her to suffer IBD. The special master, however, determined that she does not suffer IBD. Dr. Hanauer, however, the respondent's expert gastroenterologist, provided significant support for Michelle's argument. While denying that Michelle has IBD, he reluctantly conceded that she has significant

bowel symptoms. A371-A372. He also agreed she has aphthous ulcers, which can evolve into IBD, specifically Crohn's disease, and that the ulcers are often the first sign of Crohn's disease. A368-A369. He agreed that Michelle has elevated OmpC and that OmpC is elevated in 60% of Crohn's patients. A370. He agreed that diarrhea frequently occurs after measles vaccine. A373. He agreed that Michelle's lower abdominal symptoms persisted after her measles vaccine. A374-A375. He agreed that both genes and environmental triggers cause IBD, a chronic condition. A376. He conceded that a virus can trigger a chronic inflammatory response. A377. He conceded that Michelle suffers from arthritis and eye problems, both of which, he agreed, are associated with IBD. A378. He conceded that Michelle's present gastroenterologist, Dr. Ziring, treats Michelle with Humira, a medication used for IBD. A379. In light of these concessions, as well as the opinions of Michelle's present treating gastroenterologist that she has IBD (A490), the special master's finding was arbitrary, an abuse of discretion, and not in accordance with law.

iv. Dr. Diane Griffin's Concessions

Dr. Griffin**,** an immunologist and virologist, conceded: measles is one of the most infectious of all viral diseases (A235); a "target organ" of the measles virus is the gastrointestinal tract (A235*);* the attenuated measles vaccine can cause progressive, fatal respiratory disease or neurological disease in

immunocompromised individuals (A243); measles virus affects many components of the immune system (A394); measles virus causes immunosuppression for months after the period of viremia (A393); measles virus skews T cells, and that when Th1 and Th2 are not in balance the body's ability to clear viruses will be impaired (A395-A396); the measles vaccine, like the wild virus, causes lymphopenia (A397); "you can definitely identify changes [in antibodies] that are occurring as part of the induction of the immune response to the vaccine" (A398-A399); *Michelle's first fever after the MMR vaccine was related to the MMR vaccine* (A400); measles can cause neurologic disease (A401); the risk of viral persistence increases in an immunosuppressed person (A402); viruses can persist in the human body (A401); in her own study, she found the presence of a virus' RNA indicated that "viral protein may continue to be made, providing the impetus for the continued presence of [virus]-specific B cells in the brain." A246.[61]

Dr. Griffin agreed that the PCR technique used by the O'Leary lab is commonly used to detect viral RNA (A239); and that she herself has used the PCR technique and detected measles RNA in the blood of immunodeficient children long after exposure to the virus. Indeed, she wrote:

> **we believe the presence of measles virus RNA represents continued measles virus replication, not simply the persistence of measles virus RNA after cessation of viral replication.** ***This is***

[61] In her case too, Michelle submits, the presence of measles RNA in her gut tissue suggests that protein is being manufactured and the virus is replicating.

supported by detection of measles virus RNA from multiple clinical sites.

A258 (emphasis added).

Finally, Dr. Griffin agreed that a measles vaccine should not be given to an immunosuppressed child (A562-A565) and agreed that if Michelle had evidence of a persisting, replicating measles virus, it would be "an important observation" and "should definitely be followed up" by a physician. A407. The special master's refusal to consider this evidence was error.

v. Dr. Brian Ward's Concessions

Dr. Ward also provided support for Michelle's petition. He agreed that wild measles virus causes a skewing towards a Th2 response, which happens to occur during the period of maximum viremia (1-2 weeks after exposure or immunization) (A352); this skewing of the Th2 response causes immunosuppression and allows the development of opportunistic infections (A353-A354); measles vaccine can cause a skewing towards a Th2 response, like wild type measles can (A353-A354); measles virus can persist (A355); "'[t]he type of diseases that persisting viruses cause are often novel and unexpected'" (A356); "'[t]he result is a disturbance in the host's biologic equilibrium. That's one important direct effect of persistent virus replication is to disorder the normal homeostasis of the host and thereby cause disease without destroying the infected cell.'" A357-A358.

Finally, Dr. Ward was confronted with Dr. Oldstone's statement that an important direct effect of persistent virus replication might be a "'virally caused neurotransmitter defect of neurons altering cognitive learning and yielding behavioral disorders.'" A358. Asked whether this example sounds like autism, Dr. Ward said he is not an autism expert, but agreed that it would "describe some of the children with ASD." A358-A359. The special master's refusal to consider this evidence was error.

vi. Dr. Robert Fujinami's Concessions

Dr. Fujinami failed to appear at the hearing, but provided significant evidence in support of Michelle's case. He has known for decades, for example, that **measles** virus can persist in human cells, injure tissues, and cause a potentially damaging autoimmune response. A450-A457. The special master's refusal to consider this evidence was error.

vii. The Respondent's Experts' Concessions Concerning the O'Leary Lab

Dr. Bustin's testimony, once again, actually **supports** the reliability of the O'Leary lab with respect to *Michelle's* test result. At the hearing, he attempted to show that another laboratory (Dr. Finbar Cotter) in London was unable to replicate the O'Leary lab's results (i.e. detecting measles RNA in samples) using the O'Leary techniques. A360-A362. However, as Dr. Bustin's power point presentation showed, Dr. Cotter's lab ***was*** able to replicate the O'Leary results

using the O'Leary techniques for test results with SILs. Although this critical fact was discounted by the special master and Judge Wheeler, it remains in the record that **Dr. Bustin agreed that his dispute was only with the O'Leary lab's MILs** (A365), **and he did not deny that Michelle had SILs** (A366).

Next, in *Snyder*, the respondent introduced a letter from Dr. Michael Oldstone. 88 Fed.Cl. at 731. In his letter, Dr. Oldstone revealed "[i]n the early 2000s" he reviewed the O'Leary lab's protocols for detecting measles virus with PCR, and found them "to be sound." *Id*. In addition, Dr. Oldstone stated, Dr. O'Leary's test results agreed with his own in 80% of the samples he sent to the O'Leary lab. *Id*. Dr. Oldstone also indicated that there was concordance between the two laboratories with respect to SILs. *Id*. Thus, there was **concordance** among three separate laboratories for test results for patients with SILs. The only disputes concerned the results with MILs.[62]

Michelle also relied on portions of the testimony of the respondent's expert Dr. Rima, who conceded that the O'Leary lab used allelic discrimination to attempt

[62] The special master used Dr. Rima's testimony in *Snyder* against Michelle to reject this argument. In *Snyder*, Dr. Rima testified that the O'Leary lab's SILs for Colten Snyder were "[t]oo high to be believed." A561. Unable to cross-examine Dr. Rima in *Snyder*, Michelle filed the affidavit of Dr. Ronald Kennedy, who explains that Dr. Rima's opinions in *Snyder* with respect to SILs were based upon a *gross mathematical computation error*. A491. Dr. Kennedy then uses Dr. Rima's properly corrected formula to calculate Michelle's SIL, and concludes that her SIL, like that of Colten Snyder, was "very plausible." A491.

to distinguish between vaccine-strain and wild measles viruses.[63] *Snyder*, 2009 WL 332044 at 125. Dr. Rima also agreed: if measles virus RNA is present, the virus may be replicating (A556); the Uhlmann paper indicated that the O'Leary lab had detected measles protein using immunohistochemistry (A558); the respondent's expert Dr. Griffin, in her 2001 paper,[64] using PCR technology, and found positive measles RNA in samples of immunosuppressed children taken 60-90 days after exposure to the measles virus. A556. The special master's refusal to consider this evidence was error.

H. The Special Master Abused his Discretion by Ignoring Evidence Concerning Allelic Discrimination

The process of "allelic discrimination" is the method used by scientists to determine whether a virus in question is of wild origin or of vaccine-strain origin. The special master determined that Michelle had failed to prove that Michelle's measles virus RNA, if detected at all, was *vaccine-strain* measles virus.[65] A55-A56. However, in making this finding, the special master ignored the absence of evidence that Michelle was ever exposed to a wild measles virus. He also discounted Michelle's direct evidence that the O'Leary lab had used allelic

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[63] *See* A449.

[64] A257-A258.

[65] Michelle's medical records indicate that she has never been exposed to wild measles.

discrimination and that the RNA recovered was vaccine-strain measles virus. *See* A449. In addition, the O'Leary lab's method used to distinguish between wild type and vaccine strain measles, an accepted methodology, was not challenged by any of the respondent's experts. A443-A448. The special master's refusal to consider this evidence was error.

I. The Special Master Abused his Discretion by Refusing to Consider Evidence Concerning Persistent Measles Virus and Replication

Dr. Griffin, the respondent's expert virologist, discounted the results of Michelle's gut biopsy that the presence of a significant amount of measles virus RNA in her gut tissue. She indicated that the presence of measles virus RNA was not indicative of disease because **protein** was required for the virus to replicate. During cross-examination, however, she acknowledged that she had not reviewed the Uhlmann article that formed the basis for Michelle's contentions that the O'Leary laboratory engaged in good and accepted practices. A403; *See* A251-A256. Dr. Griffin was thus unaware that the O'Leary laboratory **had** found protein via the process of immunohistochemistry and that the Uhlmann article reflected that finding under Figure 4E. *See* A251-A256. In any event, once again, Dr. Griffin, herself, had found replication of measles virus, *in the absence of protein*, in one of her publications. *See* A257-A258. In this article, Dr. Griffin was able to recover measles RNA from the blood, urine and trachea of HIV positive patients

30 – 60 days post-immunization. In her article, she declared that recovery of measles RNA from multiple sites from different patients was indicative that measles virus was persistent and replicating. The special master, however, ignored this evidence. Thus, the special master ignored multiple sources of information that supported Michelle's medical theory that the measles RNA found in her gut tissue was not inert, but multiplying in her gut tissue and causing harm to her gut and her brain. The special master's refusal to consider this evidence was error.

J. The Special Master Abused his Discretion by Rejecting the Opinions of Dr. Krigsman

The special Master accepted the testimony of the respondent's expert, Dr. Hanauer, who has never seen Michelle, that she does not have IBD. In so doing, he rejected the testimony of Michelle's treating gastroenterologist, Dr. Arthur Krigsman. Indeed, special master reserved special venom for Dr. Krigsman, a board-certified gastroenterologist, accusing him of "gross medical misjudgment." A105. In fact, the special master's attack is grossly unfounded.[66] In response,

[66] The special master relied heavily upon the disciplinary action instituted by Lenox Hill against Dr. Krigsman for attacking his credibility. A82-A83. What he failed to relate was that the hospital, in violation of its own medical staff by-laws, attempted to curtail Dr. Krigsman's privileges, without due process, to prevent him from conducting further colonoscopies of autistic children. The hospital paid damages, and the parties went their separate ways. The "Texas matter," as the special master noted, involved an administrative error, and the "Florida proceeding" involved a failure to fulfill a special continuing education requirement of the Florida Board. None of these proceedings concerned the competence of Dr. Krigsman as a physician or gastroenterologist.

Michelle points out, at the time of her hearing, Dr. Krigsman had evaluated the gastrointestinal tracts of a thousand autistic children. He testified about his initial skepticism that autistic children had significantly more bowel symptoms than non-autistics; that he conducted a history and physical of the initial eight (8) autistic patients referred to him, and when appropriate, ordered non-invasive testing; when testing revealed no abnormalities, he declined to treat them further; only when shown an article by the author of a medical school textbook did Dr. Krigsman reconsider his original thinking. He offered to conduct additional evaluations of the original patients and all parents agreed. *See generally* A264-A347. The special master failed to acknowledge that most parents will not allow a physician to conduct invasive procedures on their child unless the symptoms are chronic and unremitting, cause physical and emotional distress to their child, and the child has been non-responsive to traditional treatment. All eight of Dr. Krigsman's original patients ultimately underwent colonoscopies. A274. In all eight patients, he saw similar findings as were described in the article. A274. The special master also ignored the fact that Theresa Cedillo, Michelle's mother, only sought Dr. Krigsman's help after Michelle's treating gastroenterologist refused to transfer her to the hospital where he practiced, despite the fact that she was dehydrated and had lost approximately 20 pounds. A280-A282. He ignored the fact that Dr. Krigsman obtained a proper history, conducted a proper physical exam, ordered appropriate

testing and only after doing so arrived at a diagnosis. A282-A284. He ignored Dr. Krigsman's testimony that the diagnosis of Michelle's IBD was based on all the evidence available to him, evidence that included Michelle's history, her physical examination, results of diagnostic testing that included positive serological marker for IBD (+ Omp-C), elevated inflammatory markers (C-reactive protein ("CRP")) and the presence of aphthous ulcers (pre-Crohn's lesion). Further, the special master ignored the fact that Michelle had both uveitis and arthritis, commonly associated disorders of IBD. The special master especially ignored the fact that Michelle had responded to treatment with Remicade, an anti-inflammatory agent used for the treatment of IBD. Even worse, he ignored the findings of Michelle's current treating gastroenterologist, Dr. David Ziring, who had no doubt that Michelle had inflammatory bowel disease (A490),[67] and who ordered Humira for it, specifically noting on the prescription that it was for "Crohn's Disease." A379. The special master also ignored evidence of the consensus statement formulated by a renowned body of specialists in autism and pediatric gastroenterology convened by Autism Speaks on the "appropriate diagnostic evaluation and treatment of GI symptoms in children with ASD [autistic spectrum disorder]." *See* A410-A417. He ignored the fact that Dr. Krigsman was an invited participant, and that the

[67] The records of Dr. Ziring, Michelle's current treating gastroenterologist, were not available at the time of hearing and were filed in support of a motion for reconsideration, which was denied by the special master. *See* A458-A478, A492-A494.

evaluation that was subsequently deemed proper and appropriate, mirrored the evaluation he had provided for Michelle. *See* A408-A409.

Instead, the special master credited the testimony of Dr. Hanauer, the government's paid witness, an adult gastroenterologist who does not evaluate pediatric patients, who has never looked at the gastrointestinal tract of an autistic child, and who has never examined Michelle. A83-A84. In fact, Dr. Hanauer's conclusion that Michelle does not have IBD is based on only one fact -- that inflammation was not found in Michelle's pathology slides. A90. He asserted that IBD could not be diagnosed in its absence. A90. What both Dr. Hanauer and the special master refused to acknowledge was that the successful treatment noted in Michelle after she began Remicade, was likely responsible for the lack of inflammation noted on the pathology slides. While the special master can be excused for this oversight, Dr. Hanauer does not enjoy that deference. The special master's refusal to consider this evidence was error.

K. The Special Master Abused his Discretion by Refusing to Consider Evidence of Neuroinflammation

The respondent's experts did not deny "that inflammation may be present in the brains of autistic persons, and may possibly play a causal role in autism." A54, A129. The special master conceded as much. A54, A129. He asserts, however, that Michelle failed to establish that measles caused her to suffer persistent

neuroinflammation. A54, A129. Once again, the special master ignored relevant evidence to arrive at this conclusion.

First, it is undisputed that persistent *wild* measles infection has resulted in two recognized brain disorders, subacute sclerosing panencephalitis ("SSPE") and measles inclusion body encephalitis ("MIBE"), and that both disorders involve neuroinflammation. It also is undisputed that both disorders have a prolonged latency period after exposure before the onset of symptoms. The special master failed to acknowledge, however, that *vaccine-strain measles*, was recovered from the brain of one child with MIBE. *See* A229-A233. Clearly, then, if wild type measles can cause a latent inflammation of the brain, it is reasonable to believe that the attenuated measles vaccine, which is simply a weakened version of the live measles virus, can also cause a latent infection of the brain.[68]

In addition, as the special master was well aware, if encephalitis occurs in a child 5-15 days after measles immunization, it constitutes a Table injury and it is *presumed* that the vaccine is the cause of the encephalitis. § 14. Encephalitis is an inflammation of the brain. Thus, it is difficult to fathom why the special master ruled that it is *unproven* that measles vaccine can cause neuroinflammation.

The Petitioners' Motion for Reconsideration included several chapters from a text edited by Dr. Andrew Zimmerman, one of respondent's expert pediatric

[68] Michelle was unable to present direct evidence of neuroinflammation. No autopsy can be performed as she is still alive.

neurologists, who the respondent declined to call at hearing. A461-A472. They support Michelle's theory that autism is caused by neuroinflammation. The special master ignored them. He also ignored the findings of Dr. Oldstone who has spent his career studying persistent viral infections. For him to have ignored this evidence was error.

L. The Special Master Abused his Discretion by Ignoring Evidence Concerning Michelle's Immune Dysfunction

The special master also improperly discounted the testimony of Dr. Vera Byers. At the hearing, referring to the laboratory findings of one of Michelle's treating physicians, Dr. Gupta,[69] Dr. Byers testified that Michelle "has an unusually low CD8 count, and as a result she has an elevated CD4:CD8 ratio. An elevated CD4:CD8 ratio is compatible with autoimmune disease." A348. In addition, Dr. Byers stated, Michelle had an elevated CD 20. In this regard, she testified, the significance of an elevated CD 20 is that, "you've got abnormally elevated B cell precursors, and it could go along with the abnormally elevated IgG2 and IgG4. . . .The fact that she has abnormally elevated IgG2 and IgG4. . .is consistent with TH1/TH2 skewing." A348-A350. The respondent's expert Dr.

[69] In a letter to Michelle's parents, Theresa and Michael Cedillo, Dr. Gupta wrote, "the immunology testing. . .shows that Michelle has **almost** normal immune functions." A217. In the same letter, Dr. Gupta advised Michelle's parents that she qualified for "a medical exception to the vaccination requirements of the school system." A217.

Ward, once again, acknowledged that TH2 skewing causes immunosuppression (*supra* at p. 40).

Instead, incomprehensibly, the special master accepted the testimony of the respondent's expert, Dr. McCusker, who constructing her own chart from different sources, then concluded that Michelle's immune system was normal. A351. The record clearly indicates that Michelle's immune system was damaged.

Dr. Zimmerman's text, significantly, includes a chapter by Dr. Paul Ashwood, who discusses immune abnormalities in autistic children. A461-A472. Michelle suffered from several of the abnormalities listed by Dr. Ashwood and Michelle relies upon Dr. Ashwood to support her theory that she suffers from immune dysfunction. Further, the special master ignored evidence submitted by the respondent's expert, Dr. Fujinami that some autistics, as does Michelle, suffer from a Th2 skewing of the adaptive immune system, that affects a person's ability to eliminate viruses from the body. *See generally* A450-A457.

M. The Special Master Abused His Discretion By Refusing to Consider Significant Post-Hearing Evidence[70]

Michelle asked the special master to reconsider his decision of February 12, 2009 dismissing her petition.[71] She did so in light of new evidence not available at

[70] On March 16, 2009, the special master denied Michelle's Motion for Reconsideration as both untimely filed and without "a good reason" for reconsideration. A494.

[71] *See* A458-A478.

the time of the hearing in June of 2007. This evidence, Michelle stated, is based upon the research of leading scientists in the field of autism, including the respondent's expert pediatric neurologist, Dr. Andrew Zimmerman. In sharp contrast to critical findings by the special master, this evidence demonstrates that:

- Postnatal environmental triggers may impact the immune system during the development of the brain, disrupt the normal development of the brain, and cause autism.[72]

- Regressive autism is not purely genetic and may be caused by postnatal environmental factors.[73]

- Scientists now accept the concept of gastrointestinal inflammation in autistic children.[74]

- There is a strong relationship between the immune system, gastrointestinal disorders, and autism.[75]

- Michelle has inflammatory bowel disease.[76]

- The O'Leary lab's primers are reliable in detecting measles RNA.[77]

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[72] A479.

[73] A480.

[74] A481-A483.

[75] A481-A483.

[76] A490.

[77] A484-A489.

- Dr. Bertus Rima's testimony in *Snyder*, a critical factor in the special master's rejection of Michelle's O'Leary lab result, was based upon a gross mathematical error.[78]

In Michelle's view, this new evidence significantly affects many critical aspects of the special master's decision. Given the familiarity of the special master with the science in Michelle's case, and given the limited nature of this new evidence, the special master should have been able to quickly decide if this new evidence is worthy of consideration. In light of the significance of the evidence, and in light of the impact of this decision upon thousands of autistic children in the Program, his failure to do so was an abuse of his discretion. Once again, the special master did not strike this evidence and it remains part of the record in this case.

N. The Special Master's Decision Was Not in Accordance With the Law

As legal support for his determination that Michelle's evidence is unreliable, and that her theories are not generally accepted in the scientific community, the special master relies on the Supreme Court's decision in *Daubert*[79] and a 1999 Federal Circuit decision, *Terran ex. rel. Terran v. Sec'y of HHS*,[80] that indicates that *Daubert* plays some role in Vaccine Program proceedings. Michelle submits,

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[78] A491.

[79] In his decision, the special master cites *Daubert* on eleven (11) occasions. *See* A3, A32-A33, A71-A72, A118.

[80] 195 F.3d 1302 (Fed. Cir. 1999). The special master cited *Terran* on six (6) occasions. *See* A3, A71-A73.

once again, *Daubert* interprets federal rule of evidence in civil litigation, rules that don't apply in the Vaccine Program. It refers only to the *methods* scientists use, not to the expert's *conclusions*. In this regard, Michelle says, the special master improperly applied *Daubert* to her experts' *conclusions* and improperly ignored the teachings of recent Federal Circuit decisions in *Althen and Capizzano*, *supra*.

Has Michelle satisfied the *Althen* factors? Clearly, she has a medical theory. Her evidence is overwhelming that the MMR vaccine is capable of causing a wide variety of brain injuries, including autism. Next, there was a logical sequence of cause and effect between her MMR vaccine and her injury. She was healthy, received a MMR vaccine, and as her several treating physicians attest, she was never again the same. There is no question that her symptoms first occurred within an appropriate time after her MMR vaccine. This fact is supported by Michelle's medical records and by the respondent's expert Dr. Griffin. It is even supported by the Vaccine Injury Table that lists "5-15" days after the MMR vaccine as the appropriate time frame for the onset of symptoms of brain damage. *See* § 14.

Finally, once a petitioner presents a *prima facie* case, the Federal Circuit has held, the burden of proof shifts and the government must prove that the "'injury. . . described in the petition is due to *factors unrelated to the. . .vaccine*.' 42 U.S.C. § 300aa-13(a)(1)(B)." *Knudsen by Knudsen v. Sec'y of HHS,* 35 F.3d 545, 547 (Fed. Cir. 1994). In so doing, the Court has said, the government must not merely prove

the existence of an alternative etiology. *Id*. at 549. Rather, it must prove that the alternative actually caused the injury. *Id*. In addition, the government must affirmatively show that the vaccine did not cause the injury. *Walther v. Sec'y of HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007). The respondent has failed to do so.

Instead, the respondent argues, autism is purely genetic. In this regard, Michelle submits, genetic susceptibility plays a role in all vaccine injuries. Frequently, non-vaccine environmental factors also contribute to the injury. However, when concurrent forces cause a single harm, the Federal Circuit has held, the burden is on the *governmen*t to show that the alternative cause is so predominant that the vaccine is insignificant. *See Shyface*, 165 F.3d at 1352. Therefore, the Court has stated, if evidence establishes equally plausible etiologies for an injury then the petitioner should prevail. *See Knudsen*, 35 F.3d at 550. In such cases, the government must eliminate the vaccine as a substantial contributing factor. *See Shyface*, 165 F.3d at 1353.

In this case, Michelle submits, it is not her burden to rule out all potential causes of her injury. As the Federal Circuit pointed out in *Walther*, "the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm." 485 F.3d at 1151. Michelle's burden, therefore, is to prove a *prima faci*e case that her vaccines were a substantial contributing factor to

her injury. She believes she has done so. In these circumstances, the burden has shifted to the government to show that Michelle's genetic predisposition, or some other factor, was so predominant that it rendered her vaccines insignificant. *Id*. at n. 4 (citing *Shyface*, 165 F.3d at 1352-1353). In Michelle's view, the respondent has failed to do so.

The special master improperly used *Daubert* as a clout to dismiss Michelle's petition. In so doing, the special master deprived Michelle of the benefit of these recent Federal Circuit decisions that correctly described her Vaccine Program burden. For the special master to have done so was not in accordance with law**.**

VIII. FINAL CONSIDERATIONS

Had she proceeded in 2001 outside the OAP, Michelle submits, she would have easily satisfied her statutory obligations as described by the Federal Circuit in *Althen* and *Capizzano*. Michelle clearly had a plausible medical theory supported by substantial circumstantial evidence as to how the MMR caused *her* gut and brain injuries. The records of several treating physicians support a "logical sequence" between the MMR and her injuries, an appropriate temporal relationship, and the absence of an alternative cause. She offered expert opinions supported by scientific literature. The respondent offered no evidence of an alternate cause of Michelle's injuries.

When Michelle became the first autism "test case," however, everything changed. Due process was suspended. Now, she had to convince not one, but three special masters. Phalanxes of experts were pitted against her, not just Dr. Wiznitzer. The Tribunal allowed the respondent to present surprise evidence from England on the eve of trial, use a host of experts provided by the pharmaceutical industry, and even present expert testimony against her in *another* trial. The Tribunal refused to accept any aspect of her evidence, even the major concessions made by the respondent's experts. The special master, and Judge Wheeler, even refused to accept the fact that Dr. Rima's critical testimony was based on a mathematical error. Michelle fully appreciates the emotions surrounding her case. She also appreciates the importance of vaccines. However, Michelle submits, she must not be penalized for choosing this unpopular route. She is entitled to compensation based on the evidence in accordance with the statute.

At this time, approximately 5,000 autistic children in the OAP claim vaccines harmed them. There is a $3.1 billion fund available to compensate appropriate cases. An adverse finding in her case, Michelle submits, will drive many of these autistic children into the civil arena. This Court cannot permit this to happen. Certainly, this is not what congress intended. Simply put, Michelle says, it is essential that the Vaccine Program, rather than crippling civil litigation, resolve her case as well as those of all autistic children in OAP. Persons fairly

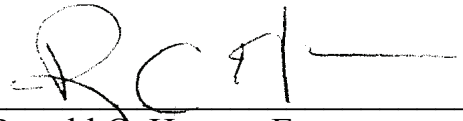
compensated in the Vaccine Program will not sue manufacturers. How can these persons be kept in the Vaccine Program? The answer is simple. An evidentiary standard that promotes congressional intent must be employed. The Vaccine Act, as interpreted by *Althen* and *Capizzano*, provides such a standard. Fundamental fairness, not hysteria, must prevail.

IX. CONCLUSION

Michelle respectfully requests that this Court rule that she has satisfied her burden as a matter of law, that she is entitled to compensation, and that her case be remanded to the special master to assess appropriate compensation.

DATED: January 19, 2010

Respectfully submitted,



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ADDENDUM

ADDENDUM

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United States Court of Appeals
for the Federal Circuit

No. 2010-5004

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THERESA CEDILLO and MICHAEL CEDILLO,
(as Parents and Natural Guardians of) Michelle Cedillo,
Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.
----------)

DECLARATION OF AUTHORITY PURSUANT TO 28 U.S.C. § 1746 AND FEDERAL CIRCUIT RULE 47.3(d)

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January 19, 2010

_____
Elissa Matias

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United States Court of Appeals
for the Federal Circuit
No. 2010-5004
----------)
THERESA CEDILLO and MICHAEL CEDILLO,
(as Parents and Natural Guardians of) Michelle Cedillo,
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v.
SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.
----------)

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